Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2012/0278(COD)
Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union See also 2012/0279(NLE) Subject 3.10.09.06 Agro-genetics, GMOs 3.50.01 European research area and policy 3.70.01 Protection of natural resources: fauna, flora, nature, wildlife, countryside; biodiversity 3.70.18 International and regional environment protection measures and agreements 4.20.02.04 Genetics and bioethics	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		23/10/2012
		Verts/ALE BÉLIER Sandrine	
		Shadow rapporteur	
		PPE GUTIÉRREZ-CORTINES Cristina	
		S&D POC Pavel	
		ALDE GERBRANDY Gerben-Jan	
		ECR ROSBACH Anna	
	Committee for opinion	Rapporteur for opinion	Appointed
	DEVE Development		03/01/2013
		Verts/ALE GRÈZE Catherine	
	ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
	REGI Regional Development	The committee decided not to give an opinion.	
	AGRI Agriculture and Rural Development		03/12/2012
		Verts/ALE BOVÉ José	
	PECH Fisheries		21/11/2012
		Verts/ALE HUDGHTON Ian	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	3308	14/04/2014
	Environment	3246	18/06/2013
	Environment	3233	21/03/2013
European Commission	Commission DG	Commissioner	
	Environment	POTOČNIK Janez	

European Economic and Social Committee
European Committee of the Regions

Key events

04/10/2012	Legislative proposal published	COM(2012)0576	Summary
19/11/2012	Committee referral announced in Parliament, 1st reading		
21/03/2013	Debate in Council	3233	Summary
18/06/2013	Debate in Council	3246	
04/07/2013	Vote in committee, 1st reading		
16/07/2013	Committee report tabled for plenary, 1st reading	A7-0263/2013	Summary
11/09/2013	Debate in Parliament		
12/09/2013	Results of vote in Parliament		
12/09/2013	Decision by Parliament, 1st reading	T7-0373/2013	Summary
11/03/2014	Decision by Parliament, 1st reading	T7-0193/2014	Summary
14/04/2014	Act adopted by Council after Parliament's 1st reading		
16/04/2014	Final act signed		
16/04/2014	End of procedure in Parliament		
20/05/2014	Final act published in Official Journal		

Technical information

Procedure reference	2012/0278(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	See also 2012/0279(NLE)
Legal basis	Treaty on the Functioning of the EU TFEU 192-p1
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/10860

Documentation gateway

Legislative proposal		COM(2012)0576	04/10/2012	EC	Summary
Document attached to the procedure		SWD(2012)0291	04/10/2012	EC	

Document attached to the procedure		SWD(2012)0292	04/10/2012	EC	
Economic and Social Committee: opinion, report		CES2314/2012	20/03/2013	ESC	
Committee draft report		PE508.195	06/05/2013	EP	
Committee opinion	DEVE	PE507.953	30/05/2013	EP	
Committee opinion	AGRI	PE507.964	30/05/2013	EP	
Amendments tabled in committee		PE513.008	30/05/2013	EP	
Committee opinion	PECH	PE504.318	18/06/2013	EP	
Amendments tabled in committee		PE514.790	28/06/2013	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0263/2013	16/07/2013	EP	Summary
Text adopted by Parliament, partial vote at 1st reading/single reading		T7-0373/2013	12/09/2013	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0193/2014	11/03/2014	EP	Summary
Draft final act		00131/2013/LEX	16/04/2014	CSL	
Commission response to text adopted in plenary		SP(2014)455	10/06/2014	EC	
Follow-up document		COM(2019)0013	24/01/2019	EC	Summary

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2014/511
OJ L 150 20.05.2014, p. 0059 Summary

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

OBJECTIVE: to implement the Nagoya Protocol in the Union and to allow the ratification of this Union Treaty with a view to creating new opportunities for nature-based research, and contribute to the development of a bio-based economy.

PROPOSED: Regulation of the European Parliament and of the Council.

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.

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

The main international instrument governing access to and use of genetic resources is the Convention on Biological Diversity (CBD) approved by Council Decision 93/626/EEC. 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. In the absence of clear rules or with very burdensome rules in most provider countries, European researchers and companies have repeatedly been accused of biopiracy by countries claiming a violation of their sovereign rights.
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 is a new international treaty adopted on 29 October 2010 by the consensus of the Parties to the CBD. It 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 Commission proposes from then on 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.

IMPACT ASESMENT: in particular, the Commission analysed in-depth two options for access measures and four options for user-compliance measures. All options were analysed against a business as usual baseline without implementing measures at EU or Member State level. It also analysed two options on the temporal application of EU-level measures as well as a range of complementary measures.

The analysis identified:

1) the preferable option on access as the establishment of an EU platform for discussing access to genetic resources and sharing best practices;

2) the identified preferable option on user-compliance as a due diligence obligation on EU users complemented by a system to identify collections as trusted sources of genetic resources.

LEGAL BASIS: Article 192(1) of the Treaty on the Functioning of the European Union.

CONTENT: the proposal sets out obligations for users of genetic resources and traditional knowledge associated with genetic resources in the Union.

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.

Obligations of users: The proposal obliges 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.

Good practice: 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.

Union trusted collections: 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.

Checks on user compliance: 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.

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

BUDGETARY IMPLICATION: the proposal does not entail any significant financial implications for the Community budget.

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

Ministers held a public debate on the draft regulation on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation in the Union. The main objective of the proposal is to implement the Nagoya Protocol in the EU and to enable its ratification by the EU.

To steer further work on the proposal, the Presidency invited ministers to answer a series of questions focusing on the proposed obligations of users of genetic resources and their monitoring by Member States:

1. Do you consider that the obligations of users contained in the legislative proposal adequately reflect the requirements of the Nagoya Protocol with regard to user compliance in the Union?
2. Will they contribute to the aim of effective implementation of benefit sharing arrangements? and
3. In your view and in the light of the Nagoya Protocol, is the proposed balance between the obligations of users and the monitoring of these obligations by Member States appropriate in order to ensure the use within the Union of genetic resources accessed in accordance with relevant requirements?

The Presidency highlighted the following points that emerged from the discussion:

- new legislation should not create an unnecessary burden for users or authorities but at the same time should be comprehensive

enough to cover the provisions of the Nagoya Protocol;
- due diligence obligations of users should be accompanied by their monitoring by authorities in order to ensure compliance with the Nagoya Protocol;
- links with other international instruments relating to the use of genetic resources should be further examined.

The Commissioner underscored the importance of having this new piece of legislation in place by July 2014 in order to fulfil EU international commitments. The European Parliaments Committee on Environment, Public Health and Food Safety is scheduled to vote on the draft regulation in July 2013.

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

The Committee on the Environment, Public Health and Food Safety adopted the report by Sandrine BÉLIER (Greens/EFA, FR) 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.

The committee recommends that the European Parliaments position at first reading, following the ordinary legislative procedure, should amend the Commissions proposal as follows:

Objective: Members specify that the objective of this Regulation is the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, thereby contributing to the conservation of biological diversity and the sustainable use of its components, in accordance with the objectives of the Convention on Biological Diversity.

The amendments also aim to:

- lay down obligations for users of genetic resources and traditional knowledge associated with genetic resources;
- include provisions encouraging activities by relevant actors to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources and related access and benefit-sharing issues, as well as activities contributing to capacity-building in developing countries.

User obligations: Members call for the utilisation of illegally acquired genetic resources to be prohibited in the Union. "Illegally acquired genetic resources" shall mean genetic resources and traditional knowledge associated with genetic resources acquired in contravention of the applicable international and national law on access and benefit-sharing in the country of origin.

With a view to improving the chain of custody of genetic resources and the associated traditional knowledge, users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources used were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, after obtainment of prior informed consent when so required and with full respect of existing duties regarding fair and equitable benefit sharing upon mutually agreed terms.

Genetic resources shall only be transferred to other users if in accordance with the internationally recognised certificate of compliance and mutually agreed terms, or prior informed consent and mutually agreed terms.

In the absence of mutually agreed terms or if subsequent users envisage utilising such genetic resources or traditional knowledge under conditions that are not included in the prior terms, those users shall be required to seek mutually agreed terms from the country of origin.

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.

Union trusted collections: Members deleted Article 5 as regards Union trusted collections. Most collections are the most accessible suppliers of genetic resources and traditional knowledge associated with genetic resources utilised in the Union. As suppliers they can play an important role in helping other users in the chain of custody to comply with their obligations. In order to do so a system of Union registered collections should be set in place which would substantially lower the risk that illegally acquired genetic resources are utilised in the Union. Union registered collections should adhere to the objective of the Nagoya Protocol.

Competent authorities and potential users: the competent authorities and the focal point on access and benefit-sharing shall provide advice to the public and potential users seeking information on the implementation of this Regulation and of the relevant provisions of the Convention and the Nagoya Protocol in the Union.

Monitoring user compliance: amendments provide that the users shall declare to the competent authorities that they have fulfilled the obligations and shall submit the related information on the occasion of establishing prior informed consent and mutually agreed terms; applying for patents or for new plant variety rights at relevant national, regional or international institutions; or requesting market approval for a product developed on the basis of genetic resources.

Competent authorities shall verify the information and transmit to the Access and Benefit Sharing Clearing House Mechanism, to the Commission and if appropriate to the competent authorities of the State concerned. The Commission shall within three months summarise the information received and make it public in an easily accessible open, internet-based, format.

Penalties: Members calls for fines to be proportional to the value of the use activities related to the genetic resources concerned and at least effectively depriving those responsible of the economic benefits derived from the infringement.

Union platform on the access and benefit-sharing: the Union platform shall contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of access regimes established in Member States, the promotion of research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries.

Any such advice, guidance or opinions provided shall have due regard for the requirement to involve the relevant indigenous and local communities concerned.

Additional measures: the Commission and the Member States should also, if necessary:

- take measures to support, including through existing research programmes, collections that contribute to the conservation of biological diversity and cultural diversity but have insufficient means, to register their collections in the Union register;
- ensure that, in situations where genetic resources and associated traditional knowledge are utilised illegally, or not in compliance with prior informed consent or mutually agreed terms, providers who are competent to grant access to genetic resources and sign mutually agreed terms are entitled to bring an action to prevent or stop such utilisation, including through injunctions, and to seek compensation for any damages resulting thereof;
- encourage users and providers to direct benefits arising from the utilisation or subsequent commercialisation of genetic resources towards the conservation of biological diversity and the sustainable use of its components;
- support, including through capacity-building, upon request, regional cooperation on benefit-sharing regarding transboundary genetic resources and associated traditional knowledge;
- support research and development of genetic catalogues both within the Union and in third countries.

Consultation Forum: Members consider that Member States experts as well as stakeholder organisations should have an opportunity to participate and contribute to the implementation of the Regulation, including the draft delegated and implementing acts. To this end, they propose the creation of a Consultation Forum based on the model in the Eco-Design Directive 2009/125/EC.

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

The European Parliament adopted amendments to 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.

The matter had been referred back to the competent committee. The vote on the legislative resolution was set back to a later session.

The main amendments adopted by Parliament concerned the following points:

Objective : Members wanted to clarify that the objective of the Regulation is the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, thereby contributing to the conservation of biological diversity and the sustainable use of its components, in accordance with the objectives of the Convention on Biological Diversity

The amendments also stated that the Regulation :

- lays down obligations for users of genetic resources and traditional knowledge associated with genetic resources;
- includes provisions encouraging activities by relevant actors to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources and related access and benefit-sharing issues, as well as activities contributing to capacity-building in developing countries, in line with the Nagoya Protocol's provisions.

User obligations: Members called for the utilisation of illegally acquired genetic resources to be prohibited in the Union. "Illegally acquired genetic resources" means genetic resources and traditional knowledge associated with genetic resources acquired in contravention of the applicable international and national law on access and benefit-sharing in the country of origin. The amendments make the following points:

With a view to improving the chain of custody of genetic resources and the associated traditional knowledge, users must exercise due diligence to ascertain that access to genetic resources was obtained with prior informed consent and based on mutually agreed terms.

Genetic resources should only be transferred to other users if in accordance with the internationally recognised certificate of compliance and mutually agreed terms.

If subsequent users envisage utilising such genetic resources or traditional knowledge under conditions that were not included in the prior terms, those users shall be required to seek mutually agreed terms from the country of origin.

Users, when negotiating mutually agreed terms with providers of genetic resources or of traditional knowledge associated with genetic resources, should seek to ensure that such terms contribute to the conservation of biological diversity

Union trusted collections: Parliament proposed deleting Article 5 as regards Union trusted collections. In a recital, it recalled that most collections are the most accessible suppliers of genetic resources and traditional knowledge associated with genetic resources utilised in the Union. As suppliers they could play an important role in helping other users in the chain of custody to comply with their obligations. In order to do so, Members suggested that a system of Union registered collections should be set in place which would substantially lower the risk that illegally acquired genetic resources are utilised in the Union. Union registered collections should adhere to the objective of the Nagoya Protocol.

Competent authorities and potential users: 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 the Regulation and of the relevant provisions of the Convention and the Nagoya Protocol in the Union.

Monitoring user compliance: amendments provided that the users shall declare to the competent authorities that they have fulfilled the obligations and shall submit the related information on the occasion of establishing prior informed consent and mutually agreed terms; applying for patents or for new plant variety rights at relevant national, regional or international institutions; or requesting market approval for a product developed on the basis of genetic resources.

Competent authorities shall verify the information and transmit to the Access and Benefit Sharing Clearing House Mechanism, to the Commission and if appropriate to the competent authorities of the State concerned. The Commission shall within three months summarise the information received and make it public in an easily accessible open, internet-based, format.

Montoring of compliance with the rules : the amendments provided that users must declare to the competent authorities that they have fulfilled the obligations and submit the related information on the occasion of: (i) establishing prior informed consent and mutually agreed terms; (ii) receiving research funding involving utilisation of genetic resources and traditional knowledge associated with genetic resources; (iii) applying for patents or for new plant variety rights covering, inter alia, the genetic resources accessed.

Competent authorities shall verify the information provided and transmit to the Access and Benefit Sharing Clearing House Mechanism, to the Commission and if appropriate to the competent authorities of the State concerned. The Commission shall summarise the information received and make it public in an internet-based format.

Penalties: Parliament called for fines to be proportional to the value of the use activities related to the genetic resources concerned and that at least effectively deprived those responsible of the economic benefits derived from the infringement.

Cooperation : Members considered that the Commission should 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.

Union platform on the access and benefit-sharing: the Union platform must contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of access regimes established in Member States, the promotion of research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries.

Any advice, guidance or opinions provided shall have due regard for the requirement to involve the relevant indigenous and local communities concerned.

Additional measures: the Commission and the Member States should also, if necessary:

- take measures to support, including through existing research programmes, collections that contribute to the conservation of biological diversity and cultural diversity but have insufficient means, to register their collections in the Union register;
- ensure that, in the event of illicit use, providers who are competent to grant access to genetic resources and sign mutually agreed terms are entitled to bring an action to prevent or stop such utilisation, including through injunctions, and to seek compensation for any damages resulting thereof;
- encourage users and providers to direct benefits arising from the utilisation or subsequent commercialisation of genetic resources towards the conservation of biological diversity;
- support regional cooperation on benefit-sharing regarding transboundary genetic resources;
- support research and development of genetic catalogues both within the Union and in third countries.

Consultation Forum: Members considered that Member States experts as well as stakeholder organisations should have an opportunity to participate and contribute to the implementation of the Regulation. To this end, they proposed the creation of a Consultation Forum based on the model in the Eco-Design Directive 2009/125/EC.

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

The European Parliament adopted by 630 votes to 14 with 38 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

The matter had been referred back to committee during the plenary session of 12 September 2013.

Parliament adopted its position in first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of an agreement negotiated between Parliament and Council.

Objective: Parliament wanted to clarify that the objective of the Regulation is the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, thereby contributing to the conservation of biological diversity and the sustainable use of its components, in accordance with the objectives of the Convention on Biological Diversity the (Nagoya Protocol).

Obligations of users: the amended text stipulates that users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements. Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilised in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements.

Accordingly, businesses, private collectors and institutions who use genetic resources that come, for example, from plants and animals in developing countries must seek, keep and transfer to subsequent users:

the internationally-recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or where no internationally-recognised certificate of compliance is available, information and relevant documents on: (i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources; (ii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users; (iii) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation; (iv) mutually agreed terms, including benefit-sharing arrangements, where applicable.

Internationally recognised certificate of compliance means a permit or its equivalent issued at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant prior informed consent, and that mutually agreed terms have been established for the user and the utilisation specified therein by a competent authority, that is made available to the Access and Benefit-sharing Clearing House established under the Nagoya Protocol.

Users acquiring a genetic resource that is determined to be the causing pathogen of a present or imminent public health emergency of international concern, or of a serious cross-border threat to health for the purpose of public health emergency preparedness in not yet affected countries and response in affected countries, shall fulfil the obligations listed the text: (i) one month after the imminent or present threat to public health is terminated, or (ii) three months after commencement of utilisation of the genetic resource, whichever is the earlier.

Register of collections: the Commission shall establish and maintain a register of collections within the Union. It shall ensure that the register is internet-based and is easily accessible to users. The register shall include the references of the collections of genetic resources, or of parts of those collections, identified as meeting the criteria set out in the regulation.

Complementary measures: the Commission and Member States shall, as appropriate:

- promote and encourage information, awareness-raising and training activities to help stakeholders and interested parties to understand their obligations arising from the implementation of this Regulation, and of the relevant provisions of the Convention and the Nagoya Protocol in the Union ;
- encourage the development of sectoral codes of conduct, model contractual clauses, guidelines and best practices, particularly where they would benefit academic, university and non-commercial researchers and small and medium-sized enterprises;
- encourage users and providers to direct benefits from the utilisation of genetic resources towards the conservation of biological diversity and the sustainable use of its components in accordance with the provisions of the Convention;
- promote measures in support of collections that contribute to the conservation of biological diversity and cultural diversity.

Consultation forum: the Commission shall ensure a balanced participation of representatives of the Member States and other interested parties in issues related to the implementation of this Regulation. They shall meet in a consultation forum.

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

PURPOSE: to promote the fair and equitable sharing of the benefits arising from the utilisation of genetic resources in accordance with the Nagoya Protocol.

LEGISLATIVE ACT: Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.

CONTENT: the 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. Its implementation should contribute to the conservation of biological diversity and the sustainable use of its components, in accordance with the provisions of the Convention on Biological Diversity.

The Nagoya Protocol, attached to the Convention on Biological Diversity, is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Protocol further elaborates upon the general rules of the Convention on access to genetic resources and sharing of monetary and non-monetary benefits arising from the utilisation of genetic resources and traditional knowledge associated with genetic resources (access and benefit-sharing). In accordance with Council Decision 2014/283/EU, the Nagoya Protocol was approved on behalf of the Union.

Scope: the Regulation applies to genetic resources over which States exercise sovereign rights and to traditional knowledge associated with genetic resources within the scope of the Convention, which are accessed after the entry into force of the Nagoya Protocol for the Union. Traditional knowledge includes knowledge, innovations and practices, of indigenous and local communities embodying traditional lifestyles, relevant for the conservation and sustainable use of biological diversity.

Rules to be respected by users: the Regulation stipulates that all users of genetic resources and traditional knowledge associated with genetic resources should exercise due diligence to ascertain whether genetic resources and traditional knowledge associated with genetic resources have been accessed in accordance with applicable legal or regulatory requirements and to ensure that benefits are fairly and equitably shared upon mutually agreed terms.

In that context, competent authorities should accept internationally-recognised certificates of compliance as evidence that the genetic resources covered were legally accessed and that mutually agreed terms were established for the user and the utilisation specified therein.

Competent authorities: each Member State shall designate one or more competent authorities to be responsible for the application of this Regulation. The competent authorities shall carry out checks to verify whether users comply with their obligations. In doing so, they should consider that the implementation of a recognised best practice for access and benefit sharing by a user reduces that users risk of non-compliance. The competent authorities shall keep, for at least five years, records of the checks.

The Commission shall make public, including via the internet, a list of the competent authorities of the Member States. In addition, it shall establish a register of collections of genetic resources within the Union which is internet-based and easily accessible to users.

Complementary measures: the Regulation provides that the Commission and the Member States will be required, among others:

- promote and encourage information, awareness-raising and training activities to help stakeholders and interested parties to understand their obligations;
- encourage the development of sectoral codes of conduct, model contractual clauses, guidelines and best practices, particularly where they would benefit academic, university and non-commercial researchers and small and medium-sized enterprises;
- promote the development and use of cost-effective communication tools in support of monitoring and tracking the utilisation of genetic resources;
- encourage users to direct benefits from the utilisation of genetic resources towards the conservation of biological diversity.

Representatives of the Member States and other interested parties in issues related to the implementation of this Regulation shall meet in a consultation forum.

Reports and review: in principle, the Member States shall submit to the Commission a report on the application of this Regulation by 11 June 2017 and every five years thereafter. Not later than one year after the time-limit for submission of reports, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation. Every 10 years after its first report the Commission shall review the functioning and effectiveness of this Regulation in achieving the objectives of the Nagoya Protocol.

ENTRY INTO FORCE: 09.06.2014.

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

The Commission presents a report on Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (EU ABS Regulation).

In accordance with the EU ABS Regulation, the Commission is required to submit a report on the application of the Regulation, including a first assessment of its effectiveness, not later than one year after the time-limit for submission of the national reports.

The report is based on information from the national reports submitted by all 28 Member States to the Commission, as well as other information available. It covers the first three years of application of the EU ABS Regulation, i.e. the period between October 2014 and August 2017, which is reduced to two years of application for provisions concerning due diligence (Art. 4), monitoring of user compliance (Art. 7) and compliance checks (Art. 9).

State of play

Implementation and enforcement

This report stated that the Regulation is in its early days of implementation. Many Member States started relatively late to take measures to set up the institutional and administrative framework necessary to implement the Regulation. The Commission proactively promoted compliance by reminding Member States of their obligation to designate competent authorities and to adopt rules on penalties. Although most Member States took the necessary measures to address the implementation gaps, letters of formal notice were sent in January 2018 to 9 Member States that were still non-compliant. Further on, reasoned opinion were issued in 2 of these cases in November 2018.

The implementation and enforcement of the Regulation was slow and uneven during the first years and remains work in progress. While many Member States have fulfilled the formal requirements of the Regulation, only a few have moved on into the actual implementation on the ground.

Member States adopted different solutions to set up the institutional framework. In some cases, consultations and coordination among different administrations contributed to slow down the process of designation. 6 Member States still need to designate competent authorities. Lack or limited human and financial resources devoted to the implementation of the EU ABS Regulation is often reported as a major obstacle. Lack of specialized personnel and qualified experts is also identified as a problem. Trainings to strengthen the institutional capacity of staff are therefore necessary. At the same time, some Member States expressed worries about the administrative burden and costs implied by the Regulation.

20 Member States adopted legislative measures setting up sanctions for infringements of the obligations of the Regulation. A varied range of sanctions (from administrative to criminal law) can be observed, which entails also a variation in the levels of sanctions.

Awareness of the Regulation

Despite the efforts undertaken both by the Member States and the Commission, a low level of awareness among stakeholders about the obligations stemming from the Nagoya Protocol and the EU ABS Regulation is often reported. Also, institutions and administrations in Member States often lack awareness of the topic. Both the Nagoya Protocol and the EU ABS Regulation are relatively new regulatory instruments and ABS issues are thus still quite an unknown subject.

Additional efforts to foster the level of awareness among a wide range of stakeholders are needed.

Several Member States reported that it is rather difficult for stakeholders to understand the complexity of the EU ABS Regulation.

Challenges

Some Member States also highlighted additional challenges related to the interpretation of some provisions of the EU ABS Regulation and mentioned the issue of unclear wording of some terms in the Regulation (which results from the use of the same concepts as those enshrined in the Nagoya Protocol). In this context, it was claimed that further guidance would be useful to clarify some terms. Also some concerns of the users were reported, namely about an excessive administrative and financial burden, while the added value deriving from the Regulation is not perceived.

In this context, the Commission will continue to use the existing tools to contribute to a more uniform application of the Regulation across the EU. Further efforts from Member States in the implementation and enforcement of the EU ABS Regulation are needed. In particular, all non-compliant Member States urgently need to designate national competent authorities, adopt sanctions, put measures in place to implement the first checkpoint and step up their efforts to develop risk-based plans to carry out checks. The current level of technical capacity and resources (both human and financial) allocated to the competent authorities does often not match the needs and should therefore be reinforced in most of the Member States.