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*****I**

REPORT

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))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Sandrine Bélier

Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**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))**

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0576),
 - having regard to Article 294(2) and Article 192(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0322/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the French Senate, the Italian Senate and the Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 20 March 2013¹,
 - after consulting the Committee of the Regions,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Development, the Committee on Agriculture and Rural Development and the Committee on Fisheries (A7-0263/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 161, 6.6.2013, p. 73..

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 step up its contribution to averting global biodiversity loss by 2020.

Justification

The Convention on Biological Diversity (CBD) and the Nagoya Protocol share an overall objective: the conservation of biological diversity. It is worth recalling in this text that the Union has its own Biodiversity Strategy, which aims to avert global biodiversity loss by 2020.

Amendment 3

Proposal for a regulation Recital 1

Text proposed by the Commission

Amendment

(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

(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.

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.

Justification

The relevance for food security of genetic resources for food and agriculture and their relevance for adapting to climate change should be noted in the Regulation.

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 research, breeding and training purposes 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 knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles 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.

Justification

This amendment is in line with Article 8 of the Convention on Biological Diversity and with the United Nations legislations. Indigenous and local communities greatly contribute to the conservation of biodiversity in situ through the preservation and application of traditional knowledge and should be recognized as such.

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.

Justification

It is important to recall the essential point of non-patentability of living as stated by the European Patent Convention. For the sake of transparency and efficiency, and in order to

enable better monitoring, the references to genetic resources and their origin should appear in patent registrations.

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.

Justification

It should not be forgotten how much of the world's population is directly dependent on biodiversity as a source of income. The consequences of taking the wrong approach to genetic resources in the poorest regions of the world would be devastating for their inhabitants. The Nagoya Protocol acknowledged this fact and should therefore be implemented properly.

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 sustainable use of biodiversity, access and benefit-sharing can contribute to poverty eradication and environmental sustainability and thereby to the 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. 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

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 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

(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

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.

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.

Justification

The scope of the Nagoya Protocol is somewhat narrower than that of the Convention on Biological Diversity and does not extend to activities taking place outwith national waters, such as exploitation beyond the EEZs. Nonetheless, nothing prevents the Union from going further in this Regulation and, indeed, Article 10 of the Protocol envisages future mechanisms to address situations where obtaining prior informed consent is not possible.

Amendment 18

Proposal for a regulation Recital 8

Text proposed by the Commission

Amendment

(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***

(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 and 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

mutually agreed terms between providers and users.

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 as well as stakeholder groups involved in access and benefit-sharing of genetic resources.

Justification

The vast majority of genetic resources are located in countries of the South, where the populations often have a close connection with this biodiversity. An efficient Regulation will increase the trust of our external partners and thereby assure a sustainable access to genetic resources for European users.

Amendment 21

Proposal for a regulation Recital 9

Text proposed by the Commission

(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.

Amendment

(9) In order to ensure legal certainty, it is important that the rules implementing the Nagoya Protocol should only apply to ***new acquisition or new utilisation 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

(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 accessed in a Party to the Nagoya Protocol.***

Amendment

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

Justification

“Research and development” as understood in the context of the Nagoya Protocol is in line with Art. 31(1) of the Vienna Convention on the Law of Treaties.

The unclear definition of ‘use/utilization’ as given in Art. 3(6) opens up a dangerous spectrum of interpretations. The definition of ‘utilization’ from the Protocol shall be employed. Consistent use of the term needs to be ensured. Here, the definition of “use of genetic resources” under Art.3 of the Regulation shall be reflected to avoid misleading interpretation and to be in line with the definition of “utilization” in Art. 2 of the Protocol.

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.

Justification

The objectives of the Nagoya Protocol, as defined in its Article 1, suggest that benefit-sharing activities should also contribute to "the conservation of biological diversity and the sustainable use of its components".

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

deleted

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.

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 the ***establishment of prior informed consent and mutually agreed terms, the 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 resources in third countries.

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 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

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

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.

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.

Justification

It is important to emphasize that the conditions for being considered a union trusted collection should not only be technical. The first condition for being "trusted" is being able to put in place fair and equitable benefit-sharing.

Since 'Trusted' is a very loaded term a more neutral term such as 'Registered' would be preferable.

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.

Justification

International negotiations under the auspices of the Convention on Biological Diversity are currently under way to implement the global multilateral mechanism of benefit-sharing as defined in Article 10 of the Nagoya Protocol. The Union is a Party to these negotiations and should show its engagement through implementation of its objectives through a Union benefit-sharing fund in anticipation of the establishment of the global mechanisms in order to contribute to the conservation of biodiversity globally.

Amendment 32

Proposal for a regulation

Recital 22 b (new)

Text proposed by the Commission

Amendment

(22b) The principle of benefit-sharing as enshrined in Article 10 of the Nagoya Protocol should be implemented by the Union pending the establishment of a global multilateral mechanism as envisaged in the Nagoya Protocol. Until the multilateral mechanism is in place, a Union benefit-sharing fund should be established to collect benefit-sharing contributions and channel them to the conservation of biological diversity globally. To that end, the power to adopt

acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of detailed criteria and rules for benefit-sharing in situations where the country of origin of such resources cannot be established, or where it is not possible to grant or obtain prior informed consent. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Justification

It is important to provide guidelines linked to the provisions for delegated acts in terms of benefit-sharing from genetic resources originating from areas beyond national jurisdiction or where the country of origin or mutually agreed terms cannot be established, the compliance mechanisms and establishment of the Union benefit-sharing fund.

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.

Justification

The Protocol provisions on access to resources specifically refer to the interests of indigenous and local communities. It is therefore appropriate for the Regulation to do likewise

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').

Justification

It is important to recall the objective of the Nagoya Protocol as contained in its Article 1 as well as the objectives of its origin, the Convention on Biological Diversity.

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 elaborated 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

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

This Regulation applies to genetic resources over which states exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed, ***or utilised*** after

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.

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, *as well as subsequent applications and commercialisation*.

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 – paragraph 1 – 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*;

Justification

Derivatives represent a considerable part of the genetic resources and should be explicitly covered by the Regulation.

Amendment 39

Proposal for a regulation

Article 3 – paragraph 1 – 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;

Justification

This amendment adds the definition contained in Article 2 of the Nagoya Protocol.

Amendment 40

Proposal for a regulation

Article 3 – paragraph 1 – 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 – paragraph 1 – 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 – paragraph 1 – 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 Community market.

Amendment 43

Proposal for a regulation

Article 3 – paragraph 1 – 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;

Justification

This amendment adds the definition contained in Article 2 of the Nagoya Protocol.

Amendment 44

Proposal for a regulation

Article 3 – paragraph 1 – 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 – paragraph 1 – 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 – paragraph 1 – 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 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 if 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 50

Proposal for a regulation

Article 4 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. In the case of genetic resources where the country of origin cannot be established, or where it is not possible to grant or obtain prior informed consent, new users shall provide benefit-sharing to a Union benefit-sharing fund dedicated to the conservation of biological diversity globally, until a global multilateral benefit-sharing mechanism is established pursuant to Article 10 of the Nagoya Protocol.

Amendment 51

Proposal for a regulation

Article 4 – paragraph 2

Text proposed by the Commission

Amendment

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

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, or 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

(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*.

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 in the sense 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.

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 ...¹. Those rules shall require benefit-sharing at least at the level of best practice in the sector concerned and establish conditions for sharing of non-monetary benefits.

¹ 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.

Justification

The objectives of the Nagoya Protocol, as defined in Article 1, suggest that benefits sharing activities should contribute" to the conservation of biological diversity and the sustainable use of its components". Article 1 also makes an explicit reference to technology transfer. Given that they must together agree mutually agreed terms, it will be up to both providers and users to jointly ensure that mutually agreed terms increase, rather than reduce, biodiversity.

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 338/97¹.

¹ OJ L 61, 3.3.1997, p. 1.

Justification

Regulation (EC) No. 338/97 "on the protection of species of wild fauna and flora by regulating trade therein", is commonly known as the EU Wildlife Trade Regulation. Setting up a mechanism to ensure effective coordination between national authorities responsible for the implementation of CITES and the Nagoya Protocol is essential to efficiently address both illegal and unsustainable trade.

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 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

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*** on the occasion of:

approval is not required.

(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

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.

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 enough 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

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.

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).***

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 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:

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, 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

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

2. The penalties provided for must be effective, proportionate and dissuasive. Those penalties may include:

- | | |
|---|--|
| (a) fines; | (a) fines <i>proportional to the value of the use activities related to the genetic resources concerned and at least effectively depriving those responsible of the economic benefits derived from the infringement;</i> |
| (b) immediate suspension of specific use activities; | (b) immediate suspension of specific use <i>activities including commercialisation of products based on genetic resources and associated traditional knowledge;</i> |
| (c) confiscation of illegally acquired genetic resources. | (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 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

Amendment

2. The competent authorities shall exchange information ***on the organisation***

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 Commission.

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 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 which***

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.

Justification

Article 6 of the Protocol requires Parties to take, as appropriate, measures to involve indigenous and local communities where those communities have rights to grant access. The Union platform should be expressly bound to respect these provisions.

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 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 thereof, 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 on Biodiversity, 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 ...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)

Justification

Delegated acts are necessary for establishing the rules for benefit-sharing for use of genetic resources originating from areas beyond national jurisdiction or where country of origin cannot be established, for procedures for checks on user compliance and the implementation of the risk based approach, and for the setting up of the Union Benefit-Sharing Fund as such acts supplement non-essential elements of the Regulation.

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.

Justification

Member States experts as well as stakeholder organisations should have an opportunity to participate and contribute to the implementation of the Regulation, including the draft delegated and implementing acts. The concept follows the Consultation Forum model in the Eco-Design Directive 2009/125/EC.

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

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**

genetic resources.

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 Articles 5.2, 6.2, 7 and 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 law¹ 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 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.

EXPLANATORY STATEMENT

Access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation (Nagoya Protocol): Union implementation and ratification 2012/0278(COD)

GENERAL CONTEXT

The loss of biodiversity is constantly increasing and accelerating. It has been calculated that one in four species of mammals, one in eight birds and more than one in three amphibians are threatened with extinction worldwide (IUCN, 2012). Almost 60% of ecosystems have deteriorated in the past 50 years (FAO, 2010). Quite aside from the ethical and moral implications, the economic and social impact of this state of affairs is immense: by 2050 economic losses caused by loss of biodiversity will amount to 7% of global GDP (TEEB 2010).

Paradoxically, biological diversity offers an inexhaustible reservoir of innovations and discoveries in terms of scientific research and technological applications as well as healthcare products, foodstuffs, cosmetics and other products. It is thus imperative to conserve biodiversity, not only for the sake of humanity in both the Global North and Global South but also for the socio-economic vitality of Europe and its people, who benefit directly from its use.

In order to help conserve biodiversity, and the peoples and knowledge associated with it, we must ensure today that the benefits arising from the utilisation of genetic resources and the associated traditional knowledge are shared fairly and equitably. This benefit-sharing must contribute to the conservation of biological and cultural diversity *in situ* and ensure its sustainable use for local populations.

It is in this spirit that the Nagoya Protocol on Access and Benefit-Sharing was signed in 2010, on the occasion of the 10th Conference of the Parties to the Convention on Biological Diversity.

THE RAPPORTEUR'S PROPOSAL

With this proposal for a regulation from the Commission, the European Union is now undertaking to transpose the Nagoya Protocol. The rapporteur believes it important for the resulting regulation to stick as closely as possible to both the spirit and text of this international treaty.

The Commission proposal constitutes a solid basis for an effective system at European level. However, if we wish to comply fully with the Nagoya Protocol, we will have to strengthen certain mechanisms, as the rapporteur proposes. If the issue of access to resources is left to the sovereignty of the Member States, we must establish a clear Community framework for the fair and equitable sharing of benefits derived from the use of natural resources.

The draft regulation that the rapporteur has submitted to the European Parliament is intended to address the various situations and needs currently known, expressed or anticipated by all European stakeholders as well as our partners in third countries.

The amendments tabled herein are intended to benefit primarily European citizens by guaranteeing traceability and ethical conduct, compliance with international legal obligations and the fair and equitable sharing of benefits.

What is more, the adoption of a clear legal framework will be beneficial for all users, including public and private economic stakeholders, since it will provide both sustainable access to genetic resources and legal certainty throughout the chain of custody.

The framework will also provide public and private research collections and institutions – key players in the European chain of custody – with simple rules that are tailored to their needs. In accordance with the relevant provisions of the Nagoya Protocol, this regulation must thus apply to all stakeholders, including not-for-profit research institutions, as these transmit genetic resources and valuable information to users who seek an assurance of traceability and legal certainty.

Finally, the amendments tabled by the rapporteur aim to reinforce international equity and the confidence of third country suppliers, and thereby to boost trade between them and user countries in the European Union. The fair and equitable sharing of benefits arising from the utilisation of their genetic resources goes beyond the sharing of financial benefits and will allow environmental conservation, social progress and sustainable use of resources *in situ*.

KEY LINES OF ACTION

Improving the chain of custody of genetic resources and the associated traditional knowledge

Ensuring the integrity of the chain of custody is essential if we wish to guarantee traceability and legal certainty for users. This means that a genetic resource must at all times be used in accordance with the terms agreed with the supplier. If any other use is considered, then a new contract for access and benefit-sharing must be drawn up beforehand to reflect the relevant changes.

The rapporteur proposes retaining checks whenever applications for marketing authorisation are made and whenever public or private research credits are granted, so as not to disadvantage public research institutes and universities.

Reporting obligations must also be introduced covering the signing of the access and benefit-sharing contract to alert the relevant authorities whenever a genetic resource comes under the European system.

Checks with the competent authorities must also be carried out whenever a patent application is made. This will chiefly concern the national patent offices, but the European Patent Office, which processes the majority of patents, will also be involved, and an agreement between it and the European Union must be secured.

Improving the chain of custody in this manner would prevent imposing a greater administrative burden as a result of the checks, as it would enable a clearly defined and functional follow-up process. Moreover, this will guarantee the avoidance of penalties at the end of the process, for example in cases where an application for marketing authorisation is denied to a company that has invested substantial resources in research and development but is proven to have used a genetic resource without due authorisation.

Increasing transparency and legal certainty

The rapporteur stresses the fundamental importance of outlawing biopiracy, the illegal acquisition and use of genetic resources, in Europe. Such practices not only lead to human tragedies; they also run counter to the principles of fairness and the values of the European Union, compromise the international image of the Member States and our relations with supplier countries, and undermine the legal situation of European users.

Due diligence requires users to take all necessary steps to comply with the proposed legislation. These rules should, however, be supplemented by prohibition of biopiracy, with a view to gradually acting as an effective deterrent. This two-pronged approach will ensure greater reliability and a smoother functioning of access and benefit-sharing mechanisms.

This entails setting a legal definition of the offence of biopiracy and establishing appropriate sanctions. The European Union will thereby have a system at its disposal which is very similar to that laid down by Parliament in accordance with Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market.

New utilisations of genetic resources and associated traditional knowledge and progressive compliance

The fair and equitable sharing of benefits arising from any utilisation of genetic resources and associated traditional knowledge is enshrined in the Convention on Biological Diversity and the Nagoya Protocol. The rapporteur therefore proposes that each new utilisation that has not been defined before the entry into force of this regulation should be covered by an access and benefit-sharing contract. Such a requirement would allow all genetic resources in Europe to gradually come into compliance. Much of the world's genetic resources are indeed already found in European collections. The Commission proposal does not cover these resources, and this poses several major problems. The most important problem, according to the rapporteur, is that some uses of resources that may have been acquired illegally could thus be legalised. It is also important, on the one hand, not to place users who already apply the principle of benefit-sharing at a disadvantage with respect to those who do not yet do so and, on the other hand, to ensure that a genetic resource in a European collection can in the future still be subject to benefit-sharing in its country of origin. This system will help encourage third countries to open their doors to secure and sustainable access to genetic resources and associated traditional knowledge.

A Union fund for the sharing of benefits and the strengthening of the multilateral global process

The rapporteur believes it to be essential for users to take the necessary steps to secure an access and benefit-sharing contract in the event of a new utilisation of any genetic resource. She does, however, recognise that the origin of some genetic resources, such as 'historical'

genetic resources or those acquired in areas beyond national jurisdictions, cannot be traced. To address this situation, the rapporteur proposes the establishment of a Union benefit-sharing fund, which will be financed by the users of genetic resources, with a view to preserving global biodiversity. This Union fund will ultimately contribute to establishing a global multilateral benefit-sharing mechanism, as set out in Article 10 of the Nagoya Protocol.

All proposals tabled by the rapporteur aim to ensure that the European Union assumes a leading role in current and future international negotiations by taking a progressive stance with a view to setting up, as soon as possible, an ambitious global multilateral mechanism to meet the challenges of preserving biodiversity and its sustainable use.

30.5.2013

OPINION OF THE COMMITTEE ON DEVELOPMENT

for the Committee on the Environment, Public Health and Food Safety

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))

Rapporteur: Catherine Grèze

SHORT JUSTIFICATION

The "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation to The Convention of Biological Diversity", adopted on 29 October 2010, aims to establish more predictable conditions for access to genetic resources; ensure benefit-sharing between users and providers of genetic resources and finally, to ensure that only legally acquired genetic resources are used. On this ground, given that developing countries dominate the provision of genetic resources and traditional knowledge associated with such resources, the Nagoya Protocol is an important tool to combat biopiracy and to restore fairness and equity in the exchange of genetic resources, especially in a context where users are mainly found in developed country. However, when elaborating its proposed system for the implementation of the Nagoya Protocol, the Commission has obviously been more mindful of users' than of providers' interests and concerns. Minimising users' burdens and costs and facilitating easy access seem to be top priorities, while the same can definitely not be said about promoting effective benefit-sharing (BS).

In line with the objective of Policy Coherence for Development Article 208 of the Treaty on the Functioning of the European Union (TFEU), this Regulation shall restore a fair balance between providers and users of genetic resources and traditional knowledge associated with such resources, while 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. In particular, provisions related to the implementation and monitoring of user's obligations on due diligence need to be strengthened so as to enable effective enforcement of PIC (prior informed consent) and MAT (mutually agreed terms) along the chain of utilisation of genetic resources or traditional knowledge associated to it. Likewise, given that traditional knowledge that is held by indigenous and local communities may provide important information for the scientific discovery of potentially valuable genetic or

biochemical properties of genetic resources, EU's Regulation should respect and facilitate implementation of 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. Furthermore, the EU should act in a proactive manner to ensure the objectives of Nagoya Protocol regarding global multilateral benefit-sharing mechanisms are achieved. In practise, until the multilateral mechanism is in place, a Union Benefit Sharing Fund should be established to collect benefit-sharing contributions and channel them to the conservation of biological diversity globally.

AMENDMENTS

The Committee on Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

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 2

Text proposed by the Commission

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

(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.

Amendment 3

Proposal for a regulation

Recital 3

Text proposed by the Commission

(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.

Amendment

(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 knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. 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 EU implementing measures should facilitate this.**

Amendment 4

Proposal for a regulation

Recital 3a (new)

Text proposed by the Commission

Amendment

(3a) It is important to recall that according to the European Patent Convention plant and animal varieties (Article 53(a)) as well a biological processes for the production of plants and animals (Article 53(b)) are not patentable. When inventions are based on genetic resources or on components of genetic resources, applications for patent

covering inter alia genetic resources, products, including derivatives, and processes derived from the use of biotechnology, or traditional knowledge associated with the genetic resource, the resources should be indicated 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 5

Proposal for a regulation Recital 4a (new)

Text proposed by the Commission

Amendment

(4a) Genetic resources should be preserved "in situ" and used in sustainable ways and the benefits arising out of their utilisation should be fairly and equitably shared. As parties to the Convention on Biological Diversity, the EU and its Member States have committed themselves to these principles. The EU and its Member States have also signed the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation. Capacity to effectively implement this Protocol should be built up.

Amendment 6

Proposal for a regulation Recital 4b (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 sustainable use of biodiversity, access and benefit-sharing can contribute to poverty eradication and environmental sustainability and thereby to the progress towards the Millennium Development Goals, as acknowledged in the preamble of the Nagoya Protocol. The implementation of the Nagoya Protocol should also aim at realising these potentials.

Amendment 7

Proposal for a regulation Recital 4c (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 must always be protected.

Amendment 8

Proposal for a regulation Recital 4d (new)

Text proposed by the Commission

Amendment

(4d) Like the genetic resources, traditional knowledge associated with such resources is largely concentrated in developing countries, in particular in indigenous and local communities. 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 EU implementing measures should facilitate this.

Amendment 9

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 10

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 significantly expands the general rules of the Convention on access and benefit-sharing for the *utilisation and subsequent commercialisation* of genetic resources and traditional knowledge associated with genetic resources.

Amendment 11

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 that should *support its main objective, notably the conservation of biological diversity and 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 12

Proposal for a regulation Recital 8a (new)

Text proposed by the Commission

Amendment

(8a) Biopiracy consisting of either unauthorised extraction of genetic resources, or unauthorised utilisation or subsequent commercialisation of products based on such resources or associated traditional knowledge, should be prohibited and subject to criminal sanctions in accordance with Directive 2008/99/EC.

Amendment 13

Proposal for a regulation Recital 8b (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 as well as stakeholder groups involved in access and benefit sharing of genetic resources.

Amendment 14

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

(9) In order to ensure legal certainty, it is important that the rules implementing the

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.

Nagoya Protocol should only apply to ***new acquisition and new utilisation of*** genetic resources and traditional knowledge associated with genetic resources that ***has commenced*** after the entry into force of the Nagoya Protocol for the Union.

Amendment 15

Proposal for a regulation

Recital 11

Text proposed by the Commission

(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 accessed in a Party to the Nagoya Protocol.

Amendment

(11) It is important to define, in accordance with the Nagoya Protocol, that ***utilization*** 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 accessed in a Party to the Nagoya Protocol.

Amendment 16

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***

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 ***fair and equitable benefit-sharing occurs whenever this should be the case***. 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. ***Tools and***

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 17

Proposal for a regulation Recital 16

Text proposed by the Commission

(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.

measures applied for *facilitating the* exercise of due diligence *which have been shown to be reliable and efficient* should be supported through the recognition of best practices. Sectoral codes of conduct, model contractual clauses, and guidelines *should also be supported* 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

(16) Best practices developed by users *or organisation with interest and expertise in the utilisation of genetic resources and access and benefit sharing* should *be evaluated. When found useful and consistent with the Nagoya Protocol and this Regulation, they should be drawn upon in the identification of* 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 *provided that they facilitate users' compliance with their obligations, which will include fair and equitable benefit-sharing.* 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 *for facilitating compliance*

with user obligations. 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.

Amendment 18

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 the ***establishment of prior informed consent and mutually agreed terms, the*** receiving of research funds, ***when applying for intellectual property rights at relevant national, regional or international institutions,*** 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 ***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 19

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 resources in third countries.

Amendment

(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 resources in third countries. ***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 might require new prior informed consent and mutually agreed terms.***

Amendment 20

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

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 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

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.

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 **registered** 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 21

Proposal for a regulation Recital 19a (new)

Text proposed by the Commission

Amendment

(19a) Union trusted 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 trusted 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 must 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 22

Proposal for a regulation Recital 21a (new)

Text proposed by the Commission

Amendment

(21a) The Nagoya Protocol's Article 18 prescribes that each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms. The agreements on the terms will be private law agreements. As parties to the Nagoya Protocol, Member States of the EU must put in place recourse mechanisms. These mechanisms should be as similar as possible.

Amendment 23

Proposal for a regulation Recital 22a (new)

Text proposed by the Commission

Amendment

(22a) The European Union should act in a proactive manner to ensure that the objectives of Nagoya Protocol regarding global multilateral benefit-sharing mechanisms are achieved in order to increase resources to support of conservation of biological diversity and the sustainable use of its component globally.

Amendment 24

Proposal for a regulation Recital 22b (new)

Text proposed by the Commission

Amendment

(22b) The principle of benefit sharing as enshrined in Article 10 of the Nagoya Protocol should be implemented on the Union side awaiting the establishment of a global multilateral mechanism as envisaged in the Protocol. Until the multilateral mechanism is in place, a Union Benefit Sharing Fund should be established to collect benefit-sharing contributions and channel them to the conservation of biological diversity globally. To that end, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of detailed criteria and rules for benefit sharing in situations where genetic resources originate from areas beyond the jurisdiction of the Member States, or the country of origin of such resources cannot be established, or it is not possible to grant or obtain prior informed consent. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Amendment 25

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.

Amendment 26

Proposal for a regulation Article 1 – subparagraph -1 (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.

Amendment 27

Proposal for a regulation Article 1 – subparagraph 1

Text proposed by the Commission

This Regulation establishes rules governing access and benefit-sharing for

Amendment

This Regulation establishes rules governing access and ***fair and equitable***

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).

benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with, ***and support of*** 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 28

Proposal for a regulation

Article 1 – subparagraph 2a (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 elaborated 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 29

Proposal for a regulation Article 2 – subparagraph 1

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.

Amendment

This Regulation applies to genetic resources and to traditional knowledge associated with genetic resources that are accessed ***or utilised*** 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 ***as well as subsequent applications and commercialisation***.

Amendment 30

Proposal for a regulation Article 3 – subparagraph 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 31

Proposal for a regulation Article 3 – subparagraph 3a (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 32

Proposal for a regulation Article 3 – subparagraph 5

Text proposed by the Commission

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

Amendment

(5) "user" means a natural or legal person **utilising** genetic resources or traditional knowledge associated with genetic resources **or subsequently commercialising genetic resources or products based on genetic resources, or traditional knowledge associated with genetic resources;**

Amendment 33

Proposal for a regulation Article 3 – subparagraph 6

Text proposed by the Commission

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

Amendment

(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 34

Proposal for a regulation Article 3 – subparagraph 10a (new)

Text proposed by the Commission

Amendment

(10a) "illegally acquired genetic resources" means genetic resources and traditional knowledge associated with genetic resources accessed in contravention to the applicable international and national legislation or regulatory requirements on access and benefit sharing in the country of origin;

Amendment 35

Proposal for a regulation

Article 3 – subparagraph 10b (new)

Text proposed by the Commission

Amendment

(10b) "biopiracy" means utilisation, or subsequent commercialisation of illegally acquired genetic resources or products derived from such resources, or associated traditional knowledge;

Amendment 36

Proposal for a regulation

Article 3b (new)

Text proposed by the Commission

Amendment

Article 3b

Definition of catalogue

Genetic catalogues are made of individuals belonging to certain species. The next item of importance are local populations (landraces, ecotypes, endemisms, varieties, or even subspecies). Genetic catalogues require as for traceability an unbiased method of bar-coding that should be based on DNA sequencing technologies.

Amendment 37

Proposal for a regulation

Article 4 – subparagraph -1 (new)

Text proposed by the Commission

Amendment

(-1) The utilisation and commercialisation of illegally acquired genetic resources shall be prohibited in the EU.

Amendment 38

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 in accordance with applicable access and benefit-sharing legislation or regulatory requirements, ***after obtainment of prior informed consent when so required and with full respect of existing duties regarding fair and equitable benefit-sharing upon mutually agreed terms***. Users shall seek, keep, and transfer to subsequent users information relevant for access and benefit-sharing ***and compliance with the provisions of this Regulation***.

Amendment 39

Proposal for a regulation Article 4 – paragraph 1a (new)

Text proposed by the Commission

Amendment

1a. Genetic resources and associated traditional knowledge shall only be transferred to other users if in accordance with prior informed consent and mutually agreed terms. Subsequent users may only utilise the material received in accordance with the original terms. If there is no prior informed consent and mutually agreed terms or subsequent users anticipate to utilise the genetic resources or traditional knowledge under conditions that are not included in the original terms, they are required to seek prior informed consent from the country of origin and mutually agreed terms preceding commencement of new utilisation.

Amendment 40

Proposal for a regulation

Article 4 – paragraph 1b (new)

Text proposed by the Commission

Amendment

1b. As regards genetic resources originating from areas beyond national jurisdiction, or where country of origin can not be established, or where it is not possible to grant or obtain prior informed consent, new users shall provide benefit sharing to a Union Benefit Sharing Fund dedicated to the conservation of biological diversity globally, until a Global Multilateral Benefit-sharing Mechanism is established pursuant to Nagoya Protocol Article 10.

Amendment 41

Proposal for a regulation

Article 4 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) seek, keep and transfer to subsequent users ***information on:***

(a) seek, keep and transfer to subsequent users ***the internationally recognised certificate of compliance, where genetic resources were accessed by Parties to the Nagoya Protocol which have exercised their sovereign rights as provided for in Article 6 of that Protocol; or, failing this:***

(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;

Justification

Article 4(2)(a)(1) to (5) go under next amendment.

Amendment 42

Proposal for a regulation

Article 4 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) 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;

Justification

Article 4(2)(a)(1) to (5) have changed position to become point aa (new).

Amendment 43

Proposal for a regulation

Article 4 – paragraph 2 – subparagraph a - point 5

Text proposed by the Commission

(5) access decisions and mutually agreed terms, where applicable

Amendment

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

Amendment 44

Proposal for a regulation

Article 4 – paragraph 4

Text proposed by the Commission

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.

Amendment

4. Users ***that have accessed*** a genetic resource ***or traditional knowledge associated with a genetic resource*** from a collection listed in the Union register of ***registered*** collections referred to in Article 5(1) ***and produce the documentation they have obtained from this collection together with the genetic resources or traditional knowledge*** 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.

Amendment 45

Proposal for a regulation

Article 4 – paragraph 4a (new)

Text proposed by the Commission

Amendment

4a. The Commission shall be empowered to adopt delegated acts in order to establish the rules for benefit-sharing in accordance with paragraph 1c by [six months after the entry into force of this Regulation]. Those rules shall require

benefit-sharing at least at the level of best practice in the sector concerned and establish conditions for sharing of non-monetary benefits.

Amendment 46

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph a

Text proposed by the Commission

(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;

Amendment

(a) apply standardised procedures for exchanging samples of genetic resources and information *on traditional knowledge associated with genetic resources* with other collections, and for supplying samples of genetic resources and information *on such knowledge* to third persons for their use;

Amendment 47

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph b

Text proposed by the Commission

(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;

Amendment

(b) have samples of genetic resources and related information supplied to third persons for their *utilisation* only with documentation providing evidence that the resources and the information were accessed in accordance with applicable *access and benefits sharing legislation or regulatory* requirements and mutually agreed terms for the fair and equitable sharing of benefits;

Amendment 48

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph e a (new)

Text proposed by the Commission

Amendment

(ea) make efforts, in cooperation with indigenous and local communities, other collections, authorities, organisations or institutions, as appropriate, to document traditional knowledge associated with genetic resources or to make information on such knowledge available for the purpose of helping to protect relevant rights and facilitate utilisation of such knowledge in full respect of relevant rights;

Amendment 49

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph e b (new)

Text proposed by the Commission

Amendment

(eb) contribute to awareness-raising on the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues, in line with Article 21 of the Nagoya Protocol;

Amendment 50

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph e c (new)

Text proposed by the Commission

Amendment

(ec) contribute to capacity-building in developing countries, in line with Article 22 of the Nagoya Protocol;

Amendment 51

Proposal for a regulation Article 7 – paragraph 2

Text proposed by the Commission

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 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.*

Amendment

2. Users shall declare to the competent authorities established under Article 6(1) that they *have complied with provisions of* Article 4 *and shall submit the related information* on the occasion of::

Amendment 52

Proposal for a regulation Article 7 – paragraph 2 – subparagraph a (new)

Text proposed by the Commission

Amendment

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

Amendment 53

Proposal for a regulation Article 7 – paragraph 2 – subparagraph b (new)

Text proposed by the Commission

Amendment

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

Amendment 54

Proposal for a regulation

Article 7 – paragraph 2 – subparagraph c (new)

Text proposed by the Commission

Amendment

(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 resource;

Amendment 55

Proposal for a regulation

Article 7 – paragraph 2 – subparagraph d (new)

Text proposed by the Commission

Amendment

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

(Text is from end of Article 7, paragraph 2)

Amendment 56

Proposal for a regulation

Article 7 – paragraph 3

Text proposed by the Commission

Amendment

3. 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.

3. Competent authorities shall ***verify the information provided under points (b) to (e) and*** transmit to the Commission ***within three months*** the information received ***pursuant to this article***. The Commission shall ***within three months*** summarise the information received and make ***the information required for internationally recognised certificate*** available to the

Amendment 57

Proposal for a regulation Article 8 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. Any association of users ***or organisation with interest and expertise in the utilisation of genetic resources and access and benefit sharing*** 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.

Amendment 58

Proposal for a regulation Article 8 – paragraph 2

Text proposed by the Commission

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.

Amendment

2. ***The Commission shall assess each application, taking into account information and evidence from the applicant, relevant providers, users, authorities, institutions, inter-governmental organisations, as well as representatives of indigenous and local communities, non-governmental organisations and other actors, as appropriate.*** On the basis of ***this*** information and evidence, the Commission shall determine whether 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, ***including those relating***

to the obtainment of prior informed consent and to fair and equitable benefit-sharing upon mutual agreed terms, where applicable. The Commission shall grant recognition as best practice to the combination of procedures, tools or mechanisms for which an application has been filed if this combination enables users to comply with their obligations and does so in a more reliable and efficient way than other existing or emerging combinations.

Amendment 59

Proposal for a regulation

Article 8 – paragraph 2 – subparagraph 2a (new)

Text proposed by the Commission

Amendment

2a. Where use of genetic resources or traditional knowledge associated with genetic resources has the potential to lead to the development of medicinal products of interest to the provider and importance to the human right of the enjoyment of the highest attainable standard of health, affordable access to these products may be an important aspect of fair and equitable benefit-sharing and best practices in relevant areas shall take account of this.

Amendment 60

Proposal for a regulation

Article 8 – paragraph 2 – subparagraph 2b (new)

Text proposed by the Commission

Amendment

2b. Where use of genetic resources or traditional knowledge associated with genetic resources may influence food security, e.g. by leading to restrictions on

farmers' possibilities to reseed or exchange seeds, avoiding negative such influences may be an important aspect of fair and equitable benefit-sharing and best practices in relevant areas shall take account of this.

Amendment 61
Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission

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

3. 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 non-compliance of a user with this Regulation.

Amendment 62

Proposal for a regulation
Article 11 – paragraph 2 – subparagraph a

Text proposed by the Commission

(a) fines;

Amendment

(a) fines *proportional to the value of the use of genetic resources concerned*;

Amendment 63

Proposal for a regulation
Article 11 – paragraph 2 – subparagraph b

Text proposed by the Commission

(b) immediate suspension of specific use activities;

Amendment

(b) immediate suspension of specific use activities *including commercialisation of products based on genetic resources and associated traditional knowledge*;

Amendment 64

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 be conducted with other relevant actors, including collections, non-governmental organisations and representatives of indigenous and local communities when important for the correct implementation of the Nagoya Protocol and this Regulation.***

Amendment 65

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 Commission.

Amendment

2. The competent authorities shall ***receive information from relevant actors and*** exchange information ***between themselves*** 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 Commission.

Amendment 66

Proposal for a regulation Article 12 – paragraph 2a (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 67

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 68

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.

Amendment 69

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 the obtainment of prior informed consent, benefit-sharing practices, the implementation and further development* of best practices *and the functioning of dispute settlement arrangements..*

Amendment 70

Proposal for a regulation Article 13 – paragraph 4

Text proposed by the Commission

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.

Amendment

4. Each Member State and the Commission may nominate one regular member for the Union platform. Stakeholders, *representatives of relevant inter-governmental and non-governmental organisations* and other experts in matters addressed by this Regulation *shall* be invited as appropriate.

Amendment 71
Proposal for a regulation

Article 14 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) compile a catalogue of available genetic resources originating in Member States, pursuant to Article 7 of the Convention on Biological Diversity, in order to establish their biological diversity. They shall, in addition, encourage third countries to produce catalogues of their genetic resources with a view to improving the transparency of user access.

Amendment 72

Proposal for a regulation

Article 14 – paragraph 1 - point d b (new)

Text proposed by the Commission

Amendment

(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, those 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.

Amendment 73

Proposal for a regulation

Article 14 – paragraph 1 - point d c (new)

Text proposed by the Commission

Amendment

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

Amendment 74

Proposal for a regulation

Article 14 – paragraph 1 - point d d (new)

Text proposed by the Commission

Amendment

(dd) support regional cooperation on benefit-sharing regarding transboundary genetic resources and associated traditional knowledge.

Amendment 75

Proposal for a regulation

Article 14 – paragraph 1 – point d e (new)

Text proposed by the Commission

Amendment

(de) once the fund to be set up under the Convention on Biological Diversity, or any other fund established for the same purpose, has entered into operation, they shall endeavour to ensure that such funds provide sources of financing for research and the compilation of genetic resource catalogues.

Amendment 76

Proposal for a regulation Article 14a (new) - Title

Text proposed by the Commission

Amendment

Union Benefit Sharing Fund

Amendment 77

Proposal for a regulation Article 14a (new) – paragraph 1

Text proposed by the Commission

Amendment

1. A Union Benefit Sharing Fund is hereby established.

Amendment 78

Proposal for a regulation Article 14a (new) – paragraph 2

Text proposed by the Commission

Amendment

2. The Fund shall receive revenues from the implementation of Article 4 (1c).

Amendment 79

Proposal for a regulation Article 14a (new) – paragraph 3

Text proposed by the Commission

Amendment

3. The Commission shall be empowered to adopt delegated acts to establish the procedures for implementing and operating the Union Benefit Sharing Fund to finance the conservation of biodiversity globally.

Amendment 80

Proposal for a regulation Article 15a (new) – Title

Text proposed by the Commission

Amendment

Consultation Forum

Amendment 81

Proposal for a regulation Article 15a (new) – paragraph 1

Text proposed by the Commission

Amendment

The Commission shall ensure that, in the implementation of the Regulation a balanced participation of Member States' representatives and relevant provider organisations, user associations, inter-governmental, non-governmental organisations as well as representatives of indigenous and local communities is ensured. Those parties shall contribute, in particular, to defining and reviewing delegated acts pursuant to Articles 4(5), 9(8), and 14a(3), and to the implementation of Articles 5, 7 and 8, and any guidelines that are drawn up for establishing mutually agreed terms. Those parties shall meet in a Consultation Forum. The rules of procedure of the Forum shall be established by the Commission.

Amendment 82

Proposal for a regulation Article 16a (new) Directive 2008/99/EC Article 3 – paragraph 1a (new)

Text proposed by the Commission

Amendment

16a. The following point shall be added to

Article 3 of Directive 2008/99/EC, with effect from ...:*

'(ia) biopiracy.'

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

Amendment 83

Proposal for a regulation

Article 16b (new)

Directive 2008/99/EC

Annex A – indent (new)

Text proposed by the Commission

Amendment

16b. The following indent shall be added to Annex A of Directive 2008/99/EC, with effect from ...:*

'– 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.'

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

PROCEDURE

Title	Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union
References	COM(2012)0576 – C7-0322/2012 – 2012/0278(COD)
Committee responsible Date announced in plenary	ENVI 19.11.2012
Opinion by Date announced in plenary	DEVE 19.11.2012
Rapporteur Date appointed	Catherine Grèze 3.1.2013
Discussed in committee	22.4.2013
Date adopted	27.5.2013
Result of final vote	+: 13 –: 10 0: 0
Members present for the final vote	Thijs Berman, Corina Crețu, Véronique De Keyser, Charles Goerens, Mikael Gustafsson, Eva Joly, Filip Kaczmarek, Miguel Angel Martínez Martínez, Gay Mitchell, Bill Newton Dunn, Andreas Pitsillides, Maurice Ponga, Jean Roatta, Alf Svensson, Keith Taylor, Ivo Vajgl, Anna Záborská, Iva Zanicchi
Substitute(s) present for the final vote	Eric Andrieu, Philippe Boulland, Emer Costello, Cristian Dan Preda, Judith Sargentini

30.5.2013

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on the Environment, Public Health and Food Safety

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))

Rapporteur: José Bové

SHORT JUSTIFICATION

Background

The proposal for a regulation under consideration is necessary for the purposes of implementing the Nagoya Protocol in the Union and enabling Union ratification. The Nagoya Protocol (NP), adopted in October 2010, results directly from the Convention on Biological Diversity (CBD), which is in force in the Union. More specifically, the NP is intended to establish a set of rules on access and benefit-sharing (ABS), for which the CBD provided little detail.

In everyday language, the expression 'access and benefit-sharing', on the international level, is intended to mean two things:

- (1) countries that hold genetic resources should make these available to public or private operators outside its borders who wish to carry out research and develop new products ('access'),
- (2) in return, the benefits, in particular profits, from the use of such genetic resources should be fairly shared between the country of origin and those operators ('benefit-sharing').

Position of the Rapporteur for the Opinion

Since the purpose of regulation proposed is, in essence, to transpose an international agreement into Union law, the rapporteur for the opinion feels that, wherever possible, the text of the proposed regulation should mirror the text of the Nagoya Protocol.

Therefore a number of amendments are proposed to bring the language of the NP and the

future regulation closer together. In particular, it is important to recall that the rules on access and benefit-sharing (ABS) are intended to serve a wider goal, which is explicitly mentioned in the CBD and the NP - the conservation of biological diversity. The NP also explicitly defines some secondary objectives, including, for instance, technology transfer to developing countries. The rapporteur for the opinion therefore feels that some of the language of the future regulation should more rigorously reflect the context of the NP.

Comments on the Amendments Proposed

The rapporteur is convinced that the text should include a reference to conserving genetic resources for agricultural use in the European Union, and therefore proposes an amendment which is intended to provide help for farmers and other local actors who preserve biodiversity, for instance of crops, localised in *in situ* collections. The goal would be to help such small-scale players to become "Union-trusted collections" in the terms of the proposed regulation. That idea is set out in amendment 38.

Another important amendment relates to the scope (Article 2). To provide legal certainty, it should be made clear that the regulation applies to genetic resources that are **utilised and commercialised**, rather than simply accessed, after the entry into force of the NP, a wording which is closer to the original text of the Protocol.

The Commission's proposal does not refer to intellectual property rights (IPR); nevertheless, the rapporteur feels that it is necessary, in the context of this regulation, to expressly refer to the fact that new patents should disclose the origin of the genetic resources used in the creation of a new product. The objective of the NP is to create a system - dependent on trust - under which genetic resources will circulate around the globe since both providers and users feel that they will benefit from such flows. For the same reasons - building a system based on trust and providing an alternative to 'biopiracy' - it makes sense to develop international rules intended to ensure that new patents are based on legally-acquired genetic resources.

Many of the rapporteur's other proposed amendments result from the need, already explained above, to insert some of the language of the NP into the future regulation, providing more context. For instance, amendments are proposed to Article 4 on obligations of users, Article 5 on Union-trusted collections and Article 8 on best practices recalling the overall objectives of the NP. The amendment proposed to penalties (Article 11) serves to make the examples of possible penalties easier to understand.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation Recital -1a (new)

Text proposed by the Commission

Amendment

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

Justification

The Convention on Biological Diversity (CBD) and the Nagoya Protocol share an overall objective: the conservation of biological diversity. It is worth recalling in this text that the Union has its own Biodiversity Strategy, which aims to avert global biodiversity loss by 2020.

Amendment 2

Proposal for a regulation

Recital 1

Text proposed by the Commission

Amendment

(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.

(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 3
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, development of medicines, 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.***

Amendment 4
Proposal for a regulation

Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) Access to genetic resources and the fair and equitable distribution of benefits resulting from their use should provide an answer to the problem of supplying enough food to meet the needs of an expanding world populace.

Amendment 5
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

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 ***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.

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 benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Amendment 6

Proposal for a regulation

Recital 9

Text proposed by the Commission

(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.

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 ***or utilised*** after the entry into force of the Nagoya Protocol for the Union.

Justification

Articles 1 and 3 of the Nagoya Protocol (NP), which respectively deal with its objectives and scope, refer to "utilization" of genetic resources, rather than simply access. Article 1 of the NP states that the "objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources".

Amendment 7

Proposal for a regulation

Recital 11 a (new)

Text proposed by the Commission

Amendment

(11a) In accordance with the Nagoya Protocol, it must be stipulated that Member States shall not be restricted in their interpretation at national level of Directive 98/44/EG on the legal protection of biotechnical inventions (bio patent

directive). In particular, the use of biological materials for the purpose of breeding, discovery and developing other plant varieties and the use by farmers of crops for propagation or multiplication by them on their own holdings must be guaranteed.

Amendment 8

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, where relevant, benefits are shared. However, given the diversity of users within the Union not all users *must be obliged* to take the same measures for exercising due diligence. *This is the case in particular for subsequent users where the due diligence obligation should only apply in the case such users access and use genetic resources in the form as originally accessed by the initial user.* The obligation on users to keep information relevant for access and benefit-sharing, *in particular documented proof that benefit-sharing obligations have been fully and legally carried out*, should be limited in time, consistent with the time-span for an eventual innovation.

Justification

It is important to clearly state that users are obliged to keep documentary proof that they have fulfilled their benefit-sharing obligations.

Amendment 9

Proposal for a regulation Recital 14a (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 Protocol's wider objective of contributing to the conservation of biological diversity.

Justification

The objectives of the Nagoya Protocol, as defined in its Article 1, suggest that benefit-sharing activities should also contribute to" the conservation of biological diversity and the sustainable use of its components".

Amendment 10

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

(16) Best practices developed by users 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.

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.

Associations of users should be able to request that the Commission determines whether a specific combination of **goals, activities**, 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.

Justification

'Best practices' should not only be about procedures, tools or mechanisms but also include objectives and activities.

Amendment 11

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

Amendment

(19) Collections are **the most accessible** suppliers of genetic resources and traditional knowledge associated with genetic resources **utilised** in the Union. A system of Union trusted collections should be set in place. It **ensures** 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 **utilised** in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as a Union trusted collection, **including**

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.

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.

Justification

It is important to emphasize that the conditions for being considered a union trusted collection should not only be technical. The first condition for being "trusted" is being able to put in place fair and equitable benefit-sharing.

Amendment 12 **Proposal for a regulation**

Recital 28

Text proposed by the Commission

(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

Amendment

(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.

proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve its objectives. ***At the same time, one objective of this regulation is the fair and equitable distribution of the benefits resulting from the use of genetic resources, thereby helping to conserve biodiversity in accordance with the ‘EU biodiversity strategy to 2020’ guidelines.***

Amendment 13

Proposal for a regulation

Article 1 – paragraph -1 (new)

Text proposed by the Commission

Amendment

(-1) 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.

Justification

It is important to include the objectives of the Convention on Biological Diversity (CBD) in Article 1. The Nagoya Protocol is a continuation of the CBD, essentially serving to develop Article 15 of the CBD into a fully-fledged international regime for access and benefit-sharing.

Amendment 14

Proposal for a regulation

Article 1 – paragraph 1

Text proposed by the Commission

Amendment

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

This Regulation establishes rules governing ***compliance with the regime of*** 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

equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

Amendment 15

Proposal for a regulation Article 2 – paragraph 1

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.

Amendment

This Regulation applies to genetic resources over which states exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed ***or utilised*** 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.

Justification

Articles 1 and 3 of the Nagoya Protocol (NP), which respectively deal with its objectives and scope, refer to "utilization" of genetic resources, rather than simply access. Article 1 of the NP states that the "objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources".

Amendment 16

Proposal for a regulation

Article 2 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

This Regulation shall not restrict the Member States in their interpretation of Directive 98/44/EG on the legal protection of biotechnical inventions (bio patent directive). In particular, the use of biological materials for the purpose of breeding, discovery and developing other plant varieties and the use by farmers of crops for propagation or multiplication by

them on their own holdings shall be guaranteed.

Amendment 17

Proposal for a regulation

Article 3 – paragraph 4a (new)

Text proposed by the Commission

Amendment

(4a) “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 18

Proposal for a regulation

Article 3 – paragraph 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 19

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

Amendment

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

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

seek, keep, and transfer to subsequent users information relevant for access and benefit-sharing.

upon mutually agreed terms. Users shall seek, keep, and transfer to subsequent users ***all*** information ***and documents*** relevant for access and benefit-sharing ***and compliance with the provisions of this Regulation, in particular all documented proof that benefit-sharing obligations have been fully and legally carried out.***

Justification

It is important to stress that users are obliged to keep documentary proof that they have fulfilled their benefit-sharing obligations under mutually agreed terms.

Amendment 20 **Proposal for a regulation**

Article 4 – paragraph 2 – point a – point 3

Text proposed by the Commission

(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;***

Amendment

(3) the source from which the resources or the knowledge were directly obtained;

Amendment 21 **Proposal for a regulation**

Article 4 – paragraph 2 – point a – point 5

Text proposed by the Commission

(5) access ***decisions*** and mutually agreed terms, where applicable;

Amendment

(5) access ***permits*** and mutually agreed terms, where applicable;

Amendment 22 **Proposal for a regulation**

Article 4 – paragraph 2 – point c

Text proposed by the Commission

(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

(c) obtain a proper access permit ***and*** establish mutually agreed terms where it appears that access was not in accordance with applicable access and benefit-sharing legislation or regulatory requirements.

Amendment 23

Proposal for a regulation

Article 4 – paragraph 4a (new)

Text proposed by the Commission

Amendment

4a. 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.

Justification

The objectives of the Nagoya Protocol, as defined in Article 1, suggest that benefits sharing activities should contribute "to the conservation of biological diversity and the sustainable use of its components". Article 1 also makes an explicit reference to technology transfer. Given that they must together agree mutually agreed terms, it will be up to both providers and users to jointly ensure that mutually agreed terms increase, rather than reduce, biodiversity.

Amendment 24

Proposal for a regulation

Article 4 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4b. The obligation referred to in paragraphs (1) to (3) shall only apply to subsequent users in case such users access and use genetic resources in the

form as originally accessed by the initial user.

Amendment 25

Proposal for a regulation

Article 5 – paragraph 3– point -a (new)

Text proposed by the Commission

Amendment

(-a) respect the broad objectives of the Nagoya Protocol, working towards a fair and equitable sharing of the benefits arising from the utilization of genetic resources whilst simultaneously contributing to the conservation of biodiversity;

Justification

It is useful to recall here that the conditions for being considered a union-trusted collection should not only be technical. It is important to underline that the first condition for being "trusted" is to demonstrate a commitment to fair and equitable benefit-sharing.

Amendment 26

Proposal for a regulation

Article 5 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Amendment

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 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; ***at the same time, the provisions adopted must not lead to increased bureaucracy or additional costs.***

Amendment 27

Proposal for a regulation

Article 6 – paragraph 3a (new)

Text proposed by the Commission

Amendment

3a. 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 the relevant provisions of the Convention and the Nagoya Protocol in the Union.

Amendment 28

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

Justification

There is no reason for applying specific rules to recipients of public research funding.

Amendment 29

Proposal for a regulation

Article 7 – paragraph 3

Text proposed by the Commission

Amendment

3. 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

3. Competent authorities **shall verify the information provided under paragraph (2) and** transmit **it** to the Commission **within six months of the receipt**. The Commission shall **within six months of the receipt**

and make *it* available to the Access and Benefit-sharing Clearing House.

summarise the information received *and make the information required for the internationally recognised certificate* available to the Access and Benefit-sharing Clearing House *as well as to the public in an easily accessible open format.*

Amendment 30

Proposal for a regulation Article 8 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. Any association of users *or organisation with interest and expertise in the utilisation of genetic resources and access and benefit sharing* may submit an application to the Commission for recognising as best practice a combination of *goals, activities*, procedures, tools or mechanisms developed and overseen by it. The application shall be supported by evidence and information. *In considering applications for recognition of best practice, the Commission shall give priority to goals, activities, procedures, tools or mechanisms that contribute to:*

- the conservation of biological diversity and the sustainable use of its components;*
- technology transfer;*
- poverty eradication in developing countries.*

Justification

The Nagoya Protocol includes objectives and language which are not mirrored in the Commission proposal. The implementation of the benefit-sharing rules are intended to be supportive of broader goals, such as the conservation of biological diversity and the eradication of poverty. 'Best practice' should include objectives as well as procedures.

Amendment 31 Proposal for a regulation

Article 9 – paragraph 2

Text proposed by the Commission

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.

Amendment

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 by means of implementing acts adopted in accordance with the examination procedure referred to in Article 15(2). Such an approach shall take into account*** 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.

Amendment 32

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The checks referred to in paragraph 1 shall include ***at least***:

Amendment

4. The checks referred to in paragraph 1 shall include:

Amendment 33

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 format***.

Amendment 34

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 Commission.

Amendment

2. The competent authorities shall exchange information on ***the organization of their checking system for monitoring user compliance with this Regulation and 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 Commission.

Amendment 35

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 36

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 is hereby established. ***Member States which envisage adopting access rules as regards their genetic resources shall first conduct an impact assessment of these rules and submit the result of this assessment to the Union platform for consideration pursuant to the procedure laid down in***

paragraph 5 of this Article.

Amendment 37

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, 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. ***In particular, the platform should advocate that where competent authorities leave requests for access unanswered, the due diligence obligation shall be deemed to be fulfilled and access should be without any further obligations.***

Amendment 38

Proposal for a regulation

Article 14 – point d a (new)

Text proposed by the Commission

Amendment

(da) take measures to support users that contribute to the conservation of biological diversity and cultural diversity with limited means to become trusted collections;

Justification

It is important to help small-scale projects, for instance developed by farmers and local communities, that contribute to preserving biological diversity to become "trusted collections" as defined in this regulation.

Amendment 39

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 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 *specific sectors*, 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.

PROCEDURE

Title	Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union						
References	COM(2012)0576 – C7-0322/2012 – 2012/0278(COD)						
Committee responsible Date announced in plenary	ENVI 19.11.2012						
Opinion by Date announced in plenary	AGRI 19.11.2012						
Rapporteur Date appointed	José Bové 3.12.2012						
Previous rapporteur	Martin Häusling						
Discussed in committee	24.4.2013						
Date adopted	30.5.2013						
Result of final vote	<table> <tr> <td>+: </td><td>31</td></tr> <tr> <td>–: </td><td>0</td></tr> <tr> <td>0: </td><td>0</td></tr> </table>	+:	31	–:	0	0:	0
+:	31						
–:	0						
0:	0						
Members present for the final vote	Eric Andrieu, José Bové, Luis Manuel Capoulas Santos, Vasilica Viorica Dăncilă, Michel Dantin, Albert Deß, Diane Dodds, Herbert Dorfmann, Robert Dušek, Iratxe García Pérez, Béla Glattfelder, Martin Häusling, Peter Jahr, Elisabeth Jeggle, Elisabeth Köstinger, George Lyon, Mairead McGuinness, James Nicholson, Wojciech Michał Olejniczak, Marit Paulsen, Britta Reimers, Alfreds Rubiks, Giancarlo Scottà, Czesław Adam Siekierski, Sergio Paolo Francesco Silvestris, Alyn Smith, Ewald Stadler, Csaba Sándor Tabajdi, Marc Tarabella, Janusz Wojciechowski						
Substitute(s) present for the final vote	Marian Harkin, Elżbieta Katarzyna Łukacijewska						
Substitute(s) under Rule 187(2) present for the final vote	Teresa Jiménez-Becerril Barrio, Jens Nilsson						

18.6.2013

OPINION OF THE COMMITTEE ON FISHERIES

for the Committee on the Environment, Public Health and Food Safety

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))

Rapporteur: Ian Hudghton

SHORT JUSTIFICATION

Introduction

One of the three objectives of the Convention on Biological Diversity (CBD) is the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. The CBD gives little information as to how this objective is to be met and accordingly the Nagoya Protocol has been adopted to fill this gap. The EU and most Member States are Parties to the Protocol and the current proposal is for a Regulation to ratify and implement its provisions.

Subject matter

The Protocol covers research and development relating to the genetic and/or biochemical composition of genetic material - e.g. DNA, genes etc. Numerous industries, including the pharmaceutical and food and drink industries, use genetic materials in their research. Industries in the developed world have stood accused of "biopiracy" and of violating the sovereign rights of other countries; the Protocol therefore aims to resolve this problem.

The Protocol has two main pillars: the access pillar and the user-compliance pillar. The access pillar gives Parties to the Protocol the choice as to whether they wish to regulate access to genetic resources falling under their sovereignty. Should they choose to do so, the Protocol goes on to stipulate international access standards which must then be adhered to.

The user-compliance pillar obliges all Parties to require that only legally acquired genetic materials are used within their jurisdiction. This covers the end-users of the resource - for example, the industries conducting genetic research.

Commission proposal

The Commission proposal deals mainly with the user-compliance pillar of the proposal - aspects which are arguably of little direct relevance to fisheries management. The Commission does however propose to create a Union platform on access which will provide non-binding advice on access issues. Access issues remain a national competence and, within the EU, different MS have taken differing approaches: the Netherlands, for example, requires no prior informed consent whilst France has indicated that it may bring forward legislation regulating access, particularly for its overseas territories.

PECH interest and rapporteur's stance

The Protocol refers specifically to the "potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity". The second stated responsibility of the PECH Committee is "the conservation of fishery resources" and so the Protocol clearly falls within the remit of the Committee.

Your rapporteur contends that at times the EU's interests in resources outwith European waters has been primarily exploitative and that the interests of indigenous and local populations come as an afterthought. The Nagoya Protocol is designed specifically with the interests of these peoples in mind - and your rapporteur welcomes the opportunity to recommend the Committee support ratification of the treaty.

The rapporteur has sought to concentrate on those areas of the Protocol falling directly within the competences of the Committee. He is therefore proposing amendments in the following areas:

- ***Involvement of indigenous and local communities*** - Article 6 of the Protocol deals with access issues and refers specifically to the involvement of indigenous and local communities. No such reference exists in the Commission text establishing a Union platform on access and the rapporteur believes that this should be rectified.
- ***Scope of the Regulation*** - Article 4 of the CBD extends its scope not only to territorial waters and the EEZ but also to activities taking place in international waters. Accordingly, fishing activities on the high seas would potentially fall under CBD. The Protocol scope is, however, narrower and does not extend to marine areas beyond national jurisdiction. Nonetheless, the Protocol does not prohibit Parties from going further and the EU could extend the scope of this Regulation to cover activities taking place in international waters.

AMENDMENTS

The Committee on Fisheries calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation Recital 2a (new)

Text proposed by the Commission

Amendment

(2a) 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 2

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 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 Protocol prevents Parties to it from extending its principles to activities taking place in such marine areas.

Justification

The scope of the Nagoya Protocol is somewhat narrower than that of the Convention on

Biological Diversity and does not extend to activities taking place outwith national waters, such as exploitation beyond the EEZs. Nonetheless, nothing prevents the Union from going further in this Regulation and, indeed, Article 10 of the Protocol envisages future mechanisms to address situations where obtaining prior informed consent is not possible.

Amendment 3

Proposal for a regulation Recital 15

Text proposed by the Commission

(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.

Amendment

(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, ***without this affecting their competitiveness***, and with high legal certainty.

Amendment 4

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 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.
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.

Justification

The Protocol provisions on access to resources specifically refer to the interests of indigenous and local communities. It is therefore appropriate for the Regulation to do likewise

Amendment 5

**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 6

**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.***

Justification

Article 6 of the Protocol requires Parties to take, as appropriate, measures to involve indigenous and local communities where those communities have rights to grant access. The

Union platform should be expressly bound to respect these provisions.

PROCEDURE

Title	Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union		
References	COM(2012)0576 – C7-0322/2012 – 2012/0278(COD)		
Committee responsible Date announced in plenary	ENVI 19.11.2012		
Opinion by Date announced in plenary	PECH 19.11.2012		
Rapporteur Date appointed	Ian Hudghton 21.11.2012		
Discussed in committee	19.2.2013	20.3.2013	23.4.2013
Date adopted	18.6.2013		
Result of final vote	+: 22 -: 0 0: 0		
Members present for the final vote	John Stuart Agnew, Antonello Antinoro, Kriton Arsenis, Alain Cadec, Chris Davies, João Ferreira, Carmen Fraga Estévez, Pat the Cope Gallagher, Dolores García-Hierro Caraballo, Marek Józef Gróbarczyk, Ian Hudghton, Werner Kuhn, Isabella Lövin, Guido Milana, Maria do Céu Patrão Neves, Crescenzo Rivellini, Ulrike Rodust, Raül Romeva i Rueda, Struan Stevenson, Isabelle Thomas		
Substitute(s) present for the final vote	Jean-Paul Besset, Diane Dodds, Barbara Matera, Mario Pirillo		
Substitute(s) under Rule 187(2) present for the final vote	Salvador Garriga Polledo		

PROCEDURE

Title	Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union			
References	COM(2012)0576 – C7-0322/2012 – 2012/0278(COD)			
Date submitted to Parliament	4.10.2012			
Committee responsible Date announced in plenary	ENVI 19.11.2012			
Committee(s) asked for opinion(s) Date announced in plenary	DEVE 19.11.2012	ITRE 19.11.2012	REGI 19.11.2012	AGRI 19.11.2012
	PECH 19.11.2012			
Not delivering opinions Date of decision	ITRE 5.11.2012	REGI 27.11.2012		
Rapporteur(s) Date appointed	Sandrine Bélier 23.10.2012			
Discussed in committee	25.4.2013	20.6.2013		
Date adopted	4.7.2013			
Result of final vote	+: –: 0:	34 1 22		
Members present for the final vote	Martina Anderson, Elena Oana Antonescu, Kriton Arsenis, Sophie Auconie, Paolo Bartolozzi, Sandrine Bélier, Lajos Bokros, Franco Bonanini, Biljana Borzan, Nessa Childers, Yves Cochet, Chris Davies, Esther de Lange, Anne Delvaux, Bas Eickhout, Jill Evans, Elisabetta Gardini, Gerben-Jan Gerbrandy, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Jolanta Emilia Hibner, Karin Kadenbach, Christa Klauf, Eija-Riitta Korhola, Jo Leinen, Corinne Lepage, Linda McAvan, Vladko Todorov Panayotov, Gilles Pargneaux, Antonyia Parvanova, Andrés Perelló Rodríguez, Mario Pirillo, Pavel Poc, Anna Rosbach, Oreste Rossi, Kārlis Šadurskis, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Theodoros Skylakakis, Bogusław Sonik, Claudiu Ciprian Tănăsescu, Thomas Ulmer, Anja Weisgerber, Glenis Willmott, Sabine Wils			
Substitute(s) present for the final vote	Erik Bánki, James Nicholson, Vittorio Prodi, Britta Reimers, Alda Sousa, Struan Stevenson, Marita Ulvskog, Vladimir Urutchev, Anna Záborská			
Date tabled	16.7.2013			