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*Committee on Agriculture and Rural Development*

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**2012/0278(COD)**

29.4.2013

**AMENDMENTS  
35 - 62**

**Draft opinion**  
**José Bové**  
(PE507.964v01)

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

Proposal for a regulation  
(COM(2012)0576 – C7-0322/2012 – 2012/0278(COD))

AM\_Com\_LegOpinion

**Proposal for a regulation**  
**Recital 1**

*Text proposed by the Commission*

(1) A broad range of **players** in the Union, including academic researchers and companies from different sectors of industry, use genetic resources for research, development and commercialisation purposes; some also use traditional knowledge associated with genetic resources.

*Amendment*

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

Or. ro

**Proposal for a regulation**  
**Recital 2**

*Text proposed by the Commission*

(2) Genetic resources represent the gene pool in both natural and cultivated or domesticated stocks and play a significant and growing role in many economic

*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.

sectors including food production, forestry, development of medicines, or development of bio-based sources of renewable energy.  
***Genetic resources play a significant role in the implementation of strategies designed to restore damaged ecosystems and safeguard endangered species.***

Or. ro

**Amendment 37**  
**Vasilica Viorica Dăncilă**

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

*Text proposed by the Commission*

*Amendment*

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

Or. ro

**Amendment 38**  
**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Elisabeth Köstinger**

**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

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol ***further***

*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.

*details* the general rules of the Convention on access and benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Or. en

#### **Amendment 39**

**Herbert Dorfmann, Albert Deß, Elisabeth Jeggle, Britta Reimers, Sergio Paolo Francesco Silvestris, Elisabeth Köstinger**

#### **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 *the* use of genetic resources refers to research and development on the genetic or biochemical composition of genetic *resources.*

Or. en

#### **Amendment 40**

**Elisabeth Jeggle, Herbert Dorfmann**

#### **Proposal for a regulation**

##### **Recital 11 a (new)**

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

###### *Amendment*

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

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

Or. de

**Amendment 41**  
**Vasilica Viorica Dăncilă**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with such resources should have to exercise due diligence to ascertain that the genetic resources and associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union *it is not appropriate to oblige* all users to take the same measures for exercising due diligence. Therefore, only minimum features of due diligence measures should be set out. The specific choices taken by users on the tools and measures applied for exercising due diligence should be *supported through* the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses, and guidelines with a view to increasing legal certainty and reducing costs. The obligation on users to keep information relevant for access and

*Amendment*

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benefit-sharing should be limited in time, consistent with the time-span for an eventual innovation.

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Or. ro

**Amendment 42**  
**Herbert Dorfmann**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with such resources should have to exercise due diligence to ascertain that the genetic resources and associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. Therefore, only minimum features of due diligence measures should be set out. The specific choices taken by users on the tools and measures applied for exercising due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses, and guidelines with a view to increasing legal certainty and reducing costs. The obligation on users to keep information relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an eventual innovation.

*Amendment*

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 *the* 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.

Or. it

### Amendment 43

Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Elisabeth Köstinger, Sergio Paolo Francesco Silvestris

#### Proposal for a regulation

##### Recital 14

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

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with such resources should have to exercise due diligence to ascertain that the genetic resources and associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. ***Therefore, only minimum features of due diligence measures should be set out. The specific choices taken by users on the tools and measures applied for exercising due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses, and guidelines with a view to increasing legal certainty and reducing costs.*** The obligation on users to keep information relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an eventual innovation.

###### *Amendment*

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with such resources should have to exercise due diligence to ascertain that the genetic resources and associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. ***This is the case in particular for subsequent users where the due diligence obligation should only apply in the case such users access and use genetic resources in the form as originally accessed by the initial user.*** The obligation on users to keep information relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an eventual innovation.

Or. en

### Amendment 44

Vasilica Viorica Dăncilă

#### 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*

Best practices developed by users play an important role in identifying due diligence measures that are particularly suitable for achieving compliance with the system of implementation of the Nagoya Protocol with high legal certainty and at low costs. Users should be enabled to build on existing access and benefit-sharing codes of conduct developed for the academic sector and different industries. Associations of users **can** 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

Or. ro

**Amendment 45**  
**Vasilica Viorica Dăncilă**

**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

*Amendment*

(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 **ensures** that collections included in the register of Union trusted collections effectively apply measures to only supply

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.

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. ro

**Amendment 46**  
**Vasilica Viorica Dăncilă**

**Proposal for a regulation**  
**Recital 28**

*Text proposed by the Commission*

(28) The objectives of this Regulation are to minimise the risk that illegally genetic resources or traditional knowledge associated with genetic resources are used in the Union, and to support the fair and equitable sharing of benefits resulting from the use of genetic resources or traditional knowledge associated with genetic resources upon mutually agreed terms. These cannot be achieved by the Member States individually, and can therefore, by reasons of their scale and to ensure functioning of the internal market, be better achieved at Union level. The Union may therefore adopt measures in accordance with the principle of subsidiarity as set out

*Amendment*

(28) The objectives of this Regulation are to minimise the risk that illegally genetic resources or traditional knowledge associated with genetic resources are used in the Union, and to support the fair and equitable sharing of benefits resulting from the use of genetic resources or traditional knowledge associated with genetic resources upon mutually agreed terms. These cannot be achieved by the Member States individually, and can therefore, by reasons of their scale and to ensure functioning of the internal market, be better achieved at Union level. The Union may therefore adopt measures in accordance with the principle of subsidiarity as set out

in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve its objectives.

in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve its objectives. ***At the same time, one objective of this regulation is the fair and equitable distribution of the benefits resulting from the use of genetic resources, thereby helping to conserve biodiversity in accordance with the ‘EU biodiversity strategy to 2020’ guidelines.***

Or. ro

#### **Amendment 47**

**Herbert Dorfmann, Albert Deß, Elisabeth Jeggle, Britta Reimers, Sergio Paolo Francesco Silvestris, Elisabeth Köstinger**

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

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

This Regulation establishes rules governing access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

##### *Amendment*

This Regulation establishes rules governing ***compliance with*** access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

Or. en

#### **Amendment 48**

**Elisabeth Jeggle, Herbert Dorfmann**

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

*Text proposed by the Commission*

*Amendment*

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

Or. de

**Amendment 49**

**Vasilica Viorica Dăncilă**

**Proposal for a regulation**

**Article 3 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

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

(5) „user" means a natural or legal person using genetic resources or traditional knowledge associated with genetic resources, ***as well as a natural or legal person subsequently marketing these genetic resources, products based on them or traditional knowledge associated with them;***

Or. ro

**Amendment 50**

**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Sergio Paolo Francesco Silvestris, Elisabeth Köstinger**

**Proposal for a regulation**

**Article 4 – paragraph 2 – point a – subpoint 3**

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*Text proposed by the Commission*

*Amendment*

(3) the source from which the resources or the knowledge were directly obtained **as well as subsequent users of genetic resources or traditional knowledge associated with such resources**;

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

Or. en

#### **Amendment 51**

**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Elisabeth Köstinger**

#### **Proposal for a regulation**

#### **Article 4 – paragraph 2 – point a – subpoint 5**

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

#### **Amendment 52**

**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Elisabeth Köstinger**

#### **Proposal for a regulation**

#### **Article 4 – paragraph 2 – point c**

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 53**  
**Vasilica Viorica Dăncilă**

**Proposal for a regulation**  
**Article 5 – paragraph 3 – point a**

*Text proposed by the Commission*

(a) apply standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their use;

*Amendment*

(a) apply standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their use; ***seek and apply improved support mechanisms for the creation, use and distribution of knowledge and access to the necessary funding;***

Or. ro

**Amendment 54**  
**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Sergio Paolo Francesco Silvestris, Elisabeth Köstinger**

**Proposal for a regulation**  
**Article 5 – paragraph 3 – point e a (new)**

*Text proposed by the Commission*

*Amendment*

***(e a) The obligation referred to in paragraphs (1) to (3) of this Article shall only apply to subsequent users in case such users access and use genetic resources in the form as originally accessed by the initial user.***

Or. en

**Amendment 55**  
**Vasilica Viorica Dăncilă**

**Proposal for a regulation**  
**Article 5 – paragraph 4 – subparagraph 1**

*Text proposed by the Commission*

Member States shall regularly verify that each collection under their jurisdiction included in the Union register of trusted collections effectively applies the measures set out in paragraph 3.

*Amendment*

Member States shall regularly verify that each collection under their jurisdiction included in the Union register of trusted collections effectively applies the measures set out in paragraph 3; ***at the same time, the provisions adopted must not lead to increased bureaucracy or additional costs.***

Or. ro

**Amendment 56**  
**José Bové**

**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 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 the utilisation of genetic resources and traditional knowledge associated with genetic resources ;***

***(c) applying for patents, bearing in mind***

*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,*

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

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

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

Or. fr

#### **Amendment 57**

**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Elisabeth Köstinger**

#### **Proposal for a regulation**

#### **Article 9 – paragraph 2**

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

2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach. ***When developing this risk-based approach, Member States shall consider*** that the implementation by a user of a best practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's risk of non-compliance.

##### *Amendment*

2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach, ***of which the key principles shall be laid down by the Commission in accordance with the procedure referred to in Article 15(2). Such an approach shall take into account*** that the implementation by a user of a best practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's risk of non-compliance.

**Amendment 58**

**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Elisabeth Köstinger**

**Proposal for a regulation**

**Article 9 – paragraph 4 – introductory part**

*Text proposed by the Commission*

*Amendment*

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

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

**Amendment 59**

**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Sergio Paolo Francesco Silvestris, Elisabeth Köstinger**

**Proposal for a regulation**

**Article 12 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

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.

2. The competent authorities shall exchange information on *the organization of their checking system for monitoring user compliance with this Regulation and on* serious shortcomings detected through checks referred to in Article 9(1) and on the types of penalties imposed in accordance with Article 11 with the competent authorities of other Member States and with the Commission.

**Amendment 60**

**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Sergio Paolo Francesco Silvestris, Elisabeth Köstinger**

**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 is hereby established. ***Member States which envisage adopting access rules as regards their genetic resources shall first conduct an impact assessment of these rules and submit the result of this assessment to the Union platform for consideration pursuant to the procedure laid down in paragraph 5 of this Article.***

Or. en

**Amendment 61**  
**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Elisabeth Köstinger**

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

*Text proposed by the Commission*

2. The Union platform shall contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of access regimes established in Member States, simplified access for non-commercial research, access practices of collections in the Union, access of Union stakeholders in third countries and the sharing of best practices.

*Amendment*

2. The Union platform shall contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of access regimes established in Member States, simplified access for non-commercial research, access practices of collections in the Union, access of Union stakeholders in third countries and the sharing of best practices. ***In particular, the platform should advocate that where competent authorities leave requests for access unanswered, the due diligence obligation shall be deemed to be fulfilled and access should be without any further obligations.***

Or. en

**Amendment 62**

**Herbert Dorfmann, Elisabeth Jeggle, Albert Deß, Britta Reimers, Elisabeth Köstinger**

**Proposal for a regulation**

**Article 16 – paragraph 3**

*Text proposed by the Commission*

3. Every ten years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative consequences for public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

*Amendment*

3. Every ten years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative consequences for *specific sectors*, public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

Or. en