



EUROPEAN PARLIAMENT

2009 - 2014

Committee on Development

2012/0278(COD)

28.3.2013

DRAFT 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

PA_Legam

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,

Or. en

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.

Or. en

Amendment 3

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

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

or biochemical properties of genetic resources.

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.***

Or. en

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 derivates, 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.

Or. en

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.

Or. en

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.

Or. en

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.

Or. en

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.

Or. en

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 Convention¹. 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 Convention². 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.

Or. en

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*

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*

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

² Annex I to Document UNEP/CBD/COP/DEC/X/1 of 29 October 2010..

and users.

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.

Or. en

Amendment 12

Proposal for a regulation Recital (8a)

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.

Or. en

Amendment 13

Proposal for a regulation Recital (8b)

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.

Or. en

Amendment 14

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 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.

Or. en

Amendment 15

Proposal for a regulation

Recital (10)

Text proposed by the Commission

(10) Council Decision 2004/869/EC of 24 February 2004 concerning the conclusion, on behalf of the European Community, of the International Treaty on Plant Genetic Resources for Food and Agriculture International Treaty on Plant Genetic Resources for Food and Agriculture¹ approved that Treaty on behalf of the Union. That Treaty constitutes a specialized international access and benefit-sharing instrument **that should not be affected by the rules implementing the Nagoya Protocol.**

Amendment

(10) Council Decision 2004/869/EC of 24 February 2004 concerning the conclusion, on behalf of the European community, of the International Treaty on Plant Genetic Resources for Food and Agriculture approved that Treaty on behalf of the Union. That Treaty constitutes a **separate**, specialized international access and benefit-sharing instrument **with its own implementing arrangements.**

Or. en

¹ OJ L 378, 23.12.2004, p. 1.

Amendment 16

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.

Or. en

Amendment 17

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**

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 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,**

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.

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.

Or. en

Amendment 18

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.

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.

Or. en

Amendment 19

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.

Or. en

Amendment 20

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.***

Or. en

Amendment 21

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 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

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.

samples of genetic resources to third persons with documentation providing evidence of legal acquisition and the establishment of mutually agreed terms, where required. A system of Union trusted collections should substantially lower the risk that illegally acquired genetic resources are used in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as Union trusted collection. Users that acquire a genetic resource from a collection listed in the Union register should be considered to have exercised due diligence as regards the seeking of all necessary information. This should prove particularly beneficial for academic researchers as well as small and medium sized enterprises.

Or. en

Amendment 22

Proposal for a regulation Recital (19 a) (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.

Or. en

Amendment 23

Proposal for a regulation

Recital (21 (a) (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.

Or. en

Amendment 24

Proposal for a regulation

Recital (22 (a) (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.

Or. en

Amendment 25

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 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 26

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 27

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 28

Proposal for a regulation Article 1 – subparagraph 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 access and ***fair and equitable*** 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).

Or. en

Amendment 29

Proposal for a regulation Article 1 – subparagraph 2 (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.

Or. en

Amendment 30

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*.

Or. en

Amendment 31

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*;

Or. en

Amendment 32

Proposal for a regulation

Article 3 – subparagraph 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;

Or. en

Amendment 33

Proposal for a regulation

Article 3 – subparagraph 4

Text proposed by the Commission

Amendment

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

(4) "access" means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in accordance with the applicable domestic access and benefit-sharing legislation or regulatory requirements of ***the country of origin***.

Or. en

Amendment 34

Proposal for a regulation

Article 3 – subparagraph 5

Text proposed by the Commission

Amendment

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

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

resources;

commercialising genetic resources or products based on genetic resources, or traditional knowledge associated with genetic resources;

Or. en

Amendment 35

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**;

Or. en

Amendment 36

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

Text proposed by the Commission

(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;

Or. en

Amendment 37

Proposal for a regulation Article 3 – subparagraph 10 (b) (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;

Or. en

Amendment 38

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.

Or. en

Amendment 39

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 seek, keep, and transfer to subsequent users

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-***

information relevant for access and benefit-sharing.

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.**

Or. en

Amendment 40

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 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.

Or. en

Amendment 41

Proposal for a regulation

Article 4 – paragraph -1 (b) (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.

Or. en

Amendment 42

Proposal for a regulation

Article 4 – paragraph 2 – subparagraph (a) (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;

Or. en

Amendment 43

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 trusted 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.

Or. en

Amendment 44

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 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.

Or. en

Amendment 45

Proposal for a regulation Article 5 – paragraph 3 (a)

Text proposed by the Commission

Amendment

(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;

(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;

Or. en

Amendment 46

Proposal for a regulation Article 5 – paragraph 3 (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;

Or. en

Amendment 47

Proposal for a regulation Article 5 – paragraph 3 (f) (new)

Text proposed by the Commission

Amendment

(f) 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;

Or. en

Amendment 48

Proposal for a regulation

Article 5 – paragraph 3 (g) (new)

Text proposed by the Commission

Amendment

(g) 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;

Or. en

Amendment 49

Proposal for a regulation

Article 5 – paragraph 3 (h) (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 50

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 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* the occasion of::

Or. en

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;

Or. en

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;

Or. en

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;

Or. en

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

Or. en

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

Amendment 56

Proposal for a regulation Article 7 – paragraph 3

Text proposed by the Commission

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.

Amendment

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 Access and Benefit-sharing Clearing House ***as well as to the public in an easily accessible open format***.

Or. en

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.

Or. en

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.**

Or. en

Amendment 59

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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.

Or. en

Amendment 60

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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.

Or. en

Amendment 61

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***;

Or. en

Amendment 62

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***;

Or. en

Amendment 63

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.

Or. en

Amendment 64

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.

Or. en

Amendment 65

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.

Or. en

Amendment 66

Proposal for a regulation Article 13 – title

Text proposed by the Commission

Union platform on access

Amendment

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

Or. en

Amendment 67

Proposal for a regulation Article 13 – paragraph 1

Text proposed by the Commission

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

Amendment

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.

Or. en

Amendment 68

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

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,***

sharing of best practices.

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*.

Or. en

Amendment 69

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.

Or. en

Amendment 70

Proposal for a regulation Article 14 – subparagraph (e) (new)

Text proposed by the Commission

Amendment

(e) 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.

Or. en

Amendment 71

Proposal for a regulation Article 14 – subparagraph (f) (new)

Text proposed by the Commission

Amendment

(f) 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.

Or. en

Amendment 72

Proposal for a regulation Article 14 – subparagraph (g) (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 73

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

Text proposed by the Commission

Amendment

Union Benefit Sharing Fund

Or. en

Amendment 74

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

Text proposed by the Commission

Amendment

1. A Union Benefit Sharing Fund is hereby established.

Or. en

Amendment 75

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 76

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

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.

Or. en

Amendment 77

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

Text proposed by the Commission

Amendment

Consultation Forum

Or. en

Amendment 78

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

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. These parties shall contribute, in particular, to defining and reviewing delegated acts pursuant to Article 4(5),

9(8), and 14a(3), and to the implementation of Articles 5, 7 and 8, and eventual guidelines for establishing mutually agreed terms. These parties shall meet in a Consultation Forum. The rules of procedure of the Forum shall be established by the Commission.

Or. en

Amendment 79

Proposal for a regulation

Article 16a (new)

Directive 2008/99/EC¹

Article 3 – paragraph ia (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: one year after the date of entry into force of this Regulation.**

Or. en

Amendment 80

Proposal for a regulation

Article 16b (new)

Directive 2008/99/EC²

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

¹ Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law, OJ L 328, 6.12.2008, p. 28.

² Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law, OJ L 328, 6.12.2008, p. 28.

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

Or. en