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PROPOSAL

from:	European Commission,
dated:	4 October 2012
No Cion doc.:	COM(2012) 576 final
Subject:	Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, Director, to Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union.

Encl.: COM(2012) 576 final

EUROPEAN
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Brussels, 4.10.2012
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2012/0278 (COD)

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

(Text with EEA relevance)

{SWD(2012) 291 final}
{SWD(2012) 292 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- Grounds for and objectives of the proposal

The main objective of 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 is to implement the Nagoya Protocol in the Union and to enable Union ratification of this treaty.

- General context

Genetic resources - the gene pool in both natural and cultivated stocks - play a significant and growing role in many economic sectors: 26% of all new approved drugs over the last 30 years are either natural products or have been derived from a natural product. [1]

A broad range of players in the Union, including academic researchers and companies from different sectors of industry (for example, plant and animal breeding, biocontrol, cosmetics, food and beverage, horticulture, industrial biotechnology, pharmaceutical) use genetic resources for research and development purposes, some also use traditional knowledge associated with genetic resources.

The European Union and all of its 27 Member States are Parties to the Convention on Biological Diversity[2] (CBD). The CBD recognizes that states have sovereign rights over genetic resources found within their jurisdiction and the authority to determine access to such resources. The Convention obliges all Parties to facilitate access to genetic resources over which they hold sovereign rights. It also obliges all Parties 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.

The CBD also addresses the rights of indigenous and local communities that hold traditional knowledge associated with genetic resources, and which may provide important lead information for the scientific discovery of interesting genetic or biochemical properties.

However, the CBD currently provides little detail on how access and benefit-sharing (ABS) for the use of genetic resources and associated traditional knowledge should be done in practice. Actors at the beginning of the genetic resources value chain in the Union (mostly collections and academic researchers) are in direct contact with the laws and authorities of provider countries. These first actors pass on samples of genetic resources and first research results to other users that engage in basic or applied research. Actors situated at the end of the genetic resources engage in often lengthy development activities that require significant investments with uncertain outcomes. They largely depend on material and information passed on to them from earlier users in the chain, including in relation to ABS. In the absence of clear rules or with very burdensome rules in most provider countries, European researchers

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[1] Newman and Cragg (2012), "Natural Products as Sources of New Drugs over the 30 Years from 1981 to 2010". *Journal of Natural Products*, 75(3), pp 311–335.

[2] Convention on Biological Diversity (Rio de Janeiro, 5 June 1992, in force 29 December 1993), available at <http://www.cbd.int/convention/text/>.

and companies have repeatedly been accused of 'biopiracy' by countries claiming a violation of their sovereign rights. A clear framework of obligations for all users of genetic resources throughout the value chain is essential for creating an enabling context for facilitated access to quality samples of genetic resources with high legal certainty.

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" (hereinafter: Nagoya Protocol) is a new international treaty adopted on 29 October 2010 by the consensus of the 193 Parties to the CBD. It is a treaty with legally binding effects that significantly expands the general ABS framework of the CBD. The Nagoya Protocol is expected to enter into force in 2014. Once operational, the Nagoya Protocol will generate significant benefits for biodiversity conservation in States that make available the genetic resources over which they hold sovereign rights. It will in particular:

- Establish more predictable conditions for access to genetic resources.
- Ensure benefit-sharing between users and providers of genetic resources.
- Ensure that only legally acquired genetic resources are used.

The Protocol rests on two main pillars: measures on access, and measures on user-compliance.

The access pillar leaves Parties discretion whether they wish to regulate access, and require prior informed consent and benefit-sharing for the use of their genetic resources or not. However, if a Party decides to do so, then it must implement the fairly detailed "international access standards" set out in the treaty through binding legislation. The Protocol also clarifies that states must engage with their indigenous and local communities in case access is sought to traditional knowledge or to genetic resources held by these communities. Main Protocol principles in relation to access include: (i) government authorities or indigenous representatives must give their prior informed consent before access can take place, (ii) specific benefit-sharing obligations must be set out in private law contracts between a provider and a user, and (iii) access frameworks must be clear and transparent, based on non-arbitrary rules, and result in reliable and timely decisions, in a cost-effective manner.

The user-compliance pillar of the Protocol obliges all Parties to the Protocol to take measures to provide that only legally acquired genetic resources and associated traditional knowledge are utilized within their jurisdiction. Parties must monitor the compliance of users within their jurisdiction and designate one or more checkpoints for this task. They must also take appropriate, effective and proportionate measures in cases where users within their jurisdiction do not comply with their ABS-related obligations. Parties must also ensure that disputes arising from specific benefit-sharing contracts can be taken to court. However, different than in the case of access, the user-compliance provisions of the Nagoya Protocol leave Parties quite some discretion on the type and mix of implementing measures chosen.

Parties to the Protocol will need to make further choices on the temporal application of implementing measures, on the respect for existing specialised ABS instruments[3], and apply

[3] For example, the International Treaty on Plant Genetic Resources for Food and Agriculture concluded in 2001 in the context of the UN Food and Agriculture Organization and to which the EU is a Party. For details see Annex 1.

special considerations to non-commercial research, to the exchange of genetic resources with pathogenic properties, and to genetic resources for food and agriculture. They will also need to address the relations with non-Parties to the Protocol. All Parties to the Protocol must furthermore establish a National Focal Point on ABS to liaise with the international Secretariat and to respond to information requests by stakeholders. Parties must also designate one or more Competent National Authorities responsible for granting access and advising on applicable procedures for requiring prior informed consent and entering into mutually agreed terms. Parties may designate a single entity to fulfill the functions of both focal points and competent national authority.

The Union and most of its Member States[4] have signed the Nagoya Protocol and thereby committed themselves to work towards implementation and ratification. Union implementation and ratification of the Protocol will create new opportunities for nature-based research, and contribute to the development of a bio-based economy.[5]

- Existing provisions in the area of the proposal

Neither the implementation of the access nor of the user-compliance pillar of the Protocol is currently addressed in Union-law.

- Consistency with the other policies and objectives of the Union

The EU and its Member States are politically committed to become Parties to the Protocol to secure access of EU researchers and companies to quality samples of genetic resources, based on reliable access decisions at low transaction costs.[6]

The proposal is also consistent with the EU's signature of the Protocol and also with target 16 of the CBD's Strategic Plan which foresees that by 2015 the Nagoya Protocol is in force and operational, consistent with national legislation.

2. RESULTS OF CONSULTATIONS WITH INTERESTED PARTIES AND IMPACT ASSESSMENT

This initiative is the result of extensive consultations with the general public and relevant stakeholders. Furthermore, the Commission carried out an impact assessment of the proposed policy options which led to the publication of a report.

- Public consultation

The Commission held a web-based public consultation from 24 October to 30 December 2011 to seek feedback on a list of questions that addressed key aspects of Nagoya Protocol implementation. Forthy-three replies were received that represented a much broader number of respondents, since the majority of replies came from European or international associations with hundreds or thousands of members each. The respondents covered most sectors potentially affected by implementation measures under the Nagoya Protocol. The list of

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4 Latvia, Malta and Slovakia have not yet signed.

5 See Commission Communication on a Bioeconomy for Europe (COM (2012) 60 final).

6 See Council Conclusions of 20 December 2010 (paragraphs 1 and 21), 23 June 2011 (paragraph 14), European Parliament Resolution of 20 April 2012 (paragraph 101), Commission Communication on an EU Biodiversity Strategy to 2020 (COM (2011) 244) (Action 20).

questions together with the results of the web-based public consultation have been published in the website of the European Commission under the following link: http://ec.europa.eu/environment/consultations/abs_en.htm.

- Ad hoc consultations

DG Environment organised a technical meeting on 26 January 2012 including all respondents to the public consultation, Brussels-based representatives of stakeholders, and experts nominated by Member States. At the meeting, the Commission presented its summary of the public consultation, whereas members of the consultant team presented tentative findings of their work. Participants used the opportunity to challenge the consultant team on some of their findings.

DG Environment officials held many meetings with representatives of botanical gardens, culture collections, industry federations or individual companies and participated in various expert conferences on the Nagoya Protocol. The consultant team conducted semi-structured interviews with representatives of stakeholders and companies.

- Consultations with third countries

In 2011, DG Environment asked several EU delegations in third countries to seek information from major partner countries on the state of play and their concrete ideas for Nagoya Protocol implementation. The feedback received was complemented by more detailed bilateral discussions with Australia, Brazil, India, Japan, Mexico and Switzerland.

- Impact Assessment Report

In line with its "Better Regulation" policy, the Commission has conducted an assessment of the economic, social and environmental impacts of different policy options for implementing the Nagoya Protocol. This report is accessible on the web site of the European Commission (DG Environment). The Commission also contracted a consultancy firm to carry out a study as an input for its report. This study is accessible at the same web site.

The Commission's impact assessment considered a broad range of options for implementing the Nagoya Protocol. Two options for access measures and four options for user-compliance measures were analyzed in-depth. All options were analyzed against a business as usual baseline without implementing measures at EU or Member State level. It also analyzed two options on the temporal application of EU-level measures as well as a range of complementary measures.

The analysis identified the establishment of an EU platform for discussing access to genetic resources and sharing best practices as the preferable option on access, whereas the identified preferable option on user-compliance is a due diligence obligation on EU users complemented by a system to identify collections as "trusted sources" of genetic resources. The due diligence obligation would only apply to genetic resources and associated traditional knowledge that are acquired after the entry into force of the Nagoya Protocol for the EU. To lower costs and enhance effectiveness, these measures should be complemented by awareness and training activities, work on contractual model clauses, work on technical tools for monitoring and tracking genetic resources flow, and where appropriate through bilateral cooperation with other countries or regions.

The due diligence obligation would ensure that minimum information relevant to ABS is available all throughout the genetic resources value chain in the Union. This will enable all users to know of and respect related rights and obligations. At the same time, the due diligence approach does not prescribe the same type of measures to all users, but leaves users some flexibility to take measures that work best for their respective context, and also to develop sectoral best practices. The system of trusted sources would substantially lower the risk that illegally acquired genetic resources are used in the Union. Acquiring samples for trusted sources would seem particularly beneficial for academic researchers as well as small and medium sized enterprises.

3. LEGAL ELEMENTS OF THE PROPOSAL

- Summary of the proposed action

The proposal sets out obligations for users of genetic resources and traditional knowledge associated with genetic resources in the Union. It would oblige all users to exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources used were accessed in accordance with applicable legal requirements and that, where relevant, benefits are fairly and equitable shared upon mutually agreed terms. To that end, all users would need to seek, keep and transfer to subsequent users certain information relevant for access and benefit-sharing. The proposal sets out minimum features of due diligence measures.

To comply, users could build on existing ABS codes of conduct developed for the academic sector and different industries. Associations of users may request the Commission to recognise a specific combination of procedures, tools or mechanisms overseen by an association as best practice. Competent authorities of the Member States would be obliged to 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.

This proposal also foresees a system of Union trusted collections that would substantially lower the risk that illegally acquired genetic resources are used in the Union. Collections that wish to be included in the register of Union trusted collection would commit to supply only fully documented samples of genetic resources to third persons for their use. The competent authorities of the Member States will have to verify if a collection meets the requirements for recognition as Union trusted collection. Users acquiring a genetic resource from a collection included in the Union register would be considered to have exercised due diligence as regards the seeking of all necessary information. A system of Union trusted collections will be particularly beneficial for academic researchers as well as small and medium sized enterprises.

Users would be obliged to declare at identified points that they complied with their due diligence obligation. Competent authorities of Member States should check on a risk-based approach whether users comply with their obligations under this Regulation. Member States should also ensure that infringements of this Regulation by users are sanctioned by effective, proportionate and dissuasive penalties.

Finally, the proposed Regulation also foresees the creation of a Union platform on access.

- Legal basis

The proposal is based on the Union's environment policy competence in Article 192(1) of the Treaty on the Functioning of the European Union as it aims at implementing the Nagoya Protocol, a global environmental agreement in favour of the conservation and sustainable use of biological diversity worldwide.

- Choice of instrument

The proposed instrument is a regulation because a regulation is necessary in order to ensure the highest level of harmonization and avoid the coexistence of different standards between Member States.

- The principles of subsidiarity and proportionality

The proposal would comprehensively implement the user-compliance pillar of the Nagoya Protocol. Member States would have discretion whether or not to require prior informed consent and benefit-sharing for genetic resources that belong to them. Their decisions on this would not be a precondition for Union ratification of the Nagoya Protocol.

Only two Member States of the Union have so far developed legislation on access to their genetic resources over which they hold sovereign rights, whereas other Member States have decided to grant free access to their genetic resources. Presently EU-harmonised access measures are not needed. In case a Member State decides to require prior informed consent and benefit-sharing it would have to implement the access-related provisions of the Nagoya Protocol. The proposed Union platform on access would be a non-binding approach for streamlining access conditions in Member States based on the method of open coordination.

A legally binding EU-level intervention on user-compliance is justified as it avoids negative effects on the internal market in nature-based products and services that would result from a fragmentation of user-compliance systems in the Member States and also has the best performance as regards the creation of an enabling context for research and development on genetic resources with benefits for the conservation and sustainable use of biological diversity worldwide.

The proposed due diligence obligation on users of genetic resources and traditional knowledge associated with genetic resources is also proportionate as it would balance the objectives of minimising the risks of the use of illegally acquired genetic resources in the Union and of supporting 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 with considerations on legal certainty, low transaction costs, and the flexibility inherent in the due diligence concept to take implementing measures that are best suited to different circumstances.

4. BUDGETARY IMPLICATION

The present proposal does not entail any significant financial implications for the Community budget.

5. EUROPEAN ECONOMIC AREA (EEA)

The proposal concerns an EEA matter and should therefore extent to the European Economic Area.

2012/0278 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[7],

Having regard to the opinion of the Committee of the Regions[8],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(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.

(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.

(3) Traditional knowledge that is held by indigenous and local communities may provide important lead information for the scientific discovery of interesting genetic or biochemical properties of genetic resources.

(4) The main international instrument governing access to and use of genetic resources is the Convention on Biological Diversity (the Convention). Council Decision

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7 OJ C , , p. .
8 OJ C , , p. .

93/626/EEC of 25 October 1993 concerning the Convention on Biological Diversity[9] approved the Convention on behalf of the Union.

(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.

(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[10]. 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.

(7) Council Decision xxxx/xx/EU of [date] on the conclusion of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity[11] approved the Nagoya Protocol on behalf of the Union.

(8) It is important to set out a clear and sound framework for implementing the Nagoya Protocol that should enhance opportunities available for nature-based research and development activities in the Union. It is also essential to prevent the use of illegally acquired genetic resources or traditional knowledge associated with genetic resources in the Union and to support the effective implementation of benefit-sharing commitments set out in mutually agreed terms between providers and users.

(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.

(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 Agriculture[12] 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.

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9 OJ L 309, 13.12.19993, p. 1.
10 Annex I to Document UNEP/CBD/COP/DEC/X/1 of 29 October 2010..
11 OJ
12 OJ L 378, 23.12.2004, p. 1.

(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.

(12) It seems important to recall CBD Decision II/11 paragraph.2 – as confirmed by CBD Decision X/1, paragraph 5 – that reaffirms the exclusion of human genetic resources from the framework of the Convention.

(13) There is currently no internationally agreed definition on "traditional knowledge associated with genetic resources" or on "holding" such knowledge by an indigenous and local community. International definitions of those terms and concepts are being negotiated in the Intergovernmental Committee of the World Intellectual Property Organization. Therefore, in order to ensure flexibility and legal certainty for providers and users, this Regulation should make reference to traditional knowledge associated with genetic resources as described in benefit-sharing agreements.

(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.

(15) The due diligence obligation should apply to all users irrespective of their size, including to micro-enterprises and small and medium-sized companies. Excluding these actors from the system would entirely undermine its effectiveness. It would also run against the international obligations of the Union under the Nagoya Protocol. However, the Regulation should offer a range of measures and tools to enable micro-enterprises and small and medium-sized companies to comply with their obligations at low cost and with high legal certainty.

(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.

(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.

(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.

(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.

(20) Competent authorities of Member States should check whether users comply with their obligations. In that context, competent authorities should accept internationally recognised certificates of compliance as evidence that the genetic resources covered were legally acquired and that mutually agreed terms were established. Competent authorities should also keep records of the checks made and relevant information should be made available in accordance with Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information.[13]

(21) Member States should ensure that infringements of the rules constituting the system of implementation of the Nagoya Protocol by users are sanctioned by means of effective, proportionate and dissuasive penalties.

(22) Taking into account the international character of access and benefit-sharing transactions, competent authorities of the Member States should cooperate between themselves, with the Commission, and with authorities of third countries to comply with their duties within the system for implementing the Nagoya Protocol.

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[13] OJ L 41, 14.2.2003, p. 26.

(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.

(24) The Commission and the Member States should take appropriate complementary measures to enhance the effectiveness of implementing this Regulation and to lower costs, particularly where this would benefit academic researchers and small and medium sized enterprises.

(25) In order to take into account the inherently international character of access and benefit-sharing activities, the Commission should also consider whether cooperation with third countries or regions could support an effective application of the system created for implementing the Nagoya Protocol.

(26) The date of entry into force of this Regulation should be directly correlated to the entry into force of the Nagoya Protocol in order to ensure equal conditions at the Union and global levels in activities related to access and benefit sharing of genetic resources. The Nagoya Protocol will enter into force on the ninetieth day after the deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organisations that are Parties to the Convention.

(27) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers [14].

(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.

[14] OJ L 55, 28.2.2011, p. 13.

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

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).

Article 2

Scope

This Regulation applies to genetic resources over which states exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the use of such genetic resources and to traditional knowledge associated with genetic resources.

This Regulation does not apply to genetic resources for which access and benefit-sharing is governed by a specialised international instrument to which the Union is a Party.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) "Nagoya Protocol" means 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;

(2) "genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity;

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

(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.

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

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

(7) "mutually agreed terms" means the contractual arrangement concluded between a provider of genetic resources or of traditional knowledge associated with genetic resources and a user of such resources or knowledge, that sets out specific conditions for the fair and equitable sharing of benefits arising from such use, and that may also include further conditions and terms for the use of such resources or knowledge;

(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;

(9) "collection" means an ensemble of collected samples of genetic resources and related information that is accumulated, stored, and taxonomically identified, whether owned by public or private entities;

(10) "association of users" means a legal person representing the interests of users that is involved in developing and overseeing best practices under Article 8 of this Regulation.

(11) "internationally recognised certificate of compliance" means an access permit or its equivalent issued by a competent national authority in accordance with Article 6(3)(e) Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing-House;

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

Article 4

Obligations of 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 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.

2. Users shall:

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

      (1) the date and place of access of genetic resources and traditional knowledge associated with such resources;

      (2) the description of genetic resources or traditional knowledge associated with such resources used, including available unique identifiers;

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

(4) the presence or absence of rights and obligations related to access and benefit-sharing;

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

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

(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.

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

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.

Article 5

Union trusted collections

1. The Commission shall establish and maintain a Union register of trusted collections. That register shall be internet-based, easily accessible to users, and shall include the collections of genetic resources identified as meeting the criteria of Union trusted collection.

2. Each Member State shall, upon request by a collection under its jurisdiction, consider the inclusion of this collection in the Union register of trusted collections. After verifying that the collection meets the criteria set out in paragraph 3, the Member State shall notify the Commission without delay of that collection's name, contact details, and type. The Commission shall without delay include the information thus received into the Union register of trusted collections.

3. In order for a collection to be included in the Union register of trusted collections, a collection owner shall demonstrate its capacity to:

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

(b) have samples of genetic resources and related information supplied to third persons for their use only with documentation providing evidence that the resources and the information were accessed in accordance with applicable legal requirements and, where relevant, mutually agreed terms for the fair and equitable sharing of benefits;

(c) keep records of all samples of genetic resources and related information supplied to third persons for their use;

(d) establish or use unique identifiers for samples of genetic resources supplied to third persons;

(e) use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.

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

Member States shall inform the Commission without delay if a collection under their jurisdiction included in the Union register no longer complies with paragraph 3.

5. Where there is evidence that a collection included in the Union register of trusted collections does not apply the measures set out in paragraph 3, the Member State concerned shall without delay identify remedial actions in dialogue with the owner of the collection concerned.

The Commission shall remove a collection from the Union register of trusted collections when, in particular on the basis of information provided pursuant to paragraph 4, it has determined that a collection included in the Union register of trusted collections faces important or persistent difficulties to comply with paragraph 3.

6. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article. The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Article 6

Competent authorities and focal point

1. Each Member State shall designate one or more competent authorities responsible for the application of this Regulation. Member States shall notify the Commission of the names and addresses of their competent authorities as of the entry into force of this Regulation. Member States shall inform the Commission without delay of any changes to the names or addresses of the competent authorities.

2. The Commission shall make public, including on the internet, a list of the competent authorities. The Commission shall keep the list up to date.

3. The Commission shall designate a focal point on access and benefit-sharing responsible for providing information to applicants seeking access to genetic resources and traditional knowledge associated with such resources in the Union and to liaise with the Secretariat of the Convention on Biological Diversity.

Article 7

Monitoring user compliance

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.

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.

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.

4. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1, 2 and 3 of this Article. The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Article 8

Best practices

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.

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.

3. An association of users shall inform the Commission of any changes or updates made to a recognised best practice for which it was granted recognition in accordance with paragraph 2.

4. If evidence from competent authorities of the Member States or other sources indicates repeated cases where users implementing a best practice fail to comply with their obligations under this Regulation, the Commission shall examine in dialogue with the relevant association of users whether the repeated cases of non-compliance indicate possible deficiencies in the best practice.

5. The Commission shall withdraw the recognition of a best practice, when it has determined that changes to the best practice compromise a user's ability to meet the conditions set out in Articles 4 and 7, or when repeated cases of non-compliance by users relate to deficiencies in the practice.

6. The Commission shall establish and keep up to date an internet-based register of recognised best practices. That register shall list in one section best practices recognised by the Commission in accordance with paragraph 2 of this Article and display in another section best practices adopted on the basis of Article 20(2) Nagoya Protocol.

7. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article. The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Article 9

Checks on user compliance

1. The competent authorities shall carry out checks to verify if users comply with the requirements set out in Articles 4 and 7.

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

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

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

   (a) examination of the measures taken by a user to exercise due diligence in accordance with Article 4;

   (b) examination of documentation and records that demonstrate the exercise of due diligence in accordance with Article 4 in relation to specific use activities;

   (c) on the spot checks, including field audits;

   (d) examination of instances where a user was obliged to make declarations under Article 7.

5. Competent authorities shall accept an internationally recognised certificate of compliance as evidence that the genetic resource it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or

regulatory requirements of the Party to the Nagoya Protocol providing the prior informed consent.

6. Users shall offer all assistance necessary to facilitate the performance of the checks referred to in paragraph 1, notably as regards access to premises and the presentation of documentation or records.

7. Without prejudice to Article 11, where, following the checks referred to in paragraph 1 of this Article, shortcomings have been detected, the competent authority shall issue a notice of remedial actions to be taken by the user.

Additionally, depending on the nature of the shortcomings detected, Member States may take immediate interim measures, including inter alia seizure of illegally acquired genetic resources and suspension of specific use activities.

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

Article 10

Records of checks

1. The competent authorities shall keep records of the checks referred to in Article 9(1), indicating in particular their nature and results, as well as of remedial actions and measures taken under Article 9(7).

Records of all checks shall be kept for at least five years.

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

Article 11

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of the provisions of Articles 4 and 7 of this Regulation and shall take all measures necessary to ensure that they are implemented.

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

(a) fines;

(b) immediate suspension of specific use activities;

(c) confiscation of illegally acquired genetic resources.

3. Member States shall notify the rules referred to in paragraph 1 to the Commission by [date] at the latest and shall notify it without delay of any subsequent amendments affecting them.

Article 12

Cooperation

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.

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.

Article 13

Union platform on access

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

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.

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

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.

5. The Union platform will take decisions by the consensus of its regular members participating in a meeting. Decisions on procedure may be taken by a two-thirds majority of the regular members participating in a meeting. The first meeting of the Union platform shall adopt by consensus its detailed rules of procedure. The Commission shall prepare, convene and chair the meetings of the platform.

Article 14

Complementary measures

The Commission and the Member States shall, as appropriate:

(a) support information, awareness raising, and training activities to help stakeholders to understand their obligations under this Regulation;

(b) support the development of sectoral codes of conduct, model contractual clauses, guidelines and best practices, particularly where they would benefit academic researchers and small and medium-sized enterprises;

(c) support the development and use of cost-effective communication tools and systems in support of monitoring and tracking the use of genetic resources and traditional knowledge associated with genetic resources by collections and users;

(d) provide technical and other guidance to users, taking into account the situation of academic researchers and small and medium-sized enterprises, in order to facilitate compliance with the requirements of this Regulation.

Article 15

Implementing acts

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a two-thirds majority of committee members so request.

4. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 16

Reporting and review

1. Member States shall submit to the Commission, three years after the date of entry into force of this Regulation and every five years thereafter, a report on the application of this Regulation.

2. Not later than one year after the time-limit for submission of the national reports, the Commission shall draw up a report to be submitted to the European Parliament and the Council. The report by the Commission shall include a first assessment of the effectiveness of this Regulation.

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.

4. The Commission shall report to the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on the measures that the Union and its Member States have taken to implement the Nagoya Protocol.

Article 17

Entry into force and application

1. The Commission shall publish a notice in the O*fficial Journal of the European Union* that the Nagoya Protocol has entered into force. This Regulation shall enter into force on the twentieth day following the publication of that notice.

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

3. This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*