EUROPEAN
COMMISSION

Brussels, 24.1.2019
COM(2019) 13 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

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

[…]

1. Introduction

The European Union (EU) adopted in 2014 Regulation (EU) No 511/2014 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 Utilisation in the Union[1] (hereinafter the EU ABS Regulation or the Regulation). It transposes into the EU legal order the required compliance measures under the Nagoya Protocol to the Convention on Biological Diversity[2].

The EU ABS Regulation establishes obligations for users of genetic resources and traditional knowledge associated with genetic resources in the Union[3]. It requires 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 equitably shared upon mutually agreed terms. All users need to seek, keep and transfer to subsequent users certain information relevant for access and benefit-sharing. Users have to declare and provide evidence that they exercised due diligence (by filing a due diligence declaration) at two checkpoints identified by the Regulation (one at the stage of receiving research funding, where such research involves utilisation of genetic resources or traditional knowledge associated with genetic resources, and the other one at the stage of final development of the product). Competent authorities designated by the Member States must check whether users comply with their obligations under the Regulation. Member States must also ensure that infringements by users are sanctioned by effective, proportionate and dissuasive penalties.

The EU ABS Regulation entered into force on 9 June 2014, and it is applicable since 12 October 2014. Some important provisions of the Regulation entered into application one year after[4]. Commission Implementing Regulation (EU) 2015/1866 entered into force on 9 November 2015 as regards the register of collections, monitoring user compliance and best practices[5].

Article 16(1) of the EU ABS Regulation requires Member States to submit to the Commission a report on the application of the Regulation by 11 June 2017 and every five years thereafter, unless an alternative interval for reports is determined, as referred to in Article 29 of the Nagoya Protocol. The first meeting of the Parties to the Nagoya Protocol requested Parties to submit an interim national report on the implementation of the Protocol, as called for under Article 29 of the Protocol, twelve months prior to the third meeting of the Parties, hence no later than 1 November 2017[6]. In line with this deadline, most Member States submitted the reports by November 2017. 11 Member States submitted their reports later (the last report was received in September 2018).

The present report follows Article 16(2) of the EU ABS Regulation, which requires the Commission to submit to the European Parliament and the Council 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

1 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0511.

2 http://www.cbd.int/abs/. A synthesis of the international legal context is provided in Annex I.

3 Examples of users of genetic resources are: academic researchers, research institutes, pharmaceutical, agriculture,cosmetic industries, botanical gardens, collectors.

4 Article 17 EU ABS Regulation.

5 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1866.

6 Decision NP-1/3, paragraph 4.

from the national reports submitted by all 28 Member States[7] to the Commission, as well as other information available.

The report 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).

2. Implementation of the EU ABS Regulation

2.1. Institutional structures and resources

2.1.2 Designation of Competent Authorities

Article 6(1) of the EU ABS Regulation requires Member States to designate national competent authorities (CAs) by the date of entry into force of the Regulation. 22 Member States reported having designated their CAs responsible for the application of the Regulation[8]. According to what is required by the EU ABS Regulation, CAs are responsible for the following tasks:

a) receive due diligence declarations under Article 7(1) and 7(2);

b) transmit information to the ABS Clearing House (ABSCH)[9] under Article 7(3);

c) carry out checks on compliance in line with Article 9;

d) recognise and verify registered collections under Article 5;

e) cooperate with third countries under Article 7(3);

f) implement complementary measures under Article 13 (awareness raising, training activities, guidance to users etc.).

Some Member States opted for one institution to cover the functions above, others distributed these functions among multiple institutions or agencies. CAs are sometimes assisted by other agencies, organisations and/or authorities (for example checks are often entrusted to inspectorate agencies)[10].

6 Member States have reported not having yet designated CAs[11] but all have informed the Commission that the adoption of the formal act of designation was ongoing.

In terms of difficulties to establish the institutional structure to implement the Regulation, some Member States signalled that a major challenge derives from their constitutional

---

7 Member States national reports are available on the Commission website: http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm

8 BG, CY, CZ, EE, DE, DK, ES, FI, FR, HR, HU, LT, LU, MT, NL, PL, PT, SE, SI, SK, RO, UK. Some of them (CY, CZ, HR and PT) designated their CAs and notified them to the Commission after August 2017 (thus outside of the official reporting period).

9 The ABSCH (art. 14 Nagoya Protocol) is an IT platform where Parties put all relevant legislative, administrative and policy measures; such as access laws, permits issued by the country, information concerning monitoring of the utilisation of genetic resources, information concerning competent national authorities etc. See the Annex for more information.

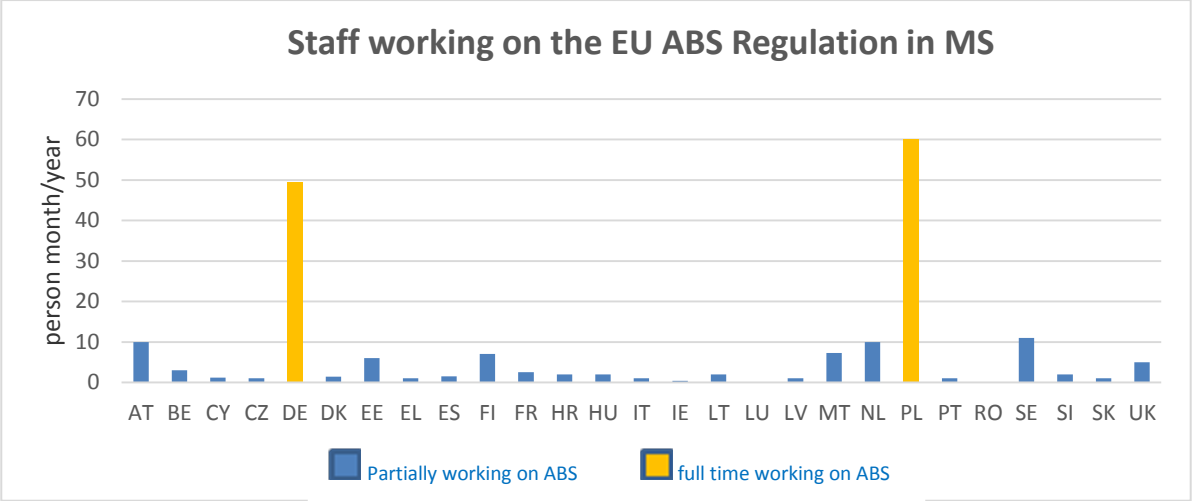
10 For instance, this is the case in PL, PT and NL.

11 AT, BE, EL, IE, IT, LV.

structures, which distribute the competences on environment among several administrations at different levels (e.g.: regional administrations, provinces or federal government). In these cases, identification of CAs required time-consuming discussions[12]. Other signalled that administrations and agencies were sometimes reluctant to take on the new tasks that the EU ABS Regulation requires. The assessment and identification of the appropriate responsible authorities as well as the establishment of cooperation mechanisms among the different institutions involved was also mentioned as a challenge[13]. Finally, a few highlighted that lack of knowledge and expertise with ABS is also a challenge, in particular taking into account the innovative nature of the Regulation[14].

2.1.3 Human and financial resources

The situation of human and financial resources available for the application and enforcement of the EU ABS Regulation in Member States is very uneven. As for human resources, they range from no one working on the implementation of the Regulation to 5 fully dedicated staff. Member States often rely on existing personnel simultaneously dealing with other tasks[15]. Only 2 Member States have reported having sufficient personnel fully dedicated to the implementation of the Regulation[16]. Finally, 2 Member States reported not having any staff dedicated to the Regulation[17].



As for financial resources (additional to staff costs), 14 Member States reported a budget for activities such as: cooperation, awareness-raising, capacity-building, reporting; in average, annual budgets are limited, varying approximately from EUR 1 500 to 60 000, with very few countries reporting EUR 100 000 or more.

12 AT.
13 DK, EE.
14 CY, PL, RO.
15 AT, BE, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IT, IE, LT, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK.
16 DE, PL.
17 LU, RO.

2.2 Administrative measures: monitoring and checks on users' compliance

2.2.1 Monitoring users' compliance (checkpoints under Article 7)

Under Article 7(1) of the EU ABS Regulation, Member States must request all recipients of research funding involving the utilization of genetic resources and traditional knowledge associated with genetic resources to declare that they exercise due diligence in accordance with Article 4 (so-called first checkpoint). 14 Member States[18] reported having adopted measures for this purpose, including:

- website notice;
- law or other legislative measure;
- direct request;
- a combination of different measures: law provision and direct request, or website notice and direct request.

The Commission also implements Article 7(1). The online application in the Horizon 2020 Portal includes an alert to request applicants to file due diligence declarations in case the application concerns funds for a research involving the utilization of genetic resources and traditional knowledge associated with genetic resources[19].

Under Article 7(2), users are required to declare at the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources, that they have fulfilled the obligations under Article 4 (so-called second checkpoint). Users must submit the reference number of the internationally-recognised certificate of compliance or, in the absence of such certificate, relevant information (like the place of access and the description of the genetic resource accessed). In both cases, users must provide information concerning the establishement of mutually agreed terms, where applicable.

Member States can identify additional checkpoints under the Nagoya Protocol. No additional checkpoints going beyond obligations under Article 7 have been designated by Member States. However, it must be highlighted that France, Germany and Spain provide for an exchange of information between their national Patent Offices and CAs in case of patent applications involving the utilization of genetic resources and/or traditional knowledge associated to genetic resources. In France and Germany, such exchange of information is meant to support CAs in their compliance checks but does not trigger any additional obligation to submit a due diligence declaration. In Spain, filing an application for patent based on genetic resources (when falling under the Spanish access legislation) triggers an obligation to submit a due diligence declaration to the CA[20].

The Commission developed a web-based tool called DECLARE to support users in submitting due diligence declarations to their CAs and to assist the Member States in transmitting the declarations to the Commission and the ABS Clearing House[21]. DECLARE

[18] DK, EE, ES, FI, FR, HU, LT, MT, PL, PT, SE, SI, SK, UK.
[19] http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm.
[20] Real Decreto 124/2017.
[21] https://webgate.ec.europa.eu/declare/web/domain.

is fully functional for both checkpoints[22]. Member States are encouraged to use DECLARE but they are free to establish national systems for the submission of due diligence declarations, or to rely on paper submissions. Two Member States decided to develop national IT platforms for the submission of due diligence declarations, to be used instead of DECLARE[23].

Two due diligence declarations have been submitted (to the German and Maltese CAs), both in 2018 using the DECLARE system. They were consequently transferred to the ABSCH as checkpoint communiqués which were then transmitted to the provider countries. At the international level they were the first checkpoint communiqués communicated to the ABSCH. The system put in place by the EU has thus proven to deliver the envisaged results. Overall, the EU and its Member States appear to be the most advanced actors in implementing the compliance measures of the Nagoya Protocol[24].

2.2.2 Checks on user compliance (Article 9(3) (a))

Article 9(1) of the EU ABS Regulation requires Member States to carry out checks to verify whether users comply with their due diligence obligations. CAs should conduct checks on the basis of a risk-based approach plan, which must be periodically reviewed, as well as when they are in possession of relevant information, including on the basis of substantiated concerns provided by third parties, regarding a user's non-compliance with this Regulation[25].

5 Member States reported having developed risk-based approach plans for checks[26]. Risk factors can include the characteristics of users of genetic resources (sectors and activities; size of company; level of awareness of ABS; internal resources). Most Member States reported to be in the process of developing plans, in particular by carrying out risk analyses to identify risk factors and potential users for checks. During a meeting of the ABS CAs organized by the German CA in April 2018, a couple of Member States presented significant progress made in developing plans for checks[27].

4 Member States reported that their CAs conducted checks[28], including on-site visits and inspections. No infringements of due diligence obligations or irregularities were detected.

2.3 Legislative measures: penalties for infringements of the EU ABS Regulation

Article 11 of the EU ABS Regulation requires Member States to adopt rules on penalties applicable to infringements of Articles 4 (users' due diligence obligations) and 7 (submission of due diligence declaration) by June 2015. 21 Member States reporting having adopted measures concerning sanctions for infringements of the obligations under the Regulation[29], and a variety of legislative measures (from administrative law to criminal law penalties) is

22 First checkpoint operational since September 2017 and second since March 2018.

23 FR (only for first checkpoint) and ES.

24 Besides the EU, only Japan and Switzerland have currently adopted compliance measures implementing the Nagoya Protocol.

25 Article 9(3) EU ABS Regulation.

26 DK, EE, NL, SK, UK. DK adopted the plan in January 2018 (thus outside the reporting period).

27 DK and DE. They are planning to carry out checks in the last part of 2018 and in 2019.

28 EE, NL, SK, UK.

29 BG, DE, DK, EE, ES, FI, FR, HR, HU, LT, LU, MT, NL, PL, RO, SE, SI, SK, UK. CY and PT adopted rules on sanctions outside the reporting period.

observed. In most cases, Member States introduced new sanctions to address infringements of the Regulation into their domestic legal frameworks; in designing the sanctions, they have often based themselves on the parameters (types and level) of existing administrative or penal sanctions in the field of environment. 15 Member States provide for a notice of remedial actions (i.e.: in case of irregularities or incomplete documentation). 19 Member States enacted administrative sanctions, while 7 made the violation of some obligations of the Regulation a criminal offence (see Table 1 below). In some cases, options have been combined: for offences of medium or lower importance, administrative fines are established while, for severe offences, criminal sanctions are enacted. 1 Member State introduced an additional sanction consisting in a proportionate skimming of the profit derived from utilization of genetic resources[30]. 2 Member States also established complementary measures such as temporal prohibition of utilization, cancellation of researchor commercialization activities or confiscation of the genetic resources[31].

Table 1. Penalties under Article 11 of the EU ABS Regulation in 21 Member States

Type of sanction	Member States	Level of the sanctions
Notice of remedial action	16 MS (BG, CY, DE, DK, ES, FI, FR, HU, MT, NL, PL, PT, SE, SI, SK, UK)	
Administrative fines	19 MS (BG, DE, EE, ES, FI, FR, HR, HU, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK, UK)	From EUR 40 to 2 000 000
Criminal sanctions	8 MS (CY, DK, FI, LU, MT, NL, SE, UK)	From fines to imprisonment
Additional measures	3 MS	
	(DE: Skimming of profits)	No maximum skimming of profit
	(ES: temporal prohibition of utilization, cancellation of research or commercialization activities, confiscation of genetic resources)	
	(PT: preventive seizure of material)	

Factors taken into account by the Member States to determine the level of sanctions include consideration of the appropriateness of existing national environmental sanctions. No

[30] DE.
[31] ES, PT.

penalties have been applied so far (since no infringement of the Regulations has been detected upon checks).

2.4 Voluntary measures

2.4.1 Register of collections

The register of collections within the Union under Article 5 is one of the two voluntary mechanisms that the EU ABS regulation provides to facilitate compliance with its obligations. The register is expected to lower the risk that illegally acquired genetic resources are utilised in the Union[32]. Users obtaining a genetic resource from a collection included in the Register of Collections within the Union shall be considered to have exercised due diligence as regards the seeking of information listed under Article 4(3)[33].

The register is established and maintained by the Commission. CAs of Member States, upon request by a collection holder under their jurisdiction, should verify if a collection meets the requirements for inclusion in the Register (as listed under Article 5(3)). Few cases of interest to become a registered collection were reported by Member States: in most cases, these manifestations of interest were requests of information about the application procedure and what costs and benefits would derive for the collection upon registration[34.] In Germany, one collection was granted the status of registered collection in 2018. In addition, Malta reported about an application received in 2018, which was assessed not to meet the criteria of Article 5 of the Regulation.

2.4.2 Recognition of best practices

The second voluntary instrument envisaged in the EU ABS Regulation to facilitate compliance is the recognition of best practices[35]. Associations of users or other interested parties may submit an application to the Commission to have a combination of procedures, tools or mechanisms, developed and overseen by them, recognised as a best practice in accordance with the requirements set by the Regulation. CAs of the Member States may consider that the implementation of a recognised best practice by a user reduces the user's risk of non-compliance and justifies a reduction in compliance checks.

Three applications for recognition of best practices have been filed to the Commission. Comments on the three applications were sent to the applicants, after consultation with the Member States. Two applicants did not return to the Commission upon receiving the initial feedback and decided to await the finalisation of work on the guidance documents[36] before proceeding further. One applicant engaged in a dialogue with the Commission with a view to have its best practice recognized. The procedure is ongoing.

2.5 Cooperation

32 Para 28 Preamble EU ABS Regulation.
33 Article 4(7) of the EU ABS Regulation.
34 AT, BE, DE, EE, ES, FR, HU, IE, IT, MT.
35 Article 8 EU ABS Regulation.
36 For more information about the draft guidance documents see Section 2.6.

Article 12 of the EU ABS Regulation requests CAs in Member States to cooperate with each others and the Commission as well as with third countries' competent national authorities for the Nagoya Protocol.

14 Member States reported about exchanges of emails and other activities to cooperate with other CAs[37]. These activities include: organization of and participation in workshops, CAs informal meetings, updates during the meetings of the ABS Expert Group in Brussels, exchange of relevant information and experiences (via emails and devoted IT platform established by the Commission[38]). Informal meetings of Member States CAs, for which the Commission offers logistic support, are regularly organised since September 2017, back-to-back with the ABS Expert Groups meetings.

7 Member States declared having undertaken initiatives or exchanged information by means of emails or other communication in order to cooperate with third countries competent national authorities[39]. In August 2017 and September 2018, Germany organized workshops with various provider countries with access legislation in place, to foster dialogue and enhance cooperation.

Cooperation between the Commission and Member States has been extensive and includes regularly held Expert Group meetings[40] on the implementation of the Regulation, as well as regular dialogue (via email and telephone).

2.6 Awareness-raising and complementary measures

Article 13 of the EU ABS Regulation requests the Commission and the Member States to 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. 22 Member States[41] reported having organized seminars, workshops, expert meetings, and developed communication strategies on ABS, and more specifically on the contents of the EU ABS Regulation. Most of these activities addressed specifically stakeholders of non-commercial research, such as universities, academics and public health research. Events addressing small and medium-sized enterprises were also organized.

The Commission has also engaged in several activities to promote and spread knowledge about ABS, the Nagoya Protocol and the EU ABS Regulation. On the web portal "Europa.eu" a dedicated section has been created and is regularly updated[42]. This webpage provides users with a list of contacts for the designated CAs in the Member States. The Commission has been actively participating in a significant number of ABS events, conferences and workshops organized mostly by pan-European associations (from public and private sectors) raising awareness about the Nagoya Protocol and the EU ABS Regulation. During the reporting period, the Commission's staff presented the EU ABS Regulation on 38 occasions to a large variety of audiences. The Commission also organized two sets of

37 AT, CZ, DE, DK, ES, HU, IT, LT, NL, PL, SE, SI, SK, UK.
38 https://europa.eu/capacity4dev/.
39 DE, DK, IT, LT, NL, SI, UK.
40 Commission Expert group on Access and benefit sharing (ABS) under the Nagoya Protocol (E03123)
41 AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, HR, HU, IE, IT, LV, MT, PL, PT, SE, SI, SK, UK.
42 http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm.

workshops for research and academia, respectively held between October and December 2015 in Brussels, London, Paris, Berlin and Florence, and between November 2016 and March 2017 in Stockholm, Warsaw, Budapest and Leiden. The Commission also engaged in a regular dialogue with business partners (i.e. pharmaceutical, cosmetic, plant breeding sectors) and research and academia.

The Commission, in close collaboration with the Member States and in consultation with the ABS Consultation Forum[43], developed a Guidance document[44] on the scope of application and core obligations of the EU ABS Regulation. The guidance, adopted in 2016, is intended to contribute to a more uniform application of the Regulation across the EU by clarifying the geographical, temporal, personal and material scope of the EU ABS Regulation and by providing explanations about the main concepts under the Regulation, such as due diligence.

Following the demand by Member States and stakeholders, the Commission engaged since 2016 in the drafting of further guidance focusing on sector-specific needs in relation to the notion of utilisation. The drafts were originally prepared for downstream users from seven sectors (animal breeding, plant breeding, biocontrol, biotechnology, food & feed, cosmetics, pharmaceutical sector); two additional drafts were also prepared for upstream users (public research institutes and collection holders). The nine drafts prepared by December 2017 identified a number of unresolved issues which have been discussed with Member States over the last year. For many issues, solutions have been found at expert level whereas, for others, discussions are still ongoing.

Finally, in order to promote and strengthen mutual trust and understanding of relevant legislations, the Commission has been involved in bilateral dialogue with third countries, such as Brazil[45]. In November 2017, the Commission also organized a workshop involving provider countries, users and CAs of the EU Member States.

3. Concluding remarks: state of play and identified challenges related to the implementation

This report describes the status of the implementation of the EU ABS Regulation. It shows 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[46]. Further on, reasoned opinion were issued in 2 of these cases[47] in November 2018.

---

43 Consultation Forum on Access and benefit sharing (Expert Group E03396) as required by Article 15 of the EU ABS Regulation

44 Commission Notice (2016/C 313/01), OJ C 313 27/08/2016, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0827(01)&from=EN.

45 Since 2014 EU and Brazil continue structured dialogue on ABS issues; so far 2 projects focused on various aspects of the Nagoya Protocol implementation have been carried out and the 3rd one is on-going.

46 AT, BE, HR, CY, CZ, EL, IE, IT and LV. The HR and the CZ cases were closed in June and November 2018 respectively.

47 EL and IE.

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. From the analysis of the 28 Member States' national reports, the following observations can be made and the following challenges in relation to implementation of specific aspects of the EU ABS Regulation can be identified.

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 CAs. 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.

Delay in designating CAs slowed down the implementation of other provisions of the EU ABS Regulation, such as for instance the adoption of **administrative measures** enacting **monitoring**. Currently, only 14 Member States have adopted measures to implement the **first checkpoint**.

Only 5 Member States have developed and adopted **risk-based check plans** and only 4 of them conducted actual **checks**. Several Member States are in the process of developing check plans. Other Member States claim that identification of potential users and risk factors are a challenge for CAs.

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.

Until now, only two **due diligence declarations** were filed (both in 2018, hence outside the reporting period). The temporal applicability of the Regulation could explain this low number: on-going cases of utilisation of genetic resources in the Union mostly concern genetic resources acquired before the entry into application of the Regulation. Further, both research projects[48] and the development of a product involving the utilisation of genetic resources or traditional knowledge associated to genetic resources often last long-time; hence the due diligence obligation is likely to take place later in time. Also the fact that not all Member States designated CAs or implemented the requirement of Article 7(1) to require such declarations affects the possibility for users to submit the declaration.

The low level of interest in becoming a registered collection in the **register of collections** of the Union may be due to the following reasons, as reported by Member States: uncertainty regarding the exact standards to be fulfilled, unclear added value of becoming a registered collection, fear of financial and/or administrative burden to meet the registration requirements, concern about potential risks for the liability of registered collections. In general, there seems to be more interest for applying for the recognition of **best practices** rather than the Register of Collections.

[48] For the first checkpoint, users can submit a due diligence declaration from the moment they receive the first instalment of the grant until the moment they submit the final report.

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. In general, additional efforts to foster the level of awareness among a wide range of stakeholders are needed, and in particular among those at the beginning of the value chain, such as researchers who often do not feel concerned by the obligations of the EU ABS Regulation.

Several Member States reported that it is rather difficult for stakeholders to understand the complexity of the EU ABS Regulation. For example it is not always clear that being compliant with the terms of the EU ABS Regulation might not be sufficient to be also compliant with the national access legislation of the provider country, because such measures may have a broader scope of application than the EU ABS Regulation (for example broader temporal scope).

Cooperation among Member States CAs is ongoing. Member States consider the Expert Group and CAs informal meetings as a good opportunity to exchange views on concrete experiences and challenges related to the implementation of the Regulation as well as to make progress towards a more harmonized implementation. Cooperation among Member States CAs and third countries' competent national authorities for the implementation of the Nagoya Protocol seems to be still underdeveloped.

Finally, 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. Others think that more real experience on implementation will be helpful to clarify the issues. 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. The Commission remains also committed to facilitate communication through meetings of the relevant Expert Group and Consultation Forum. 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 CAs under Article 6, adopt sanctions under Article 11, 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 CAs does often not match the needs and should therefore be reinforced in most of the Member States.