Country	
1. Member State:	España *Spain*
General information	
2. Responsible authority:	Dirección General de Calidad y Evaluación Ambiental y Medio Natural. Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente. *Directorate General for Environmental Quality and Assessment and Nature. Ministry of Agriculture and Fisheries, Food and Environment*.
3. Contributing agencies, organisations and other authorities:	
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?	**X** Yes

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?	**X** Yes └ *Please identify the designated competent authority/-ies1:* El artículo 13 del Real Decreto 124/2017, de 24 de febrero, relativo al acceso a los recursos genéticos procedentes de taxones silvestres y al control de la utilización (https://www.boe.es/boe/dias/2017/03/14/pdfs/BOE-A-2017-2743.pdf) establece que, a lo dispuesto en el artículo 6 del Reglamento UE 511/2014, son autoridades competentes españolas los siguientes órganos de las administraciones publicas: 1. Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente. (Funciones descritas en el artículo 13.1. del RD 124/2017, de 24 de febrero). 2. Órganos competentes que designen las comunidades autónomas en el ámbito de sus competencias. (Funciones descritas en el artículo 13.2 del RD 124/2017, de 24 de febrero). En relación al punto 2, los órganos designados por las

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

	comunidades autónomas son los siguientes: Comunidad Autónoma de Andalucía: Dirección General de Gestión del Medio Natural y Espacios Protegidos. Consejería de Medio Ambiente y Ordenación del Territorio. Comunidad Autónoma de Aragón: Servicios Provinciales del Departamento de Desarrollo Rural y Sostenibilidad. Comunidad Autónoma del Principado de Asturias: Director General de Recursos Naturales. Consejería de Desarrollo Rural y Recursos Naturales. Comunidad Autónoma de las Illes Balears: Consejero titular en materia de medio ambiente del Gobierno Balear. Consejería de Medio Ambiente, Agricultura y Pesa. Comunidad Autónoma de Canarias: Controles sobre los usuarios y notificación de medidas de rectificación: Dirección General de Protección de la Naturaleza. Consejería de Política Territorial, Sostenibilidad y Seguridad. Sanciones: Agencia de Protección del Medio Urbano y Natural. C/ Rambla de Santa Cruz, 149. 35071, Santa Cruz de Tenerife. Comunidad Autónoma de Cantabria: Dirección General de Medio Natural. Consejería de Medio Rural, Pesca y Alimentación. Comunidad de Castilla y León: Dirección General de Medio Natural. Consejería de Fomento y Medio Ambiente. Comunidad Autónoma de Castilla-La Mancha: Dirección General de Política Forestal y Espacios Naturales. Consejería de Agricultura, Medio Ambiente y Desarrollo Rural. Comunidad Autónoma de Cataluña: Dirección General de Políticas Ambientales y Medio Natural. Departamento de Territorio y Sostenibilidad. Ciudad Autónoma de Ceuta: Consejería de Medio Ambiente y Sostenibilidad. Comunidad Autónoma de Extremadura: Dirección General de Medio Ambiente. Consejería de Medio Ambiente y Rural, Políticas Agrarias y Territorio. Comunidad Autónoma de Galicia: Dirección General del Patrimonio Natural. Consejería de Medio Ambiente y Ordenación del Territorio. Comunidad Autónoma de Madrid: Director General del Medio Ambiente. Consejería de Medio Ambiente, Administración Local y Ordenación del Territorio. Ciudad Autónoma de Melilla: Coordinación de Medio Ambiente. Consejería de Coordinación y Medio Ambiente. Comunidad Foral de Navarra: Director del Servicio de Medio Natural. Dirección General de Medio Ambiente y Ordenación del Territorio. Departamento de Desarrollo Rural, Medio Ambiente y Administración Local.

	Comunidad Autónoma de La Rioja: Dirección General de Medio Natural. Consejería de Agricultura, Ganadería y Medio Ambiente. Comunidad Autónoma de la Región de Murcia: Oficina de Impulso Socioeconómico del Medio Ambiente. Consejería de Agua, Agricultura y Medio Ambiente. Comunidad Autónoma del País Vasco: Departamento de Medio Ambiente, Planificación Territorial y Vivienda. Comunidad Valenciana: Director General de Medio Natural y de Evaluación Ambiental. Consejería de Agricultura, Medio Ambiente, Cambio Climático y Desarrollo Rural. *Article 13 of Real Decreto 124/2017, de 24 de febrero, relativo al acceso a los recursos genéticos procedentes de taxones silvestres y al control de la utilización (https://www.boe.es/boe/dias/2017/03/14/pdfs/BOE-A-2017-2743.pdf) indicates the authorities with regard to article 6 of EU Regulation 511/2014. These are:* 1. *Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente. (Functions established under article 13.1 of Real Decreto 124/2017).* 2. *Competent bodies designated by the Autonomous communities. (Functions established under article 13.2.RD 124/2017). (See the list of competent bodies in the Autonomous communities in the Spanish version as these have not been translated into English)*
7. Is (one of) the competent authority (authorities) in your country responsible for: - receiving due diligence declarations under Article 7(1) and 7(2)	**X** Yes └ *If yes and more than one competent authority established,* please indicate which institution is responsible for receiving due diligence declarations2*:* Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente.
- transmitting information to the ABS Clearing House under Article 7(3)	**X** Yes └ *If yes and more than one competent authority established,* please indicate which institution is responsible for transmitting information to ABS CH: Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente.

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

- carrying out checks on compliance in line with Article 9	X Yes └ *If yes and more than one competent authority established,* please indicate which institution is responsible for carrying out checks: Autoridades competentes referidas en los puntos 1 y 2 de la pregunta anterior. Ver artículo 13.1 y 13.2 del RD 124/2017 para los detalles. *Competent authorities under points 1 and 2 of the question above. See article 13.1 and 13.2 of RD 124/2017 for the details.*
- recognition and verification of registered collections	X Yes └ *If yes and more than one competent authority established,* please indicate which institution is responsible for recognition and verification of collections: Autoridades competentes referidas en los puntos 1 y 2 de la pregunta 6. Ver artículo 17 del RD 124/2017 para los detalles. *Competent authorities under points 1 and 2 of question 6 above. See article 17 of RD 124/2017 for the details.*
- cooperation with third countries under Article 7(3)	**X** Yes └ *If yes and more than one competent authority established,* please indicate which institution is responsible for cooperation with third countries: Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente.
- implementation of complementary measures under Article 13 (awareness raising, training activities, guidance to users etc.)	**X** Yes └ *If yes and more than one competent authority established,* please indicate which institution is responsible for implementation of complementary measures: Principalemente son realizadas por el punto focal nacional del Protocolo de Nagoya. Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente. *Mainly undertaken by the national focal point to the Nagoya Protocol. Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente.*

8. Has your country designated any checkpoints beyond those envisaged in Article 7(1) –7(2) of the Regulation?	**X** Yes └ *Please provide information about the additional checkpoints:* Artículo 14.3 del RD 124/2017. Usuarios de recursos genéticos y conocimientos tradicionales asociados a dichos recursos cuando soliciten una patente. *Article 14.3 of RD 124/2017. Users of genetic resources and traditional knowledge associated with genetic resources at the stage of patent application.*
9. Does your country have specific staff to administer functions directly related to the implementation of the Regulation?[3]	**X** Yes *If selected*, please indicate how many (person-months per year): Una persona y media para todas las cuestiones relativas a acceso y utilización de recursos genéticos. *One and a half person for all matters related to access and utilization of genetic resources.* Involved in enforcement of the Regulation (person-months per year[4]): Involved in other activities (cooperation, awareness-raising, capacity-building, reporting) (person-months per year):
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: _____ 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:*

Legislative measures	
Penalties (Article 11)	
12. Has your country set up a penalty system as required by Article 11?	**X** Yes
13. What are the types of penalties foreseen for infringements of Article 4 and 7 of the Regulation?	**X** Notice of remedial action **X** Administrative fines ☐ Criminal sanctions

[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);

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

	☐ Others └ *If selected,* please specify: Sanciones previstas en la Ley 42/2007, de 13 de diciembre, para las infracciones administrativas. La utilización de recursos genéticos o conocimientos tradicionales asociados a recursos genéticos sin haber respetado las obligaciones previstas en el Reglamento (UE) 511/2014 del Parlamento Europeo y del Consejo, de 16 de abril de 2014 podrá considerarse una infracción administrativa: - *Muy grave* cuando los beneficios obtenidos superen los 100.000 euros, en cuyo caso serán aplicables multas de 200.001 a 2.000.000 de euros. - *Grave* cuando los cuando los beneficios obtenidos sean inferiores a los 100.000 euros, en cuyo caso serán aplicables multas de 3.001 a 200.000 euros. Conforme a lo establecido en el Real Decreto 124/2017, el incumplimiento de la obligación de presentación de diligencia debida conlleva: 1) Si el usuario es beneficiario de fondos de investigación, se le podrá retirar la financiación o se le podrá obligar a la devolución, total o parcial, de la financiación recibida. 2) Si el usuario se encuentra en la etapa final de elaboración de un producto, se podrá no autorizar la puesta en el mercado del producto, o retirarlo del mercado si ya se había procedido a su comercialización. Sin perjuicio del régimen sancionador que pueda ser de aplicación en cada caso, cuando el órgano competente haya detectado insuficiencias en los controles podrá expedir una notificación de medidas de rectificación que deberá adoptar el usuario, y podrá adoptar medidas provisionales inmediatas de carácter preventivo como la prohibición temporal de la utilización, la suspensión de las actividades específicas de investigación o comercialización, o la confiscación de los recursos genéticos. *Sanctions established under Law 42/2007, of 13 December, will be applicable. User's non-compliance with 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, is considered an administrative infringement:* - *Very serious infringement when profits are higher than 100.000 euros. In this case, the user may be fined 200.001 to 2.000.000 euros.* - *Serious infringement when profits are lower than 100.000 euros. In this case, the user may be fined 3.001 to 200.000 euros.*

	As established under RD 124/2017, not complying with the obligation of the due diligence declarations implies: *1) At the stage of research funding, grant may be cancelled or paid back partially or totally.* *2) At the stage of final development of a product, placing on market may be not authorized, or if the product was already commercialized it may be removed from the market.* *Without prejudice to the applicable sanction's regime in each case, when the competent authority identifies insufficiencies during the checks, a notification for remedial actions can be extended to the user and corrective measures to be adopted immediately by the user can be established, such as temporal prohibition of utilization, cancellation of research or commercialization activities, or confiscation of genetics resources.*
14. What is the level of penalties established for breaches of the Regulation?	*Please provide examples for penalties applicable to offences that are considered to be severe, medium, and of lower importance*. Ver respuesta a la pregunta anterior. *See reply to question above.*
15. Additional information	*Please provide any additional relevant information, including – where relevant – a summary of the main challenges when putting penalty systems in place*: *Please provide link(s) to the relevant legislation:* http://www.mapama.gob.es/es/biodiversidad/temas/recursos-geneticos/default.aspx

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?	**X** Yes └*If selected,* please fill in section 17 below
17. How is the request under Article 7(1) made?	**X** By law or other legislative measures └*If selected, please provide reference to relevant legal provisions:* Artículo 14.1 del Real Decreto 124/2017, de 24 de febrero, relativo al acceso a los recursos genéticos procedentes de taxones silvestres y al control de la utilización.

	Article 14.1 of RD 124/2017. OR/ AND ☐ By direct requests to applicants for funding └ *If selected, specify which organization is responsible for making the request:* └*If selected, please indicate how many requests have been made so far:* OR/ AND ☐ By means of a website └*If selected, please provide URL and explain the reasons for the choice of that site:* OR/ AND ☐ By other means └*If selected, please specify:*
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):*
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:* <Text entry> Previsto en la legislación pero aún no desarrollado. *Forsee in the legislation but not yet developed.* El artículo 16 del Real Decreto 124/2017, de 24 de febrero, relativo al acceso a los recursos genéticos procedentes de taxones silvestres y al control de la utilización está dedicado al Plan Estatal para el control de la legalidad de la utilización de los recursos genéticos y conocimientos tradicionales asociados en España. Este Plan se elaborará por el Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente, en coordinación con el resto de administraciones públicas implicadas, con el fin de reducir el riesgo de utilización en todo el territorio nacional de recursos genéticos y conocimientos tradicionales asociados a recursos genéticos obtenidos de forma ilegal tanto en España como en terceros países Parte del Protocolo de Nagoya. Este Plan se elaborará aplicando criterios de riesgo, para los cuales existe en estos momentos una reflexión inicial interna. *Article 16 of Royal Decree 124/2017 is dedicated to the State Plan for the control of the legality of the utilization of genetic resources and traditional knowledge associated in Spain.*

	This Plan has to be elaborated by the Ministry of Agriculture and Fisheries, Food and Environment, in coordination with the rest of the public administrations involved, in order to reduce the risk of utilization throughout the national territory of genetic resources and traditional knowledge associated to genetic resources obtained illegally both in Spain and in third countries Party to the Nagoya Protocol. *This Plan has to be elaborated applying risk criteria, for which there is at the moment an initial internal reflection.*
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: Please describe any other criteria:
21. Which period does the current plan cover? When and how often will the plan be revised?	La vigencia del Plan será de cinco años, procediendo a su revisión y actualización una vez finalizado dicho plazo. *The validity of the Plan will be five years, and will be reviewed and updated once the said term expires.*
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*: *Please provide link to the plan:* *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)?	0
24. How many due diligence declarations have been received based on Article 7(2)?	0
25. Number of checkpoint communiques transferred to the ABS Clearing House	0

[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.

26. Number of checkpoints communique transferred to the competent authority referred to in Article 13(2) of the Protocol for confidentiality reasons	0
27. Additional information	*Please provide a summary of the main difficulties related to monitoring of user compliance as per Article 7(1), if any:* *Please provide a summary of the main difficulties and challenges in relation to implementation of Article 7(2), if any:*
Checks on users (Article 9)	
28. How many checks have been carried out during the reporting period?	0
29. What types of checks were carried out?	☐ Examination of documents provided upon request ☐ On-site visits ☐ Inspections ☐ Other └ *Please specify:*
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:*
31. In how many situations the checks were initiated due to substantiated concerns as referred to in Article 9(3)(b)?	
32. In how many cases were shortcomings identified?	
33. Additional information	*Please provide a summary of the main types of shortcomings identified:* *Please provide a summary of the main difficulties and challenges in relation to checks*:
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: ☐ Fines └ *If selected,* please specify how many: ☐ Criminal sanctions └ *If selected,* please specify how many:

	☐ Others └ *If selected,* please specify how many:
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:*
36. Additional information:	*Please provide a summary of the main difficulties and challenges concerning enforcement measures (if any)*:
Register of collections (Article 5)	
37. Are you aware of any interest by institutions in your country to become a registered collection?	**X** Yes └ *Please indicate how many collections expressed their interest:* 1 OR ☐ No
38. Number of applications received	0
39. Number of verifications carried out	0
40. Additional information	*Please provide any additional information, including on what might explain the level of interest in becoming a registered collection:*

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?	**X** Yes └ *Please specify countries with which the cooperation was undertaken:* └ *Please provide examples of such cooperation:* Intercambio informal de información sobre la organización del sistema de control del cumplimiento. *Informal exchange of information on the organization of the system of checks for monitoring user compliance.* 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:* └ *Please specify areas of cooperation:* Was the cooperation related to any identified shortcomings? ☐ Yes OR ☐ No └ *If yes, please specify the shortcomings:* OR **X** 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 arising from the EU ABS Regulation and relevant provisions of the Protocol and the Convention? [8]	X Yes └ Please specify type and number of activities carried out: Training sessions: Workshops: Conferences: Others: Materiales informativos actualizados en la web. *Materials updated in the website.* En octubre de 2017 comenzará la serie de 9 jornadas con los diferentes sectores que utilizan recursos genéticos (incluyendo a las universidades y centros de investigación) enmarcadas dentro de las actuaciones de información y sensibilización dirigidas a las partes interesadas, al objeto de apoyar la comprensión de las obligaciones existentes en materia de acceso y utilización de recursos genéticos. *In October 2017 a series of 9 workshops with the different sectors*

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;

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

	that utilize genetic resources (including universities and research institutions) will start within the framework of the information and awareness raising actions addressed to stakeholders, in order to support the understanding of existing obligations regarding access and use of genetic resources. └ 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.): OR ☐ No
44. Has your country organized any activities addressed specifically to academic, university and non-commercial researchers, and small and medium enterprises?	Se remite a respuesta anterior. *See reply to question above.* ☐ Yes └ Please specify type and number of activities carried out: Training sessions: Workshops: Conferences: Others: └ Please estimate number of users that participated in the activities carried out/ that received assistance: OR ☐ No
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: OR **X** No

Submission addresses:

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