

---

# IMAGE

## Innovative Management of Animal Genetic Resources

---

Grant Agreement Number: 677353

Horizon 2020 FRAMEWORK PROGRAMME

**TOPIC: MANAGEMENT AND SUSTAINABLE USE OF GENETIC RESOURCES**

Topic identifier: SFS-07b-2015

**Type of Action: Research and Innovation Action (RIA)**

Deliverable D 1.6

Deliverable title: **Status, regulations and needs of ABS in genetic collections**

Abstract: The input on ABS issues related to the management of genebanks was provided during development of the survey undertaken in the Task 2.1. The questionnaire for the second survey was aimed to gather information on national ABS measures in European countries and in overseas partners of the IMAGE. The customized survey was distributed in Month 18 to the ABS National Focal Points/National Competent Authorities. The responses to the survey were being submitted up to the early 2019. Other sources of information, provided by countries to the ABS CH, as well as information contained in the Interim National Reports, and presented at various workshops with Provider countries, were also analyzed in preparation of the Deliverable D1.6.

Due date of deliverable [M36](#)

Actual submission date: [M47](#)

Start date of the project: March 1st, 2016 Duration: 48 months

Organization name of lead contractor: Task Leader: SGGW; WP Leader: BOKU

Contributors: DLO, BOKU, SAVE, EFFAB, FAO

Dissemination level: [PU](#)

Revision N°: V1

## Table of contents

Executive Summary .....	2
1. Introduction.....	3
2. Sources of information.....	3
3. Survey on animal genetic collections .....	4
4. Survey on national ABS legislations .....	5
4.1 Methodology .....	5
4.2 Respondents .....	5
4.3 Results of the survey for ABS NFP .....	7
I. General information .....	7
II. Scope or potential scope of the national ABS legislation .....	8
III. Genetic resources for food and agriculture (GRFA) .....	10
IV. Implementation of the provisions of 511/2014 Regulation and Implementation of the provisions of the Nagoya Protocol .....	17
V. Other activities to support implementation of the ABS EU legislation and the Nagoya Protocol .....	22
5. Other reporting processes .....	29
5.1 Interim National Reports on the Implementation of the Nagoya Protocol .....	29
5.2 EU reporting process on implementation of the Regulation (EU) no 511/2015 .....	29
5.3 Commission report .....	30
6. Other sources of information.....	31
6.1 ABS CH .....	31
6.2 Workshops with Provider countries .....	42
7. Pending issues .....	43
8. Conclusions and recommendations .....	46
8.1 Status of ABS in genetic collections .....	46
8.2 Regulations of ABS in genetic collections .....	46
8.3 Needs of ABS in genetic collections .....	47
8.4 Establishing obligations of users .....	48
8.5 Impact of ABS measures on animal breeding, conservation and research .....	49
8.6 Impact of ABS measures on animal gene banks .....	51
9. References.....	52

### Authors:

Elżbieta Martyniuk, Aleksandra Haska & Wioleta Drobik,  
Department of Animal Breeding and Conservation, SGGW

## Executive Summary

---

<b>Background</b>	Since the adoption of the EU Access and Benefit Sharing Regulation in 2014 and its entering fully into force in 2015, all users of genetic resources have to exercise due diligence and fulfill their obligations set in Articles 4 and 7 of the EU ABS Regulation. The IMAGE will provide support for users of genetic resources to comply with ABS measures.
<b>Objectives</b>	The ABS issues constituted a part of the comprehensive, detailed gene bank survey conducted in Task 2.1. It provided initial information about awareness of ABS measures and their implementation by collections. A second survey for ABS National Focal Points (NFP) or National Competent Authorities (NCA) determined ABS provisions in the national legislation developed to implement the Nagoya Protocol and EU Regulation 511/2014. The overall goal was to inform collections and users of genetic resources in research about their obligations and assist them in a process to determine if their activities are in the scope of EU ABS Regulation.
<b>Methods</b>	The task included development of a survey at two levels. The first survey gathered information on existing practices, internal gene banks' procedures and protocols on acquisition, exchange and transfer of biological material in EU countries. The second survey dedicated to ABS NFP/NCA provided information about the scope of national legislation and the way it is addressing genetic resources for food and agriculture.
<b>Results &amp; implications</b>	<p>The work undertaken in Task 1.3 of the IMAGE will allow to understand what are the ABS measures undertaken by Parties to the Nagoya Protocol, and will help users to navigate in complicated ABS landscape while looking for information on access measures established by Provider countries, and determine if their activities are in the scope of the EU ABS Regulation. A feedback on this work has been provided to stakeholders through the Fourth Dialogue Forum held August 30, 2019.</p> <p>Collections should be aware of legal requirements and procedures of all Provider countries as they have to follow such procedures and obtain all necessary permits. Therefore, it is so important that Parties to Nagoya Protocol fulfil their obligations arising from the Article 14 and post at least the minimum set of information on ABS CH.</p> <p>Collection need an updated information on the country requirements before submitting request for access, as the current situation is very dynamic and legal arrangements might be changing.</p> <p>Moreover, each genebank should develop own or adapt already existing MAA and MTA standard models to be integrated into their workflow.</p>

## 1. Introduction

---

The IMAGE (Innovative Management of Animal Genetic Resources) project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 677353. IMAGE aims to enhance the use of genetic collections and to upgrade animal gene banks management by further developing genomic methodologies, biotechnologies and bioinformatics for a better knowledge and exploitation of animal genetic resources.

One of IMAGE goals (Work Package 1, Task 1.3) was to obtain and consolidate information about the implementation of the Nagoya Protocol and EU ABS Regulation 511/2014 by the European animal genetic resources collections. The level of awareness of collection holders of new obligations resulting from the ABS international agreements to some extent depends on national developments, including adoption of national legislation, efforts to implement EU legislation (in case of EU Member States) and to communicate the ABS legal framework to stakeholders, especially holders and users of genetic resources.

Therefore, the Task 1.3 combined undertaking surveys at two levels, the first one addressing directly holders of germplasm and genomic collections, the second designed for ABS National Focal Points (ABS NFP) in European countries as well as countries of the IMAGE partners.

The ABS related questions were part of the survey undertaken within Task 2.1 Inventory and mapping of European animal genetic collections and their specific characteristics. These questions were meant to obtain information on existing practices, internal genebanks' procedures and protocols used to acquire, exchange and provide/transfer germplasm or other animal biological material.

The second survey allowed to gather information on the scope and provisions of ABS legislation in European countries. The special focus of the survey for ABS NFP or Competent National Authorities (NCA), was related to the way national legislation is addressing genetic resources for food and agriculture, including potential provisions related to utilization of animal genetic resources from ex-situ collections.

As the Nagoya Protocol and EU ABS Regulation 511/2014 are still at the early stage of implementation and the situation is changing in a dynamic way, some other sources of information were used in preparation of this report. They include outcomes of reporting process adopted by the Parties of the Nagoya Protocol, internal EU reporting process as well as information posted at the ABS Clearing House and information provided during a number of meetings/ workshops with representatives of various countries.

The objective of this report is to provide information on the **Status, regulations and needs of ABS in genetic collections.**

## 2. Sources of information

---

The report has been prepared based on the following sources of information:

- Results of the IMAGE survey on genetic collections in Europe
- Results of the survey for National Focal Points for ABS in European countries

- Interim national reports on implementation of the Nagoya Protocol
- Reports on implementation of the EU Regulation 514/2014 from the Member States
- Report from the Commission to the European Parliament and the Council on implementation of the EU Regulation 514/2014
- Information posted by countries at the ABS Clearing House (ABS CH) of the Convention on Biological Diversity
- Meetings of the ABS Expert Group established by the European Commission
- Information from various sources including workshops and meetings
- Decisions by Parties to the Nagoya Protocol and Convention of Biological Diversity

### 3. Survey on animal genetic collections

---

The survey was developed by a group of experts involved in the WP2 of the IMAGE project. It included 182 questions, focusing on various aspects of genbanks management and current scope and content of their collections. The survey is included in Appendix of the Deliverable D2.1 (Survey questionnaire to collect detailed information about germplasm and genomic collections). The detailed report of the survey (The Inventory and mapping of European animal genetic collections) prepared by IDELE is available at <http://www.imageh2020.eu/deliverable/WP2.pdf>

The survey was answered by 61 organisations from 21 countries, that hold 51 germplasm collections and 30 genomic collections.

Ten questions in the survey were related to the implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention to Biological Diversity in germplasm and in genetic collections. These questions were meant to gather information on current procedures applied by gene banks when germplasm/ genetic material is entering the gene bank (3) or is being transferred out of the gene bank (6).

The survey showed that only 12 germplasm collections and only 1 genomic collection, out of 41 and 19 respectively that have answered this question, were using some sort of internal agreement /contract to regulate and document acquisition of animal genetic resources material for the collection. Such documents can be considered as MAA (Material Acquisition Agreement).

In MAA documents, the major focus was on information related to the sample itself: the donor animal, sample property rights and its sanitary status. Only 8 respondents also mentioned access conditions related to the acquired material.

As regards access to and transfer of material stored in the collection, only 9 germplasm collections and 4 genomic collections (out of 40 and 19 respectively) were implementing MAA (Material Acquisition Agreement) and MTA (Material Transfer Agreement).

MTA documents mainly included information on samples and on applicant and proposed use of the material. The detailed information on the outcome of the survey can be found in the final report of the survey.

The survey showed that implementation of the MAA and MTA is very low in genetic and genomic collections. These documents should be routinely used by all germplasm collections holding animal genetic resources but also by genomic collections holding DNA and other biological material, sometimes accompanied by DSI (Digital Sequence Information), in lights of implementation of the Nagoya Protocol as well as the EU ABS Regulation 514/2014, in the case of EU Member States.

## **4. Survey on national ABS legislations**

---

The draft survey was developed by the SGGW, as Task 1.3 leader and then consulted by a group of experts involved in the IMAGE project and participating in the Task 1.3. This group included the following persons: Maria Wurzinger, Gabor Meszaros, Michael Klaffenboeck, Johann Soelkner, Sipke Joost Hiemstra and the IMAGE coordinator, Michele Tixier-Boichard.

### **4.1 Methodology**

The survey was developed for four sub-groups of respondents: from EU Member States, both Parties to the Nagoya Protocol and non-Parties to the Nagoya Protocol; and then other European countries both Parties and non-Parties to the Nagoya Protocol. The survey was also prepared for non-European partners of the IMAGE project. The division between Parties and non-Parties was valid at the point of conducting the survey, in early 2018.

The survey was personalized at the country level, and included information already available in the ABS CH for individual countries in order to be able to double check if all data are correct and also encourage respondents to reply to the survey.

The survey for EU member states included 22 questions divided into six parts, namely:

- I. General information
- II. Scope or potential scope of the national ABS legislation
- III. Genetic resources for food and agriculture (GRFA)
- IV. Implementation of the provisions of 511/2014 Regulation
- V. Other activities to support implementation of the ABS EU legislation and the Nagoya Protocol

While the majority of questions were the same for all countries, the survey for other European and non-EU countries represented in IMAGE partners in part V and VI referred only to implementation of the Nagoya Protocol (and not EU Regulation 511/2014) and included in total 20 questions. Many questions included options for multiple choices.

All the information gathered from the survey were stored in an Excel database.

### **4.2 Respondents**

The survey was sent in December 2017 to 57 ABS National Focal Points (ABS NFP) and where relevant to National Competent Authorities (NCA), as posted on the ABS Clearing House of the Convention on Biological Diversity. The reminder was sent again early March 2018.

Follow-up with individual countries was carried out over 2018. The last response was obtained in February 2019.

A total of 27 national ABS authorities (either ABS NFP or NCA) returned the questionnaire (Figure 1). It is clear that the highest returned rate was observed among ABS NFP of countries that were at that point of time already Parties to the Nagoya Protocol (81.5%) in comparison with Non-Parties (18.5%). Although the survey have not included any mandatory questions, most of the returned surveys were fully completed.

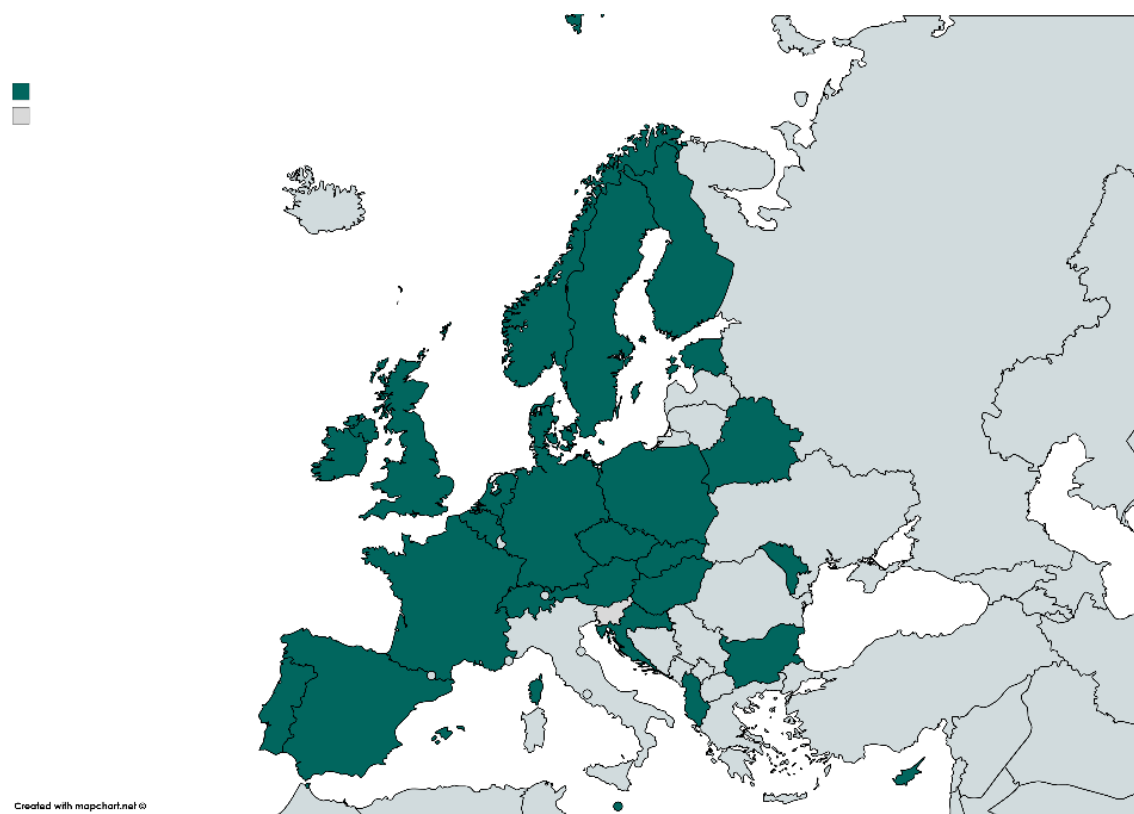


Figure 1: Map of the countries which filled up the survey

Moreover, two countries, Italy and Bosnia-and-Herzegovina, being Non Parties to the NP have replied that they are not able to provide information related to national ABS legislation as their internal processes related to implementation on of the Nagoya Protocol /EU Regulation 511/2014 were still ongoing.

The details of respondents and their organisations are contained in Table I.

**Table 1.** The outcome of the personalised survey sent to ABS NFP or NCA.

GROUP OF COUNTRIES	SENT	RETURNED	Return Rate %
EU MS: Parties	18	17	94.4
EU MS: Non-Parties	11	5	45.5
Other European Countries: Parties	8	5	62.5
Other European Countries: Non-Parties	16	0	0
IMAGE overseas Partners	4	0	0
TOTAL	57	27	47.4

The list of Parties to the Nagoya Protocol responding to the questionnaire included EU Member states: Belgium, Bulgaria, Croatia, Czechia, Denmark, France, Finland, Germany, Hungary, Malta, Netherlands, Portugal, Slovakia, Spain, Sweden, UK and EU. Other European Parties to the Nagoya Protocol participated in the survey were Albania, Belarus, Moldova, Norway and, Switzerland. EU non-Parties that provided information included: Austria, Cyprus, Estonia, Ireland and Poland.

### 4.3 Results of the survey for ABS NFP

The responses obtained to individual questions (highlighted) are presented below. While the responses were predefined, most of the questions gave respondents an opportunity to provide comments or additional information and some of them are presented in the report.

#### I. General information

##### 1. Is the information in the ABS Clearing House up to date for your country?

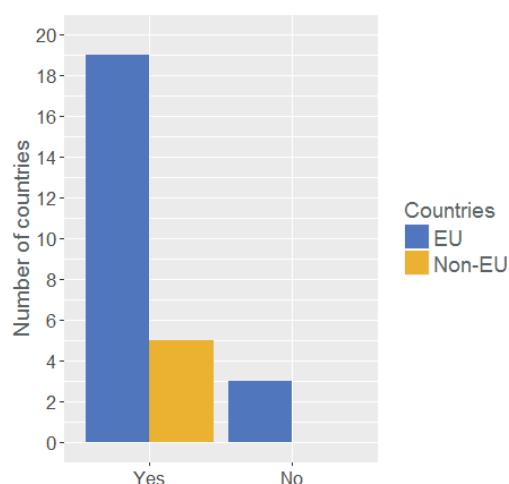


Figure 2. Accuracy of national information posted on ABS CH.

Only 3 out of 27 national ABS authorities replied that the information downloaded from the ABS CH for their country and included in the customized survey is not up to date. It shows that countries are feeling obliged to post relevant information on the ABS CH and update them, as necessary. However, such conclusion is relevant mainly for the Parties to the Nagoya Protocol, that constituted majority of the respondents.

##### 2. State of the national ABS legislation to implement EU ABS Regulation and the Nagoya Protocol.

Most of countries (66.7%) have already adopted their national ABS legislation, in others (11.1%) an adoption process was underway and in 22.2% of countries the ABS law was under discussion. One country put temporary measures in place and only one country has not taken any action in this area.

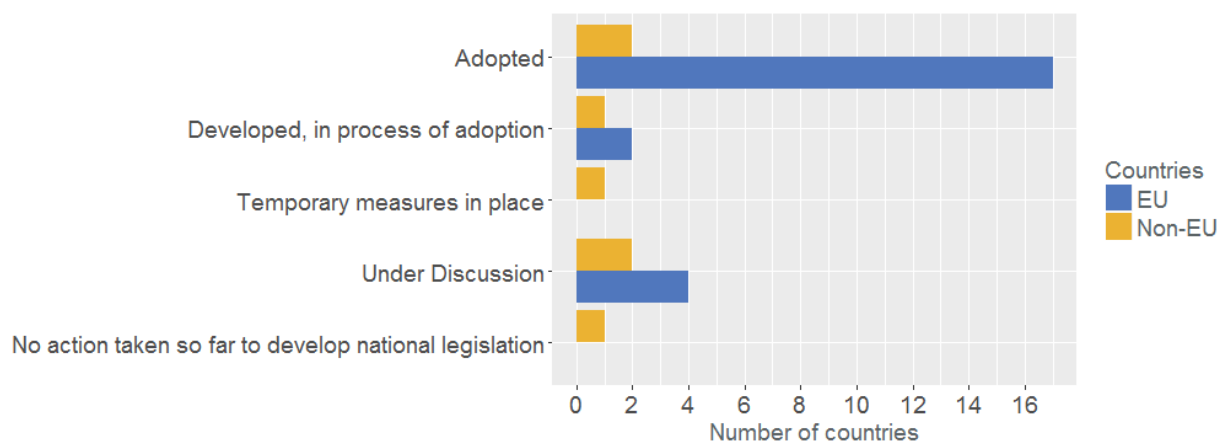


Figure 3. Advancement in development of the national ABS legislation.

Development of a national ABS legislation or regulatory measures is the obligation of the Parties to the Nagoya Protocol and a most important source of information for potential users of genetic resources from this country. Belarus, Norway and Portugal provided multiple answers to this question.

### 3. Format of the national ABS legislation

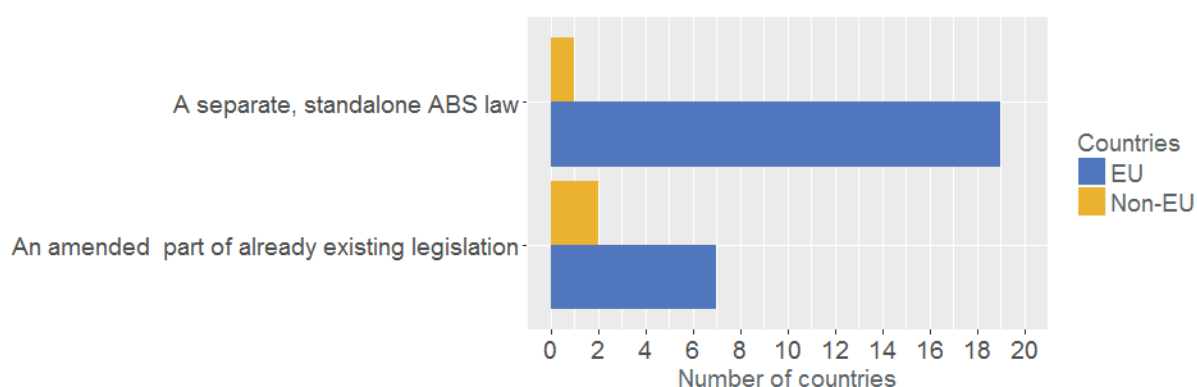


Figure 4. Type of the national ABS legislation.

Majority of countries (70.3%) have decided to establish ABS legislation as a separate, standalone law. Such decision may also require to amend already existed legislation and four countries (Belgium, Croatia, Malta and Spain) marked both replies. Albania and Moldova did not respond to this question.

## II. Scope or potential scope of the national ABS legislation

The issues most often addressed in the national legislation included establishment of the NCA (95.5% of EU MS and 60% of Non-EU European countries).

### 4. National ABS legislation addresses/ will address issues such as:

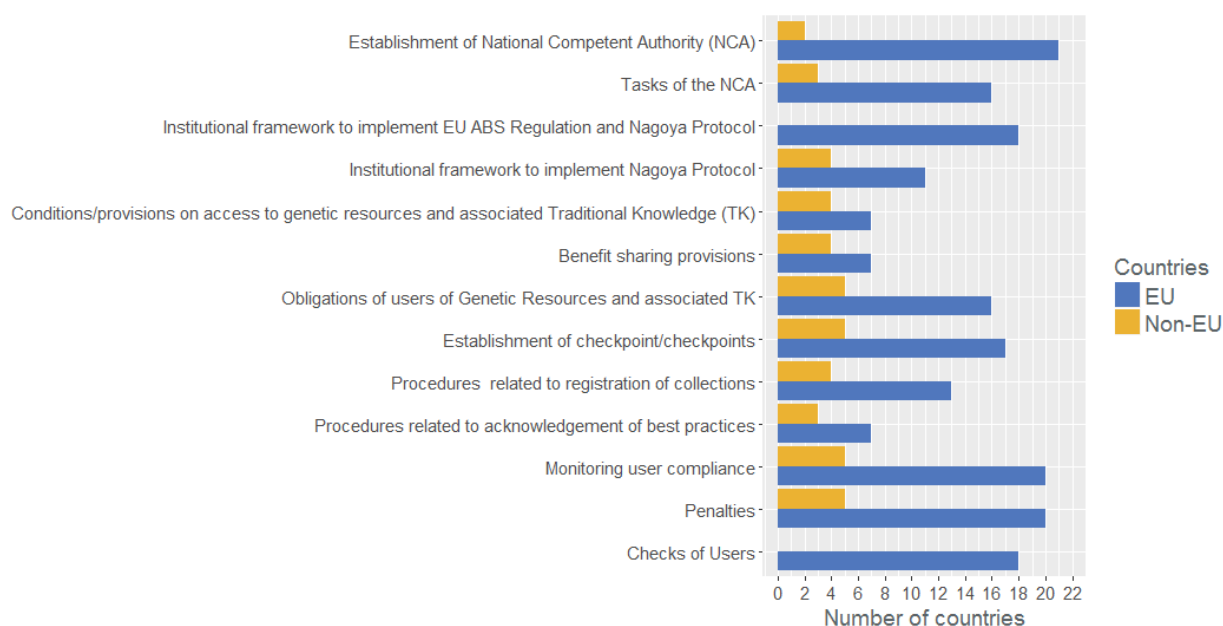


Figure 5. Scope of issues addressed by the national ABS legislation.

A similar high score was observed both for monitoring user compliance and establishment of penalties (90.9% and 100% respectively). Institutional framework to implement the Nagoya Protocol and EU ABS Regulation as well as provisions for checks on users were/will be addressed in the national ABS legislation in 81.8% of the EU MS.

Relatively a small group of EU countries included in their national legislation provisions for access to genetic resources and associated traditional knowledge as well as benefit sharing (31.8%) while it was a case of 80.0% of Non-EU countries.

## 5. Access to genetic resources

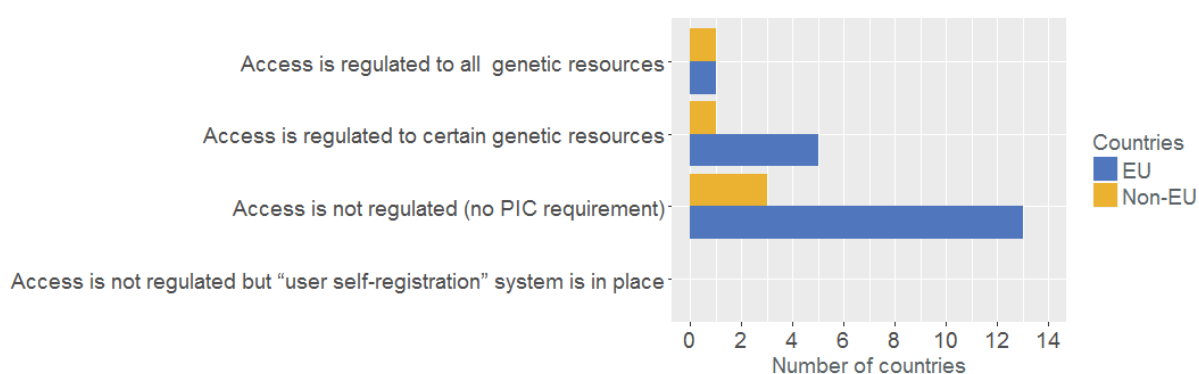


Figure 6. Access regulation options applied in national ABS legislation.

Thirteen out of 22 EU MS and 3 out of 5 Non-EU countries taking part in the survey do not regulate access to their genetic resources. Only one EU country (Bulgaria) regulates access to all its genetic resources while Croatia, France, Malta, Portugal and Spain regulate access to certain genetic resources. Belgium and Ireland were still considering this issue.

Belarus regulates access to all genetic resources while Albania has differentiated access measures; Republic of Moldova, Norway and Switzerland do not require PIC.

6. Please provide rationale regarding decision on access to GR of your country, choosing one or more answers from the following options:

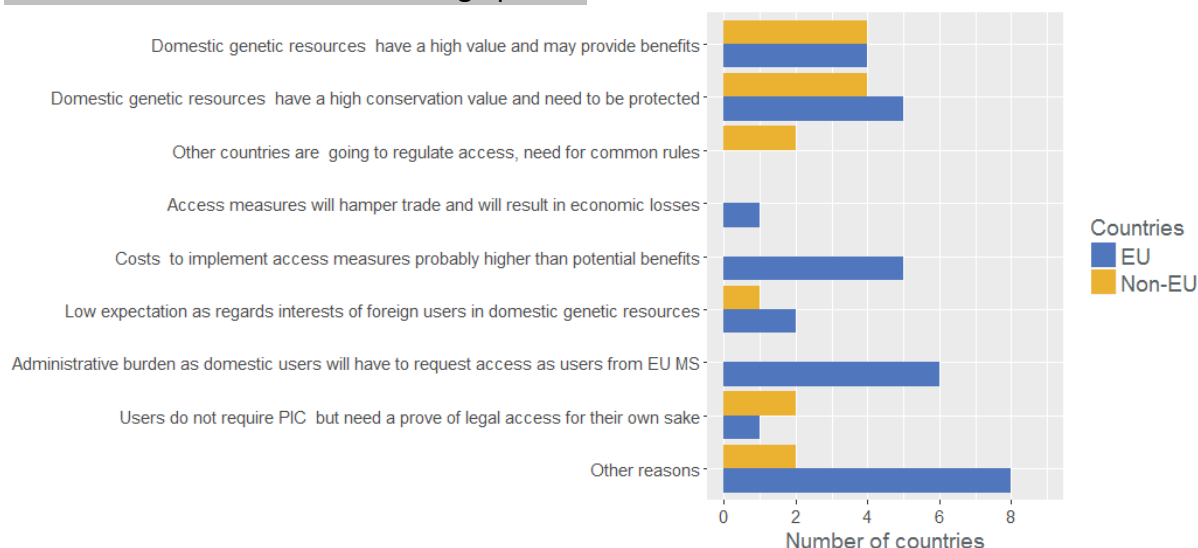


Figure 7. Rationale regarding decision on access measures.

Decision on establishment of access measures or lack of PIC requirements was often based on evaluation of opportunities and needs and cost-benefit assessment. For a number of countries domestic genetic resources either have a high economic potential and can generate benefits or have a high conservation value and need to be protected. For other countries the major argument was that the costs of putting in place access measures may be higher than expected economic benefits or that such measures will generate administrative burden when applied both for foreign and for domestic users.

There was also a number of other reasons, identified by respondents, e.g. that access measures may hamper non-commercial research (Germany), that genetic resources under sovereign rights of the country should remain accessible for free use as long as the access is in agreement with other provisions for collecting biological material or living organisms (Sweden) or that there are already substantial existing legislation covering access – physical access rights, property rights, protected areas/species legislation and phytosanitary regulations (UK).

On the other hand, there were additional arguments provided in favor of regulating access such as that access measures are also designed to enhance legal certainty for users' activities (France) or that when genetic resources are limited, the ABS regulatory system adds an additional layer of protection and possibly a further mean for funding conservation efforts (Malta).

### III. Genetic resources for food and agriculture (GRFA)

7. In preparation of your ABS legislation have you considered the special role of GRFA?

Most of countries participating in the survey (77.8%) have considered the special role of genetic resources for food and agriculture when developing domestic access measures, as

required by Article 8c of the Nagoya Protocol. Four countries not replied to this question (Slovakia, Cyprus, Albania, Moldova) and one have indicated both options (Belarus).

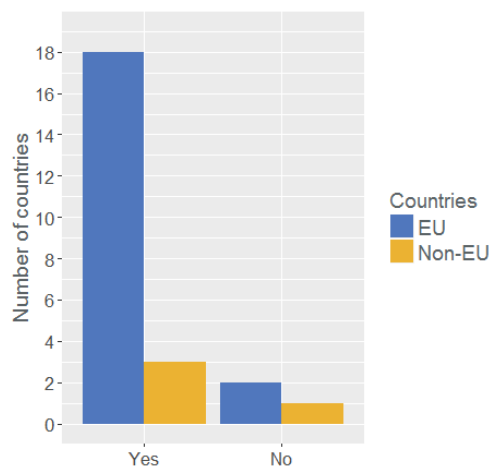


Figure 8. Special consideration of GRFA while developing national ABS legislation.

8. Are you familiar with the document adopted by the FAO Commission on Genetic Resources for Food and Agriculture “*Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture*”?

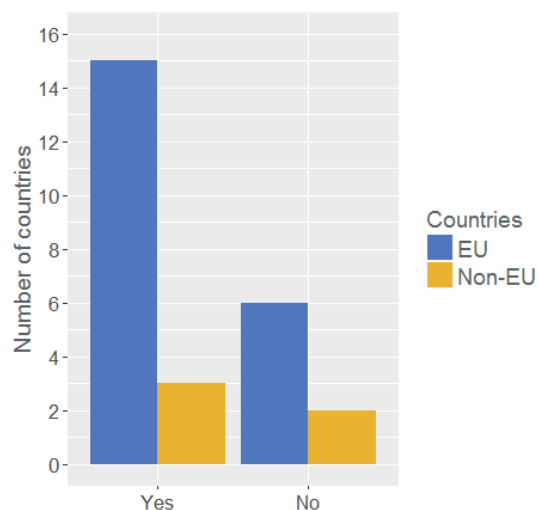


Figure 9. Awareness about the FAO voluntary guidance document: ABS Elements to facilitate implementation of domestic ABS measures for GRFA.

Since 2011, the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) has been working on ABS issues related to GRFA. The major output of this work was an adoption in 2015 of the voluntary guidance document “Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture”, so called ABS Elements (<http://www.fao.org/3/a-i5033e.pdf>). This

document was meant to draw attention of the national legislators on specific roles and characteristics of GRFA and differences between subsectors of GRFA including differences in ABS practices. As implementation of the Nagoya Protocol is usually under auspices of ministries responsible for environmental permits, the international agricultural community wanted to contribute to the process of development of national legislation through providing information on specific issues related to ABS and GRFA.

Out of 26 respondents 18 (69.2%) were familiar with ABS Elements. Moreover, there was a number of comments underlying an importance of the ABS work carried out by the CGRFA.

For instance, Portugal suggested that the document can be helpful when drafting legislation on ABS for GRFA, in order to prepare rules and procedures that are transparent and effective and to not add excessive delays or burden to the users of GRFA; France stated that the FAO guidelines were useful to convince Government and stakeholders to plan a specific regulation, that provides exemption for genetic resources developed in agriculture (livestock and crops) and forestry (cultivated forest species). According to Malta, the document clarifies the relationship between the Nagoya Protocol and dedicated ABS instruments such as the ITPGRFA, and suggests approaches to develop suitable legislative measures.

Although the document suggests developing specialized ABS legal instruments that deal with GRFAs, the current national ABS laws cover a broad range of genetic resources and do not specifically distinguish genetic resources on the basis of whether they are useful for food and agriculture or otherwise. Norway suggested that ABS Elements serves as a reference document.

There were also suggestions that ABS Elements document is very general, therefore more detailed guidelines would be helpful (Estonia) and that it still needs further development (Finland).

Some countries, although familiar with this document, did not found it applicable since they have decided not to establish access measures (Czechia, The Netherlands). One country did not respond to this question (Cyprus).

#### 9. Do you have different access measures for different subsectors of GRFA?

In total, seven countries (Albania, Austria, Croatia, Estonia, Germany, Norway and Spain) reported on specific measures for different subsectors of GRFA, while 17 have not established such measures. Hungary, Cyprus and Moldova have not provided answers to this question.

There was a number of explanatory comments, e.g. Germany stated that although no access measures were established under the Nagoya Protocol, but as Contracting Party of the ITPGRFA, Germany supplies Plant Genetic Resources for Food and Agriculture via SMTA. Similar contribution provided by Austria indicated a facilitated access for PGRFA under the multilateral system of the ITPGRFA and use of the SMTA. Albania also reported on specific procedures for cultivated plant genetic resources.

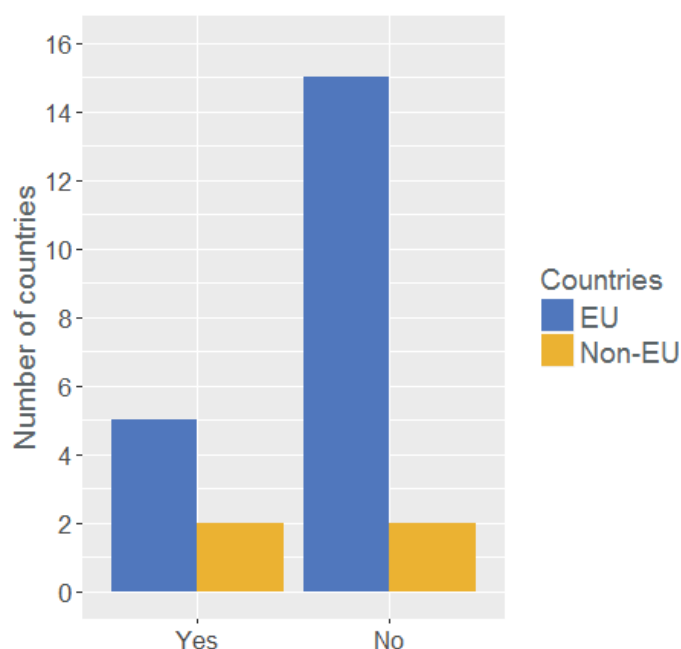


Figure 10. Differentiation of access measures for different subsectors of GRFA.

Malta stated that in relation to access measures, as understood in the context of the Nagoya Protocol, all genetic resources for food and agriculture that are not governed by specialized ABS instruments are considered to fall under the same process stipulated by the national legislation (S.L. 549.111).

Denmark explained that AnGR are conserved in the national ex situ genebanks and the National Advisory Board on AnGR sets restrictions for access to the AnGR. Semen from bulls is routinely accessible for breeders of native or locally adapted breeds. In Nordic countries plant vegetative material is conserved in national ex situ genebanks and accessions of seeds are conserved by the joint Nordic Genetic Resource Centre (NordGen). All PGRFA are freely available upon request.

Estonia indicated separate measures for plant genetic resources and animal genetic resources and Finland explained that access is not regulated for any subsectors, unless traditional knowledge is associated with specific genetic resources.

#### 10. Do you have specific measures for subsector of animal genetic resources (AnGR)?

Only five countries (Croatia, Denmark, Estonia, Portugal and Albania) reported on specific measures for animal genetic resources.

Denmark reported that only breeders of the Danish native or locally adapted endangered breeds have a routine access to bull semen in the National Genebank for pure breeding, due to the small population sizes of local breeds. Other requests for AnGR stored in the gene bank are individually taken into consideration by the responsible Agency, which is advised by the National Advisory Board on AnGR.

Albania reported that in case of animal genetic resources the provisions of the national legal framework on biodiversity protection, including wild fauna protection, applies. Especially the red listed species of wild fauna are restricted in terms of exploitation. However even for

other species of wild fauna authorization based on the current status of population have to be obtained.

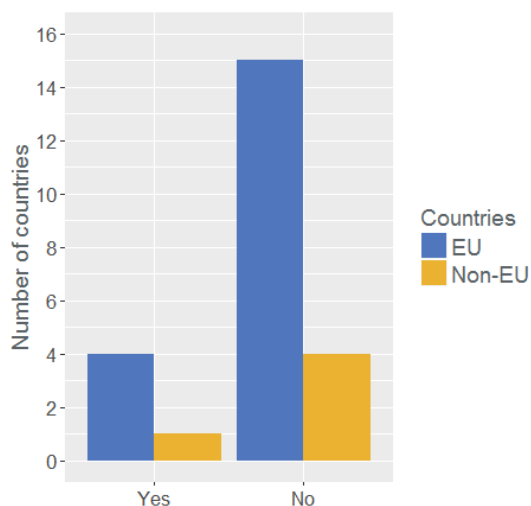


Figure 11. Differentiation of access measures for Animal Genetic Resources.

No additional information was provided by other three countries, that indicated specific measures for AnGR. Three countries (Cyprus, Hungary and Spain) have not responded to this question.

Moreover, France has set up access measures for wild relatives of domestic animals. Spain explained that there are no access measures for animal genetic resources for food and agriculture. Access to animal genetic resources for their utilization in food and agriculture are out of the scope of access measures established under the ABS bylaw Real Decreto 124/2017.

Austria stated that most national and international exchange of AnGR is based on commercial trade. In Austria currently there are no specific regulations on MTA or MAA. The Austrian Genebank for Farm Animals is a member of the EUGENA network where model MTA and MAA will be developed.

#### 11. Have you developed specific ABS policy /regulatory measures applicable to your ex-situ animal genetic resources collections?

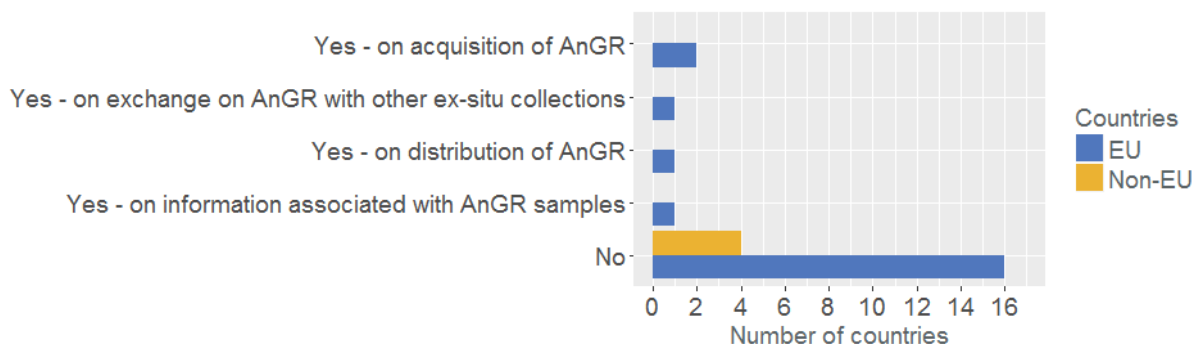


Figure 12. Policy or regulatory measures related to ex-situ AnGR collections.

Only three countries (Bulgaria, Denmark and Croatia) reported to have in place specific ABS regulatory measures for management of ex-situ AnGR collections. Bulgaria and Denmark reported on protocols related to acquisition of AnGR into gene banks; Denmark has also measures on distribution of AnGR from gene banks while Croatia have measures on exchange of AnGR biological material with other gene banks and on information associated with AnGR samples. Remaining 20 respondents have not developed domestic measures in this respect.

Cyprus, Estonia, Hungary and Switzerland have not responded to this question.

Danish government supports collection and storage of genetic material from cattle, pigs, horses, sheep and goats of the native and locally adapted breeds. The government is the owner of the stored AnGR. Distribution of the material is free of charge after approval of the National Advisory Board on AnGR.

Access measures developed in Spain under Real Decreto 124/2017 apply both to in situ and ex situ genetic resources. The access to animal genetic resources for their utilization in food and agriculture is out of the scope of access measures established under the ABS bylaw Real Decreto 124/2017.

In Moldova, the GD Nr. 1107 of 11.09.2003 on Regulation on establishment, registration, completion, maintenance, export and import of collections of animals and plants of the wild flora and fauna to some extent provides the regulatory measures on collections (<http://lex.justice.md/viewdoc.php?action=view&view=doc&id=335224&lang=1> ).

Bulgaria also informed on procedures put in place for granting access. An official letter has to be sent to the Minister of Environment and Water, containing a brief annotation of the scope of research work. Furthermore, an official response is required from the Ministry of Agriculture, Food and Forestry, as a competent authority for animal genetic resources, setting certain conditions for the utilization of given genetic material.

## 12. Access to animal genetic resources held in ex-situ collections. Please choose from the following options

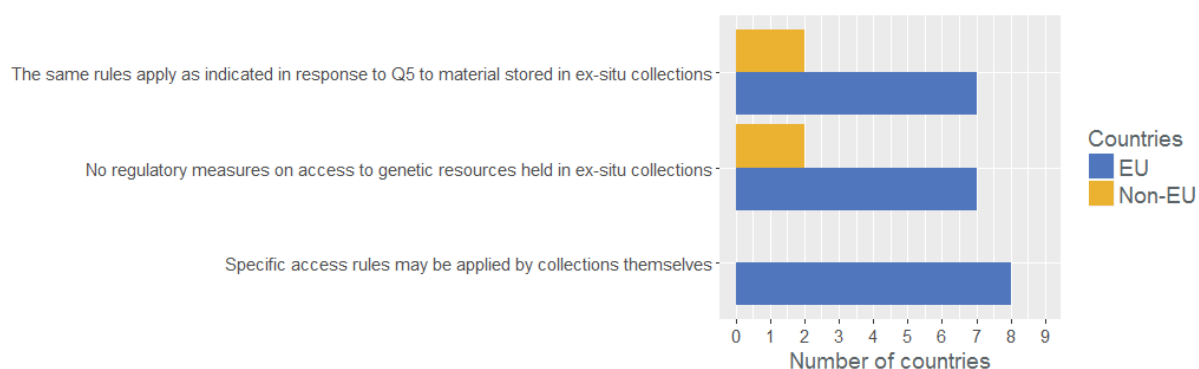


Figure 13. Access rules for AnGR material stored in ex-situ collections.

Nine countries indicated that the same rules apply to all genetic resources stored in ex-situ collection. Also nine countries reported no access restrictions to AnGR stored in gene banks imposed by the national legislation. However gene banks themselves can apply specific access rules.

As was already reported, there is no access measures under the Nagoya Protocol in Germany. At the European Level, Germany is involved in the ABS activities of the European Regional Focal Point for Animal Genetic Resources (ERFP), such as the establishment of a European genebank Network for AnGR (EUGENA) and the development of a standardized Material Acquisition Agreement and a standardized Material Transfer Agreement.

Czechia reported that in the case of access to AnGR provisions of Act No. 154/2000 Coll. (Breeding Act) apply. A sample of genetic material is provided on request to third parties with the consent of a designated person if there is sufficient AnGR samples in stock and providing the sample does not endanger the genetic resources of the breed. A sample of material is provided by genebank at a cost that does not exceed the cost of processing the sample. The minimal number of samples in stock considered as sufficient is set by the Ministry of Agriculture in an implementing regulation.

The Portuguese Bank of Animal Germplasm provides specific rules for the use of germinal products for selection, reproduction, research and exchange with other national or international users.

In Sweden, the semen stored in the ex-situ genebank can only be used for purebred inseminations. The goal is to support an endangered breed, if needed. A part of the stored semen can be sold and the income belongs to the authority, who owns the genebank.

Malta national legislation does not distinguish between genetic resources based on their occurrence, and addresses all relevant genetic resources based on sovereignty rights; this is also understood to include traditional / historical breeds that originated in Malta and which are not protected by intellectual property rights.

Belgium, Cyprus, Estonia, Moldova and Switzerland have not responded to this question, while four countries (Denmark, Hungary Portugal, France) marked two last options in their replies. French Biodiversity law refers to the registration procedure set up by the European Union for collections, and acknowledges that users of registered collections are considered having demonstrated due diligence when access takes place after the entry into force of the French law.

- 13. Have you developed any standards and/or model documentation to be used by ex-situ collections of AnGR?

Majority of countries (68%) reported lack of any official documentation to be used at the national level by gene banks, or suggested that gene banks can develop such documentation themselves.

In total, 15 responses coming from only eight countries (32%) were indicating development of some standard documentation at the national level to be used by gene banks in case of acquisition of AnGR for collection, its transfer between collection and transfer to users. Some additional comments provided details on existing standard documentation.

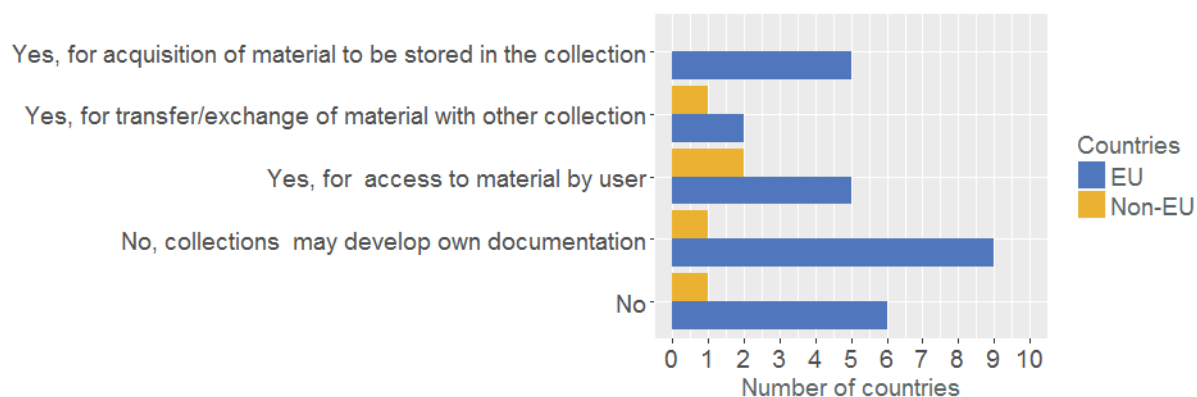


Figure 14. Standard/model documentation addressing ABS in ex-situ AnGR collections.

Estonia and Cyprus have not responded to this question while a few countries marked multiple answers reporting on existence of various types of documentation.

For instance, a gene bank in the Czechia was established for the storage of domestic genetic resources, and the acquisition of foreign animal genetic resources is not expected. Genetic material is stored on the basis of a contract between the owner (provider) of the genetic resource and the designated person. The conditions for the supply of material are stipulated in the contract as well. These contracts (MTAs) are used in domestic gene bank operations since 2008 and will be applied in the same way if genetic material is provided abroad.

Norway public collections are managed in accordance with the principles set out in section 57 of the Nature Diversity Act. The person managing the collection has a duty to register any genetic material removed from the collection and provide public access to such information, according to the Nature Diversity Act section 59 (genetic material in public collections), para 1. Any person that receives genetic material derived from a public collection shall refrain, in Norway or abroad, from claiming intellectual property rights or other rights to the material that would limit the use of the material, such as use for food or agriculture, unless the material has been modified in a way that results in substantial change (see Nature Diversity Act section 59, para 3).

The German Gene bank for Animal Genetic Resources is developing own standard Material Transfer Agreement, and the Austrian Gene bank is expected in the future to use model MAA and MTA developed by the network of the European gene banks EUGENA.

#### IV. Implementation of the provisions of 511/2014 Regulation and Implementation of the provisions of the Nagoya Protocol

##### 14. Have you established Checkpoint/Checkpoints?

The EU ABS Regulation requires establishment of two checkpoints: one when research funds are received (where such research involves utilization of genetic resources and associated traditional knowledge); and the other at the final stage of development of a product. These two checkpoints are implemented at the MS level. Most of countries participating in the survey (66.7%) have already established their checkpoints.

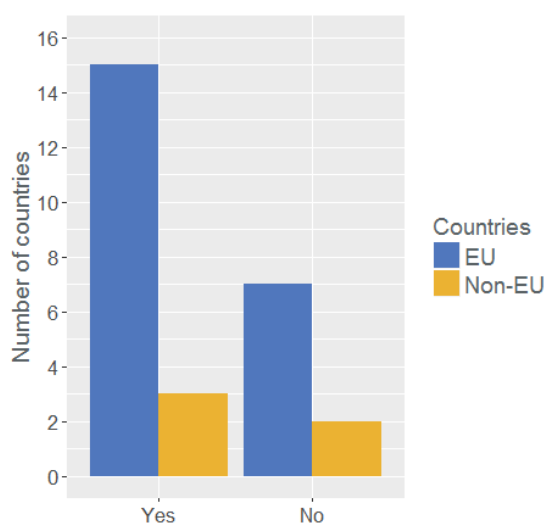


Figure 15. Establishment of checkpoint(s).

A wide range of institutions have been designated at the national level to serve as checkpoints. Some examples provided by respondents are summarized below (Table 2).

**Table 2.** Examples of the institutional and functional checkpoints in European countries.

Country	Institutional and/or functional checkpoints
	-
Croatia	<ul style="list-style-type: none"> <li>• Ministry of Environment and Energy</li> <li>• Ministry of Agriculture</li> </ul>
France	<ul style="list-style-type: none"> <li>• Ministry of Research</li> <li>• Ministry of Environment</li> </ul>
Poland	<ul style="list-style-type: none"> <li>• Ministry of Environment</li> </ul>
Portugal	<ul style="list-style-type: none"> <li>• Competent National Authority (ICNF, Lisbon)</li> <li>• the Regional Competent Authorities</li> </ul>
Slovakia	<p>7 checkpoints in areas: plant breeding, animal breeding, human pharmacy, veterinary pharmacy, biocidal products, food statement, feed, research funding</p> <ul style="list-style-type: none"> <li>• Ministry of Environment</li> <li>• Other authorities in the area of genetic resource: this group includes research funding agencies that accept declarations under the article 7(1) of the EU Regulation.</li> </ul>
Denmark	<ul style="list-style-type: none"> <li>• Environmental Protection Agency</li> </ul>
Finland	<ul style="list-style-type: none"> <li>• Finnish Environment Institute</li> <li>• Natural Resources Institute Finland, at the import of GR</li> </ul>
Germany	<ul style="list-style-type: none"> <li>• Institutional Checkpoint: Federal Agency for Nature Conservation</li> <li>• Functional Checkpoints have been established in line with the EU Regulation at the stage of research funding and at the final stage of product development</li> </ul>
Hungary	<ul style="list-style-type: none"> <li>• Pest County Government Office</li> <li>• National Office of Research, Development and Innovation</li> </ul>

	<ul style="list-style-type: none"> <li>• Hungarian Academy of Sciences</li> <li>• National Institute of Pharmacy and Nutrition</li> </ul>
Sweden	<ul style="list-style-type: none"> <li>• The Swedish Environmental Protection Agency (EPA)</li> </ul>
Switzerland	<ul style="list-style-type: none"> <li>• FOEN: Federal Office for the Environment</li> <li>• IPI: Swiss Federal Institute for Intellectual Property</li> </ul>
Belarus	<ul style="list-style-type: none"> <li>• Institute of Genetics and Cytology, National Academy of Sciences of Belarus</li> </ul>
Albania	<ul style="list-style-type: none"> <li>• Checkpoints on major border crossing points, namely 10 border crossing points in the country.</li> </ul>
Spain	<ul style="list-style-type: none"> <li>• At the stage of research funding</li> <li>• At the stage of final development of a product</li> <li>• At the stage of patent application</li> </ul>

- 15. Please select from the following what activities related to checks on users have been already performed

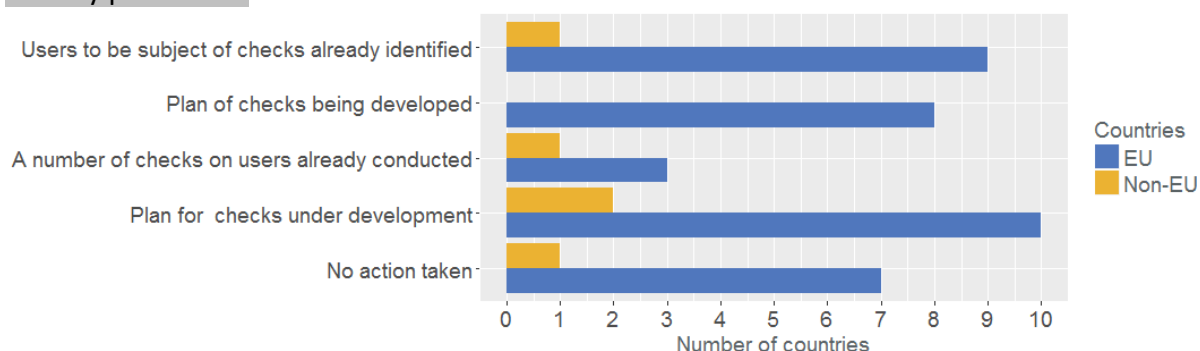


Figure 16. Activities related to checks on users. (MC)

Only 8 countries (30.7%) have not initiated any activities related to monitoring users of genetic resources and associated traditional knowledge that operate within their jurisdiction.

Malta reported that identified potential users will be queried through a mandatory survey; thereafter, a selected number of users will be inspected and interviewed on site to identify the status of compliance.

The monitoring system in Portugal is set in accordance with article 9 of Decree-Law 122/2017, of 21st September. Within the scope of their inspection and oversight responsibilities, a group of entities cooperate with the national competent authority for the purpose of monitoring the application of the ABS regime, namely carrying out checks on compliance in line with Article 9 of EU ABS Regulation. All entities involved (Economic and Food Safety Authority; Tax and Customs Authority; National Republican Guard or Public Security Police, according to their territorial jurisdiction; General-Inspection for Agriculture, Sea, Environment and Spatial Planning; General-Inspection for Education and Science; INFARMED - National Authority of Medicines and Health Products, I.P.; Regional Competent Authority of Azores; Regional Competent Authority of Madeira) must nominate responsible persons for this process before next steps are taken.

Cyprus reported on a study recently undertaken by the Department of Environment, using questionnaires to map the utilization of genetic resources in Cyprus and assess the degree to which users are affected by the ABS Regulation. Based on results from this study, checks on users will be designed in the near future. So far, most industries in Cyprus do not seem to be impacted since their activities do not fall under utilization in the sense of the EU ABS Regulation (pharmaceutical and cosmetics companies do not perform R&D but receive their raw material from other suppliers mostly from the EU countries and simply manufacture new products). The degree to which academia and research institutions in Cyprus are impacted is expected to be clarified with the development by the COM of the guidance document on Research.

In the Netherlands users are partly identified, but changes were observed over time.

Belarus reported that in the framework of the Global project "Strengthening human resources, legal systems and institutional capacities to implement the Nagoya Protocol in the Republic of Belarus" further work is planned to refine the list of holders of genetic resources and holders of traditional knowledge associated with the genetic resources.

Norway reported that although formal checkpoints were not in place yet, the import to Norway for utilization of genetic material from a state that requires consent for collection or export of such material may only take place in accordance with such consent (Nature Diversity Act section 60, first para). The Ministry monitors compliance with these provisions and can impose sanctions (see section 63 and Chapter IX).

In Slovak Republic, Slovak Environmental Inspectorate prepares plan of its work in December every year and this plan is approved by Ministry of Environment. In the next step inspectorate also prepares its quarterly plan of checks. These checks, regularly conducted, are based on prevention approach or information that was received from institutions that play role of checkpoints (especially in case of private companies).

Finland reported on planning to conduct the first checks on users in May 2018.

France pointed out that the first step before conducting checks is to inform and educate users.

#### - 16. Have you established penalties for violation of ABS laws and regulations by users in your jurisdiction?

Most countries have established penalties (Figure 17), only 4 did not in the EU. Six countries have adopted both criminal penalties and administrative sanctions for users for infringement of their obligations (Croatia, Malta, NL, UK, Switzerland and Norway).

In Poland, in the Act of 19 July 2016 on Access to Genetic Resources and Sharing of Benefits Arising from their Utilization, only administrative penalties have been envisaged.

In Slovak Republic, competent authority shall impose penalty for a legal person or an entrepreneur, that may vary from 500 EUR to 100.000 EUR, depending on the type of the offense. For infringement by natural person, competent authority shall impose penalty that may vary from 100 EUR to 2.500 EUR, depending on the offense. If legal or natural person breaks provisions repeatedly, competent authority shall impose penalty up to twice the upper limit of the fines that were established by the legislation. It means up to 200.000 EUR (legal person) or 5.000 EUR (natural person). Remedial actions can be ordered together with fines.

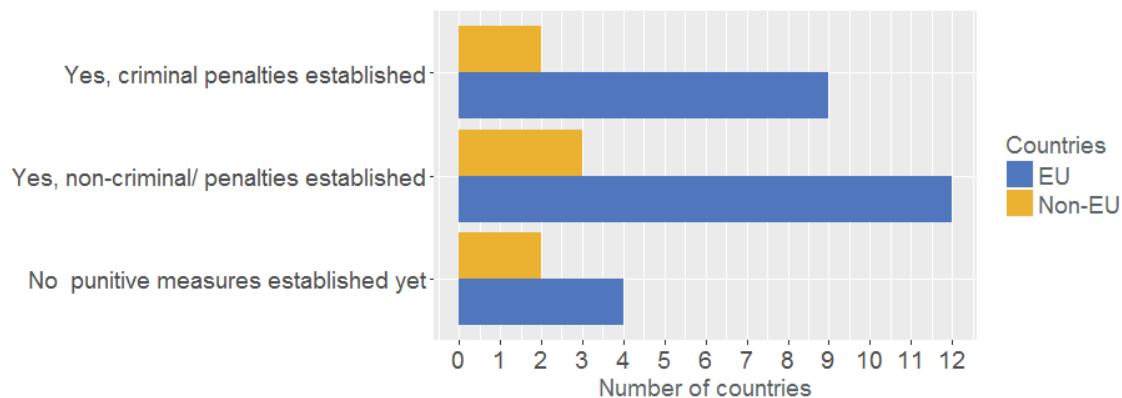


Figure 17. Punitive measures on users.

In Portugal, in accordance with Article 14 of Decree-Law 122/2017, of 21st September, penalties applicable to infringements of Regulation (EU) no. 511/2104 are levelled according to what is established in the Framework Law on Environmental Offences. There are three levels of applicable penalties according to specific infringements:

- Severe environmental offence regarding infringements on:
  - the obligation of exercising due diligence;
  - the obligation of discontinuing utilization when in the possession of insufficient information or when uncertainties persist about the legality of access and utilization;
  - the prohibition of claiming exclusive rights on any developments via the use of pathogens for which no PIC/MAT were obtained/established;
  - the obligation of providing evidence regarding the information provided at checkpoints when so requested by the Competent Authority.
- Medium environmental offence regarding infringements on:
  - the obligation of submitting due diligence declarations by all recipients of research funding;
  - the obligation of submitting due diligence declarations at the stage of final development of a product;
  - the obligation of offering all necessary assistance to facilitate the performance of checks on user compliance;
  - the obligation of complying with the remedial action or measures identified by the competent authority following check on user compliance.
- Light environmental offence regarding infringements on:
  - the obligation of keeping the information relevant to ABS for 20 years after the end of utilization;
  - the obligation of notifying competent authorities regarding any significant changes that influence a collection's capacity to comply with the criteria for inclusion in the register of collections of the Union.

Furthermore, within the scope and possibilities established in the Framework Law on Environmental Offences, Article 15 of Decree-Law 122/2017, of 21st September,

contemplates the possibility of preventive seizure of material and Article 18 the possibility of establishing complementary sanctions.

In Sweden, both criminal penalties and sanction charges are established, if the user does not follow obligations set out in Regulation (EU) No. 511/2014.

In France the maximum fine for failure to report is set as 150.000 EUR; for infringements during commercial use the maximum fine is 1 million EUR and 1 year imprisonment.

In the UK both civil and criminal penalties are established in the national legislation.

- 17. Have you received any due diligence declarations from users of genetic resources in your jurisdiction? and 17. Have you received any information from users of genetic resources in your jurisdiction?

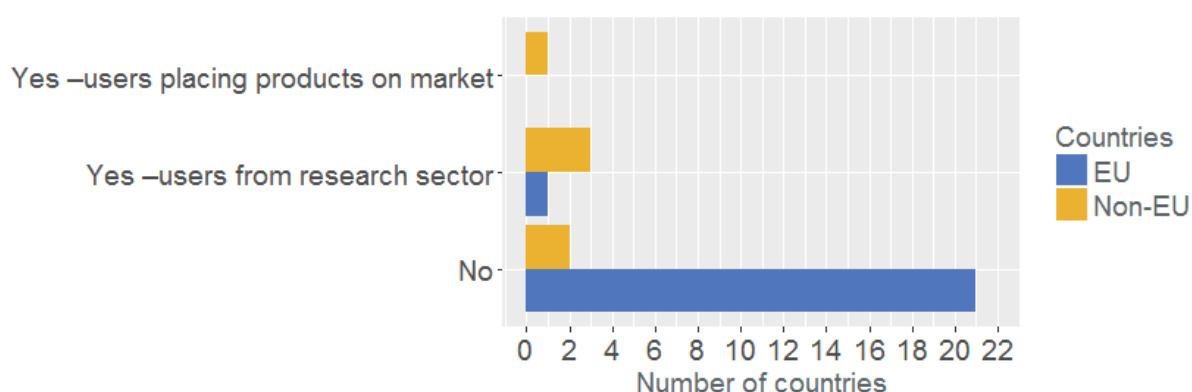


Figure 18. Information from users (in a form of due diligence declaration in the EU MS.

Only four countries reported that their NCA obtained information from user of genetic resources (France, Belarus, Albania and Switzerland (2)). Four cases regarded users in research sector and only one a commercial user.

## V. Other activities to support implementation of the ABS EU legislation and the Nagoya Protocol

- 18. Have you developed measures to enable communication with users on ABS related issues?

Most countries (61.5%) have developed measures to communicate with users of genetic resources and associated traditional knowledge on their obligations resulting from the Nagoya Protocol and EU ABS Reregulation in case of the EU MS. Table 3 provides examples of measures undertaken by countries to communicate with users of genetic resources.

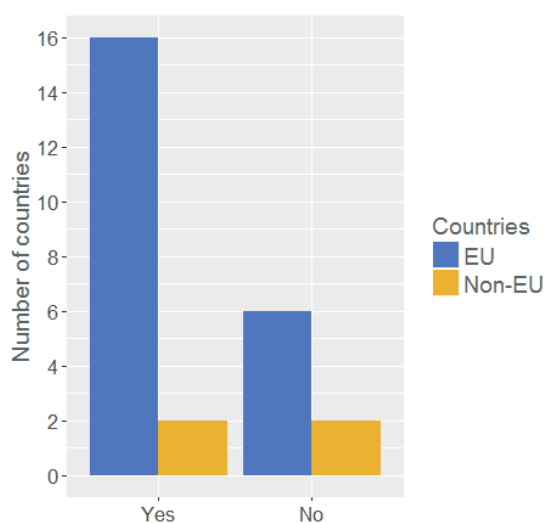


Figure 19. Communication measures for users.

**Table 3.** Communication measures developed by countries on ABS issues.

Country	Communication measures
Albania	Measures on communication are under development
Austria	Communication in the GR Networks (ECPGR – for PGRFA; ERFP for AnGR), EU-Commission working groups
Belarus	National Coordination Centre on Access to Genetic Resources and Benefit-sharing (NCC-ABS) is undertaking consultations for the holders of genetic resources. A national ABS website was designed as the national ABS Clearing-House ( <a href="http://abs.igc.by">http://abs.igc.by</a> ). Information about the provisions of the Nagoya Protocol, the functions and tasks of the NCC-ABS are published at the website of the National Competent Authority (Ministry of Natural Resources and Environmental Protection of the Republic of Belarus). Current information related to the issues of the access to genetic resources and benefit-sharing are regularly published on the website.
Croatia	Currently no measures have been developed to enable communication with users on ABS related issues but there is intention to organize workshops for different target group audience.
Czechia	Communication and awareness-raising activities include, inter alia, meetings and consultations with relevant stakeholders, participating at conferences and workshops, providing information through national clearing-house, direct contact with NFP or information leaflets.
Cyprus	A list of potential users was compiled and further elaborated through the study undertaken recently to map utilization of GR in Cyprus. Potential users were contacted and informed about the

	Regulation via email, official letters and phone communications.
Denmark	Consultations, special website by 2017. Supplemented by workshops and conferences in 2018.
Estonia	Development of relevant questionnaire that was addressed to all possible genetic resources users that included also an informative introduction about the Protocol. Bilateral consultations with universities and info days for different sectors.
EU	Development of sectorial guidance documents, development of an IT tool for submission of due diligence declarations and related information (Manual for users); series of workshops for researchers; participation of EC staff in numerous conferences; direct interaction with stakeholders upon request; information about ABS policy in the EU on the Europa website; support to stakeholders via ABS Consultation Forum.
Finland	Website
France	Different means of communication are used by the national competent authorities: internet (ministries' website, dedicated email address to contact the national competent authority in charge of PIC&MAT), publications, presentations at workshops, conferences with researchers all over French territories, etc.
Germany	Special website, information brochure, information flyer, newsletter, conferences, stakeholder roundtable, etc.
Malta	ABS information is available on the website of the NCA at: [ <a href="https://agriculture.gov.mt/en/phd/Pages/a_WP.aspx">https://agriculture.gov.mt/en/phd/Pages/a_WP.aspx</a> ]; Contact information for the national contact points is available on the same website.
Moldova	The ABS Clearing House published the available information and database on the Moldovan ABS activities. The National Interim Report provides an overview of current state of ABS in the country. The NBSAP 2015-2020, contains planned activities to implement the Nagoya Protocol. It refers especially to development of the legal and procedural norms in accordance with the ABS international law.
Netherlands	Website, national focal point, workshops, survey, stakeholder meetings, presentations during congresses and symposia, visits to users or umbrella organizations.
Poland	Annual conferences, workshops, lectures.
Portugal	No specific measures were taken to enable communication with users. Notwithstanding the NCA website has information on the Nagoya Protocol, on the EU ABS Regulation, on Decree-law 122/2017 and FAQ on ABS. Further, on a weekly basis (2 to 3 emails weekly) the Competent National Authority provides clarifications to requests of information regarding the ABS regime in Portugal. The overwhelming majority of which regards clarifications on the rights and obligations resulting from EU

	Regulation 511/2014 and clarifications regarding the access framework in Portugal.
Spain	Workshops, consultations, website.
Sweden	Information on the Nagoya Protocol and Regulation (EU) No. 511/2014 can be found on the Swedish EPA's website. Users can also send their questions to a specific Nagoya-email address: <a href="mailto:nagoya@naturvardsverket.se">nagoya@naturvardsverket.se</a> . Several seminars, webinars, consultations were organized and users were invited to fill out questionnaires. Posters and brochures have been developed on the subject both in English and Swedish.
Switzerland	All of the above
UK	Both Defra and the NCA have undertaken a large amount of awareness raising – including workshops and publication of articles across a number of relevant sectors, pamphlets have also been produced. The NCA website contains a large amount of guidance for users.

- 19. Have you conducted awareness raising activities to inform users on ABS legislation?

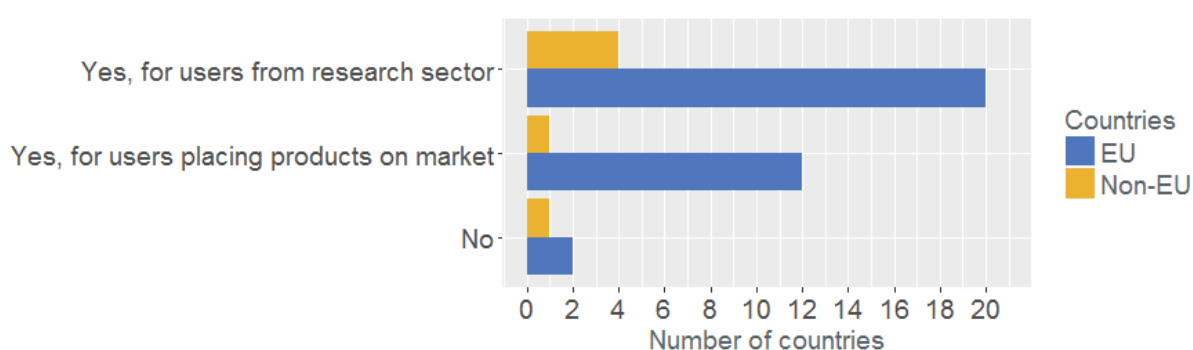


Figure 20. Awareness raising activities for users.

Only three countries (11.1%) were not actively engaged in awareness raising activities among their user communities. All other countries conducted awareness raising activities in research sector and almost half of countries also addresses commercial sectors, where users are expected to put on the market final product, being the outcome of the R&D on genetic resources and associated traditional knowledge.

The examples of specific awareness raising activities being reported by countries are presented in Table 4.

**Table 4.** Examples of awareness raising activities directed towards users of genetic resources and associated traditional knowledge.

Country	Awareness raising activities
Austria	Some workshops and meetings, there are also email-contacts.
Belarus	Article publication in the local scientific journal "Science and Innovations" and the newspaper "Navuka" ("Science").

Bulgaria	International Scientific Conference entitled "State and Perspectives for the Development of Genetic Resources in Livestock", 14-14 December 2012, Hissar
Croatia	So far, awareness raising activities and meetings with presentations have been conducted for the members of inter-sectoral groups in the period proceeding to the ratification of the Nagoya Protocol and some additional activities and meetings have been conducted in the period of preparation of the national Act on Implementation of the Regulation (EU) No 511/2014.
Czechia	Communication and awareness-raising activities include, inter alia, meetings and consultations with relevant stakeholders, participating at conferences and workshops, providing information through national clearing-house, direct contact with NFP or information leaflets.
Denmark	Information provided at website and by mails/ replies directly to the potential users.
EU	The Commission organized series of workshops on ABS addressed to research community (5 workshops in 2015, 4 workshops in 2017). EC staff also took part to multiple events (workshop, seminars, meetings) to explain the obligations stemming from the EU ABS Regulation.
France	Ministries participate to seminars and workshops with users (research sector and companies) to raise awareness.
Germany	Anonymous survey on ABS/NP awareness among potential German users.
Malta	ABS information is available on the website of the NCA at: [ <a href="https://agriculture.gov.mt/en/phd/Pages/a_WP.aspx">https://agriculture.gov.mt/en/phd/Pages/a_WP.aspx</a> ]; Additionally, a guide to help users with obtaining prior informed consent has been made available on the same website and distributed to a near-comprehensive mailing list. Two information posters have been produced and made available to the public by email, on the website and through an international scientific conference in 2017.
Moldova	Informal consultations and meetings on ABS Nagoya Protocol has been held with researchers from the Institute of Botany (Botanical Garden), Institute of Zoology, Institute of Ecology, Institute of Genetics, Plant Physiology and Plant Protection of the Academy of Sciences, as well as State university of Moldova. However, there is a need to organise larger consultation and awareness on specific topics on implementation of the Nagoya Protocol.
Portugal	The NCA was involved in ad hoc initiatives such as a Seminar on "Access and Benefit Sharing: Global and EU Frameworks for access to and utilization of genetic resources" 17th February 2016 at the CCMAR (Centre of Marine Sciences of the University of Algarve - <a href="https://www.ccmар.ualg.pt/">https://www.ccmар.ualg.pt/</a> ), a seminar on the 29th November 2017 in the Research Centre in Biodiversity and Genetic Resources ( <a href="https://cibio.up.pt/about">https://cibio.up.pt/about</a> / <a href="https://cibio.up.pt/seminars-in-biodiversity-and-evolution/details/the-regime-on-the-utilization-of-">https://cibio.up.pt/seminars-in-biodiversity-and-evolution/details/the-regime-on-the-utilization-of-</a>

	genetic-resources-rights-and-obligations-of-users ) with the aim of informing the wider research community of their rights and obligations under the ABS legal framework and a seminar on the 14th November 2017 in the Global Health and Tropical Medicine Institute with the same purpose.
Sweden	The plan during 2018 is to conduct awareness raising activities for users placing products on the market.

- 20. Have you received applications for the registration of domestic ex-situ collection? (EU MS only)

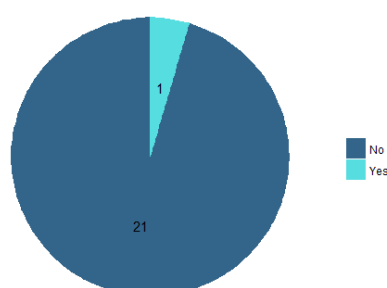


Figure 21. Application for the registration of ex-situ collections.

Only one country, Germany, was involved in the process to assess application for the registration of ex-situ collection. The application was submitted by DSMZ (Leibniz-Institut DSMZ - Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH - Leibniz Institute DSMZ, German Collection of Microorganisms and Cell Cultures) in November 2016. The process was successfully completed and the DSMZ collection became the first one included in the EC register of ex-situ collection

(<https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register%20of%20Collections.pdf>).

Malta reported that the NCA receives applications for the registration of traditional genetic resources for inclusion within the remit of the ABS regulatory system, however these are not the same as the collections to be registered through the process stipulated by Article 5 of the EU ABS Regulation.

France indicated, that although they have not received any application for registration of the collection so far, a process to deal with applications is already in place.

- 21. Have you been involved in the evaluation of applications for recognition of the best practices? (EU MS only)

Only Bulgaria, Germany, Spain and the European Commission have been involved in evaluation of application of the best practices. France has not responded to this question. The organizations that applied for recognition of best practices include: CETAF, organizations of cosmetic sector and cosmetic suppliers.

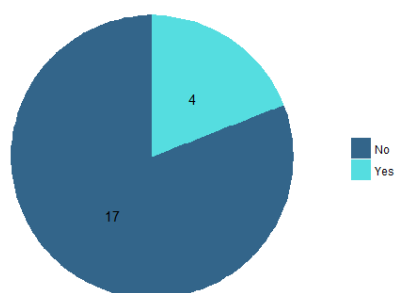


Figure 22. Evaluation of application for recognition of best practices.

So far only CETAF has received EU recognition of best practices (<https://cetaf.org/news/european-commission-recognition-cetaf-code-conduct-and-best-practice-access-and-benefit-sharing>).

22. Have you encountered any specific problems in implementation of the 511/2014 Regulation? and 20. Have you encountered any specific problems in implementation of the Nagoya Protocol?

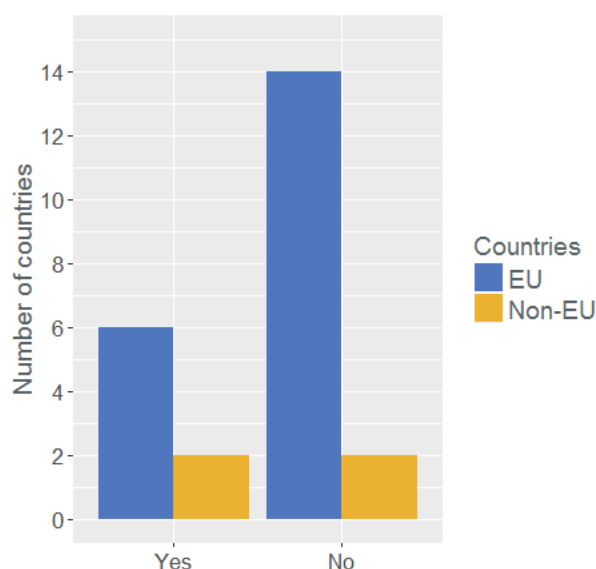


Figure 23. Specific problems related to implementation of the EU ABS Regulation (EU MS) and the Nagoya Protocol.

Three countries have not responded to this question (Austria, Spain, Switzerland). Eight countries indicated that they encountered some problems in implementation either the EU ABS Regulation or the Nagoya Protocol. Austria and Croatia suggested that at early state of implementation it is difficult to identify problems while Spain and Belarus have not encountered any problems so far.

Belgium reported that difficulties in implementation are rather at international than national level, due to a number of unresolved issues. Czechia pointed out a significant delay in adopting ABS national legislation. Estonia reported difficulties in identification of possible

users of genetic resources. Implementation of compliance measures it is even more complicated as the EU ABS sectoral guidelines are not ready yet and there are many gray areas that has made it even more difficult to decide whether some users and/or activities are within the scope of EU ABS Regulation.

European Commission suggested that major problems encountered derive from the difficulties to ensure a uniform interpretation of users' obligations under the EU ABS Regulations, in particular in relation to the terms used by the Protocol and the Regulation which are perceived as not sufficiently clear. Additional guidance is thus needed. In addition, awareness about the ABS is still very low. Finally, the delay by Member States in establishing their Competent Authorities slows down the implementation's efforts.

France reported that the operational implementation of the EU ABS Regulation raises some questions (e.g. : scope) and difficulties (e.g. : lack of relevant information available to develop a risk based analysis for development of plan for checks).

Other problems were related to insufficient human resources that exceeds capacities to conduct extensive awareness-raising for users. Limited human resources and capacities and as well as lack of dedicated financial support to the ABS activities create obstacles for timely and efficient implementation of the provisions of the Nagoya Protocol. The GR users, as domestic as well as external, are not aware or recognise the importance of access to GR and necessity to regulate the benefit sharing (Hungary and Moldova).

Albania pointed out the need for a better cooperation and coordination of the national network of institutions involved in the process to ensure the full implementation of the Nagoya Protocol.

## 5. Other reporting processes

---

### 5.1 Interim National Reports on the Implementation of the Nagoya Protocol

Under Article 29 of the Protocol, Parties were obliged to submit interim national report on the implementation of the Nagoya Protocol twelve months prior to the third meeting of the COP-MOP. In Decision NP-1/3 both Parties and non-Parties were invited to submit to the Secretariat their interim national report no later than 1 November 2017. The reports had to be submitted through the ABS Clearing-House.

Interim national reports were an important source of information for evaluation of the progress in implementation of the Nagoya Protocol. The outcome of this reporting process was considered by the Compliance Committee (April 2018), the second meeting of the Subsidiary Body on Implementation (June 2018), and the third meeting of the COP-MOP (November 2018).

### 5.2 EU reporting process on implementation of the Regulation (EU) no 511/2014

Under Article 16(1) of Regulation EU ABS Regulation Member States were obliged to submit to the Commission a report on the national application of this Regulation by 11 June 2017 and every five years thereafter. The reporting period for this first Implementation Report

was from 12 October 2014 to 31 August 2017. It covered the first three years of application of the EU ABS Regulation, with exemption of application for provisions concerning due diligence (Art. 4), monitoring of user compliance (Art. 7) and compliance checks (Art. 9), that came into force on 12 October 2015, so the reporting period was reduced to two years.

National I reports of all 28 Member States are available on the Commission website: [http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation\\_en.htm](http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm).

### **5.3 Commission report**

Article 16(2) of the EU ABS Regulation requires the Commission to submit to the European Parliament and the Council a report on the application of the Regulation, including an assessment of its effectiveness. The first EU ABS Regulation Implementation Report was adopted on 24 January 2019. It is based on information from the national reports submitted by all 28 Member States to the Commission, as well as other information available. Member States' National Reports are available here:

The Report from the Commission to the European Parliament and the Council on implementation of 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 published on 24<sup>th</sup> January 2019 can be found at: <https://ec.europa.eu/transparency/regdoc/rep/1/2019/EN/COM-2019-13-F1-EN-MAIN-PART-1.PDF>.

It provides information on the status of the implementation of the EU ABS Regulation. the key conclusion was that the Regulation is in its early stage of implementation. Firstly, a number of MS took measures to set up the required institutional and administrative framework to implement the EU ABS Regulation relatively late. Moreover, only a few MS beyond fulfilling the formal requirements of the Regulation have initiated the actual implementation of its specific provisions.

The analysis of the 28 Member States' national reports identified the following challenges in implementation of the EU ABS Regulation:

- different solutions to set up the institutional framework
- consultations and coordination among different administrations resulted in slowing down the process of designation of NCA
- lack or limited human and financial resources allocated for implementation of the EU ABS Regulation
- lack of specialized personnel and qualified experts
- administrative burden and costs implied by the EU ABS Regulation.
- difficulties in identification of potential users and risk factors
- a low level of awareness among stakeholders about the obligations stemming from the Nagoya Protocol and the EU ABS Regulation

The Commission concluded that there seems to be more interest to apply for the recognition of best practices rather than to be included in the Register of Collections. The low level of

interest of collections in becoming a registered collection of the Union may be due to the following reasons:

- 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.

Commission report also recognized that additional efforts are needed to enhance the level of awareness among a wide range of stakeholders, 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.

Commission also reported that valuable cooperation among Member States CAs is increasing, both through CAs informal meetings as well as through the ABS Expert Group. These fora provide good opportunities to exchange views on experiences and challenges in the implementation of the Regulation as well as support a more harmonized implementation.

It is also important to underline that Commission made a lot of efforts to facilitate cooperation among Member States and third countries' CAs for the implementation of the Nagoya Protocol, although it is still a room for improvement.

The Commission will continue to use the existing tools to contribute to a more uniform application of the Regulation across the Member States and facilitate communication through meetings of the relevant Expert Group and Consultation Forum.

It was clear from the report that further efforts from Member States in the implementation and enforcement of the EU ABS Regulation are needed.

## 6. Other sources of information

---

### 6.1 ABS CH

The analysis of the ABS clearing house has been conducted for the 1st September 2019.

The information contained in the ABS CH is presented in four tables (Tables 5 – 8), for European and other countries, either parties or non-Parties to the Nagoya Protocol. The abbreviations in the tables are as follows: ABS National Focal Point (NFP), National Competent Authority (NCA) Legislative, Administrative or Policy Measure (MSR), ABS Procedure (PRO) National Model Contractual Clause (MNCC) Internationally Recognized Certificates of Compliance (IRCC), National Websites or Databases (NDB), Checkpoint (CP), Checkpoint Communiqué (CPC), Interim National Reports on the Implementation of the Nagoya Protocol (NR). For comparison, some general information was also checked at 15th December, 2019.

**Table 5. National records in the ABS CH submitted by the European countries, Parties to the Nagoya Protocol as of 1st September 2019**

	Country	NFP	CNA	MSR	PRO	NMCC	IRCC	NDB	CP	CPC	NR
1	Albania	1	1	2	0	0	0	0	0	0	1
2	Austria	1	1	2	0	0	0	2	0	0	1
3	Belarus	1	2	6	2	0	7	1	1	0	1
4	Belgium	1	2	2	0	0	0	1	0	0	1
5	Bulgaria	1	1	1	0	0	3	1	1	0	1
6	Croatia	1	1	1	0	0	0	0	0	0	0
7	Czech Republic	1	1	1	0	0	0	1	1	0	1
8	Denmark	1	1	2	0	0	0	2	1	4	1
9	Estonia	1	2	1	0	0	0	0	0	0	1
10	Finland	1	2	1	0	0	0	1	2	0	1
11	France	1	2	4	0	0	171	3	2	0	1
12	Germany	1	1	3	0	0	0	1	1	3	1
13	Hungary	1	1	2	0	0	0	1	4	0	1
14	Luxembourg	1	0	0	0	0	0	0	0	0	0
15	Malta	1	1	1	0	0	1	1	1	1	1
16	Netherlands	1	1	3	0	0	0	1	1	0	1
17	Norway	1	1	6	0	0	0	0	0	0	1
18	Portugal	1	1	1	0	0	0	4	1	0	1
19	Republic of Moldova	1	1	3	0	0	0	0	0	0	1
20	Romania	1	0	0	0	0	0	0	0	0	0
21	Serbia	1	1	1	0	0	0	0	0	0	0
22	Slovakia	1	1	1	0	0	0	0	6	0	1
23	Spain	1	20	2	0	0	43	1	1	0	1
24	Sweden	1	1	3	0	0	0	1	1	0	1
25	Switzerland	1	1	3	0	0	0	1	2	0	1
26	United Kingdom of Great Britain and Northern Ireland	1	1	1	0	0	0	0	1	0	1

**Table 6. National records in the ABS CH submitted by the European countries, Non-Parties to the Nagoya Protocol as of 1st September 2019**

	Country	NFP	NCA	MRS	PRO	NMCC	IRCC	NDB	CP	CPC	NR
1	Andorra	0	0	0	0	0	0	0	0	0	0
2	Bosnia and Herzegovina	1	0	0	0	0	0	0	0	0	0
3	Cyprus	1	0	0	0	0	0	0	0	0	0
4	Greece	0	0	0	0	0	0	0	0	0	0
5	Holy See	0	0	0	0	0	0	0	0	0	0
6	Iceland	0	0	0	0	0	0	0	0	0	0

7	Ireland	1	0	0	0	0	0	0	0	0	0
8	Italy	0	0	0	0	0	0	0	0	0	0
9	Latvia	1	0	0	0	0	0	0	0	0	0
10	Liechtenstein	0	0	0	0	0	0	0	0	0	0
11	Lithuania	1	0	0	0	0	0	0	0	0	0
12	Monaco	0	0	0	0	0	0	0	0	0	0
13	Montenegro	1	0	0	0	0	0	0	0	0	0
14	Poland	1	1	1	0	0	0	0	1	0	1
15	Russian Federation	0	0	0	0	0	0	0	0	0	0
16	San Marino	0	0	0	0	0	0	0	0	0	0
17	Slovenia	1	0	0	0	0	0	0	0	0	0
18	The Republic of North Macedonia	1	0	0	0	0	0	0	0	0	0

**Table 7. National records in the ABS CH submitted by the other countries, Parties to the Nagoya Protocol as of 1st September 2019**

-	Country	Regions	NFP	NCA	MRS	PRO	NMCC	IRCC	NDB	CP	CPC	NR
1	Afghanistan	Asia	1	0	0	0	0	0	0	0	0	0
2	Angola	Africa	1	0	0	0	0	0	0	0	0	1
3	Antigua and Barbuda	Americas	1	1	2	0	0	0	0	0	0	1
4	Argentina	Americas	1	0	0	0	0	0	0	0	0	1
5	Benin	Africa	1	1	2	0	0	0	0	0	0	1
6	Bhutan	Asia	1	1	2	0	0	0	0	3	0	1
7	Bolivia (Plurinational State of)	Americas	1	0	0	0	0	0	0	0	0	0
8	Botswana	Africa	1	0	0	0	0	0	0	0	0	1
9	Burkina Faso	Africa	1	0	2	0	0	0	1	0	0	1
10	Burundi	Africa	1	1	4	0	0	0	1	0	0	1
11	Cambodia	Asia	1	1	0	0	0	0	0	0	0	1
12	Cameroon	Africa	1	0	3	1	0	0	1	0	0	1
13	Central African Republic	Africa	1	0	0	0	0	0	0	0	0	0
14	Chad	Africa	1	0	0	0	0	0	0	0	0	0
15	China	Asia	1	0	0	0	0	0	0	0	0	1
16	Comoros	Africa	1	1	0	0	0	0	0	0	0	1
17	Congo	Africa	1	0	1	0	0	0	0	0	0	1
18	Cuba	Americas	1	0	0	0	0	0	0	0	0	1
19	Côte d'Ivoire	Africa	1	1	7	0	0	0	0	0	0	1
20	Democratic Republic of the Congo	Africa	1	1	1	0	0	0	0	0	0	1

21	Djibouti	Africa	1	0	0	0	0	0	0	0	0	0
22	Dominican Republic	Americas	1	2	7	0	0	2	1	2	0	1
23	Ecuador	Americas	1	4	6	0	0	0	0	0	0	0
24	Egypt	Africa	1	0	0	0	0	0	0	0	0	1
25	Eswatini	Africa	1	1	0	0	0	0	0	0	0	1
26	Ethiopia	Africa	1	1	1	0	0	0	0	0	0	1
27	Fiji	Oceania	1	0	0	0	0	0	0	0	0	0
28	Gabon	Africa	1	0	0	0	0	0	0	0	0	1
29	Gambia (the)	Africa	1	1	0	0	0	0	0	0	0	1
30	Guatemala	Americas	1	1	7	0	0	2	1	0	0	1
31	Guinea	Africa	1	0	0	0	0	0	0	0	0	1
32	Guinea-Bissau	Africa	1	1	0	0	0	0	0	0	0	1
33	Guyana	Americas	1	1	0	0	0	0	0	0	0	1
34	Honduras	Americas	1	1	11	0	0	0	2	0	0	1
35	India	Asia	1	1	29	1	0	220	0	0	0	1
36	Indonesia	Asia	1	0	0	0	0	0	0	0	0	0
37	Japan	Asia	1	0	2	0	0	0	1	1	2	1
38	Jordan	Asia	1	0	0	0	0	0	0	0	0	0
39	Kazakhstan	Asia	1	0	0	0	0	0	0	0	0	1
40	Kenya	Africa	1	1	11	1	0	38	1	9	0	1
41	Kuwait	Asia	1	0	0	0	0	0	0	0	0	1
42	Kyrgyzstan	Asia	1	0	0	0	0	0	0	0	0	1
43	Lao People's Democratic Republic	Asia	1	1	2	0	0	5	0	0	0	1
44	Lebanon	Asia	1	0	0	0	0	0	0	0	0	0
45	Lesotho	Africa	1	0	0	0	0	0	0	0	0	0
46	Liberia	Africa	1	0	0	0	0	0	0	0	0	1
47	Madagascar	Africa	1	1	2	0	0	0	1	0	0	1
48	Malawi	Africa	1	1	1	0	0	0	0	0	0	1
49	Malaysia	Asia	1	0	0	0	0	0	0	0	0	0
50	Mali	Africa	1	0	0	0	0	0	0	0	0	1
51	Marshall Islands	Oceania	1	0	0	0	0	0	0	0	0	0
52	Mauritania	Africa	1	1	7	0	0	0	0	5	0	1
53	Mauritius	Africa	1	0	0	0	0	0	0	0	0	0
54	Mexico	Americas	1	6	22	0	0	8	0	0	0	1
55	Micronesia (Federated States of)	Oceania	1	0	0	0	0	0	0	0	0	0
56	Mongolia	Asia	1	0	0	0	0	0	0	0	0	1
57	Mozambique	Africa	1	0	0	0	0	0	0	0	0	1
58	Myanmar	Asia	1	0	0	0	0	0	0	0	0	1
59	Namibia	Africa	1	0	0	0	0	0	0	0	0	0
60	Nepal	Asia	1	0	0	0	0	0	0	0	0	0

61	Niger	Africa	1	0	7	0	0	0	2	0	0	1
62	Pakistan	Asia	1	0	0	0	0	0	0	0	0	1
63	Palau	Oceania	1	0	0	0	0	0	0	0	0	0
64	Panama	Americas	1	1	1	0	0	19	0	0	0	1
65	Peru	Americas	1	5	10	0	0	5	3	2	0	1
66	Philippines	Asia	1	0	0	0	0	0	0	0	0	1
67	Qatar	Asia	1	1	1	0	0	0	1	1	1	1
68	Republic of Korea	Asia	1	0	3	0	0	0	0	0	0	1
69	Rwanda	Africa	1	0	0	0	0	0	0	0	0	1
70	Saint Kitts and Nevis	Americas	1	1	0	0	0	0	0	0	0	0
71	Samoa	Oceania	1	0	0	0	0	0	0	0	0	1
72	Sao Tome and Principe	Africa	1	1	0	0	0	0	0	0	0	1
73	Senegal	Africa	1	0	1	0	0	0	0	0	0	1
74	Seychelles	Africa	1	1	0	0	0	0	0	0	0	1
75	Sierra Leone	Africa	1	0	0	0	0	0	0	0	0	1
76	South Africa	Africa	1	1	3	0	0	28	1	1	0	1
77	Sudan	Africa	1	0	2	0	0	0	0	0	0	1
78	Syrian Arab Republic	Asia	1	4	0	0	0	0	0	0	0	0
79	Tajikistan	Asia	1	1	0	0	0	0	1	0	0	1
80	Togo	Africa	1	0	3	0	0	0	0	0	0	1
81	Tuvalu	Oceania	1	0	0	0	0	0	0	0	0	0
82	Uganda	Africa	1	1	1	0	0	0	1	0	0	1
83	United Arab Emirates	Asia	1	0	0	0	0	0	0	0	0	0
84	United Republic of Tanzania	Africa	1	0	0	0	0	0	0	0	0	0
85	Uruguay	Americas	1	1	2	0	0	2	1	0	0	1
86	Vanuatu	Oceania	1	0	0	0	0	0	0	0	0	0
87	Venezuela (Bolivarian Republic of)	Americas	1	1	0	0	0	0	1	0	0	1
88	Viet Nam	Asia	1	2	5	0	0	28	0	0	0	1
89	Zambia	Africa	1	0	0	0	0	0	0	0	0	1
90	Zimbabwe	Africa	1	3	2	1	0	0	1	0	0	0

**Table 8. National records in the ABS CH submitted by the other countries,  
Non-Parties to the Nagoya Protocol as of 1st September 2019**

	Country	Regions	NFP	NCA	MRS	PRO	NMCC	IRCC	NDB	CP	CPC	NR
1	Algeria	Africa	1	0	0	0	0	0	0	0	0	0
2	Armenia	Asia	1	0	0	0	0	0	0	0	0	0
3	Australia	Oceania	1	0	0	0	0	0	0	0	0	0
4	Azerbaijan	Asia	1	0	0	0	0	0	0	0	0	0
5	Bahamas	Americas	0	0	0	0	0	0	0	0	0	0
6	Bahrain	Asia	1	0	0	0	0	0	0	0	0	0
7	Bangladesh	Asia	1	0	0	0	0	0	0	0	0	0
8	Barbados	Americas	1	0	0	0	0	0	0	0	0	1
9	Belize	Americas	0	0	0	0	0	0	0	0	0	0
10	Brazil	Americas	1	1	3	0	0	0	0	0	0	0
11	Brunei Darussalam	Asia	0	0	0	0	0	0	0	0	0	0
12	Cabo Verde	Africa	1	0	0	0	0	0	0	0	0	0
13	Canada	Americas	1	0	0	0	0	0	0	0	0	0
14	Chile	Americas	1	0	0	0	0	0	0	0	0	0
15	Colombia	Americas	1	0	0	0	0	0	0	0	0	0
16	Cook Islands	Oceania	1	0	0	0	0	0	0	0	0	0
17	Costa Rica	Americas	1	1	4	0	0	0	2	0	0	0
18	Democratic People's Republic of Korea	Asia	1	0	0	0	0	0	0	0	0	0
19	Dominica	Americas	1	0	0	0	0	0	0	0	0	0
20	El Salvador	Americas	0	0	0	0	0	0	0	0	0	0
21	Equatorial Guinea	Africa	1	0	0	0	0	0	0	0	0	0
22	Eritrea	Africa	0	0	0	0	0	0	0	0	0	0
23	Georgia	Asia	0	0	0	0	0	0	0	0	0	0
24	Ghana	Africa	1	0	0	0	0	0	0	0	0	0
25	Grenada	Americas	1	1	0	0	0	0	0	0	0	0
26	Haiti	Americas	1	0	0	0	0	0	0	0	0	0
27	Iran (Islamic Republic of)	Asia	1	0	0	0	0	0	0	0	0	0
28	Iraq	Asia	1	0	0	0	0	0	0	0	0	0
29	Israel	Asia	1	0	0	0	0	0	0	0	0	0
30	Jamaica	Americas	1	0	0	0	0	0	0	0	0	0
31	Kiribati	Oceania	1	0	0	0	0	0	0	0	0	0
32	Libya	Africa	1	0	0	0	0	0	0	0	0	0
33	Maldives	Asia	1	0	0	0	0	0	0	0	0	0
34	Morocco	Africa	1	0	1	0	0	0	1	0	0	1
35	Nauru	Oceania	0	0	0	0	0	0	0	0	0	0
36	New Zealand	Oceania	1	0	0	0	0	0	0	0	0	0
37	Nicaragua	Americas	0	0	0	0	0	0	0	0	0	0

38	Nigeria	Africa	1	0	0	0	0	0	0	0	0	1
39	Niue	Oceania	1	0	0	0	0	0	0	0	0	0
40	Oman	Asia	1	0	0	0	0	0	0	0	0	0
41	Papua New Guinea	Oceania	1	0	0	0	0	0	0	0	0	0
42	Paraguay	Americas	0	0	0	0	0	0	0	0	0	0
43	Saint Lucia	Americas	1	0	0	0	0	0	0	0	0	0
44	Saint Vincent and the Grenadines	Americas	1	0	0	0	0	0	0	0	0	0
45	Saudi Arabia	Asia	1	0	0	0	0	0	0	0	0	0
46	Singapore	Asia	1	1	0	0	0	0	0	0	0	0
47	Solomon Islands	Oceania	0	0	0	0	0	0	0	0	0	0
48	Somalia	Africa	1	0	0	0	0	0	0	0	0	0
49	South Sudan	Africa	0	0	0	0	0	0	0	0	0	0
50	Sri Lanka	Asia	1	0	0	0	0	0	0	0	0	0
51	State of Palestine	Asia	0	0	0	0	0	0	0	0	0	0
52	Suriname	Americas	0	0	0	0	0	0	0	0	0	0
53	Thailand	Asia	1	0	0	0	0	0	0	0	0	0
54	Timor-Leste	Asia	1	0	0	0	0	0	0	0	0	0
55	Tonga	Oceania	0	0	0	0	0	0	0	0	0	0
56	Trinidad and Tobago	Americas	0	0	0	0	0	0	0	0	0	0
57	Tunisia	Africa	1	0	0	0	0	0	0	0	0	0
58	Turkey	Asia	1	0	0	0	0	0	0	0	0	0
59	Turkmenistan	Asia	0	0	0	0	0	0	0	0	0	0
60	United States of America	Americas	1	0	0	0	0	0	0	0	0	0
61	Uzbekistan	Asia	1	0	0	0	0	0	0	0	0	0
62	Yemen	Asia	1	0	0	0	0	0	0	0	0	0

In general, the information contained in the ABS CH is still far from being complete. On 1st September only 64 countries provided information on their national ABS legislation, and till 15th December only one more has added such vital information, vital for users of genetic resources (Table 9). It is important to underline, that among these 65 countries providing information on their ABS access measures some are yet non-Parties to the Nagoya Protocol, e.g. (Brazil and Poland). It highlights that many of Parties to the Nagoya Protocol (as for 15th December 120 +3) are not fulfilling their obligations arising from the Article 14: The Access and Benefit-Sharing Clearing-House and Information-Sharing as well as Articles 6 and 7. Moreover, many documents posted at ABS CH are in local languages, or in one of the UN official languages and EN official/courtesy translation is not always provided what imposes additional difficulty.

Therefore potential users are often forced to look for other sources of information, one of the best being the Interim National Reports on the Implementation of the Nagoya Protocol, submitted by countries to the Secretariat of the Convention on Biological Diversity.

Table 9. Comparison of data published on ABS CH as of 1st September and 11th November.

	Sept 1st		Nov 11th	
	Number of records published	Number of governments who have published	Number of records published	Number of governments who have published
<b>ABS National Focal Point</b>	<b>173</b>	<b>173</b>	<b>174</b>	<b>173</b>
<b>National Competent Authority</b>	<b>110</b>	<b>67</b>	<b>116</b>	<b>69</b>
<b>Legislative, Administrative or Policy Measure</b>	<b>238</b>	<b>64</b>	<b>245</b>	<b>65</b>
<b>ABS Procedure</b>	<b>6</b>	<b>5</b>	<b>9</b>	<b>8</b>
<b>National Model Contractual Clause</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>
<b>Internationally Recognized Certificates of Compliance</b>	<b>582</b>	<b>16</b>	<b>1123</b>	<b>19</b>
<b>National Websites or Databases</b>	<b>48</b>	<b>36</b>	<b>48</b>	<b>36</b>
<b>Checkpoint</b>	<b>52</b>	<b>25</b>	<b>57</b>	<b>26</b>
<b>Checkpoint Communiqué</b>	<b>11</b>	<b>5</b>	<b>15</b>	<b>5</b>
<b>Interim National Reports on the Implementation of the Nagoya Protocol</b>	<b>92</b>	<b>92</b>	<b>95</b>	<b>95</b>

The Interim Report contains a specific section on *Legislative, administrative or policy measures on access and benefit sharing (ABS measures)* that includes the following questions:

11. Is access to genetic resources subject to PIC as provided in Article 6.1?
12. Does your country have fair and non-arbitrary rules and procedures on accessing genetic resources as provided in Article 6.3 (b)?
13. Does your country provide information on how to apply for PIC as provided in Article 6.3(c)?
14. Does your country provide for a clear and transparent written decision by a competent national authority as provided in Article 6.3 (d)?
15. Does your country provide for the issuance at the time of access of a permit or its equivalent as provided in Article 6.3 (e)?
16. Please provide the number of permits or their equivalents made available through the ABS-Clearing-House since the entry into force of the Protocol for your country.
17. Does your country have rules and procedures for requiring and establishing MAT as provided in Article 6.3 (g)?
18. Benefits received since entry into force of the Protocol for your country from the utilization of genetic resources

Responses contained in this section might be very informative for the user considering access to genetic resources from a given country. Another set of questions regards the fair and equitable benefit sharing (Article 5). However, some countries that have provided Interim National Report, are not yet the Parties to the Nagoya Protocol.

So the only other option for the potential user is to contact directly the ABS National Focal Point/National Competent Authorities of the country of interest to learn about its national legislation. This solution sometimes does not work as well.

Since the Nagoya Protocol entered into force, the number of Internationally Recognized Certificates of Compliance (IRCC) was growing very fast (Figure 24). The first IRCC was issued by the government of India for the PhD student for accessing ethno-medicinal knowledge of the Siddi Community from Gujarat for research. The permit was issued on 27th March 2015 and was valid for 3 years, its unique number is: **ABSCH-IRCC-IN-204353-1**.

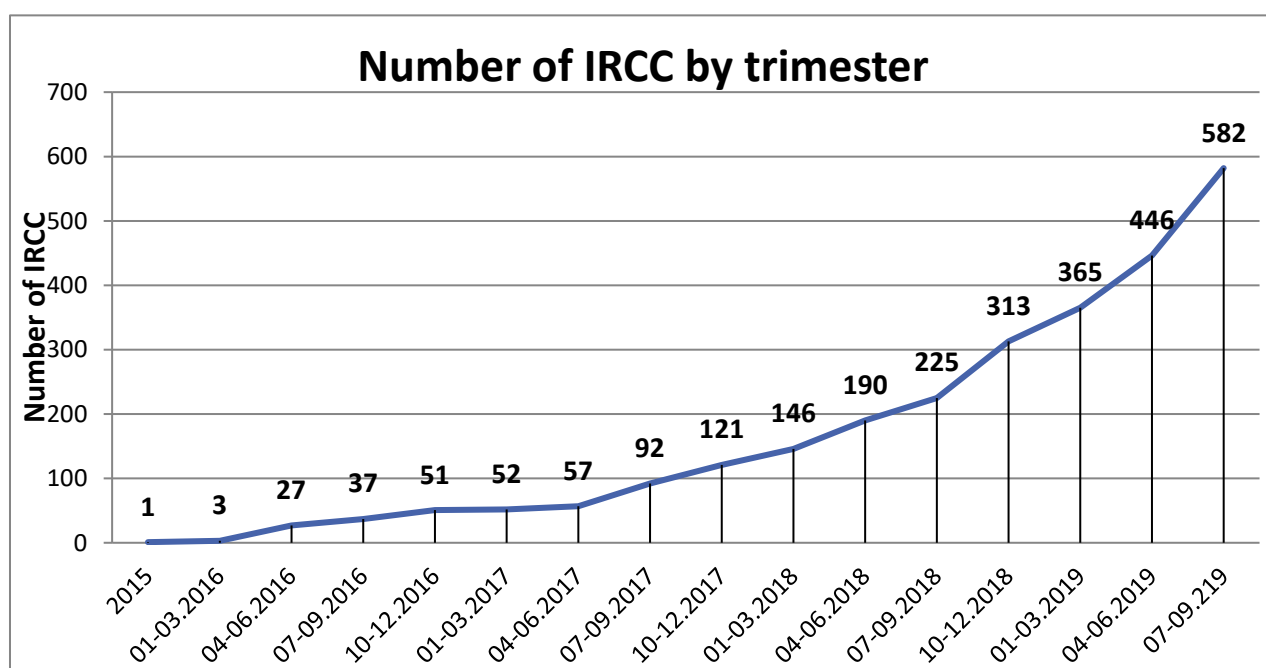


Figure 24. Trend in issuing the IRCC from 2015 until 1st September 2019.

The increase in the number of IRCC was very dynamic and fast, especially in the last three months, when from 1st September 2019 till 15th December 2019 its number almost doubled (+ 541 IRCC). However, it is most important that currently only 19 Parties to the Nagoya Protocol (8%) have established domestic institutional framework to issue IRCC. These group include, as for 15th December 2019: Belarus (7), Bulgaria (3), Dominican Republic (2), Ethiopia (1), France (173), Guatemala(2), Guyana (5), India (741), Kenya(38), Lao PDR (6), Malta (1), Mexico (8), Panama (19), Peru (6), South Africa (29), Spain (50), Uruguay (2) and Viet Nam (30). A distribution of IRCC being issued by Parties is very uneven, from 1 to 741. Three most active Parties to the Nagoya Protocol have issued jointly almost 86% of all IRCC while the remaining 16 Parties, with capacities to do so, only 14%.

It is important to realize that the high number of IRCC comes from the fact that Parties to the Nagoya Protocol require that both domestic users/entities and the foreign ones have to obtain PIC to access genetic resources and have to establish MAT. The number of IRCC issued for domestic users is high and it cause some confusion in interpretation and disturb the picture how ABS measures are implemented in case when provider and user are from different countries.

A detailed analysis of data on 1st September 2019 shows the distribution of genetic resources being the subject of IRCCs (Table 10). In many cases (153) such information was not provided due to confidentiality. The most IRCC were issued for plant genetic resources (31.9% of all known types of genetic resources) microbes and fungi (21.7%), invertebrates (12.6 %) while only 15.9% for vertebrate animals. Only 2 IRCC were related to Traditional Knowledge, while 58 covered species from different systematic groups.

Table 10. The type of genetic resources being a subject of IRCC

	BY	BG	DO	FR	GT	IN	KE	LA	MT	MX	PA	PE	ZA	ES	UY	VN	Sum
Plants	3	1		31	2	48	2	1	1	6	6	3	24	9		10	137
Fungi				13		8	1							2			24
Microbes				30		7	4	1		1	1	1		16	2	6	69
Invertebrates		1	2	35		4	4				4			4		9	54
Fish	1			9							5					1	15
Amphibians				5		1											6
Reptiles				6									1			1	7
Birds	2	1		4		1	6										14
Mammals				9		1	12				3		1			1	26
Traditional knowledge						2											2
Confidential/no information						142		2		1				8			153
Mix	1			29		6	9	1				1	2	4			53
Sum	7	3	2	171	2	220	38	5	1	8	19	5	28	43	2	28	582

Out of the analysed 582 IRCC only 15 have mentioned that genetic resources have been accessed from ex-situ genebank. None of them had specified animal genetic resources neither wild nor domesticated as obtained from the genebank. It proves that animal genebanks are still rare in Provider countries and also that access to genetic resources is granted mainly for in-situ acquisition.

IRCC	Country	Type of use	Genetic resources	Issue date
BY-239176-1	Belarus	Non-Commercial	Plants; Ex-situ; Agricultural areas	23 Jan 2018
IN-206802-1	India	Commercial	Microorganism	05 Apr 2016
IN-206825-1	India	Commercial	Microorganism; Fungi	06 Apr 2016
IN-208306-1	India	Commercial	Microorganism; Fungi	22 Nov 2016
IN-208309-1	India	Non-Commercial	Plants	22 Nov 2016
IN-237807-1	India	Non-Commercial	Plants	12 Jul 2017
IN-240468-1	India	Non-Commercial	Plants	29 Jun 2018
IN-240473-1	India	Non-Commercial	All types of genetic resources	29 Jun 2018
IN-241114-1	India	Commercial	Microorganism	14 Nov 2018
IN-241115-1	India	Commercial; Non- Commercial	Fungi	14 Nov 2018
MX-208823-1	Mexico	Non-Commercial	Plants; Domesticated species and/or cultivated species; Ex-situ	28 Feb 2017
MX-240640-1	Mexico	Non-Commercial	Plants; Wild species	02 Aug 2018
MX-240822-1	Mexico	Non-Commercial	Plants	20 Sep 2018
MX-241563-1	Mexico	Non-Commercial	Plants; Domesticated species and/or cultivated species; Agricultural areas	08 Jan 2019
LA-242860-1	Lao	Non-Commercial	Microorganism	21 Feb 2019

## 6.2 Workshops with Provider countries

Other important sources of information are coming from direct meetings with representatives of the Provider countries. The EU organized a few ABS meetings/ workshops with Provider countries, important one on 21 - 23 November 2017 (PP available at [https://ec.europa.eu/environment/nature/biodiversity/international/abs/ec\\_abs\\_workshop\\_november\\_2017/index\\_en.htm](https://ec.europa.eu/environment/nature/biodiversity/international/abs/ec_abs_workshop_november_2017/index_en.htm)).

Partners from Provider countries were invited to present in details their access measures and describe practicalities related to implementation their national legislation. Also, users and EU Competent National Authorities were invited to share their perspectives and views on presented approaches and solutions.

Similar initiative was taken by the Government of Germany, organizing two workshops, described as Vilm ABS Dialogue: Informing about Domestic Measures for Access to Genetic Resources. The meetings were organized on behalf of the Nagoya NCA by the German Federal Agency for Nature Conservation (BfN). The workshops took place at the Isle of Vilm, Baltic Sea, at the International Academy for Nature Conservation. The first one was organized on 27 - 31 August, 2017 and the second on 10-14th September 2018. To identify countries that already have clear and structured transparent access procedures in place, BfN commissioned an overview study to guide the selection of Provider countries that have structured, clear, and transparent access measures in place.

The objective of the meetings was to facilitate information sharing by representatives of Provider countries on their legal ABS requirements and the European NCA. The ultimate goal was to enable the end the users of genetic resources within the Union to be better informed by their NCA and to support legal certainty of users.

One of the discussed implementation challenges was the availability of transparent and reliable national access regulations in Provider countries. The ABS Clearing House, should play a role of the key tool for information exchange to enhance legal certainty, clarity, and transparency on procedures for access to genetic resources. Unfortunately, the ABS CH is not yet sufficiently populated and thus does not allow users to obtain relevant information for the vast majority of countries.

Just to give an example: as of 15th December of 2019 Colombia was not yet a Party to the Nagoya Protocol, and the only information posted on ABS CH from this country is information on ABS National Focal Point. Colombia has not provided Interim report either. However, during the workshop organized by the European Commission “Advancing implementation of the Nagoya Protocol, Brussels. 21.11-23.11.2017” the representative of Columbia presented well established and operational national law on Access to Genetic Resources and their Derivatives in Colombia that has been developed over a number of years, based on the Andean Decision 391 of 1996. In 2017 the implementation of this law already resulted in 154 Access Agreements to Genetic Resources and their Derivative Products and 14 patents.

The steps in development of the legal ABS framework in Colombia included:

- 1994 CBD Law 165/94
- 1996 Andean Decision 391
- 2011 Decree 3570: competences of MADS dependences
- 2012 Creation of the group of genetic resources
- 2013 Decrees 1375, 1376, Today Decree 1076 of 2015
- 2014 Resolution 1348: define activities that imply access
- 2015 Manual for requesting the contract for access to genetic resources and their derivative products
- 2015 Law 1753 NDP: update legal
- 2017 Resolution 1352 Modify the Resolution 1348 de 2014

The Manual for users to request the contract for access to genetic resources and their derivative products is available at <http://www.minambiente.gov.co/index.php/bosques-biodiversidad-y-servicios-ecosistematicos/recursos-geneticos/recursos-geneticos#documentos-de-interés>, but in order to find it the user should enter the website of the Ministry [www.minambiente.gov.co](http://www.minambiente.gov.co) and then follow the number of steps:

“Temáticas”.

“Bosques, Biodiversidad y Servicios Ecosistémicos”.

“Recursos genéticos”.

“Documentos de interés”.

“Manual de Solicitud del Contrato de Acceso a Recursos Genéticos y sus Productos Derivados en Colombia”.

It is clear that for a user who does not speak Spanish it is very difficult to find necessary information and be able to learn about legal ABS requirements of Columbia. As was shown by the example of Colombia, the information provided by representatives of Provider countries during various events might be the only source of initial information on ABS measures of a given country. Such information should be verified by the National Focal Point on ABS as the official source of information. In the case of IMAGE, partner AgroSavia was in charge of checking compliance, as described in D9.1.

## 7. Pending issues

---

The ABS issues are in the centre of political debate at the international fora; at present they are discussed in the process of preparation of the Post 2020 Biodiversity Framework. The Fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-sharing (COP/MOP4 of the Nagoya Protocol) and Fifteenth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP-CBD 15) will take place 15 - 29 October 2020 in Kunming, China. The key ABS related elements to be discussed at these meetings include DSI (Digital Sequence Information) on genetic resources, mainly the DNA information. The main issue is related to benefit sharing obligations resulting from utilisation of DNA information on genetic resources.

Another issue for further discussion by the Parties of the Nagoya Protocol is potential establishment of the Global Multilateral Benefit Sharing Mechanism (Article 10 of the Protocol). Those two issues, DSI and Article 10 might be linked in discussion and potential decisions.

At FAO forum, the ABS has been discussed in relation to Genetic Resources for Food and Agriculture (GRFA) since 2007. A successful completion of the voluntary guidelines called *ABS Elements: Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture* by the Team of Technical and Legal Experts on ABS established by the Commission on Genetic Resources for Food and Agriculture (CGRFA) and its further adoption by the CGRFA draw attention to specific characteristics of the GRFA while developing national ABS legislation.

The recognition of the specific and unique characteristics of sub-sectors of GRFA during the 16<sup>th</sup> session of the CGRFA led to the decision of expanding ABS Elements by so called “explanatory notes”, providing insights into various aspects of ABS in sub-sectors of GRFA. These ABS Elements with explanatory notes were adopted by the CGRFA in 2019 and recently published (FAO, 2019a). Such development is in line with suggestions made in the survey for NFP/NCA conducted in Task 1.3. Additional information provided to Q 8: *Suggestion to expand ABS Elements*, included views that document is very general, and still needs further development, and more detailed guidelines for sub-sectors would be helpful.

The current work on ABS by the CGRFA will concentrate on sharing information on existing legislative, administrative and policy approaches, including best practices for ABS for the different subsectors of GRFA and traditional knowledge associated with GRFA held by indigenous peoples and local communities with the aim of identifying typical approaches and lessons learned from their implementation, as well as challenges and possible solutions (FAO, 2019b). The CGRFA Secretariat will initiate a survey to gather information on these issues from FAO Member states.

Another important developments regarding ABS are taking place at the EU level. The adoption of the EU ABS Regulation (2014) and Implementing Regulation (European Commission, 2015) led to development of Horizontal guidelines on the scope of application and core obligations of Regulation (EU) No 511/2014 (European Commission, 2016).

The need to support users of genetic resources and traditional knowledge associated with genetic resources in the Union encouraged the European Commission to prepare sectoral guidance documents for seven sectors: animal breeding, plant breeding, food and feed, biocontrol and bio- stimulants, pharmaceuticals, cosmetics and biotechnology. The draft guidance documents were developed by the Guidance Development Groups and subsequently discussed during sectoral workshops, with stakeholders and representatives of the Member States. The documents were further discussed by the ABS Expert Group and the Consultation Forum.

In 2017, the need for additional guidance documents for upstream users (research sector and collection holders) was identified, and work on them had been initiated. The key elements of each guidance documents were so called “case studies” describing specific situation/activity performed by the user. The description was followed by an analysis leading to the conclusion if a given activity is in the scope of the EU ABS Regulation or not. As a number of crosscutting issues have been identified in many draft guidance documents (e.g.

taxonomic identification, large-scale screening, characterisation of genetic resources, breeding, derivatives, invasive alien species) a decision was taken to consolidate all sectoral documents into one sectoral guidance document. New elements introduced to the sectoral guidance resulted in a need to amend already published horizontal guidance document. This work is almost completed and users of genetic resources within the Union will have much more clear view if activities they are engaged in are within the scope of EU ABS Regulation. The new sectoral guidance documents cover all type of activities related to genetic resources, from acquisition, storage, through identification, characterisation to breeding and then product development. The consolidated sectoral guidance document was well received during the last ABS Consultation Forum in November 2019. It should be adopted through the official process and published by mid-2020. The content of the latest document is provided below. It will give an overview of type of case studies included in the document. The major objective of the guidance document is to help user in the EU to establish if his/her activity is considered utilisation and falls into scope of the EU ABS Regulation.

## 1. INTRODUCTION

- 1.1. Overview of the legal framework
- 1.2. Definitions used in this guidance
- 1.3. Structure and purpose of this Specific Guidance document

## 2. ACQUISITION

- 2.1. Direct or through supply chain
- 2.2. Confiscated material

## 3. STORAGE AND COLLECTION MANAGEMENT

## 4. REARING AND MULTIPLICATION

## 5. EXCHANGE AND TRANSFER

## 6. IDENTIFICATION AND CHARACTERIZATION OF ORGANISMS AND OTHER ACTIVITIES AT THE BEGINNING OF THE VALUE CHAIN

- 6.1. Taxonomic identification of organisms and taxonomic research
- 6.2. Characterisation
- 6.3. Phylogenetic analysis
- 6.4. Identification of derivatives
- 6.5. Large-scale screening
- 6.6. Behavioural studies

## 7. GENETIC RESOURCES AS TOOLS

- 7.1. Using genetic resources as testing or reference tools
- 7.2. Development of testing or reference tools
- 7.3. Vector or host
- 7.4. Biofactory
- 7.5. Laboratory strains

## 8. BREEDING

- 8.1. Crossing and selection
- 8.2. Reproductive technologies
- 8.3. Genome editing and targeted mutation
- 8.4. Use of commercial plant varieties
- 8.5. Use of forest reproductive material
- 8.6. Use of animals for breeding

## 9. PRODUCT DEVELOPMENT, PROCESSING AND PRODUCT FORMULATION

9.1. Product development

9.2. Processing

9.3. Product formulation

## 10. PRODUCT TESTING

10.1. Product testing (including regulatory tests)

10.2. Clinical trials

## 11. MARKETING AND APPLICATION

It is very important to understand that obligations of users arising from implementation of the EU ABS Regulation constitute only one set of obligations. The other set, equally important, arise from the ABS measures of the Provider country and conditions specified in both PIC and MAT.

# 8. Conclusions and recommendations

---

## 8.1 Status of ABS in genetic collections

As showed by the survey conducted within the Task 2.1, the level of implementation of ABS measures in collections was very limited with 29% of germplasm collections and 5% of genomic collection using Material Acquisition Agreements (MAA). As regards transfer of material from the collection Material Transfer Agreements (MTA) or similar tools were being reported by 25% of germplasm collections and 37% of genomic collections.

It suggests that the level of awareness regarding necessity to document the source of material entering into collection and to document transfer of material to other collection or the user is still very limited. Such documentation is absolutely needed to prove legal status of the genetic resources anytime it is transferred or used by the collection for research purposes.

Another issue is the content of the rare MAA and MTA documents that have been reported in the T2.1 survey. The information on ABS conditions attached to given genetic resources was very rare if any.

## 8.2 Regulations of ABS in genetic collections

Genetic collections while developing own ABS protocols, procedure etc. have to follow national legislation of their own country that may affect the scope and provisions of such documents.

If collections are acquiring and storing material accessed from a country regulating access to own genetic resources, all necessary documentation to prove that the material was legally acquired have to be obtained. Such documentation include PIC, MAT and IRCC, if Provider country is issuing such permits.

The storage as such is not considered as utilisation, so that collections only storing material do not need to submit Due Diligence Declaration to comply with EU ABS Regulation. Storage, as activity associated with genetic resources is out of scope of the EU ABS Regulation as it does not constitute research and development. However, the collections have to prove the source of material when it is transfered to any other entity, so getting all relevant

documentation from the Provider country to prove legal access to these resources is absolutely necessary.

Collection should also consider making available material acquired and entered into collection before 12 October 2014, when the Nagoya Protocol came into force. While it is a condition putting users of genetic resources in the EU out of the scope of EU ABS Regulation, the Provider country may have different domestic access measures, also their national ABS law might be in force long before 12 October 2014.

### **8.3 Needs of ABS in genetic collections**

The collections, as any other potential users of genetic resources, either for research or for commercial purposes, require information on ABS legislation and access measures of all Parties to the Nagoya Protocol, to make informed decision on acquisition of genetic resources.

Collection managers should be aware of legal requirements and procedures of all Provider countries as they have to follow such procedures and obtain all necessary permits. Therefore, it is so important that Parties to Nagoya Protocol fulfil their obligations arising from the Article 14 and post at least the minimum set of information on ABS CH.

Collection managers have to be aware of legal ABS provisions of Provider countries they are interested in and update this information before submitting request for access as at present situation is very dynamic and legal arrangements might be changing.

Moreover, each genebank should develop own or adapt already existing MAA and MTA standard models for own use on routine basis. Such documents should be integrated into the work flow of the collection. It would be very easy if the system automatically required filling these documents at any acquisition/ transfer. Such integration, as implemented in France, is considered as a good practice of the genebank.

The need for supporting genebanks in development of their standard model documentation was recognized by the National Coordinators for Animal Genetic Resources in Europe, working together in the framework of the European Regional Focal Point on Animal Genetic Resources.

The work on development of model MAA and MTA initiated by the Working Group on *Ex-situ* Conservation and the ABS Task Force led to preparation of guidance documents for development of MAA, then MTA for Conservation and Breeding and MTA for Research (ERFP, 2019).

It was recognized by the National Coordinators that each gene bank operates in a given legal environment and has got specific circumstances and practices, so it is more appropriate to provide advice on the scope and content of MAA and MTA than try to develop standard documents to fit all gene banks.

The Animal Genetic Resources gene banks are invited to consider the guidelines while developing their own, custom-made model documentation of MAA and MTA. See for example the workfkow of the CRB-Anim network of gene banks in France: <https://crb-anim.fr/access-to-collection/#/>

It is clear that such work should be initiated as soon as possible, taking into account the fast developments in the ABS domain at international level. Also, in light of the pending

discussion on DSI, the source of DNA and other genomic information entering into genomic collections (databases) should be documented, as we do not know at present the outcome of the DSI debate that is foreseen for 2020.

#### 8.4 Establishing obligations of users

The horizontal guidance (EU, 2016) in Annex 1 provide a clear instruction to help users to determine if they are in the scope of the EU ABS Regulation. All conditions, geographical 1 and 2, temporal and material, listed in the column three have to be met simultaneously in order for the user to be in the scope of the EU ABS Regulation.

*ANNEX I*  
**Overview of conditions for applicability of the EU ABS Regulation**

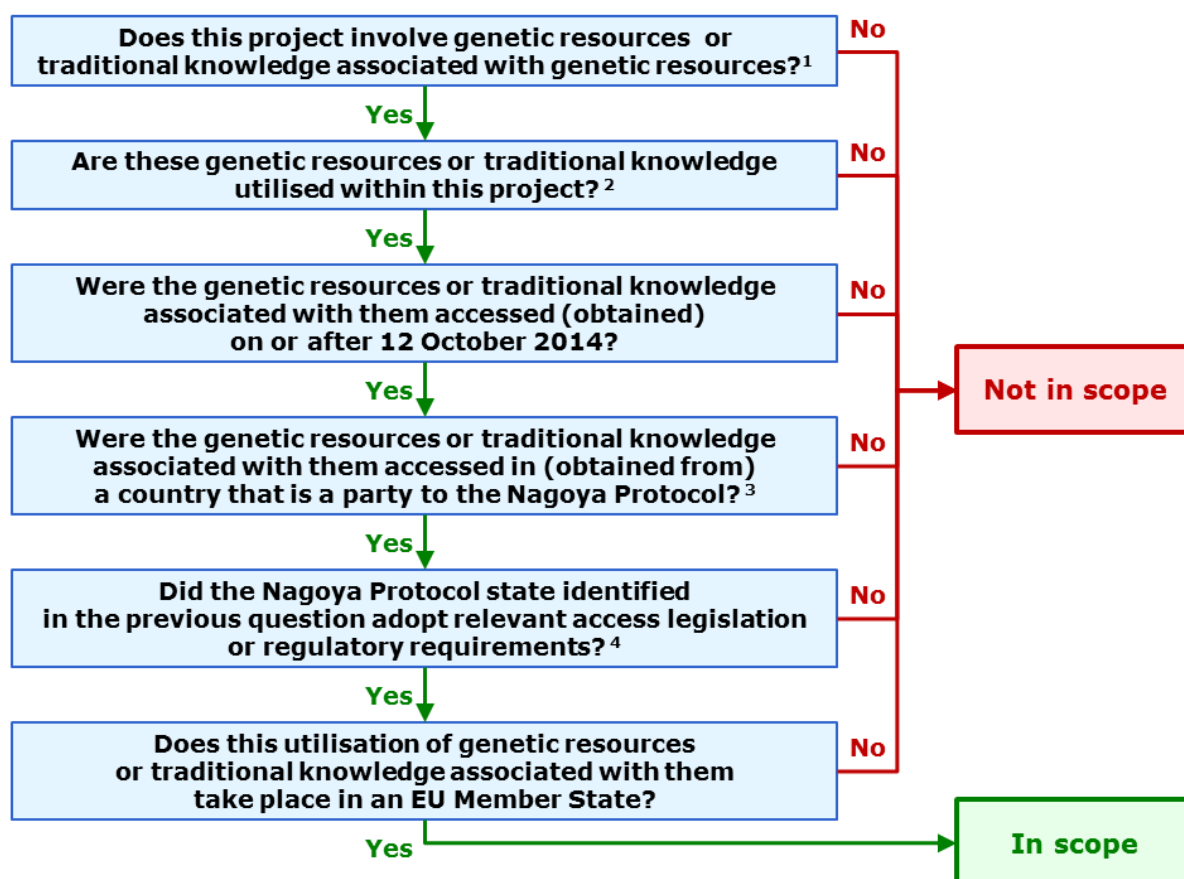
		Within scope (cumulative conditions (*))	Outside of scope
Geographic scope (provenance of GR (**))	<i>Access in ...</i>	Areas within a country's jurisdiction	Areas beyond national jurisdiction or covered by Antarctic Treaty System
	<i>Provider country is ...</i>	Party to the Nagoya Protocol	Not a Party to the Protocol
	<i>Provider country has ...</i>	Applicable access legislation	No applicable access legislation
Temporal scope	<i>Access ...</i>	On or after 12 October 2014	Before 12 October 2014
Material scope	<i>Genetic resources</i>	Not covered by a specialised international ABS instrument	Covered by a specialised international ABS instrument
		Non-human	Human
		Obtained as commodities but subsequently subject to R & D	Used as commodities
	<i>Utilisation</i>	R & D on genetic and/or biochemical composition	No such R & D
Personal scope		Natural or legal persons utilising GR	Persons <i>only</i> transferring GR or commercialising products based on it
Geographic scope (utilisation)	<i>R &amp; D ...</i>	Within the EU	<i>Exclusively</i> outside of the EU

(\*) To be within the scope, *all* conditions must be fulfilled.

(\*\*) GR = genetic resource; to be read as also including 'traditional knowledge associated with genetic resources', where appropriate.

In Deliverable 9.1, the decision tree proposed by the EU (shown below) was cited as it is meant to serve the same purpose, to help user to determine if he/she is in the scope of EU ABS Regulation.

The most difficult part is to establish if activity of the user is considered “utilization” as defined by the Nagoya Protocol. The sectoral guidance document, that will be adopted in 2020, contains a lot of “case studies” - examples to help user to interpret if he/she is indeed involved in utilisation of genetic resources and associated traditional knowledge.



The other important step is to determine a legal status of the Provider country. The ABS CH will provide an information if a given country is already a Party to the Nagoya Protocol, as such information is uploaded by the Secretariat of the CBD based on the submission of ratification documents.

Any other documents uploaded in the system depend on discretion of a given country. If information on legislative, administrative and policy measures is not available on ABS CH, the next step would be to check if this country have provided Interim National Report and look at the section on access measures. If the report is available, the section on access measures will provide a preliminary information on the legal ABS arrangements in this country.

The next step would be to contact ABS NFP to get detailed information on access measures and procedures to submit request for access to given genetic resources. Unfortunately, sometimes there is no response from the ABS NFP or the person responsible is not yet in a position to answer all the questions as national legislation is either not finalized and adopted

or internal domestic procedures and division of competences for issuing PIC and negotiating MAT with users are not in place. Such situations have to be carefully considered. Although user is not in scope of the ABS EU Regulation (condition on geographical scope – provenance of genetic resources is not met), still user is not in a position to legally acquire genetic resources from this Provider country.

If the same genetic resources can be accessed for the neighboring country that have got ABS measures in place, it is safer to follow this solution.

### **8.5 Impact of ABS measures on animal breeding, conservation and research**

According to the European breeding sector, at present there is no need for exotic AnGR (from Provider countries in the South) to ensure genetic progress in mainstream breeds, used in commercial production (Martyniuk et al. 2018). The major geneflow of AnGR is between North-North and North-South. In Europe genetic improvement programmes for mainstream breeds are carried out within selected populations by the breeding industry, breeding cooperative companies and farmers participating in the national breeding programmes.

However, it is possible that in the future specific traits of local breeds from the South related to for instance resistance to diseases or adaptation to hotter and dryer climate might be of interest for the European breeders. So far it is not the case.

Some European countries (e.g. EU: Bulgaria, Croatia, France, Malta and Spain and non EU: Albania, Belarus) already decided to regulate access to their genetic resources. Livestock genetic resources are exempted from access measures so far in France and Spain. How it will look like in other countries is not clear yet. Genetic resources of transboundary breeds or imported breeds may require influx or exchange of breeding material and in such cases the situation might be complicated if livestock genetic resources are included in domestic access measures and breeding stock is needed from this country. However, such cases are rare.

The impact of ABS measures on conservation of AnGR should be even smaller. AnGR conservation activities are usually undertaken and implemented at the national level and cover endangered native breeds.

In case of endangered transboundary breed, if there are national ABS measures in one country then the access to breeding stock or its reproductive material, collection of samples for *ex-situ* conservation and cooperation in development of joint conservation strategies might be more difficult for breeders from the other country, where this breed is also present.

It seems that in the trade of AnGR, different rules may apply according to the type of breeds.

Global trade in international breeds selected in the North will continue, business as usual. Such geneflow, especially from North to the South contributed to enhancement of livestock production in developing countries but endangered local breeds. The trade is profitable for buyers, and breeding companies do not expect additional benefits arising from utilisation of their breeding stock by customers. The price paid and ability to supply at the global market „genetic products” for intensive production systems provides sufficient benefits.

In the same time, potential exchange of native and locally adapted breeds from the South that may have desirable traits for future breeding needs or unique cultural /social value will

be covered by domestic access measures. Such situation will provide major obstacles mainly in the trade between developing countries, the South-South gene flow.

The most affected livestock related activity by the ABS measures will be research. Many research projects do require AnGR from various, sometimes specific regions and countries.

Exchange of AnGR (reproductive and biological material) for research purposes are usually governed by scientific cooperation contracts, and some research organisations already developed own model contracts, specifying roles and responsibilities of all parties involved and a way to deal with samples, other inputs, results, publications, potential IPRs, remaining material, confidentiality and so on.

The global research community considers that facilitated exchange of AnGR for research is highly important and beneficial for a global livestock production. Unfortunately, strict domestic access measures to local livestock breeds may provide substantial obstacles in this exchange and in the consequence slow down development of a new knowledge and progress in livestock sector worldwide.

While undertaking a research project with AnGR from countries regulating access to GR, including AnGR, it is necessary to follow requirements on access and benefit sharing of the Provider country what often requires a lot of time and efforts. It is then necessary to fulfil user obligations set by the EU ABS Regulation, if user works in the Union as well as respect domestic ABS legislation of own country.

When considering inclusion in the project AnGR from country regulating access one need to consider which Provider country should be chosen if the same AnGR can be acquired from more than one country. What are access application procedure and requirements in these countries? What are experiences of other users with accessing AnGR from these countries?

A decision where from access AnGR has to be carefully considered, as there are substantial differences in national ABS legislation and regulatory framework among Provider countries as well as in efficiency of their practical implementation. The procedures substantially differ as regards time and costs involved.

## **8.6 Impact of ABS measures on animal gene banks**

So far, the majority of AnGR stored in animal gene banks are collected from animals kept in their own country. Thus, gene banks only rarely may encounter a situation that they will require PIC from the Provider country to acquire samples.

The major impact of ABS measures on animal gene banks is to ensure establishing detailed documentation of the source of material that is introduced into the gene bank. Such information has to accompany samples and be stored and made available for users.

In order to have a clear and transparent internal procedures genebanks should develop own standard documentation, MAA and MTA and implement voluntary best practices to serve the best their users

## 9. References

---

ERFP, 2019. Final version of the Guidelines of Material Acquisition Agreements and Material Transfer Agreement for Genebanks.

<https://www.animalgeneticresources.net/index.php/news/final-version-of-the-guidelines-of-material-acquisition-agreements-and-material-transfer-agreement-for-genebanks/>

EU ABS Regulation, 2014. *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* OJ L 150, 20.5.2014, p. 59–71 (available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0511>).

European Commission, 2015. *Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices* OJ L 275, 20.10.2015, p. 4–19 (available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866>).

European Commission, 2016. *Commission notice – 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 Utilization in the Union* OJ C 313, 27.8.2016, p. 1–19 (available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0827%2801%29>).

European Commission, 2017. *User guide / Questions and answers – DECLARE NAGOYA IT system* CONTACT: [ENV-DECLARE-NAGOYA@ec.europa.eu](mailto:ENV-DECLARE-NAGOYA@ec.europa.eu)

FAO, 2019a. ABS Elements: Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture – with explanatory notes. FAO, Rome. 84 pp Licence: CC BY-NC-SA 3.0 IGO. <http://www.fao.org/3/ca5088en/ca5088en.pdf>

FAO, 2019b. CGRFA-17/19/Report Seventeenth Regular Session of the Commission on Genetic Resources for Food and Agriculture Rome, 18–22 February 2019 <http://www.fao.org/3/mz618en/mz618en.pdf>