

Country	
1. Member State:	ITALY
General information	
2. Responsible authority:	Provisionally this report has been elaborated by the Italian Ministry of Environment, Land and Sea. IMELS is not, however, currently responsible for any of the obligations of the ABS Regulation, pending the formal designation of the competent Authority.
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?	<input type="checkbox"/> Yes OR <input checked="" type="checkbox"/> No <p style="margin-left: 40px;">⌞ <i>If selected, please indicate if there is any national process in place towards becoming a Party?</i></p> <p style="margin-left: 80px;"><input checked="" type="checkbox"/> Yes ⌞ <i>Please provide a summary of the status of the process:</i> <Text entry>The draft law to ratify the NP is pending.</p> OR <input type="checkbox"/> No <p style="margin-left: 40px;">⌞ <i>Please provide a summary of the main difficulties and challenges encountered for becoming a Party to the Nagoya Protocol:</i> <Text entry>Identifying the competent authorities to implement the Protocol requires coordination among different competent administrations. Further, implementation of the NP would require additional financial resources and specialized personnels.</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 type="checkbox"/> Yes <p style="margin-left: 40px;">⌞ <i>Please identify the designated competent authority/-ies</i>: <Text entry></p>

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

	<p>⌞ <i>If selected, please fill in also section 7</i></p> <p>OR</p> <p><input checked="" type="checkbox"/> No</p> <p>⌞ <i>Please provide explanation why not:</i> <Text entry> NCAs have been identified but the interministerial decree to formally designate them has not been adopted yet. The draft decree is now passing the interministerial consultation, involving also Italian regions. Italy will inform the Commission as soon as the decree will be formally adopted.</p> <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><input 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 declarations²:</i> <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 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 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 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</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>- cooperation with third countries under Article 7(3)</p> <p>- implementation of complementary measures under Article 13 (awareness raising, training activities, guidance to users etc.)</p>	<p>collections: <Text entry></p> <p>↳ <i>If no</i>, please indicate which other institution is responsible for recognizing and verifying registered collections: <Text entry></p> <p><input 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 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 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</p> <p>OR</p> <p><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 type="checkbox"/> Yes</p> <p><i>If selected</i>, please indicate how many (person-months per year): <Text entry></p> <p>Involved in enforcement of the Regulation (person-months per year⁴): <Text entry></p> <p>Involved in other activities (cooperation, awareness-raising, capacity-building, reporting) (person-months per year): <Text entry></p> <p>OR</p> <p><input checked="" type="checkbox"/> No</p> <p>↳ <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:</i> Lack of human and financial resources, lack of expertise. Currently, existing staff working on CBD is also dealing with issues related to the EU ABS Regulation and the NP.</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);

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	<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> ABS is cross-sectoral and requires coordination among different institutions at various level (local, regional, national). Lack of financial resources, expertise and specialized staff is also a challenge.

Legislative measures	
Penalties (Article 11)	
12. Has your country set up a penalty system as required by Article 11?	<input type="checkbox"/> Yes <i>↳ If selected, please fill in sections 13-15</i> OR <input checked="" type="checkbox"/> No <i>↳ If selected, please explain why not and provide a timetable for adoption of penalties: Penalties have been defined but they have not been adopted yet.</i>
13. What are the types of penalties foreseen for infringements of Article 4 and 7 of the Regulation?	<input type="checkbox"/> Notice of remedial action <input type="checkbox"/> Administrative fines <input type="checkbox"/> Criminal sanctions <input type="checkbox"/> Others <i>↳ If selected, please specify:</i>
14. What is the level of penalties established for breaches of the Regulation?	<Text entry> <i>Please provide examples for penalties applicable to offences that are considered to be severe, medium, and of lower importance.</i>
15. Additional information	<i>Please provide any additional relevant information, including – where relevant – a summary of the main challenges when putting penalty systems in place:</i> <Text entry> <i>Please provide link(s) to the relevant legislation:</i> <URL and website name>

Administrative measures put in place for implementation of the Regulation
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⁵ Such as public procurement procedures, consultancies, studies, outsourced communication campaigns, etc.

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): the Competent Authorities to implement article 7 have not been formally designated

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: <Text entry>
- 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: <Text entry>
- 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): <Text entry>

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>

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	<p><i>Please provide any additional relevant information, including – where relevant – a summary of the main difficulties and challenges when preparing the plan: <Text entry></i></p> <p><i>Please provide link to the plan: <URL and website name> and/or <Attachment></i></p>

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)?	<Text entry>
24. How many due diligence declarations have been received based on Article 7(2)?	<Text entry>
25. Number of checkpoint communiques transferred to the ABS Clearing House	<Text entry>
26. Number of checkpoints communique transferred to the competent authority referred to in Article 13(2) of the Protocol for confidentiality reasons	<Text entry>
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: <Text entry></i></p> <p><i>Please provide a summary of the main difficulties and challenges in relation to implementation of Article 7(2), if any: <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.

Checks on users (Article 9)	
28. How many checks have been carried out during the reporting period?	<Text entry>
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 ↳ Please specify: <Text entry>
30. Were all the checks carried out in line with the plan developed based on Article 9(3)(a)?	<input type="checkbox"/> Yes OR <input type="checkbox"/> 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	<i>Please provide a summary of the main types of shortcomings identified:</i> <Text entry> <i>Please provide a summary of the main difficulties and challenges in relation to checks:</i> <Text entry>
Penalties (Article 11)	
34. Penalties imposed during the reporting period	<i>Please specify if your country imposed any penalties</i> <input type="checkbox"/> Notice of remedial action ↳ If selected, please specify how many: <Text entry> <input type="checkbox"/> Fines ↳ If selected, please specify how many: <Text entry> <input type="checkbox"/> Criminal sanctions ↳ If selected, please specify how many: <Text entry> <input type="checkbox"/> 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: <input type="checkbox"/> Article 4 – due diligence <input type="checkbox"/> Article 7 – duty to file due diligence declaration <input type="checkbox"/> Other ↳ Please specify: <Text entry>

36. Additional information:	<i>Please provide a summary of the main difficulties and challenges concerning enforcement measures (if any):</i> <Text entry>
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 ↳ <i>Please indicate how many collections expressed their interest:</i> <Text entry> One collection, mainly request of information about the register. OR <input type="checkbox"/> No
38. Number of applications received	<Text entry>
39. Number of verifications carried out	<Text entry>
40. Additional information	<i>Please provide any additional information, including on what might explain the level of interest in becoming a registered collection:</i> <Text entry>

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 checked="" type="checkbox"/> Yes <p style="margin-left: 20px;"><i>↳ Please specify countries with which the cooperation was undertaken:</i> <Text entry></p> <p style="margin-left: 20px;"><i>↳ Please provide examples of such cooperation:</i> Organization of informal ABS expert meetings with EU MS in Rome; exchange of emails (FR, SP, NL, UK); participation to EU ABS expert group meetings in Brussels; exchange of information</p> <p style="text-align: center;">OR</p> <input type="checkbox"/> No
42. Has your country cooperated with (third countries') competent national authorities referred to in Article 13(2) of the Protocol?	<input checked="" type="checkbox"/> Yes <p style="margin-left: 20px;"><i>↳ Please specify the countries with which the cooperation was undertaken:</i> <Text entry>Ethiopia</p> <p style="margin-left: 20px;"><i>↳ Please specify areas of cooperation:</i> <Text entry>To solve the issue related to the ensuring letter required by Ethiopia to grant access to its genetic resource to an Italian researcher.</p> <p style="margin-left: 20px;">Was the cooperation related to any identified shortcomings?</p> <p style="margin-left: 40px;"><input type="checkbox"/> Yes OR <input type="checkbox"/> No</p> <p style="margin-left: 20px;"><i>↳ If yes, please specify the shortcomings:</i> <Text entry></p> <p style="text-align: center;">OR</p> <input 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 <p style="margin-left: 20px;"><i>↳ Please specify type and number of activities carried out:</i></p> <p style="margin-left: 40px;">Training sessions: <Text entry></p> <p style="margin-left: 40px;">Workshops:</p> <p style="margin-left: 40px;">Conferences: <Text entry>One conference addressing researchers, universities and other stakeholders</p> <p style="margin-left: 40px;">Others: A brochure describing the concept of ABS, and the content of the NP and the EU ABS Regulation has been published on line and on paper.</p> <p style="margin-left: 40px;">Answering emails and request of information about the EU ABS Regulation</p> <p style="margin-left: 20px;"><i>↳ 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.):</i> more or less</p>

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>100 persons</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: <Text entry></p> <p>Workshops: <Text entry></p> <p>Conferences: see above (n. 43)</p> <p>Others: <Text entry></p> <p>↳ Please estimate number of users that participated in the activities carried out/ that received assistance: <Text entry></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 type="checkbox"/> Yes</p> <p>↳ Please summarise the nature of complaints received: <Text entry></p> <p>OR</p> <p><input checked="" type="checkbox"/> No</p>

Submission addresses:

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