

Country	
1. Member State:	Malta
General information	
2. Responsible authority:	Plant Protection Directorate, MESDC
3. Contributing agencies, organisations and other authorities:	Environment and Resources Authority, MESDC Department of Fisheries and Aquaculture, MESDC Wild Birds Regulation Unit, MESDC
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?	<input checked="" type="checkbox"/> Yes OR <input type="checkbox"/> No <p style="margin-left: 40px;">└ If selected, please indicate if there is any national process in place towards becoming a Party?</p> <p style="margin-left: 80px;"><input type="checkbox"/> Yes</p> <p style="margin-left: 40px;">└ Please provide a summary of the status of the process: <Text entry></p> <p style="margin-left: 40px;">OR</p> <p style="margin-left: 80px;"><input type="checkbox"/> No</p> <p style="margin-left: 40px;">└ Please provide a summary of the main difficulties and challenges encountered for becoming a Party to the Nagoya Protocol: <Text entry></p>

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?	<input checked="" type="checkbox"/> Yes <p style="margin-left: 40px;">└ Please identify the designated competent authority/ies¹: Director (Plant Protection), Plant Protection Directorate, MESDC</p> <p style="margin-left: 40px;">└ If selected, please fill in also section 7</p> OR <input type="checkbox"/> No <p style="margin-left: 40px;">└ Please provide explanation why not: <Text entry></p>

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

	<p>⌞ <i>If selected, please move to section 8</i></p>
<p>7. Is (one of) the competent authority (authorities) in your country responsible for:</p> <p>- receiving due diligence declarations under Article 7(1) and 7(2)</p> <p>- transmitting information to the ABS Clearing House under Article 7(3)</p> <p>- carrying out checks on compliance in line with Article 9</p> <p>- recognition and verification of registered collections</p> <p>- cooperation with third countries under Article 7(3)</p>	<p><input checked="" type="checkbox"/> Yes OR <input type="checkbox"/> No</p> <p>⌞ <i>If yes and more than one competent authority established, please indicate which institution is responsible for receiving due diligence declarations</i>₂: <Text entry></p> <p>⌞ <i>If no, please indicate which other institution is responsible for receiving due diligence declarations</i>: <Text entry></p> <p><input checked="" type="checkbox"/> Yes OR <input type="checkbox"/> No</p> <p>⌞ <i>If yes and more than one competent authority established, please indicate which institution is responsible for transmitting information to ABS CH</i>: <Text entry></p> <p>⌞ <i>If no, please indicate which other institution is responsible for transmitting information</i>: <Text entry></p> <p><input checked="" type="checkbox"/> Yes OR <input type="checkbox"/> No</p> <p>⌞ <i>If yes and more than one competent authority established, please indicate which institution is responsible for carrying out checks</i>: <Text entry></p> <p>⌞ <i>If no, please indicate which other institution is responsible for checking compliance</i>: <Text entry></p> <p><input checked="" type="checkbox"/> Yes OR <input type="checkbox"/> No</p> <p>⌞ <i>If yes and more than one competent authority established, please indicate which institution is responsible for recognition and verification of collections</i>: <Text entry></p> <p>⌞ <i>If no, please indicate which other institution is responsible for recognizing and verifying registered collections</i>: <Text entry></p> <p><input checked="" type="checkbox"/> Yes OR <input type="checkbox"/> No</p> <p>⌞ <i>If yes and more than one competent authority established, please indicate which institution is</i></p>

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

<p>- implementation of complementary measures under Article 13 (awareness raising, training activities, guidance to users etc.)</p>	<p>responsible for cooperation with third countries: <Text entry></p> <p>↳ <i>If no</i>, please indicate which other institution is responsible for the cooperation: <Text entry></p> <p><input checked="" type="checkbox"/> Yes OR <input type="checkbox"/> No</p> <p>↳ <i>If yes and more than one competent authority established</i>, please indicate which institution is responsible for implementation of complementary measures: <Text entry></p> <p>↳ <i>If no</i>, please indicate which other institution is responsible for implementation of complementary measures: <Text entry></p>
<p>8. Has your country designated any checkpoints beyond those envisaged in Article 7(1)–7(2) of the Regulation?</p>	<p><input checked="" type="checkbox"/> No OR <input type="checkbox"/> Yes</p> <p>↳ <i>Please provide information about the additional checkpoints</i>: <Text entry></p>
<p>9. Does your country have specific staff to administer functions directly related to the implementation of the Regulation?³</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><i>If selected</i>, please indicate how many (person-months per year):</p> <p>12 Oct 2014 - 31 Dec 2014 : 0.75 01 Jan 2015 - 31 Dec 2015 : 3 01 Jan 2016 - 31 Dec 2016 : 6 01 Jan 2017 - 31 Aug 2017 : 12</p> <p>Involved in enforcement of the Regulation (person-months per year ⁴):</p> <p>12 Oct 2014 - 31 Dec 2014 : 0 01 Jan 2015 - 31 Dec 2015 : 0 01 Jan 2016 - 31 Dec 2016 : 7.2 01 Jan 2017 - 31 Aug 2017 : 14</p> <p>Involved in other activities (cooperation, awareness-raising, capacity-building, reporting) (person-months per year):</p> <p>12 Oct 2014 - 31 Dec 2014 : 0.75 01 Jan 2015 - 31 Dec 2015 : 3 01 Jan 2016 - 31 Dec 2016 : 6 01 Jan 2017 - 31 Aug 2017 : 16.8</p> <p>OR</p>

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);

	<input type="checkbox"/> No <i>⌞ 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></i>
10. An estimate of external annual budget for implementation of the Regulation	An estimate for total external <u>5</u> annual budget for EU ABS Regulation implementation, including cooperation, awareness-raising, capacity-building, reporting: 0 EUR
11. Additional information	<i>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:</i> The implementation of the ABS regime required the creation of a system at national level from the ground up; the creation of a simple system which is both efficient and relatively burden-free is the most challenging aspect because a compromise needs to be met between the two. The implementation aspect is still not completely fleshed out, lacking training of inspectors and creation of a control plan; difficulty with identifying potential and new users exists. Low public awareness exists about the ABS law and awareness raising exercises about the national legal system and the obligations of the users is being carried out through the dissemination of informative guides, articles, and posters.

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

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

<p>14. What is the level of penalties established for breaches of the Regulation?</p>	<p>Penalties against the ABS law may be applicable based on the results of inspections and will depend on judicial decision. In summary, first offences can be fined between €800 and €4,658.75; Second offences can be fined between €6,000 and €10,000, or imprisonment not exceeding 2 years, or both fine and imprisonment.</p> <p>Administrative fines may be imposed by the competent authority, however such fines still need to be published.</p> <p><i>Please provide examples for penalties applicable to offences that are considered to be severe, medium, and of lower importance.</i></p>
<p>15. Additional information</p>	<p><i>Please provide any additional relevant information, including – where relevant – a summary of the main challenges when putting penalty systems in place:</i></p> <p>Creating a penalty system which would match all business sizes and types of users whilst rendering such penalties effective, proportionate and dissuasive was a challenge. It is possible that the current penalties may not be sufficiently large to be dissuasive and proportionate for large enterprises, however there is insufficient experience on the application and implementation of the ABS laws at national level to be able to make an informed judgement on this matter.</p> <p><i>Please provide link(s) to the relevant legislation: <URL and website name></i></p> <p>Subsidiary Legislation 549.111, Ministry for Justice, Culture and Local Government</p>

Administrative measures put in place for implementation of the Regulation	
Monitoring of user compliance (Article 7)	
<p>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?</p>	<p><input checked="" type="checkbox"/> Yes</p> <p style="padding-left: 40px;"><i>↳ If selected, please fill in section 17 below</i></p> <p>OR</p> <p><input type="checkbox"/> No</p> <p style="padding-left: 40px;"><i>↳ If selected, please explain why not and indicate if there is any other way of ensuring compliance with Article 7(1): <Text entry></i></p>
<p>17. How is the request under Article 7(1) made?</p>	<p><input type="checkbox"/> By law or other legislative measures</p> <p style="padding-left: 40px;"><i>↳ If selected, please provide reference to relevant legal provisions: <Text entry></i></p> <p>OR/ AND</p> <p><input checked="" type="checkbox"/> By direct requests to applicants for funding</p> <p style="padding-left: 40px;"><i>↳ If selected, specify which organization is responsible for making the request:</i></p> <p>The ABS national competent authority informs users that due diligence declarations are required at the time of</p>

	<p>application to request access to genetic resources; if mutually agreed terms are established, such requirement is included in the same agreement.</p> <p>An agreement with the Patent Office is also underway to ensure that those R&D projects which use resources that are accessed from Malta or other countries are notified to the ABS competent authority so that the necessary communication is established to ensure that due diligence obligations are obeyed.</p> <p><i>↳If selected, please indicate how many requests have been made so far:0</i></p> <p>OR/ AND</p> <p><input type="checkbox"/> By means of a website</p> <p><i>↳If selected, please provide URL and explain the reasons for the choice of that site: <Text entry></i></p> <p>OR/ AND</p> <p><input type="checkbox"/> By other means</p> <p><i>↳If selected, please specify: <Text entry></i></p>
18. Additional information	<i>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): <Text entry></i>
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)?	<p><input type="checkbox"/> Yes</p> <p><i>↳If selected, please fill in sections 20 to 22 below</i></p> <p>OR</p> <p><input checked="" type="checkbox"/> No</p> <p><i>↳ Please explain why not and provide a timeline for when the plan is expected to be developed:</i></p> <p>The users still need to be identified therefore a plan as referred to in Article 9(3)(a) and a timeline for its development cannot be stated.</p>
20. What are the risk factors applied in the preparation of the plan and any other criteria considered in its development?	<p>Please describe the risk factors: <Text entry></p> <p>Please describe any other criteria: <Text entry></p>
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	<i>Please provide any additional relevant information, including – where relevant – a summary of the main difficulties and challenges when preparing the plan: N/A</i>

	<i>Please provide link to the plan: <URL and website name> and/or <Attachment></i>
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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
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	<p><i>Please provide a summary of the main difficulties related to monitoring of user compliance as per Article 7(1), if any:</i></p> <p>N/A</p> <p><i>Please provide a summary of the main difficulties and challenges in relation to implementation of Article 7(2), if any:</i></p> <p>N/A</p>
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?	<input type="checkbox"/> Examination of documents provided upon request <input type="checkbox"/> On-site visits <input type="checkbox"/> Inspections <input type="checkbox"/> Other <p style="text-align: right;"><i>↳ Please specify: <Text entry></i></p>

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.

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

Register of collections (Article 5)	
37. Are you aware of any interest by institutions in your country to become a registered collection?	<input checked="" type="checkbox"/> Yes <p style="text-align: center;"><i>↳ Please indicate how many collections expressed their interest:</i></p> <p>One institution has expressed interest in potentially registering 25 crop collections; two private individuals expressed interest in potentially registering one crop collection each.</p> <p>OR</p> <input type="checkbox"/> No
38. Number of applications received	3
39. Number of verifications carried out	3
40. Additional information	<p><i>Please provide any additional information, including on what might explain the level of interest in becoming a registered collection:</i></p> <p>The ABS Competent National Authority issued a press release (http://bit.ly/2ypKeEh ; EN translation not available) calling for all interested parties to indicate their interest in registering their collections.</p> <p>Applications were received from two owners of one ancient Maltese cattle breed, and from the national Directorate for Competitiveness and Diversification for the possible registration of 25 landraces. Information provided complied for the most part with the requirements of Annex I Part A of the ABS Implementing Regulation, however processing is still in progress. The ABS Competent National Authority concluded that the applications to register collections are not compliant with the requirements required by collections as understood under Article 5 of the EU ABS Regulation as they are unable to comply with the requirements provided in Annex I of the same Regulation, particularly Part B.</p>

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?	<input type="checkbox"/> Yes ↳ Please specify countries with which the cooperation was undertaken: <Text entry> ↳ Please provide examples of such cooperation: <Text entry> OR <input checked="" type="checkbox"/> No
42. Has your country cooperated with (third countries') competent national authorities referred to in Article 13(2) of the Protocol?	<input type="checkbox"/> 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? <input type="checkbox"/> Yes OR <input type="checkbox"/> No ↳ If yes, please specify the shortcomings: <Text entry> OR <input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Yes ↳ Please specify type and number of activities carried out: Training sessions: 0 Workshops: 0 Conferences: 0 Others: The ABS Competent National Authority (CNA) has produced an information poster, and a user guide to help educate the public and potential users about the obligations emanating from the EU ABS Regulation. This user guide information was disseminated to a mailing list of potential users as well as notified to the general public through a press release (http://bit.ly/2ypKeEh ; EN translation not available) which also requested entities to notify the ABS CNA about the interest to register collections. The ABS CNA will also be involved in the 4th International Congress on Biodiversity to aim to raise awareness about the ABS regime and its benefits, as well as other science-related events organised at national level for the general public also aiming towards awareness

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

	<p>raising.</p> <p>⌞ 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.): A definite number cannot be estimated as various initiatives were aimed at nation-wide scale.</p> <p>Dissemination of information through a mailing list was coupled with a voluntary scoping questionnaire to attempt to identify the activities carried out by companies operating at national level; approximately 185 entities were contacted.</p> <p>OR</p> <p><input type="checkbox"/> No</p>
<p>44. Has your country organized any activities addressed specifically to academic, university and non-commercial researchers, and small and medium enterprises?</p>	<p><input checked="" type="checkbox"/> Yes</p> <p>⌞ Please specify type and number of activities carried out:</p> <p>Training sessions: 0</p> <p>Workshops: 0</p> <p>Conferences: 0</p> <p>Others: Advisory Committee meetings (3).</p> <p>⌞ Please estimate number of users that participated in the activities carried out/ that received assistance: Representatives from various sectors are regularly involved in discussions of ABS issues and PIC/MAT applications; representative for the national academic institutions and for the economic development agency are involved in such discussions.</p> <p>OR</p> <p><input type="checkbox"/> No</p>
<p>45. Have any complaints been received from users in relation to implementation of the EU ABS Regulation?</p>	<p><input checked="" type="checkbox"/> Yes</p> <p>⌞ Please summarise the nature of complaints received:</p> <p>The Competent Authority queried companies about their knowledge and experience with the ABS regulatory regime through a voluntary scoping questionnaire. When given the option to opine on the ABS regulatory system, one company out of 10 of the respondents for which the ABS regime may potentially apply stated that the system is burdensome. Another company which did not reply to the questionnaire but applied with the Competent authority for permission to access and utilize genetic resources, in summary, emphasized that the new system adds new obligations which were not required in previous years.</p> <p>OR</p> <p><input type="checkbox"/> No</p>

Submission addresses:

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

