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#### **INFORMATION NOTE**

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from: General Secretariat  
to: Permanent Representatives Committee/Council  
Subject: 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  
– Outcome of the European Parliament's proceedings  
(Strasbourg, 9 to 12 September 2013)

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#### **I. INTRODUCTION**

The Rapporteur, Mrs Sandrine BÉLIER (Greens/EFA - FR), presented a report consisting of 78 amendments to the proposal for a Regulation on behalf of the Committee on the Environment, Public Health and Food Safety.

## II. DEBATE

The Rapporteur opened the debate, which was held on 11 September 2013 and:

- stressed the critical importance of the proposed Regulation in the context of international negotiations on biodiversity;
- stated that it is not enough to ratify the Nagoya Protocol without also adopting a European regulation which respects the Protocol's objectives;
- defended the report approved by the Committee on the Environment, Public Health and Food Safety, singling out for particular mention the 'new use' mechanism, which will guarantee that no competitive imbalance will appear in Europe, and the creation of an innovative funding mechanism for biodiversity; and
- called for strong European legislation to put an end to the pillaging of natural resources, otherwise known as 'biopiracy'.

Commissioner POTOČNIK:

- stated that the Committee's report would be a solid basis for negotiations between the EU institutions, even though certain parts are not comfortable for the Commission;
- called for trilogues to begin as soon as possible;
- warned that the deadline for ratifying the Nagoya Protocol falls in July 2014 and that ratification is a lengthy and very formal process. If the EU fails to ratify in time, then the EU will only attend the first meeting in October 2014 of the parties to the Nagoya Protocol as observers and without voting rights - with serious implications for the EU's ability to influence how essential provisions of the Protocol will be implemented. This would seriously harm EU interests, including the ability of EU companies to access genetic resources abroad and thereby produce bio-based innovations. Many countries might even stop granting access to genetic resources to EU researchers and industry;
- noted that failure to adopt EU measures in a timely manner would not mean that there would be no legislation at all in the EU, but rather that some Member States would probably adopt their own national legislation in the interim, thus creating a legislative patchwork which would not be in the best interests of the Common Market and which would reduce predictability and clarity for business operators and researchers;

- recalled that the Nagoya Protocol is a package deal. European users wished to secure access to genetic resources in biodiversity-rich, mostly developing countries. In return, the EU has to ensure the compliance of users of those genetic resources in EU territory so that the provider countries receive a share of the benefits. The currently proposed Regulation is intended to create the legal framework for this compliance. Failure to adopt this Regulation in a timely manner may cause third countries to view the EU as an unsafe or uncooperative jurisdiction and to become reluctant to grant access to their genetic resources to EU users;
- warned that delayed ratification would damage the EU's image as a credible international partner in the field of environment and of biodiversity in particular; and
- reasoned that it is only natural that the different institutions have different positions when entering the trilogue phase. The very purpose of trilogues is to resolve the outstanding issues and arrive at a common position. He was confident that the coming trilogues would result in an acceptable compromise.

Speaking on behalf of the Committee on Development, Mrs Catherine GRÈZE (Greens/EFA - FR):

- condemned biopiracy; and
- called for the plenary to support the report of the Committee on the Environment, Public Health and Food Safety.

Speaking on behalf of the Committee on Fisheries, Mrs Isabella LÖVIN (Greens/EFA - SE):

- stressed the need to involve indigenous and local communities regarding access to genetic resources; and
- noted the possibility for the EU to extend the Protocol's scope to activities taking place in international waters beyond the economic zone, outside the 200 nautical miles limit. This is extremely important, given that two thirds of the world's oceans lie outside national jurisdictions.

Speaking on behalf of the EPP political group, Mrs Cristina GUTIÉRREZ-CORTINES (EPP - ES):

- recognised that the Nagoya Protocol is fair, but argued that it is not yet fully mature, but rather a work in progress which still lacks certain mechanisms. Rights are not yet fully clarified. Not all countries/companies have a catalogue and can list what they own; and
- called for the deletion of retroactive applicability.

Speaking on behalf of the S&D political group, Mr Pavel POC (S&D - CZ) stressed the need for prompt ratification of the Nagoya Protocol.

Speaking on behalf of the ALDE political group, Mr Gerben-Jan GERBRANDY (ALDE - NL):

- welcomed the agreement reached on the Nagoya Protocol in 2010;
- noted the growing concerns of many companies active in the use of genetic resources. It is not yet clear whether their main concern is legal uncertainty or rather a reluctance to share the benefits of genetic resources;
- noted that the proposal targets users who are conducting research and development on genetic resources. It does not directly concern farmers or traders. The breeders' exemptions and all other FAO guarantees are secured; and
- asked the Commission how important it is to include new utilisation in the proposal.

Mr Herbert DORFMANN (EPP - IT):

- noted that the EU is a world-leader in seasoned young plants. Many SMEs are involved in this trade and would like to have clear rules on access to genetic resources (legal certainty and facilitated access to genetic resources); and
- argued that it is important not to introduce rules that will place European companies at a competitive disadvantage. The EU should not go beyond the Nagoya Protocol. Regulation should not be applied retroactively. There is no need for a special fund for a purpose which no one knows. The Regulation should not call into question the privileges of the business. Consumers must be protected.

Mrs Christa KLAß (EPP - DE):

- welcomed the Nagoya Protocol and called for its swift ratification by the EU;
- warned against over-complicating the currently proposed Regulation, especially since the EU is competing with third countries in this area;
- stressed the importance of agricultural research as a means to feeding the world's population;
- emphasised the need for the breeders' exemption; and
- called for genetic resources to be available in the form used by their first user.

Mr Jaroslav PAŠKA (EFD - SK):

- stated that the Nagoya Protocol is a useful tool against piracy of genetic resources and ensuring a just redistribution of the benefits that they offer. He called for the plenary to support the amendments relating to these points;
- stressed the need always to state the origin of genetic resources and that they were acquired lawfully; and
- called for support to native communities, whose local knowledge is of great value.

Commissioner POTOČNIK:

- responded to Mr Gerbrandy's question by stating that the proposal is to apply the Access and Benefit-Sharing Regulation to genetic resources that already exist in the EU at the time of the Protocol's entry into force. The Commission is not entirely comfortable with the application of the regulation to new utilisation. The report of the Committee on the Environment, Public Health and Food Safety can nonetheless form a solid basis for negotiations between the EU's institutions;
- argued that positions are already so close that it is worth making an effort to obtain a negotiating mandate. Failure to negotiate would have enormous and unpredictable consequences;
- recalled that in early 2012 the Parliament urged the Commission to propose legislation to implement the Nagoya Protocol so that the EU could ratify the Protocol as soon as possible; and
- stated that a positive vote in plenary would be an indispensable step in terms of the EU being able to ratify the Protocol.

The Rapporteur once more took the floor and:

- agreed on the need for swift ratification of the Protocol, but also stressed the Parliament's responsibility to the EU's citizens, rather than to industry;
- argued that the report of the Committee on the Environment, Public Health and Food Safety is well balanced; and
- stated that the Committee's amendments, including those on new utilisation, have nothing to do with retroactivity. Suggestions that they do are little short of disinformation. Any attempt to introduce retroactivity at this stage would be a pointless waste of time. The amendments on new utilisation are intended simply to provide legal clarity.

### **III. VOTE**

When it voted on 12 September 2013, the Parliament adopted 76 amendments (amendments 1-31, 33-49 and 51-78).

The vote on the legislative resolution was, however, postponed to a later session, thereby not closing the first reading. Pursuant to Rule 57(2) of the European Parliament's Rules of Procedure, the matter was then referred back to the Committee on the Environment, Public Health and Food Safety.

The amendments adopted by the Parliament are set out in the annex to this document.

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## **Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union \*\*\*I**

**Amendments adopted by the European Parliament on 12 September 2013 on the 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 (COM(2012)0576 – C7-0322/2012 – 2012/0278(COD))<sup>1</sup>**

**(Ordinary legislative procedure: first reading)**

### **Amendment 1**

**Proposal for a regulation  
Citation -1 (new)**

*Text proposed by the Commission*

*Amendment*

*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,*

### **Amendment 2**

**Proposal for a regulation  
Recital -1 (new)**

*Text proposed by the Commission*

*Amendment*

*(-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.*

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<sup>1</sup> The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0263/2013).

### Amendment 3

#### Proposal for a regulation

##### Recital 1

###### *Text proposed by the Commission*

(1) A broad range of **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.

###### *Amendment*

(1) A broad range of **users and suppliers** 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’.**

### Amendment 4

#### Proposal for a regulation

##### Recital 2

###### *Text proposed by the Commission*

(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, development of medicines, or development of bio-based sources of **renewable** energy.

###### *Amendment*

(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 energy. **Genetic resources play a significant role in the implementation of strategies designed to restore damaged**



*ecosystems and safeguard endangered species.*

## **Amendment 5**

### **Proposal for a regulation Recital 2 a (new)**

*Text proposed by the Commission*

*Amendment*

*(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.*

## **Amendment 6**

### **Proposal for a regulation Recital 2 b (new)**

*Text proposed by the Commission*

*Amendment*

*(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.*

## Amendment 7

### Proposal for a regulation Recital 2 c (new)

*Text proposed by the Commission*

*Amendment*

*(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.*

## Amendment 8

### Proposal for a regulation Recital 3

*Text proposed by the Commission*

*Amendment*

(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.

(3) Traditional knowledge that is held by indigenous and local communities may provide important lead information for the scientific discovery of *potentially valuable* 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.*

## **Amendment 9**

### **Proposal for a regulation Recital 3 a (new)**

*Text proposed by the Commission*

*Amendment*

*(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.*

## **Amendment 10**

### **Proposal for a regulation Recital 3 b (new)**

*Text proposed by the Commission*

*Amendment*

*(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.*

## **Amendment 11**

### **Proposal for a regulation Recital 4 a (new)**

*Text proposed by the Commission*

*Amendment*

*(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.*

## **Amendment 12**

### **Proposal for a regulation Recital 4 b (new)**

*Text proposed by the Commission*

*Amendment*

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

## **Amendment 13**

### **Proposal for a regulation Recital 4 c (new)**

*Text proposed by the Commission*

*Amendment*

*(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.*

## **Amendment 14**

### **Proposal for a regulation Recital 4 d (new)**

*Text proposed by the Commission*

*Amendment*

*(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.*

## Amendment 15

### Proposal for a regulation

#### Recital 5

##### *Text proposed by the Commission*

(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 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 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.

##### *Amendment*

(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.*

## Amendment 16

### Proposal for a regulation

#### Recital 6

##### *Text proposed by the Commission*

(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 Convention. The Nagoya Protocol ***significantly expands*** the general rules of the Convention on access and benefit-sharing for the ***use*** of genetic resources and traditional knowledge associated with genetic resources.

##### *Amendment*

(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 Convention. The Nagoya Protocol ***further details*** the general rules of the Convention on access and ***monetary and non-monetary*** benefit-sharing for the ***utilisation and subsequent commercialisation*** of genetic resources and traditional knowledge associated with genetic resources.

## Amendment 17

### Proposal for a regulation

#### Recital 7 a (new)

##### *Text proposed by the Commission*

##### *Amendment*

***(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.***

## Amendment 18

### Proposal for a regulation

#### Recital 8

##### *Text proposed by the Commission*

(8) It is important to set out a clear and sound framework for implementing the Nagoya Protocol that should ***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*** resources in the Union ***and to support the effective implementation of benefit-sharing commitments set out in mutually agreed terms between providers and users.***

##### *Amendment*

(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*** the use of illegally acquired genetic resources or traditional knowledge associated with ***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.***

## Amendment 19

### Proposal for a regulation

#### Recital 8 a (new)

##### *Text proposed by the Commission*

##### *Amendment*

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



## Amendment 20

### Proposal for a regulation

#### Recital 8 b (new)

*Text proposed by the Commission*

*Amendment*

***(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.***

## Amendment 21

### Proposal for a regulation

#### Recital 9

*Text proposed by the Commission*

*Amendment*

(9) In order to ensure legal certainty, it is important that the rules implementing the Nagoya Protocol should only apply to genetic resources and traditional knowledge associated with genetic resources that ***are accessed*** after the entry into force of the Nagoya Protocol for the Union.

(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 ***take place or commence*** after the entry into force of the Nagoya Protocol for the Union.

## Amendment 22

### Proposal for a regulation

#### Recital 11

*Text proposed by the Commission*

*Amendment*

(11) It is important to define, in accordance with the Nagoya Protocol, that ***use*** of genetic resources refers to research and development on the genetic or biochemical composition of ***samples of*** genetic material, ***which includes research and development on isolated compounds extracted from genetic material that was***

(11) It is important to define, in accordance with the Nagoya Protocol, that ***utilisation*** of genetic resources refers to research and development on the genetic or biochemical composition of genetic ***resources***. ***Research and development should be understood to mean the investigation and study of the genetic or biochemical***

*accessed in a Party to the Nagoya Protocol.*

*composition of genetic resources in order to establish facts and reach conclusions, including the creation of innovations and practical applications.*

## Amendment 23

### Proposal for a regulation

#### Recital 14

##### *Text proposed by the Commission*

(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.

##### *Amendment*

(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, 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. 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 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.

## Amendment 24

### Proposal for a regulation Recital 14 a (new)

*Text proposed by the Commission*

*Amendment*

***(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.***

## Amendment 25

### Proposal for a regulation Recital 16

*Text proposed by the Commission*

*Amendment*

***(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***

***deleted***

*adopted by the collective of the Parties to the Nagoya Protocol.*

## Amendment 26

### Proposal for a regulation

#### Recital 17

##### *Text proposed by the Commission*

(17) Users should declare at identified points in the chain of activities that ***constitute use that*** they have exercised due diligence. Suitable points for such declarations are the ***receiving of public*** research ***funds***, when 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 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.

##### *Amendment*

(17) Users should declare at identified points in the chain of activities 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 of research funding, when applying for intellectual property rights at relevant national, regional or international institutions***, 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*** requesting market approval would not constitute part of the approval procedure as such and would be directed to competent authorities established under this Regulation.

## Amendment 27

### Proposal for a regulation

#### Recital 18

##### *Text proposed by the Commission*

(18) Collecting of genetic resources in the wild is ***mostly*** undertaken ***for non-commercial purposes by university-based*** researchers or ***collectors***. 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

##### *Amendment*

(18) Collecting of genetic resources in the wild is mostly undertaken ***by private collectors and companies, often serving commercial purposes, and by academic*** researchers or ***scientific institutions serving non-commercial purposes***. In the vast majority of cases and in almost all sectors, access to newly collected genetic

resources in third countries.

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.***

## Amendment 28

### Proposal for a regulation

#### Recital 19

##### *Text proposed by the Commission*

(19) Collections are ***major*** suppliers of genetic resources and traditional knowledge associated with genetic resources ***used*** in the Union. A system of Union ***trusted*** collections should be set in place. It ***would ensure*** that collections ***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*** collections should substantially lower the risk that illegally acquired genetic resources are ***used*** in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as Union ***trusted*** collection. 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.

##### *Amendment*

(19) ***Most*** collections are ***the most accessible*** 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 Union ***registered*** collections should be set in place. It ***ensures*** that collections ***registered at Union level*** 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 ***registered*** collections should substantially lower the risk that illegally acquired genetic resources are ***utilised*** in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as ***a Union registered*** 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.

## **Amendment 29**

### **Proposal for a regulation Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(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.***

## Amendment 30

### Proposal for a regulation Recital 20

#### *Text proposed by the Commission*

(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. 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.

#### *Amendment*

(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.

## Amendment 31

### Proposal for a regulation Recital 22 a (new)

#### *Text proposed by the Commission*

#### *Amendment*

***(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.***

## Amendment 33

### Proposal for a regulation

#### Recital 23

##### *Text proposed by the Commission*

(23) A Union platform on access should enable discussions on and contribute to the streamlining of access conditions in Member States, the design and performances of access regimes, simplified access for non-commercial research, access practices of collections in the Union, access of Union stakeholders in third countries and the sharing of best practices.

##### *Amendment*

(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 ***and benefit-sharing*** 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.***

## Amendment 34

### Proposal for a regulation

#### Article 1 – paragraph 1

##### *Text proposed by the Commission*

This Regulation establishes rules governing 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).

##### *Amendment*

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).



## Amendment 35

### Proposal for a regulation Article 1 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

*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").*

## Amendment 36

### Proposal for a regulation Article 1 – paragraph 1 b (new)

*Text proposed by the Commission*

*Amendment*

*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.*

## Amendment 37

### Proposal for a regulation

#### Article 2

##### *Text proposed by the Commission*

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* 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.

##### *Amendment*

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 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.*

## Amendment 38

### Proposal for a regulation

#### Article 3 – point 3

##### *Text proposed by the Commission*

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

##### *Amendment*

(3) "genetic resources" means genetic material of actual or potential value, *or derivatives thereof*;

## Amendment 39

### Proposal for a regulation Article 3 – point 3 a (new)

*Text proposed by the Commission*

*Amendment*

*(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;*

## Amendment 40

### Proposal for a regulation Article 3 – point 5

*Text proposed by the Commission*

*Amendment*

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

(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;*

## Amendment 41

### Proposal for a regulation Article 3 – point 6

*Text proposed by the Commission*

*Amendment*

(6) "*use* of genetic resources" means to conduct research and development on the genetic or biochemical composition of genetic resources;

(6) "*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;*

## Amendment 42

### Proposal for a regulation Article 3 – point 6 a (new)

*Text proposed by the Commission*

*Amendment*

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

## Amendment 43

### Proposal for a regulation Article 3 – point 6 b (new)

*Text proposed by the Commission*

*Amendment*

***(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;***

## Amendment 44

### Proposal for a regulation Article 3 – point 8 a (new)

*Text proposed by the Commission*

*Amendment*

***(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;***

## Amendment 45

### Proposal for a regulation

#### Article 3 – point 11

##### *Text proposed by the Commission*

(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) Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing-House;

##### *Amendment*

(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;

## Amendment 46

### Proposal for a regulation

#### Article 3 – point 12

##### *Text proposed by the Commission*

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

##### *Amendment*

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

## Amendment 47

### Proposal for a regulation

#### Article 4 – paragraph -1 (new)

##### *Text proposed by the Commission*

##### *Amendment*

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

## Amendment 48

### Proposal for a regulation

#### Article 4 – paragraph 1

##### *Text proposed by the Commission*

1. Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources used were accessed ***in accordance*** with applicable access and benefit-sharing legislation or regulatory requirements and that, ***where relevant***, benefits are fairly and equitably shared upon ***mutually*** agreed terms. Users shall seek, keep, and transfer to subsequent users information relevant for access and benefit-sharing.

##### *Amendment*

1. Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources used were accessed with ***prior informed consent and based on mutually agreed terms as defined by*** applicable access and benefit-sharing legislation or regulatory requirements and that benefits are fairly and equitably shared upon ***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.***

## Amendment 49

### Proposal for a regulation

#### Article 4 – paragraph 1 a (new)

##### *Text proposed by the Commission*

##### *Amendment*

***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.***

## Amendment 51

### Proposal for a regulation

#### Article 4 – paragraph 2

##### *Text proposed by the Commission*

2. Users shall:

(a) seek, keep and transfer to subsequent users 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* and mutually agreed terms, where applicable;

(b) obtain additional information or evidence where uncertainties about the legality of access and use persist; and

##### *Amendment*

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 ***permits*** and mutually agreed terms, ***including benefit-sharing arrangements***, where applicable;

***(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.

(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.

## **Amendment 52**

### **Proposal for a regulation Article 4 – paragraph 3**

*Text proposed by the Commission*

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

*Amendment*

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***.

## **Amendment 53**

### **Proposal for a regulation Article 4 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***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 ...<sup>1</sup>. 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.***

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<sup>1</sup> ***OJ: six months after the entry into force of this Regulation.***



## Amendment 54

### Proposal for a regulation Article 4 – paragraph 4 b (new)

*Text proposed by the Commission*

*Amendment*

***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.***

## Amendment 55

### Proposal for a regulation Article 5

*Text proposed by the Commission*

*Amendment*

***Article 5***

***deleted***

***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).*

## **Amendment 56**

### **Proposal for a regulation Article 6 – paragraph 2**

*Text proposed by the Commission*

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.

*Amendment*

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.***

## **Amendment 57**

### **Proposal for a regulation Article 6 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***(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 338/97<sup>1</sup>.***

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<sup>1</sup> OJ L 61, 3.3.1997, p. 1.

## Amendment 58

### Proposal for a regulation Article 6 – paragraph 3 b (new)

*Text proposed by the Commission*

*Amendment*

***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.***

## Amendment 59

### Proposal for a regulation Article 7 – paragraph 1

*Text proposed by the Commission*

*Amendment*

***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.***

***deleted***

## Amendment 60

### Proposal for a regulation Article 7 – paragraph 2

*Text proposed by the Commission*

*Amendment*

**2. Users shall declare to the competent authorities established under Article 6(1) that they *exercised due diligence in accordance with* Article 4 on the occasion**

**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***

of requesting market approval for a product developed on the basis of genetic resources or traditional knowledge associated with such resources, or at the time of commercialisation where a market approval is not required.

*related information* 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.*

## Amendment 61

### Proposal for a regulation Article 7 – paragraph 3

#### *Text proposed by the Commission*

Competent authorities shall transmit to the Commission every two years the information received on the basis of paragraphs 1 and 2. The Commission shall summarise the information received and make it available to the Access and Benefit-sharing Clearing House.

#### *Amendment*

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* the information received *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.*

## Amendment 62

### Proposal for a regulation Article 8

*Text proposed by the Commission*

*Amendment*

#### ***Best practices***

***deleted***

***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.***

***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.***

***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.***

***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.***

***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.*

*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.*

*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).*

## Amendment 63

### Proposal for a regulation Article 9

#### *Text proposed by the Commission*

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. ***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. Checks *may* be conducted when a competent authority is in possession of relevant information, including on the basis of substantiated concerns provided by third parties, concerning non-compliance of a user with this Regulation.

#### *Amendment*

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).***
3. ***Additional*** checks ***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 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.

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 **paragraph** 1 of this Article, shortcomings have been detected, the competent authority shall issue a notice of remedial actions to be taken by the user.

*Additionally*, depending on the nature of the shortcomings detected, Member States may take immediate interim measures,

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*** depending on the nature of the shortcomings detected,



including inter alia seizure of illegally acquired genetic resources and suspension of specific use activities.

8. The Commission shall be empowered to adopt **implementing** acts to establish the procedures for implementing paragraphs 1 to 7 of this Article. **The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).**

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 **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.**

#### **Amendment 64**

##### **Proposal for a regulation Article 10 – paragraph 2**

*Text proposed by the Commission*

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

*Amendment*

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.**

#### **Amendment 65**

##### **Proposal for a regulation Article 11 – paragraph 2**

*Text proposed by the Commission*

2. The penalties provided for must be effective, proportionate and dissuasive. Those penalties may include:  
(a) fines;

*Amendment*

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**

(b) immediate suspension of specific use activities;

(c) confiscation of illegally acquired genetic resources.

*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.

## Amendment 66

### Proposal for a regulation

#### Article 12 – paragraph 1

*Text proposed by the Commission*

1. The competent authorities shall cooperate with each other, with the administrative authorities of third countries and with the Commission in order to ensure compliance of users with this Regulation.

*Amendment*

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.***

## Amendment 67

### Proposal for a regulation

#### Article 12 – paragraph 2

*Text proposed by the Commission*

2. The competent authorities shall exchange information on serious shortcomings detected through checks referred to in ***Article 9(1)*** and on the types of penalties imposed in accordance with Article 11 with the competent authorities of other Member States and with the

*Amendment*

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(4) and Article 10(1),*** and on the types of penalties

Commission.

imposed in accordance with Article 11 with the competent authorities of other Member States and with the Commission.

## Amendment 68

### Proposal for a regulation Article 12 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

***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.***

## Amendment 69

### Proposal for a regulation Article 13 – title

*Text proposed by the Commission*

*Amendment*

Union platform on access

Union platform on access ***and benefit-sharing***

## Amendment 70

### Proposal for a regulation Article 13 – paragraph 1

*Text proposed by the Commission*

*Amendment*

1. A Union platform on access to genetic resources and traditional knowledge associated with genetic resources is hereby established.

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.*

## Amendment 71

### Proposal for a regulation Article 13 – paragraph 2

*Text proposed by the Commission*

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, simplified access for non-commercial research, access practices of collections in the Union, access of Union stakeholders in third countries **and** the **sharing** of best practices.

*Amendment*

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, the implementation and further development*** of best practices, ***and the functioning of dispute settlement arrangements..***

## Amendment 72

### Proposal for a regulation Article 13 – paragraph 3

*Text proposed by the Commission*

3. The Union platform may provide non-binding advice, guidance or opinions on issues under its mandate.

*Amendment*

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.***

## Amendment 73

### Proposal for a regulation

#### Article 14 – points da, db, dc, dd, de and df (new)

*Text proposed by the Commission*

*Amendment*

*(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.*

## Amendment 74

### Proposal for a regulation Article 14 a (new)

*Text proposed by the Commission*

*Amendment*

#### *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 ...<sup>1</sup>. 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.*

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<sup>1</sup> *OJ please insert date: the date referred to in Article 17(1)*

## **Amendment 75**

### **Proposal for a regulation Article 15 a (new)**

*Text proposed by the Commission*

*Amendment*

#### *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.*

## Amendment 76

### Proposal for a regulation

#### Article 16 – paragraph 3

##### *Text proposed by the Commission*

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. In its reporting the Commission shall in particular consider the administrative consequences for public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

##### *Amendment*

3. Every *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.*

## Amendment 77

### Proposal for a regulation

#### Article 16 a (new)

##### *Text proposed by the Commission*

##### *Amendment*

##### *Article 16 a*

##### *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<sup>1</sup> 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".*

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<sup>1</sup> *OJ L 328, 6.12.2008, p. 28.*

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

## **Amendment 78**

### **Proposal for a regulation Article 17 – paragraph 2**

*Text proposed by the Commission*

2. *Articles* 4, 7, and 9 shall apply one year after the date of entry into force of this Regulation

*Amendment*

2. *Article* 4(1) to (4), *Article* 7, and *Article* 9 shall apply one year after the date of entry into force of this Regulation.