Country	
1. Member State:	Portugal
General information	
2. Responsible authority:	Institute for Nature Conservation and Forests
3. Contributing agencies, organisations and other authorities:	Autonomous Region of Azores Autonomous Region of Madeira
4. Reporting period	12 October 2014 – 31 August 2017

Parties to the Nagoya Protocol on Access and Benefit-sharing	
5. Is your country a Party to the Nagoya Protocol?	☒ Yes OR ☐ No └ *If selected*, please indicate if there is any national process in place towards becoming a Party? ☐ Yes └ *Please provide a summary of the status of the process:* <Text entry> OR ☐ No └ *Please provide a summary of the main difficulties and challenges encountered for becoming a Party to the Nagoya Protocol*: <Text entry>

Institutional structures and resources for the implementation of the Regulation	
6. Has your country designated one or more competent authorities as provided in Article 6?	☒ Yes └ *Please identify the designated competent authority/-ies1:* No. 1 of article 4 of Decree-Law 122/2017, of 21st September (https://dre.pt/web/guest/pesquisa/-/search/108192977/details/maximized), establishes the Institute for Nature Conservation and Forests as the Portuguese **National Competent Authority** for the purposes of Regulation (EU) no. 511/2104. No. 2 of article 4 of Decree-Law 122/2017, of 21st September further determines that the competent bodies of the Autonomous Regions of Azores and Madeira shall designate one **Regional Competent**

1 If more than one competent authority established, please number them in point 6.

	Authority for each region. As of the date of the submission of the present report the process for the designation of the Regional Competent Authorities is ongoing. └ *If selected,* please fill in also section 7 OR ☐ No └ *Please provide explanation why not:* <Text entry> └ *If selected,* please move to section 8
7. Is (one of) the competent authority (authorities) in your country responsible for: - receiving due diligence declarations under Article 7(1) and 7(2)	☒ Yes OR ☐ No └ *If yes and more than one competent authority established,* please indicate which institution is responsible for receiving due diligence declarations2*:* Due diligence declarations are to be received either by the national competent authority or by the regional competent authorities on the basis of the geographical location of the submitter (where utilization takes place). └ *If no,* please indicate which other institution is responsible for receiving due diligence declarations*:* <Text entry>
- transmitting information to the ABS Clearing House under Article 7(3)	☒ Yes OR ☐ No └ *If yes and more than one competent authority established,* please indicate which institution is responsible for transmitting information to ABS CH: The national competent authority is responsible for transmitting information to ABS CH and also serves as Publishing Authority next to the ABS-CHM. └ *If no,* please indicate which other institution is responsible for transmitting information: <Text entry>
- carrying out checks on compliance in line with Article 9	☒ Yes OR ☐ No └ *If yes and more than one competent authority established,* please indicate which institution is responsible for carrying out checks: 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

2 In all point 7, if the first option is selected, it is sufficient to refer to a number/(s) corresponding to the authority indicated under point 6

		compliance in line with Article 9. The group of entities includes: - **Economic and Food Safety Authority** (*Autoridade de Segurança Alimentar e Económica*); - **Tax and Customs Authority** (*Autoridade* Tributária e Aduaneira); - **National Republican Guard** (*Guarda Nacional Republicana*) or **Public Security Police** (*Polícia de Segurança Pública*), according to their territorial jurisdiction; - **General-Inspection for Agriculture, Sea, Environment and Spatial Planning** (*Inspeção-Geral da Agricultura, do Mar, do Ambiente e do Ordenamento do Território*); - **General-Inspection for Education and Science** (*Inspeção-Geral da Educação e Ciência*); - **INFARMED - National Authority of Medicines and Health Products, I.P.** (*INFARMED — Autoridade Nacional do Medicamento e Produtos de Saúde, I. P*) - **Regional Competent Authority of Azores**; - **Regional Competent Authority of Madeira.** └ *If no*, please indicate which other institution is responsible for checking compliance: <Text entry>
- recognition and verification of registered collections	☒ Yes OR ☐ No	└ *If yes and more than one competent authority established*, please indicate which institution is responsible for recognition and verification of collections: In accordance with article 10 of Decree-Law 122/2017, of 21st September, on the basis of the geographical location of the collection, the responsibility for recognition and verification of collections lays either with the **National Competent Authority**, with the **Regional Competent Authority of Azores**, or with the **Regional Competent Authority of Madeira**. └ *If no*, please indicate which other institution is responsible for recognizing and verifying registered collections: <Text entry>
- cooperation with third countries under Article 7(3)	☒ Yes OR ☐ No	

- implementation of complementary measures under Article 13 (awareness raising, training activities, guidance to users etc.)	└ *If yes and more than one competent authority established*, please indicate which institution is responsible for cooperation with third countries: Although there are no specific provisions in this regard in Decree-Law 122/2017, of 21st September, cooperation with third countries is among the responsibilities of the **National Competent Authority**, as it is responsible for the overall implementation of Regulation (EU) no. 511/2104. └ *If no*, please indicate which other institution is responsible for the cooperation: <Text entry> ☒ Yes OR ☐ No └ *If yes and more than one competent authority established*, please indicate which institution is responsible for implementation of complementary measures: Although there are no specific provisions in this regard in Decree-Law 122/2017, of 21st September, on the basis of the geographical location, awareness raising, training activities, guidance to users etc. are among the responsibilities of either the **National Competent Authority**, the **Regional Competent Authority of Azores**, or the **Regional Competent Authority of Madeira**. └ *If no*, please indicate which other institution is responsible for implementation of complementary measures: <Text entry>
8. Has your country designated any checkpoints beyond those envisaged in Article 7(1) –7(2) of the Regulation?	☒ No OR ☐ Yes └ *Please provide information about the additional checkpoints:* <Text entry>
9. Does your country have specific staff to administer functions directly related to the implementation of the Regulation?[3]	☒ Yes *If selected*, please indicate how many (person-months per year): 1 person 30%/year Involved in enforcement of the Regulation (person-months per year[4]): <Text entry> Involved in other activities (cooperation, awareness-raising, capacity-building, reporting) (person-months per year): <Text entry> OR ☐ No

[3] This information could be useful for the evaluation of the effectiveness of the Regulation under Article 16.

[4] Note that this information can be provided in a aggregated format (average per year for the reporting period);

	└ *Please provide a summary of the main difficulties and challenges encountered in assigning specific staff to administer functions related to the implementation of the Regulation:* <Text entry>
10. An estimate of external annual budget for implementation of the Regulation	An estimate for total external[5] annual budget for EU ABS Regulation implementation, including cooperation, awareness-raising, capacity-building, reporting: 0 EUR
11. Additional information	*Please provide any additional relevant information, including – where relevant – a summary of the main difficulties and challenges encountered when establishing the institutional structure for the implementation of the Regulation*: No dedicated staff including experts (incl. legal experts); No assessment available on RG users community in Portugal; Low communication and awareness of the regime together RG users community and other relevant stakeholders

Legislative measures	
Penalties (Article 11)	
12. Has your country set up a penalty system as required by Article 11?	☒ Yes └ *If selected*, please fill in sections 13-15 OR ☐ No └ *If selected*, please explain why not and provide a timetable for adoption of penalties: <Text entry>
13. What are the types of penalties foreseen for infringements of Article 4 and 7 of the Regulation?	☒ Notice of remedial action ☒ Administrative fines ☐ Criminal sanctions ☐ Others └ *If selected*, please specify: <Text entry>

5 Such as public procurement procedures, consultancies, studies, outsourced communication campaigns, etc.

14. What is the level of penalties established for breaches of the Regulation?	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 acording to what is established in the Framework Law on Environmental Offences. There are three levels of applicable penalties according to specific infingements:
	- **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 of Decree-Law 122/2017, of 21st September, the possibility of establishing complementary sanctions
	
	Please provide examples for penalties applicable to offences that are considered to be severe, medium, and of lower importance.

15. Additional information	*Please provide any additional relevant information, including – where relevant – a summary of the main challenges when putting penalty systems in place*: <Text entry>

	Please provide link(s) to the relevant legislation: Decree-Law 122/2017, of 21st September - https://dre.pt/web/guest/pesquisa/-/search/108192977/details/maximized

Administrative measures put in place for implementation of the Regulation	
Monitoring of user compliance (Article 7)	
16. Has your country put in place measures to ensure that a request is made to all recipients of research funding involving utilisation of genetic resources and traditional knowledge associated with genetic resources, to declare that they exercise due diligence?	☒ Yes └*If selected,* please fill in section 17 below OR ☐ No └*If selected, please explain why not and indicate if there is any other way of ensuring compliance with Article 7(1):* <Text entry>
17. How is the request under Article 7(1) made?	☒ By law or other legislative measures └*If selected, please provide reference to relevant legal provisions:* Article 8.1 and 8.2 of Decree-Law 122/2017 OR/ AND ☐ By direct requests to applicants for funding └ *If selected, specify which organization is responsible for making the request:* <Text entry> └*If selected, please indicate how many requests have been made so far:* <Text entry> OR/ AND ☒ By means of a website └*If selected, please provide URL and explain the reasons for the choice of that site:* http://www.icnf.pt/portal/pn/biodiversidade/ei/dl-122-2017 as Article 8.1 of Decree-Law 122/2017 determines that the template to be completed and submitted by recipients of research funding are available at the website of the National Competent Authority. OR/ AND ☐ By other means └*If selected, please specify:* <Text entry>
18. Additional information	*Please provide any additional relevant information, including – where relevant – a summary of the main difficulties related to implementing a request referred to in Article 7(1):* No practical experience with the implementation of Decree-Law 122/2017 which was just recently published.
Risk-based plan for checks on user compliance (Article 9(3)(a))	

19. Has your country developed a plan as referred to in Article 9(3)(a)?	☐ Yes └*If selected*, please fill in sections 20 to 22 below OR ☒ No └ *Please explain why not and provide a timeline for when the plan is expected to be developed:* Decree-Law 122/2017 was published on the 21st September 2017. Immediately after its publication, the National Competent Authority promoted contacts with all relevant entities in order to identify the: (i) responsible bodies within the regional administrations of Azores and Madeira – **Regional Competent Authorities**, (ii) persons designated by each organization identified in article 9 of Decree Law 122/2017 (please see answer to Q. 7) to be responsible for assisting the NCA regarding **compliance** (iii) persons designated by each organization identified in article 5 of Decree Law 122/2017 to participate in the **Advisory Group on ABS**. Once the Regional Competent Authorities are established and all relevant responsible counterparts for compliance are identified a first formal meeting will be convened in order to establish the process for the development of a risk-based plan for checks on user compliance. It is envisioned that this meeting takes place within the first semester of 2018.
20. What are the risk factors applied in the preparation of the plan and any other criteria considered in its development?	Please describe the risk factors: <Text entry> Please describe any other criteria: <Text entry>
21. Which period does the current plan cover? When and how often will the plan be revised?	<Text entry>
22. Additional information concerning development of the plans	*Please provide any additional relevant information, including – where relevant – a summary of the main difficulties and challenges when preparing the plan*: <Text entry> *Please provide link to the plan:* <URL and website name> *and/or* <Attachment>

Enforcement and compliance measures

Monitoring of user compliance (Article 7)[6]	
23. How many due diligence declarations have been received based on Article 7(1)?	No due diligence declarations were received on the basis of article 7(1) in the reporting period.
24. How many due diligence declarations have been received based on Article 7(2)?	No due diligence declarations were received in the reporting period.
25. Number of checkpoint communiques transferred to the ABS Clearing House	No checkpoint communiques were transferred to the ABS CHM in the reporting period.
26. Number of checkpoints communique transferred to the competent authority referred to in Article 13(2) of the Protocol for confidentiality reasons	No checkpoint communiques were transferred to the competent authorities of article 13(2) in the reporting period.
27. Additional information	*Please provide a summary of the main difficulties related to monitoring of user compliance as per Article 7(1), if any: <Text entry>* *Please provide a summary of the main difficulties and challenges in relation to implementation of Article 7(2), if any: <Text entry>*
Checks on users (Article 9)	
28. How many checks have been carried out during the reporting period?	No checks were carried out in the reporting period. Checks will be carried according to the risk-based plan for checks on user compliance, once it is established or if the National Competent Authority becomes aware of relevant information regarding non-compliance with Regulation (EU) no. 511/2104.
29. What types of checks were carried out?	☐ Examination of documents provided upon request ☐ On-site visits ☐ Inspections ☐ Other └ *Please specify:* <Text entry>

[6] With regard to Questions 23 to 25, information needs to be provided for the current reporting period, while in the future it will need to be provided only if the DECLARE system was not used.

30. Were all the checks carried out in line with the plan developed based on Article 9(3)(a)?	☐ Yes OR ☐ No └ *Please specify what were the reasons/triggers for carrying out the other checks:* <Text entry>
31. In how many situations the checks were initiated due to substantiated concerns as referred to in Article 9(3)(b)?	<Text entry>
32. In how many cases were shortcomings identified?	<Text entry>
33. Additional information	*Please provide a summary of the main types of shortcomings identified:* <Text entry> *Please provide a summary of the main difficulties and challenges in relation to checks*: <Text entry>
Penalties (Article 11)	
34. Penalties imposed during the reporting period	*Please specify if your country imposed any penalties* ☐ Notice of remedial action └ *If selected*, please specify how many: <Text entry> ☐ Fines └ *If selected*, please specify how many: <Text entry> ☐ Criminal sanctions └ *If selected*, please specify how many: <Text entry> ☐ Others └ *If selected*, please specify how many: <Text entry>
35. If penalties were applied during the reporting period, which types of infringements were penalised?	Infringement of duties stemming from: ☐ Article 4 – due diligence ☐ Article 7 – duty to file due diligence declaration ☐ Other └ *Please specify:* <Text entry>
36. Additional information:	*Please provide a summary of the main difficulties and challenges concerning enforcement measures (if any)*: <Text entry>
Register of collections (Article 5)	
37. Are you aware of any interest by institutions in your country to become a registered collection?	☐ Yes

	└ *Please indicate how many collections expressed their interest:* <Text entry> OR ☒ No
38. Number of applications received	No applications for the registration of collections were received during the reporting period.
39. Number of verifications carried out	Zero verifications on collections carried out during the reporting period.
40. Additional information	*Please provide any additional information, including on what might explain the level of interest in becoming a registered collection:* Generally, Collection holders are either unaware or are just becoming acquainted with the ABS regime and the possibility of registering collections.

Cooperation and complementary measures	
Cooperation (Article 12)	
41. Has your country[7] cooperated with competent authorities or other relevant organizations in other EU Member States?	☐ Yes └ *Please specify countries with which the cooperation was undertaken:* <Text entry> └ *Please provide examples of such cooperation:* <Text entry> OR ☒ No
42. Has your country cooperated with (third countries') competent national authorities referred to in Article 13(2) of the Protocol?	☐ Yes └ *Please specify the countries with which the cooperation was undertaken:* <Text entry> └ *Please specify areas of cooperation:* <Text entry> Was the cooperation related to any identified shortcomings? ☐ Yes OR ☐ No └ *If yes, please specify the shortcomings:* <Text entry> OR ☒ No
Complementary measures (Article 13)	
43. Has your country carried out any training and awareness-raising activities to assist the stakeholders and interested parties in building understanding of their obligations	☒ Yes └ Please specify type and number of activities carried out: Training sessions: <Text entry>

7 When reference to "country" is made in this part, it shall be understood as covering activities carried out by the authorities, or carried out on their behalf;

arising from the EU ABS Regulation and relevant provisions of the Protocol and the Convention? 8	Workshops: <Text entry> Conferences: <Text entry> Others: 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, involving clarifications on the rights and obligations drawing from Regulation 511/2014 and clarifications regarding the access framework in Portugal. └ Please estimate the number of users that participated in the activities carried out or that received other assistance (e.g. in the form of responses to requests for clarification etc.): <Text entry> OR ☐ No
44. Has your country organized any activities addressed specifically to academic, university and non-commercial researchers, and small and medium enterprises?	☐ Yes └ Please specify type and number of activities carried out: Training sessions: <Text entry> Workshops: <Text entry> Conferences: 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 - https://www.ccmar.ualg.pt/). A seminar is planned to take place on the 29th November 2017 in the Research Centre in Biodiversity and Genetic Resources (https://cibio.up.pt/about / https://cibio.up.pt/seminars-in-biodiversity-and-evolution/details/the-regime-on-the-utilization-of-genetic-resources-rights-and-obligations-of-users) with the aim of informing the wider researcher community of the University of their rights and obligations under the ABS legal framework. Others: Meeting with the Global Health and Tropical Medicine Institute (http://www.ihmt.unl.pt/) of the Nova University of Lisboa 9th june 2017 with the objective of informing and providing clarifications on ABS to people responsible for legal conformity of projects within the University. Building on the interest resulting from this meeting, a seminar was held on the 14th November 2017 in the Global Health and Tropical Medicine Institute with the aim of informing the wider researcher community of the University of their rights and obligations under the ABS legal framework. └ Please estimate number of users that participated in the activities carried out/ that received assistance: 60 OR ☐ No

8 See also response to question 54 from the Nagoya Protocol reporting format

45. Have any complaints been received from users in relation to implementation of the EU ABS Regulation?	☐ Yes └Please summarise the nature of complaints received: <Text entry> OR ☒ No

Submission addresses:

This form should be completed and sent ***by email*** *to* ENV-F3-NAGOYA-ABS@ec.europa.eu