ADVANCES AND UNCERTAINTIES IN COMPLIANCE MEASURES FOR USERS FROM THE NAGOYA PROTOCOL IN THE EUROPEAN UNION

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Abstract

The Nagoya Protocol developed the legal regime of the access to genetic resources and the fair and equitable sharing of benefits arising from their utilization that were already enshrined in the Convention on Biological Diversity (CBD) and introduced binding rules on compliance. With its Regulation (EU) 511/2014 adopted in 2014 (EU ABS Regulation), the European Union (EU)—the second most important geographical area in the global biotechnology market—has developed and tried to harmonize the compliance and monitoring measures for users from the Nagoya Protocol in the EU territory. This paper presents and assesses the progress made in this recent EU legal field, including the challenges in the form of several uncertainties that still lie ahead.

Keywords

Genetic resources; access and benefit sharing (ABS); Nagoya Protocol; Regulation (EU) 511/2014; European Union.

1 INTRODUCTION

The European Union (EU) has become the second major geographic area in the global biotechnology market, ahead of Japan and behind the United States.[1] It also hosts a considerable amount of genetic resources from all regions of the world through an extensive network of botanical gardens, collections and gene banks.[2] In line with this, the EU has given important financial support in recent years to research and development in this field.[3] Specially worth noting is the promotion of the so-called 'blue biotechnology'—that which uses living marine resources—within the framework of the EU Blue Growth strategy.[4]

The EU played an important role in the negotiation of the Nagoya Protocol.[5] In the absence of the United States, it was the most relevant actor representing the interests of developed countries and the biotechnology industry. The EU represents nothing less than

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[1] S Oberthür and F Rabitz, 'On the EU's performance and leadership in global environmental governance: the case of the Nagoya Protocol' (2014) 21 (1) Journal of European Public Policy 39, 49-50.

[2] B Coolsaet, 'Conclusion. Comparing access and benefit-sharing in Europe' in B Coolsaet et al (eds), Implementing the Nagoya Protocol. Comparing Access and Benefit-Sharing Regimes in Europe (Brill Nijhoff 2015) 363, 364.

[3] This has been done within the framework of the former Seventh Framework Program for Research (2007-2013) and currently it is being done through the Horizon 2020 Program and Marie Sklodowska-Curie Actions. A joint public-private initiative—the Biobased Industries Joint Undertaking (BBI JU)—that provides funding opportunities for biotechnology innovation has also been established.

[4] Commission (EU), 'Blue Growth opportunities for marine and maritime sustainable growth' (Communication) COM (2012) 494 final, 13 September 2012.

[5] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (adopted 29 October 2010, entered into force 12 October 2014) (Nagoya Protocol).

approximately half of the global utilization, excluding that of the United States, of the genetic resources that had to be regulated.[6] The EU had, both in the negotiations of the Nagoya Protocol and in the elaboration of its internal regulations in this field, the not so easy task of reconciling two major issues. On the one hand, the EU had to deal with the pressure against the Protocol by pharmaceutical companies and industrial associations[7] and to avoid hindering the development of biotechnology in its territory, which could move to other territories with less strict access and benefit-sharing (ABS) requirements. On the other hand, developing and developed countries had entered the negotiations on the Nagoya Protocol with very different agendas, with developing countries strongly advocating against biopiracy[8] and for the establishment of strong ABS obligations.[9]

The EU has developed its own internal regulation developing and applying the compliance measures on ABS imposed by the Nagoya Protocol to users of genetic resources and associated traditional knowledge (aTK) in its territory. The main purpose of this paper is to analyse the implementation of this recent unique regional legislation[10] in light of the first report of the Commission (First ABS Commission Report)[11] on the application of its key instrument: the Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 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). [12] This analysis will show advances and uncertainties in the legislation's implementation, the latter mainly due to the still little experience with its application and the inherent complexity of the global ABS legal regime.

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[6] S Oberthür and F Rabitz, 'The role of the European Union in the Nagoya Protocol negotiations. Self-interest bridge building' in S Oberthür and GK Rosendal (eds): Global governance of genetic resources. Access and benefit sharing after the Nagoya Protocol (Routledge 2014) 79, 79.

[7] K Kariyawasam and M Tsai, 'Access to genetic resources and benefit sharing: Implications of Nagoya Protocol on providers and users' (2018) 21 (5-6) The Journal of World Intellectual Property 289, 300.

[8] G. Dutfield, 'What is Biopiracy?', paper presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca (Mexico), 24-27 Oct. 2004, available at < http://moderncms.ecosystemmarketplace.com/repository/moderncms_documents/I.3.pdf.>

[9] L Wallbott, F Wolff and J Pozarowska, The negotiations of the Nagoya Protocol. Issues, coalitions and process' in S Oberthür and GK Rosendal (eds): Global governance of genetic resources. Access and benefit sharing after the Nagoya Protocol (Routledge 2014) 33. The role of the EU in the negotiations in relation to the search for a balance of interests between developed and developing countries has been evaluated as conservative at its beginnings and as more moderate in the final stage. See Oberthür and Rabitz (n 1) 47-53.

[10] There are very few other regional ABS legal frameworks: one on access in the Andean Community (Decisión No. 1375 de la Comunidad Andina 'Marco Normativo Andino de Medidas de Salvaguarda de los Recursos Genéticos y los Conocimientos Tradicionales Asociados', XLIX Periodo Ordinario de Sesiones de la Plenaria del Parlamento Andino, 24 de febrero de 2017, Bogotá, Colombia), 'The African Union Strategic Guidelines for the Coordinated Implementation of the Nagoya Protocol and the Fair and Equitable Sharing of Benefits arising from their Utilization', adopted by the 25th ordinary session of the Assembly of the African Union in June 2015, and the 'Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore Within the Framework of the African Regional Intellectual Property Organization (ARIPO)', adopted by the Diplomatic Conference of ARIPO at Swakopmund (Namibia) on 11 August 2010.

[11] Commission (EU) 'Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 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' (Report) COM(2019) 13 final, 24 January 2019.

[12] OJ L 150/59.

2 THE EU LEGISLATION ON COMPLIANCE MEASURES FORM USERS OF THE NAGOYA PROTOCOL

The Nagoya Protocol developed in 2010 the obligations of access and benefit-sharing already included in the Convention on Biological Diversity (CBD) in 1992[13]. However and for the first time in the global ABS regime, the Protocol introduces binding rules on compliance. In this way, each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to ensure that genetic resources and aTK utilized within its jurisdiction have been accessed in accordance with prior informed consent (PIC) and that mutually agreed terms (MAT) have been established, as required by the domestic ABS requirements of the other Party.[14] They shall also take appropriate, effective and proportionate measures to address situations of non-compliance,[15] cooperate in cases of alleged violation of domestic ABS requirements,[16] as well as monitor and enhance transparency of the utilization of genetic resources, including the establishment of checkpoints.[17]

At least at the end of 2018, not all Parties had finished adopting these legislative, administrative and policy measures on ABS and established the corresponding institutional arrangements.[18] The first assessment and review of the effectiveness of the Protocol, adopted by the third meeting of the Parties to the Nagoya Protocol in Sharm El-Sheikh (Egypt) in November 2018, highlighted the provisions on compliance and monitoring of the use of genetic resources, including the designation of checkpoints, as one of the two particular challenges in the implementation of some of the new elements introduced by the Protocol.[19] The European legislation on ABS focuses precisely on these last elements and tries to harmonize compliance and monitoring measures on the use of genetic resources among its Member States.

The EU ABS legislation places the EU at the forefront of the development and implementation of the compliance measures for users from the Nagoya Protocol. To date, only Japan and Switzerland have also adopted compliance measures on the application of the Protocol.[20] As stated by Robinson and von Brown, 'as the largest CBD "user" group, the EU is likely to not only set precedent with its interpretation to other users but also influence the way provider countries, in response, will implement their access regulations'.[21]

2.1 Development of the EU ABS legislation

[13] Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993) 1760 UNTS 79 (CBD).
[14] Nagoya Protocol, arts 15.1 and 16.1.
[15] ibid arts 15.2 and 16.2.
[16] ibid arts 15.3 and 16.3.
[17] ibid art 17.
[18] ABS COP-MOP Decision 3/1 'Assessment and review of the effectiveness of the Protocol (Article 31)' CBD/NP/MOP/DEC/3/1 (30 November 2018).
[19] ibid 5. The other new element of the Protocol highlighted as a particular challenge in the implementation of the Nagoya Protocol were the obligations related to indigenous peoples and local communities.
[20] First ABS Commission Report (n 11) 5.
[21] D F Robinson & J von Braun, 'New Challenges for the Nagoya Protocol: Diverging Implementation Regimes for Access and Benefit-Sharing' in Intellectual Property and Development: Understanding the Interfaces (Springer 2019) 377, 378.

The EU ABS legislation has its origins in the 'EU Biodiversity Strategy to 2020'', adopted in 2011,[22] itself part of the 'Europe 2020 Strategy'[23] and the 7th Environment Action Programme (2013-2020).[24] One of the objectives of this strategy was the regulation of access to genetic resources and the fair and equitable sharing of benefits arising from their use, for which the Commission proposed legislation to implement the Nagoya Protocol so that the EU could ratify it as soon as possible.[25]

Thus, a proposal for a Regulation of the Council and Parliament was adopted in October 2012,[26] accompanied by an impact assessment carried out by the Commission.[27] Finally, the EU ABS Regulation was adopted on 16 April 2014. Its legal basis is the shared environmental policy enshrined in art. 192. 1 of the Treaty on the Functioning of the European Union (TFEU), although the EU ABS Regulation also emphasizes its usefulness in ensuring the functioning of the internal market.[28] The Regulation partially entered into force on 12 October 2014, and the remaining provisions—relating to relevant issues such as the obligations of users, monitoring and checks on users' compliance (articles 4, 7 and 9)—did so a year later.[29]

The EU ABS Regulation itself attributed powers to the Commission to ensure uniform conditions for its application.[30] Making use of them, on 13 October 2015, the Commission Implementing Regulation (EU) 2015/1866 laying down the detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council regarding the register of collections, monitoring user compliance and best practices (EU ABS Implementing Regulation) was adopted.[31] It entered into force on 11 November 2015.

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[22] Commission (EU) 'Our life insurance, our natural capital: an EU biodiversity strategy to 2020', (Communication) COM (2011) 244 final, 3 May 2011.
[23] Commission (EU) 'EUROPE 2020. A strategy for smart, sustainable and inclusive growth', Commission (EU) COM (2010) 2020 final, 3 March 2010.
[24] Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' [2013] OJ L 354/171.
[25] Commission (EU) (n 22), Annex, target 6, action 20.
[26] COM (2012) 576 final, 4 October 2012.
[27] Commission (EU) Impact Assessment Accompanying the document 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 (Commission Staff Working Document), SWD (2012) 292 final. During its drafting, the Commission relied on various consultations, including a public consultation (http://ec.europa.eu/environment/consultations/APB_en.htm) and a report from external consultants that analysed the legal and economic impacts of the application of the Nagoya Protocol in the EU (IEEP, Ecologic and GHK, 'Study to analyze legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union. Final report for the European Commission' (Institute for European Environmental Policy, 2012). The proposal for a Regulation was the subject of an opinion of the Economic and Social Committee in 2013 (OJ C 16/14), some of whose observations were included in the final version of the Regulation.
[28] EU ABS Regulation, preamble, para 35. At the same time, it is striking that despite relying on the EU's environmental competence, the EU ABS Regulation does not refer to environmental issues related to biotechnology. See Coolsaet (n 2) 378-379.
[29] Its entry into force was made to coincide with the entry into force of the Nagoya Protocol in the EU 'in order to ensure equal conditions at Union and global level in activities relating to access and benefit-sharing of genetic resources'. See EU ABS Regulation, preamble, para 36; and arts 17.1 and 17.2.
[30] EU ABS Regulation, preamble, para 34.
[31] OJ L 275/4.

In addition, due to some ambiguities still present in the EU ABS Regulation, a Guidance document on the scope of application of the EU ABS Regulation (EU ABS Guidance Document) was discussed and elaborated in cooperation with the representatives of the Member States and submitted to the opinion of stakeholders gathered at the ABS Consultation Forum.[32] It is a non-legally binding document intended to provide further guidance to citizens, companies and national authorities when applying the EU ABS legislation.[33] At present, the EU is developing additional sectoral guidance on cosmetics, animal breeding, plant breeding, biocontrol, pharmaceuticals, food and feed, and biotechnologies and upstream actors (collections and research).

In accordance with article 16 of the EU ABS Regulation, Member States have already submitted a first report on the national implementation of this Regulation, and the Parliament and the Commission have produced a report that includes a first official evaluation of its effectiveness.[34]

2.2 Purpose and scope of the EU ABS Regulation

The purpose of the EU ABS Regulation is to establish the rules governing compliance with ABS obligations for genetic resources and aTK, in accordance with the provisions of the Nagoya Protocol.[35] It regulates compliance measures for users in the EU territory but not the access to its genetic resources and traditional knowledge. The decision on the establishment of access regulation in accordance with the Nagoya Protocol corresponds to each of the Member States. [36] So far, some Member States—at least, Spain, France, Croatia, Malta and Bulgaria—and the Autonomous Region of the Azores have opted to establish regulations for access to their genetic resources; others are considering it, and others have opted for not doing it at the moment.

The EU ABS regulation reproduces the definitions of genetic material and genetic resources used by the CBD in its article 2.[37] In addition, it provides a concept of traditional knowledge that has been criticized for conditioning its existence on its description in the

[32] Commission (EU), Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the 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 (Commission notice) (2016/C 313/01) C 313/1, 27 August 2016. See, on the Consultative Forum on ABS: EU ABS Regulation, art 15.
[33] EU ABS Guidance Document (n 32) 2.
[34] First ABS Commission Report (n 11). This report covers the first three years of application of the EU ABS Regulation—from October 2014 to August 2017. This period is reduced to two years of application for provisions concerning due diligence (art 4), monitoring of user compliance (art 7) and checks on users' compliance (art 9), which entered into force one year later. Henceforth, the functioning and effectiveness of the EU ABS Regulation will be reviewed every 10 years (art 16. 3).
[35] EU ABS Regulation, art 1. ABS Regulation will contribute to the conservation of biological diversity and the sustainable use of its components, in accordance with the provisions of the CBD. However, the EU ABS legislation has not further developed how these objectives will be achieved.
[36] See EU ABS Regulation, art 2.3.
[37] Therefore, 'genetic material' is defined as 'any material of plant, animal, microbial or other origin containing functional units of heredity' and 'genetic resources' as 'genetic material of actual or potential value'. ibid arts 3.1) and 3.2).

respective MAT applying to the utilization of genetic resources.[38] As a consequence, within EU jurisdiction, only aTK that is included in MAP will enjoy the protection foreseen in the Nagoya Protocol.[39]

The EU ABS Regulation does not apply to genetic resources governed by specialized international instruments.[40] The two current existing specialized international instruments are the ITPGRFA and the WHO Global Influenza Preparedness (PIP) Framework,[41] in both of which the EU also participates. However, the EU ABS Regulation does apply to genetic resources covered by those two specialized instruments if they are accessed in a country that is not a Party to those agreements but is a Party to the Nagoya Protocol, or if they are utilized for purposes other than those of the ITPGRFA and the PIP Framework.[42]

In substance, its scope covers genetic resources over which States exercise sovereign rights and aTK that have been accessed after the entry into force of the Nagoya Protocol for the EU, as well as the benefits derived from the use of such genetic resources and traditional knowledge.[43] Thus, the EU ABS Regulation, such as the Nagoya Protocol, neither applies to areas beyond national jurisdiction nor does it have retroactive application. Regarding its temporal scope, the regulations reflects a very narrow interpretation of the Nagoya Protocol[44] and the moment that triggers its application is that of access, not that of the utilization of the genetic resources or aTK. Hence, the genetic resources that were accessed before the entry into force of the Nagoya Protocol do not fall within the scope of the EU ABS Regulation, even if they are used after that date.[45] As for its geographical scope, the EU ABS Regulation only applies to the genetic resources and aTK utilized within the EU territory[46] from provider countries that have ratified the Nagoya Protocol and established applicable access measures.[47] This not very wide scope of the EU ABS Regulation compared to other national ABS frameworks,[48] was the result achieved in the search for a balance between the interest of the different stakeholders and sectors, provider States, and competent national authorities.[49]

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[38] Traditional knowledge is defined in art 3.7 of the EU ABS regulations as 'traditional knowledge held by an indigenous or local community that is relevant for the utilization of genetic resources and that is as such described in MAT terms applying to the utilization of genetic resources'.

[39] See Coolsaet (n 2) 381-382, Robinson & von Braun (n 21) 388 and 399-400, B Lassen, *et al*., The two worlds of Nagoya. ABS legislation in the EU and provider countries: Discrepancies and how to deal with them (Public Eye and Natural Justice 2016) 13.

[40] EU ABS Regulation, art 2.2. See ABS COP-MOP Decision 3/14 'Specialized international access and benefit sharing instruments in the context of Article 4, paragraph 4, of the Nagoya Protocol' CBD/NP/MOP/DEC/3/14 (30 November 2018).

[41] WHO Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits (effective 24 May 2011) WHO Doc WHA64.5.

[42] EU ABS Guidance Document (n 32) 6 and 15-18.

[43] EU ABS Regulation, art 2.1. It does not distinguish between *in situ* and *ex situ* access.

[44] Robinson & von Braun (n 21) 383.

[45] EU ABS Guidance Document (n 32) 5, B Lassen, et al. (n 39) 5, J von Braun, & F Meienberg, Access or utilisation—What triggers user obligations? (Berne Declaration and Natural Justice 2013) 11.

[46] Therefore, its scope does not cover the utilization of genetic resources outside the EU. It is also not applicable when a company commercializes a product in the EU developed from the utilization of genetic resources if that utilization—all the R&D processes—took place outside the EU. EU ABS Guidance Document (n 32) 10.

[47] EU ABS Regulation, art 2.4. See also EU ABS Guidance Document (n 32) 4.

[48] Robinson & von Braun (n 21) 383 and 398.

[49] T Greiber, 'Implementation of the Nagoya Protocol in the European Union and in Germany' (2019) 53 Phytomedicine 313, 317.

This Regulation also reproduces the definition of 'utilization of genetic resources' used by the Nagoya Protocol: to conduct research and development (R&D) on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.[50] However, it does not clarify—and neither does the Protocol—what is meant by R&D, nor does it include a list of covered activities.[51] In practice, R&D are terms that are broadly interpreted. They are also likely to be nuanced and adapted to the different areas of biotechnology as more experience is gained in this field and as the European Commission publishes the sectoral guides that it is developing.

Regarding the digital information obtained from gene sequencing, often included in open access databases, the EU ABS Guidance Document considers it to be outside the scope of the EU ABS Regulation, although it does recognize that it could be covered by conditions set in MAT.[52] Therefore, the EU seems to adopt a fairly conservative position in relation to *in silico* access to genetic resources. However, this position is also likely to evolve as the global debates on this matter also evolve, both within the framework of the CBD and its Nagoya Protocol, as well as in other fora such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[53] or the current negotiations on an international legally binding instrument under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction.[54]

3 IMPLEMENTATION OF THE ABS REGULATION

After just four years since the most relevant provisions of the EU ABS Regulation entered into force, it is probably too early to make a thorough assessment of the practical effectiveness of this recent legal regime. However, both Member States and users have already started implementing it, and the First ABS Commission Report helps to shed some light on how its implementation is being carried out.

3.1 Scarce human and financial resources

At the institutional level, Member States had to designate one or more competent authorities responsible for the application of the Regulation.[55] The main functions of these authorities are a) to receive the declarations of due diligence from the users and transmit

[50] EU ABS Regulation, art 3.5. EU ABS Regulation, art 3 (7), and Nagoya Protocol art 2 (c). At the same time, according to both the CBD and the Nagoya protocol, 'biotechnology' means 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use' (CBD, art 2, para 1, and Nagoya Protocol, art 2 (d).

[51] See E Morgera and M Geelhoed 'Consultancy on the Notion of 'Utilisation' in the Nagoya Protocol and the EU ABS Regulation for the Upstream Actors', 13 January 2016, available at < http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/ABS%20Final%20Report%20upstream%20users.pdf>

[52] EU ABS Guidance Document (n 32) 10.

[53] Adopted by the Thirty-First Session of the Conference of the Food and Agriculture Organization of the United Nations on 3 November 2001, in force since 29 June 2004.

[54] See < https://www.un.org/bbnj/>

[55] EU ABS Regulation, art 6.1.

that information to the Access and Benefit-Sharing Clearing House (ABSCH) established by the Nagoya Protocol;[56] b) carry out checks on user compliance;[57] c) verify collections requesting their inclusion in the register of collections;[58] and d) cooperate with the Commission and the competent authorities of other Member States and third States.[59]

Although many Member States started to take measures relatively late to establish the institutional and administrative framework required by the EU ABS Regulation,[60] the vast majority of them have already established competent authorities.[61] Some States have chosen to designate a single institution, which can sometimes receive assistance from other agencies, organizations or authorities, while others have distributed their functions among several institutions or agencies.[62] The main difficulties alleged by the Member States in relation to the establishment of this institutional and administrative framework have been constitutional structures that distribute competences on the environment among several administrations at different levels; the reluctance of some administrations and agencies to take on the new tasks required by the EU ABS Regulation; the difficulty of identifying the appropriate responsible authorities and of establishing cooperation mechanisms between the different institutions involved; and the lack of knowledge and expertise related to this still recent Regulation.[63] Conversely, cooperation between the competent authorities of the Member States has been constant, both through informal meetings and the Expert Group, the latter established by the Commission to ensure uniform implementation of the EU ABS legislation and provide a platform for cooperation with the competent national authorities.[64] In contrast, cooperation with the competent authorities of third countries that are Party to the Nagoya Protocol is still underdeveloped.[65]

In addition, the First ABS Commission Report shows a very uneven situation in the Member States regarding human and financial resources available for the application and enforcement of the EU ABS Regulation. Human resources range from their absence to five fully dedicated employees, and it is usual that they simultaneously deal with other tasks.[66] For its part, financial resources—supplementary to staff costs—are, on average, limited.[67]

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[56] ibid arts 7.1, 7.2 and 7.3. See section 7.
[57] ibid art 9.1. See section 8.
[58] ibid art 5.2. See section 11
[59] ibid arts 7.1, 2.2, 7.3, 9.5, and 12.
[60] First ABS Commission Report (n 11) 11.
[61] See <http://ec.europa.eu/environment/nature/biodiversity/international/APB/pdf/Competent%20Authorities%20under%20the%20EU%20APB%20Regulation.pdf>
[62] For example, in Spain, the territorial organization of the state has led to the establishment of a competent state authority and several regional authorities, which will exercise their powers depending on the exact location and type of the genetic resource. Real Decreto 124/2017, de 24 de febrero, relativo al acceso a los recursos genéticos procedentes de taxones silvestres y al control de la utilización, arts 5 and 13.
[63] First ABS Commission Report (n 11) 3.
[64] See: <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3123&NewSearch=1&NewSearch=1>.
[65] ibid 11.
[66] ibid 3.
[67] ibid 3.

3.2 Uncertainties around the users' obligation of due diligence

The key provision of the EU ABS Regulation is found in article 4, which translates the users' obligations of compliance from the Nagoya Protocol in an obligation of due diligence. Accordingly, users must exercise due diligence to ascertain that genetic resources and aTK that they utilize have been accessed in accordance with applicable ABS legislation or regulatory requirements and that benefits are fairly and equitably shared upon MAT, in accordance with any applicable legislation or regulatory requirements.[68] Likewise, genetic resources and aTK shall only be transferred and utilized in accordance with MAT if they are required by the applicable legislation or regulatory requirements.[69]

This diligence obligation requires users to seek, keep and transfer to the subsequent users the documentation that proves that those obligations have been fulfilled. Ideally, they should transfer an internationally recognized certificate of compliance (IRCC) under the Nagoya Protocol,[70] as well as information on the content of the MAT relevant for subsequent users.[71] Where no IRCC is available, they will seek, keep and transfer the following: the date and place of access; the description of the genetic resources or of traditional knowledge; the source from which they were directly obtained, as well as subsequent users; the presence or absence of ABS rights and obligations, including rights and obligations regarding the subsequent applications and commercialization; and, if applicable, access permits and MAT.[72] Users need to keep all the relevant ABS information for twenty years following the end of the period of utilization.[73]

In contrast, if the information in their possession is insufficient or uncertainties about the legality of access and utilization persist, users must a) obtain an access permit or its equivalent and establish MAT or b) discontinue utilization.[74] Therefore, the obligation of due diligence in this context constitutes both a standard of conduct and an obligation of result.[75]

This configuration of the core obligation on users as an obligation of due diligence to seek, keep and transfer information, instead of establishing a total prohibition on utilizing genetic material and aTK lacking or against PIC and MAT, has been considered weak and not very ambitious by some authors.[76]

In addition, there is still great uncertainty around the scope of the due diligence. The EU ABS Guidance Document tried to clarify the scope by using criteria of 'reasonableness' and 'best possible efforts' when seeking, conserving, transferring and analysing

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[68] EU ABS Regulation, art 4.1.
[69] ibid art 4.2.
[70] Nagoya Protocol, art 17.2
[71] EU ABS Regulation, art 4.3 (a).
[72] ibid art 4.3 (b).
[73] ibid art 4.6.
[74] ibid art 4.5.
[75] See EU ABS Guidance Document (n 32) 11.
[76] C Godt 'The Multi-level Implementation of the Nagoya Protocol in the European Union' in B. Coolsaet et al. (eds) Implementing the Nagoya Protocol. Comparing Access and Benefit-Sharing Regimes in Europe (Brill Nijhoff, 2015) 308, 314-316, Robinson & von Braun (n 21) 393.

information.[77] At the same time, it acknowledges that due diligence does not prescribe the same type of measures for all users, giving them some flexibility to take specific measures that work best in their respective circumstances and taking into account their capabilities.[78]

The Guidance Document also provides guidelines for users to comply with this obligation of due diligence, e.g., when determining whether a given genetic resource falls within the scope of the Nagoya Protocol or the EU ABS Regulation. In these cases, these steps are recommended to be followed: 1) check at the ABSCH if the provider State is a party to the Protocol; 2) if it is, check with the same centre if it has established applicable ABS legislative or regulatory requirements; 3) if this information does not appear at the ABSCH but there are reasons to believe that access legislation or regulatory requirements may nonetheless exist, as well as in other situations where the potential user considers that it might be useful, directly contact the National Focal Point (NFP) of the provider county; 4) if despite reasonable attempts to obtain a response from the NFP there is none, the necessary due diligence measures are considered to have been taken; 5) in some cases, the user may consider that undertaking measures that go beyond those described is desirable.[79] Expressions that do not provide certainty (e.g., 'if there are reasons to believe', 'when it is considered that it might be useful', 'may consider it desirable') continue to be used and, therefore, doubts on how far the users should carry out the verifications remain.

The application of this obligation of due diligence in the coming years will enable a more rigorous assessment of its real effectiveness and of whether it will be finally become, as some fear, a simple 'tick box' compliance that will ultimately frustrate the purpose of the Nagoya Protocol.[80]

3.3. Implementing checkpoints to monitor users' compliance

The EU ABS Regulation establishes two mandatory checkpoints to monitor users' compliance, although States can establish additional checkpoints. Besides, there may be other non-governmental checkpoints, such as those set up by the ethics committees of research centres located in the users' territory.

Regarding the first mandatory checkpoint, Member States must request all recipients of research funding[81] involving the utilization of genetic resources and aTK to declare that they exercise due diligence in accordance with the EU ABS regulation.[82] The declaration must be submitted after the reception of the first instalment of funds and all the genetic resources and aTK utilized in the funded research are obtained, but no later than at the

[77] EU ABS Guidance Document (n 32) 10-11.
[78] Ibid 11
[79] ibid 12.
[80] E C Kamau & G Winter, 'An introduction to the international ABS regime and a comment on its transposition by the EU' (2013) 9 (2) Law Environment and Development Journal 106, 125, S Thambisetty 'Due diligence and ABS compliance under EUR 511/2014: a LSE INMARE recommendation' (2019) 33 LSE Law Policy Briefing Papers Series, 2.
[81] According to the EU ABS Implementing Regulation, 'funding for research' means 'any financial contribution by means of a grant to carry out research, whether from commercial or non-commercial sources.' It does not cover internal budgetary resources of private or public entities (art 5.5).
[82] EU ABS Regulation, art 7.1

final report.[83] Just over half of the Member States have reported that they have taken steps to establish this checkpoint.[84] In addition, the European Commission itself requires applicants for funding from the Horizon 2020 Programme whose research involves the utilization of genetic resources and aTK that falls within the scope of the ABS regulation to submit this due diligence declaration.[85]

The second checkpoint is located at the final development stage of a product for which genetic resources or aTK has been utilized.[86] The due diligence declaration must be submitted to the competent authority of the Member State in which the user is established before placing these products on the market.[87] This checkpoint has been considered late and as not encouraging the legal acquisition of genetic resources by the initial users while increasing the legal uncertainty of the final users.[88]

In a context of growing interest in patent disclosure requirements in this field,[89] the lack of a mandatory checkpoint at the time of applying for a patent on a product involving the utilization of genetic resources or aTK has also been criticized.[90] However, some Member States have put in place measures to monitor compliance related to patents. In this sense, France and Germany have established a procedure for the exchange of information between their competent national authorities and their national patent offices to assist the competent authorities in their compliance checks.[91] For its part, Spain has included a real third checkpoint in its national legislation accompanying any patent application of this kind of a product.[92]

In the two examined mandatory checkpoints, the competent national authorities must transmit the due diligence declarations to the ABSCH and the Commission and, where appropriate, to other competent national authorities.[93] The competent authorities must also take into due account the respect for the confidentiality of commercial or industrial information protected by national or EU law to protect legitimate economic interests.[94]

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[83] The information must be transmitted to the competent authority of the Member State in which the beneficiary is established. For details, see EU ABS Implementing Regulation, art 5.
[84] First ABS Commission Report (n 11) 5.
[85] See the section on 'Ethics' of the Participant Portal H2020 Online Manual available at < http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm>
[86] EU ABS Regulation, art 7.2.
[87] For details, see EU ABS Implementing Regulation, art 6.2.
[88] Coolsaet (n 2) 378, B Vanheusden 'The implementation of 'access and benefit-sharing' in five EU member states: the achievements and deficiencies of the Nagoya Protocol and the EU Regulation 511/2014' (2017) 14 Journal for European Environmental & Planning Law, 716, Robinson & von Braun (n 21) 393.
[89] See C Chiarolla, 'Intellectual Property from a Global Environmental Law Perspective: Key Lessons from the Implementation of Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge' (2019) Transnational Environmental Law 1.
[90] This would thus miss the opportunity to complement the 1998 Directive on the legal protection of biotechnological inventions and make the requirement to provide information on the geographical origin of the genetic material used mandatory (OJ L 213/13, preamble, para 27). Coolsaet (n 2) 381.
[91] First ABS Commission Report (n 11) 4.
[92] Real Decreto 124/2017 (n 62) art 14.3. See also Ley 24/2015, de 24 de julio, de Patentes, art 23.2.
[93] EU ABS Regulation, preamble, para 25, and art 7. See also EU ABS Implementing Regulation, arts 5 and 6.
[94] EU ABS Regulation, art 7.5. See also EU ABS Implementing Regulation, art 7.

To facilitate the online submission of the due diligence declaration, the EU has developed a web-based application—DECLARE—[95]and a user manual. [96]

At the date of publication of the First ABS Commission Report, slightly more than half of the Member States had taken measures to implement the first verification point, mainly due to the delay in some States in the designation of the authorities.[97] However, in 2018, two due diligence declarations were sent to the competent authorities of Germany and Malta through DECLARE. They had the merit of being the first communications received from checkpoints in the ABSCH.[98] This small number of submitted declarations is partly explained by the temporary scope of the EU ABS Regulation: as has already been pointed out, it does not cover genetic resources acquired before its entry into force, and these still constitute a good part of the genetic resources currently being used in the EU. [99]

3.4 Insufficient complementary measures, ongoing implementation of checks on users' compliance and uneven sanctions

The EU ABS Regulation includes the possibility of the Commission and the Member States carrying out complementary measures of information, awareness-raising and training activities to help stakeholders understand their ABS obligations. At the same time, Member States have the obligation to carry out checks on users' compliance and to establish sanctions in the case of non-compliance.

Thus far, several informative, awareness-raising and training activities have already been carried out, especially for stakeholders in non-commercial research.[100] This was also the context for the development of the EU ABS Guidance Document by the Commission, in close collaboration with the Member States and the ABS Consultative Forum, and of the sectoral guidelines currently in progress. However, a low level of awareness among stakeholders about their ABS obligation persists, in part due to the complexity of the EU ABS Regulation itself.[101]

In relation to the checks on user compliance, competent national authorities must first carry out effective, proportionate and dissuasive controls to verify that users comply with their due diligence obligations. They must do so on a regular basis, according to a periodically reviewed plan developed using a risk-based approach reviewed and elaborated by applying risk criteria, as well as when there are indications of non-compliance by users, including on the basis of substantiated concerns provided by third

[95] Available at <https://bit.ly/2r6fMhm>. Member States may stablish national systems for submissions of due diligence declarations by users located in their territory. Spain has already done this, and France has done this only for the first checkpoint.
[96] https://bit.ly/2vWxB7e. See also EU ABS Implementing Regulation, Annexes II and III.
[97] First ABS Commission Report (n 11) 12.
[98] ibid 6.
[99] ibid 11.
[100] The Commission has also participated in several activities for these purposes and a special section on ABS has been created on the EU web portal:<http://ec.europa.eu/environment/nature/biodiversity/international/APB/index_en.htm>. See First ABS Commission Report (n 11) 10-11.
[101] Ibid 12-13.

parties.[102] Some authors have already raised concerns about this configuration of the checks, which may finally place the burden of monitoring compliance and complaining to EU Member States on provider countries.[103]

At the date of the First ABS Commission Report, at least five States notified the Commission that they had prepared plans applying a risk-based approach to carry out these controls, and most of the others are in the process of elaborating them. Four of these five States have also reported on the carrying out of these controls by their national authorities, without detecting cases of non-compliance or irregularities.[104]

States must also establish sanctions applicable to non-compliance with arts. 4 (obligations of due diligence of users) and 7 (presentation of the due diligence obligations declaration at the checkpoints) of the EU ABS Regulation.[105] However, the approach adopted by the regulation leaves a considerable margin for discretion to the States in the configuration of the sanctions. A wide variety of legislative measures can already be observed in practice, ranging from administrative law to criminal law sanctions –the French law even foresees a penalty of one year imprisonment[106]-, although none have been applied so far.[107] This very open approach to sanctions has been criticized by those who believe that non-compliant users should be treated, judged and sanctioned in the same way in all EU countries,[108] especially when the EU ABS Regulations precisely aims to unify users' compliance obligations from the Nagoya Protocol in the territory of the EU. In this sense, there may even be the risk that this disparity could lead to the displacement of the biotechnology industry towards those States with less burdensome sanctions.

3.5 Limited interest in the registration of collections

The EU ABS Regulation foresees two voluntary mechanisms for users with the purpose of reducing the risk of non-compliance: the possibility of registering collections and of recognizing good practices. In relation to the first one, the Regulation contemplates the establishment and maintenance of a register of collections by the Commission.[109] This measure becomes particularly relevant if we take into account that collections play a

[102] See EU ABS Regulation, arts 9 and 10.
[103] Robinson & von Braun (n 21) 394-395.
[104] First ABS Commission Report (n 11) 6-7.
[105] EU ABS Regulation, art 11.
[106] LOI n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages, art. 39.
[107] At the time of the first ABS Commission Report, fifteen Member States established remedial actions, nineteen enacted administrative sanctions, and seven made the violation of some obligations a criminal offence. In some cases, options were combined, depending on the severity of the offence. One Member State introduced an additional sanction consisting in a proportionate skimming of the profit derived from the utilization of genetic resources. Two Member States also established complementary measures such as the temporal prohibition of utilization, cancellation of research or commercialization activities or confiscation of the genetic resources. In detail: First ABS Commission Report (n 11) 5-7.
[108] L Silvestri and LCandeira 'Implementing the Nagoya Protocol in Spain, Implementing the Nagoya Protocol. Comparing Access and Benefit-sharing Regimes in Europe' in B Coolsaet et al (eds) Implementing the Nagoya Protocol. Comparing Access and Benefit-Sharing Regimes in Europe (Brill Nijhoff 2015) 210, 225.
[109] EU ABS Regulation, art 5. The information on each collection or part thereof contained in the register is listed in art. 2 of the EU ABS Implementing Regulation. The register is available at <http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register%20of%20Collections.pdf>.

central role in the conservation of and research on biodiversity[110] and that they are the main suppliers of genetic resources and aTK used in the EU.[111] As the collections are primarily located in users' countries, the collections in the EU territory mainly provide services to users and/or to user country governments, as opposed to collections located in provider countries, which are often charged with regulatory provider state duties.[112]

The request[113] for inclusion in the register must be submitted to the corresponding State, which will verify if all or part of it meets the requirements contained in article 5.3 of the EU ABS Regulation. These include, among others, the demonstration of its capacity to 'supply genetic resources and related information to third persons for their utilization only with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable ABS legislation or regulatory requirements and, where relevant, with MAT'.[114] Member States must periodically verify that each collection under their jurisdiction included in the register continues meeting these criteria. If breaches are detected, States need to identify remedial actions or measures in dialogue with the collection holder. If a collection definitively ceases to fulfil the criteria, it will be withdrawn from the register by the Commission.[115]

The main advantage of the inclusion of a collection in this register is for the users that access genetic resources from them, since they will be considered to have exercised due diligence regarding the seeking of the pertinent ABS information.[116] In contrast, the benefits for the collection holders do not seem so evident. So far, only one collection of German nationality that hosts microorganisms and cell cultures –DSMZ- has been included in this register[117] and very few additional cases of interest in the inclusion in the register have been notified by Member States.

According to the First ABS Commission Report, this lack of interest is mainly due to the uncertainty regarding the exact standards that must be met, unclear added value of becoming a registered collection, fear of the financial and/or administrative burdens –the preparation of the register of the DSMZ collection had an estimated cost of around €200000[118]-, and concerns about potential risks associated with the liability of registered collections.[119] In this last sense, it is clear that users of a registered collection are only exempt from the obligation of due diligence in relation to the search for information and that, ultimately, they are the ones who have to comply with the rest of the ABS obligations. However, there is still a significant level of uncertainty about the exact scope of the informative competence and the liability assumed by the registered collections. In

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[110] C Godt, 'Networks of *ex situ* collections of genetic resources' in E Chege Kamau and G Winter (eds) Common pools of genetic resources : equity and innovation in international biodiversity law (Routledge 2013) 246, 246.
[111] See EU ABS Regulation, Preamble, paras 27 and 28.
[112] Godt (n 103) 246.
[113] Annex I of the EU ABS Implementing Regulation details the information that must be provided with a request for inclusion in the register of collections.
[114] EU ABS Regulation, art 5.3(b). For detail, see all paragraphs of art 5.3 for the rest of the requirements.
[115] ibid art 4.7. See also EU ABS Implementing Regulation, arts 2-5.
[116] ibid para 2; and art 4.7. See also EU ABS Implementing Regulation, arts 2-5.
[117] *Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH- German Collection of Microorganisms and Cell Cultures, Leibniz Institute DSMZ: <https://www.dsmz.de/home.html>*. See A Yurkov, H Püschner & A Scholz, 'DSMZ: the European Union's first Registered Collection under the Nagoya Protocol' (2019) 3 Microbiology Australia 108.
[118] ibid 109.
[119] First ABS Commission Report (n 11) 10.

addition, the benefit they provide to users in relation to the search for information could become very limited in practice if, for instance, the MAT associated with a specific genetic resource requires them to negotiate again in case there is a change in the intended use of the genetic resource or even in the case of transfer to a subsequent user.

Moreover, the fact that Member States are the ones who decide on the registration of the collections creates a risk of a possible lack of uniformity in the decisions that are adopted in this regard.

3.6 Growing interest in the recognition of best practices

The EU ABS Regulation urges the Commission and Member States to encourage the development of ABS best practices, particularly where they would benefit academic, university and non-commercial researchers and small and medium-sized enterprises.[120] In addition, it enables a procedure that allows user associations or other interested parties to submit an application for 'a combination of procedures, tools or mechanisms, developed and overseen by them' to be recognized as a best practice.[121] The ABS regulation expressly recognizes the implementation of a recognized best practice by a user as an indication of a reduction in the risk of non-compliance.[122]

The request, addressed to the Commission—not to the Member States, as in the case of the request for inclusion in the register of collections—must be supported by evidence and information.[123] The best practices that, according to the Commission, meet the requirements will be listed in an Internet-based register.[124] However, this recognition may be withdrawn by the Commission in the following two cases: if it determines that the modifications introduced in the best practices compromise the users' ability to comply with their ABS obligations or when there have been repeated or significant cases of non-compliance by users due to deficiencies in the best practice.[125]

Thus far, only one best practice has already been registered,[126] but several other requests for recognition have been submitted.[127] There seems to be a greater interest in the recognition of good practices than in the registration of collections. This higher interest is probably due to the reasons indicated above as the cause of the low interest in the registration of collections, including the uncertainties about the scope of liability assumed by the registered collections, which seem lower or non-existent in the case of best practices.

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[120] ibid art 13 (b).
[121] ibid art 8.1.
[122] ibid art 9.1.
[123] ibid art 8.1.
[124] The register is available at <http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register%20of%20Best%20Practices.pdf>
[125] EU ABS Regulation, art 8.5. See, in detail, EU ABS Implementing Regulation, arts 8-11.
[126] Consortium of European Taxonomic Facilities (CETAF). 'Code of Conduct and Best Practice for Access and Benefit-Sharing', January 2019.
[127] First ABS Commission Report (n 11) 7.

4 FINAL REMARKS

Both the Nagoya Protocol and the EU ABS legislation are still in an initial state of application and development. This circumstance, together with the inherent complexity of the ABS legal regime, still makes them face problems of interpretation and compliance, as well as questions—such as the legal regime of *in silico* access—that lack a global consensus.

The EU ABS Regulation is an internal reflection of the international commitment already shown by the EU in the negotiations of the Nagoya Protocol, in which it was the main representative of the global biotechnology industry. With the adoption of this regulation, the EU has become a benchmark for both the development of a regional legal framework on ABS and for the application of compliance measures.

Despite this, at this stage of implementation of the EU ABS Regulation, Member States still need to devote more financial and human resources to its implementation, and more information, awareness-raising and training activities on ABS are also necessary, especially for the private sector. Although the EU ABS Regulation establishes a certain uniformity in the obligations of users in the EU, several issues, e.g., the configuration of sanctions or the decision on the inclusion of collections in the register, still require a higher level of harmonization.

The EU ABS Implementation Regulation and the EU ABS Guidance Document have tried to alleviate some of the initial ambiguities in the content of the ABS Regulation. However, important uncertainties still persist, such as the exact scope of the liability of the holders of registered collections. The very pillar of the Regulation, the users' obligation of due diligence, also does not escape the uncertainty in relation to its specific scope and content. However, as the First ABS Commission Report ventures, these uncertainties may dissipate as more experience is gained in the application of the Regulation and as specific sectoral guidelines are developed. The feedback and active involvement of the main users and actors in this field—private companies, universities, research centres and collections—in the further development and application of this legislation will be crucial.