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Committee on Agriculture and Rural Development

2012/0278(COD)

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DRAFT 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

PA_Legam

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 33.

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;

Or. en

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 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 as 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 patents 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.

Or. en

Amendment 3

Proposal for a regulation Recital 6

Text proposed by the Commission

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-

(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.

sharing for the *utilisation and subsequent commercialisation* of genetic resources and traditional knowledge associated with genetic resources.

Or. en

Amendment 4

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.

Or. en

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 5

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

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 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.

associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. Users 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, ***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.

Or. en

Justification

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

Amendment 6

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.

Or. en

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 7

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 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 **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.

Or. en

Justification

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

Amendment 8

Proposal for a regulation

Recital 19

Text proposed by the Commission

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

Amendment

(19) 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 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 **utilised** in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as Union trusted collection, **including demonstrating the capacity to respect the broad objectives of the Nagoya Protocol in terms of achieving a fair and equitable sharing of the benefits arising from the utilisation of genetic resources and contributing to the conservation of biodiversity**. Users that acquire a genetic resource from a collection listed in the Union register should be considered to have exercised due diligence as regards the seeking of all necessary information. This should prove particularly beneficial for academic researchers as well as small and medium sized enterprises.

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 9

Proposal for a regulation

Recital 25a (new)

Text proposed by the Commission

Amendment

(25a) The Union and Member States, for the purposes of fully implementing the Nagoya Protocol over coming years, should consider taking complementary measures under their respective research and development (R&D), agricultural and development policies to intensify cooperation with developing countries aimed at reinforcing their capacities for the conservation of biological diversity.

Justification

The Union's activities to implement the Protocol will not end with the entry into force of this proposal for a regulation; they should be given practical expression in the Common Agricultural Policy (CAP), Horizon 2020 and Development Policy.

Amendment 10

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.

Or. en

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 11

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.

Or. en

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 12

Proposal for a regulation Article 3 – paragraph 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 13

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;

Or. en

Amendment 14

Proposal for a regulation Article 3 – paragraph 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 15

Proposal for a regulation Article 3 – paragraph 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 16

Proposal for a regulation Article 3 – paragraph 8

Text proposed by the Commission

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

Amendment

(8) "traditional knowledge associated with genetic resources" means traditional knowledge held by an indigenous or local community that is relevant for the use of genetic resources;

Or. en

Amendment 17

Proposal for a regulation Article 3 – paragraph 8 a (new)

Text proposed by the Commission

Amendment

(8a) "biopiracy" means utilisation, or subsequent commercialisation of illegally acquired genetic resources or products derived from such resources, or

associated traditional knowledge;

Or. en

Amendment 18

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

Text proposed by the Commission

Amendment

(-1) Biopiracy shall be prohibited in the Union.

Or. en

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

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 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.***

Or. en

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 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 new prior informed consent from the country of origin and new mutually agreed terms preceding commencement of new utilisation.

Or. en

Justification

It is important for the purposes of legal certainty and overall clarity to state that users, if they wish to use the genetic resources or traditional knowledge in a different way from the terms agreed by the preceding user, should go back to the country of origin to seek new mutually agreed terms.

Amendment 21

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.

Or. en

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 22

Proposal for a regulation

Article 5 – paragraph 1

Text proposed by the Commission

Amendment

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.

1. In order to ensure that only genetic resources acquired in accordance with applicable requirements are supplied, a voluntary system of Union trusted collections is hereby established. The Commission shall establish and maintain a Union register of trusted collections. That register shall be ***open format***, internet-based, easily accessible to users, and shall include the collections of genetic resources identified as meeting the criteria of Union trusted collection.

Amendment 23

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;

Or. en

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 24

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.

Or. en

Amendment 25

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

Or. en

Justification

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

Amendment 26

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 approval is not required.

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

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

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

(c) applying for patents or for new plant

variety rights at relevant national, regional or international institutions covering inter alia the accessed genetic resources, products, including derivatives, and processes derived from the use of biotechnology, or traditional knowledge associated with the genetic resource;

(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.

Or. en

Amendment 27

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 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*.

Or. en

Amendment 28

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.***

Or. en

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 29

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

Amendment

2. The Commission shall assess each application, taking into account

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.

information and evidence from the applicant, relevant providers, users, authorities, institutions, inter-governmental and non-governmental organisations, as well as representatives of indigenous and local communities and other actors, as appropriate. Where, on the basis of information and evidence supplied to it by an association of users, the Commission determines that the specific combination of *goals, activities,* 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.

Or. en

Amendment 30

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.*

Or. en

Amendment 31

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

Text proposed by the Commission

(b) immediate suspension of specific use activities;

Amendment

(b) immediate suspension of specific use activities, *including withdrawal of market approval or of the right of commercialisation of products or*

suspension of research and development activities;

Or. en

Amendment 32

**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 33

**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;

Or. en

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 34

Proposal for a regulation Article 14 – point d b (new)

Text proposed by the Commission

Amendment

***(db) support, under their respective
research and development (R&D)
agricultural and development policies:***

***- capacity-building activities in developing
countries aimed at reinforcing their
administrative and legal structures for the
purposes of successfully implementing the
Nagoya Protocol;***

***- technology transfer aimed at increasing
developing countries' capacities for the
conservation of biological diversity and
the sustainable use of its components;***

Or. en