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| **Ministeru għall-Agrikoltura, Sajd u Drittijiet tal-Annimali** | downloadfile | **Ministry for Agriculture, Fisheries and**  **Animal Rights** |
| Dipartiment għall-Affarijiet Rurali  *Direttorat għall-Ħarsien tal-Pjanti* | MALTA | Rural Affairs Department  *Plant Protection Directorate* |

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|  | **Ref. no.:**  *For official use only* |
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| **Application to obtain Prior Informed Consent (PIC) to access Genetic Resources for which Malta has sovereign rights** | |
| For the utilization in Research and Development activities involving genetic resources (GR) from plants, animals or micro-organisms, or their associated traditional knowledge (aTK), excluding those genetic resources listed in regulation 2(2) of Subsidiary Legislation 549.111 and including the process of researching their properties, or to develop new commercial products;  This application implements regulation 7 of Subsidiary Legislation 549.111, Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization Regulations, 2016;  The ABS Competent Authority shall use the personal information provided on this form in accordance with the Data Protection Act (Chapter 440.)​​ | |

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| **0.** | **Type of Applicant** |

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| Legal Person  (Entity) |  | Natural Person (Individual) |  |

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| **1.** | **Contact Information** |

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| Surname: |  | Name: |  |
| Position: |  | Citizenship: |  |
| ID or Passport number: |  | E-mail address: |  |
| Address: |  | | |
| Telephone or Mobile number: |  | | |

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| **2.** | **Information on the Legal Person[[1]](#footnote-1)** |

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| Name of institution, legal entity or affiliation: |  |
| Postal Address: |  |
| Physical Address: |  |
| Contact person: |  |
| Telephone number: |  |
| E-mail address: |  |

| **3.** | **Genetic Resources** |
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| I, the undersigned, would like to apply for the permission to access the following genetic resources. Specify further details below: | | | |
| Species name[[2]](#footnote-2) | Projected quantity to be used | Functional Unit | Source locality coordinates and name |
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| **4.** | **Access Activities Requested** |

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| I, the undersigned, would like to apply for the following access activities for the specimens mentioned in Section 3 (above): | | | |
| 4.1 | Obtaining GRs from wild sources |  | |
| 4.2 | Obtaining GRs from in situ conservation sources |  | |
| 4.3 | Obtaining GRs from ex situ conservation sources |  | |
| 4.4 | Obtaining GRs from private sources or other users |  | |
| 4.5 | Obtaining GRs from local sellers |  | |
| 4.6 | Obtaining GRs from foreign sources [Specify]: |  | |
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| 4.7 | Obtaining GRs from other sources [Specify]: | |  |
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| 4.8 | Obtaining aTK associated with genetic resources | |  |

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| 4.9 | If the GR is to be obtained from public or private holders, state its Registration ID |  |

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| **5. Utilization of Genetic Resources** |  |

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| I, the undersigned, declare that Utilization of the specimens mentioned in Section 3: | | | |
| Will involve a research phase |  | Will involve a product development phase |  |
| Will be aimed to culminate in commercial benefits |  | Will be aimed to culminate in non-commercial benefits |  |

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| I, the undersigned, would like to utilize the specimens mentioned in Section 3 for the following purposes: | | | | | | | |
| 5.1  Cosmetics |  | 5.2  Medicinal products |  | 5.3  Feed, Food and beverage |  | 5.4  Biological control |  |
| 5.5  Plant breeding |  | 5.6  Animal breeding |  | 5.7  Biostimulants |  | 5.8  Conservation Purposes |  |
| 5.10  Others [Specify]: |  | | | | | |  |
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| **6.** | **Detailed Project Description** |

| *Please provide the following details about the project for which access for the utilization of GR / aTK is being requested. Indicate “N/A” if the field is not applicable, or “Annex” if the information has been annexed separately. Relevant sections may be skipped if the information is already provided in an annexed complementary application to an assistant authority or a project description.* | | | | | |
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| **Scope** | | | | | |
| 6.1 | Title of the project proposal |  | | | |
| **Access** | | | | | |
| 6.2 | Dates of collection activity of the GR |  | | | |
| 6.3 | Number of persons to be involved in the collection activity |  | | | |
| 6.4 | Type of vehicles and means by which the site where the GR occurs will be accessed |  | | | |
| 6.5 | Description of potential negative ecological impacts of the collection activity |  | | | |
| **Utilization** | | | | | |
| 6.6 | Information on the intended use of the GR / aTK |  | | | |
| 6.7 | Brief description of what the research and development will involve |  | | | |
| 6.8 | Address of the research facility where product research will take place |  | | | |
| 6.9 | Planned starting date of the research phase |  | | | |
| 6.10 | Planned ending date of the research phase |  | | | |
| 6.11 | Address of the development facility where product development will take place |  | | | |
| 6.12 | Planned starting date of the development phase |  | | | |
| 6.13 | Planned ending date of the development phase |  | | | |
| 6.14 | Contact details of stakeholders involved in research or development |  | | | |
| 6.15 | Role of stakeholders involved in research or development |  | | | |
| 6.16 | The GR / aTK is intended to be transferred to third parties during the research or development | Yes |  | No |  |
| 6.17 | Contact details of third parties involved in research or development |  | | | |
| 6.18 | Role of third parties in research or development |  | | | |
| **Funding** | | | | | |
| 6.19 | Budgetary value of the project |  | | | |
| 6.20 | Name of the entity funding the project |  | | | |
| 6.21 | Address of the entity funding the project |  | | | |
| 6.22 | Funding scheme reference ID |  | | | |
| 6.23 | Amount to be received in funding |  | | | |
| 6.24 | Expected date of receipt of the first instalment of research funding, grant or other financial contribution |  | | | |
| **Expected Benefits** | | | | | |
| 6.25 | Monetary and other benefits expected to be derived from the completion of the project and commercialization |  | | | |
| 6.26 | Name of the country in which the product is to be placed on the market |  | | | |

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| **7.** | **Other Information** |

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| *The following documents should be provided with the application.* | |
| 7.1 | Copy of the Curriculum Vitae of the individual(s) leading the collection of GR / aTK |
| 7.2 | Copy of the Curriculum Vitae of the individual(s) leading the research or development |
| 7.3 | Copy of memorandum of association of the legal person |

| *The following documents should be provided with the application, where applicable.* | |
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| 7.4 | Copy of a letter by the company director authorising the applicant to act as representative of the legal person |
| 7.5 | Permission to access from privately owned land |
| 7.6 | Copy of Prior Informed Consent and Mutually Agreed Terms documentation of the preceding user, if the GR / aTK is to be transferred to the applicant[[3]](#footnote-3) |
| 7.7 | Copy of Internationally Recognized Certificates of Compliance of the preceding user, if the GR / aTK is to be transferred to the applicant3 |
| 7.8 | Detailed Project Description |
| 7.9 | Complementary application to an assistant authority |

| *If applicable, provide the following information.* | | |
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| 7.8 | Number of pages of additional information attached |  |
| 7.9 | Sections or subsections in this application form to be treated as confidential, where disclosure of their information affects one or more of the items mentioned in the Freedom of Access to Information on the Environment Regulations, 2005 (Legal Notice 166 of 2005) |  |

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| Please note that a new permit would be required, for any changes in use e.g. from non-commercial to commercial. In compliance with Article 5 of Commission Implementing Regulation (EU) 2015/1866, a due diligence declaration must be provided at the time of receipt of the first instalment of research funding or at the time of collection of the genetic resource, whichever is the earliest. Another due diligence declaration is required at the final stage of development of a product in the eventuality that the research is furthered into development. |

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| **8.** | **Declaration by the applicant** |

| Upon signature of this application, I, the applicant: | |
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| 8.1 | Agree that a permit provided as a result of this application does not prejudice the applicant’s obligations under national and international legal instruments.; |
| 8.2 | Guarantee to utilize the genetic resource listed under Section 3, or its associated traditional knowledge, only for the purposes consistent with this application; |
| 8.3 | Acknowledge that any permit issued in connection with this application will be valid for a limited period, to be established under mutually agreed terms, and may be extended through another application; |
| 8.4 | Acknowledge that alternative uses of the genetic resource listed in Section 3, or its associated traditional knowledge, would require an additional application and permit; |
| 8.5 | Agree to negotiate with the ABS Competent Authority the sharing of benefits arising from research or development carried out on the genetic resource(s) or the associated traditional knowledge for which the permit has been issued; |
| 8.6 | Assume the responsibility of all the details provided in this application and the supporting documentation being attached to this application form; |
| 8.7 | Agree to inform the ABS Competent Authority of any changes in the information provided, particularly any change in utilization such as from research to R&D; |
| 8.8 | Agree that the information provided with this application will be utilised for this application’s processing; |
| 8.9 | Agree that the ABS Competent Authority or pertinent Assistant Authority will not process further the application in the event that it transpires that false or incorrect declarations have been provided; |
| 8.10 | Guarantee that there are no pending legal procedures which limit the applicant from serving all the obligations listed in the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations, 2016; |
| 8.11 | Agree that the ABS Competent Authority may take administrative actions, which in severe cases may include the cancellation of the permit issued in correspondence with this application if anomalies are identified; |
| 8.12 | Acknowledge that this application is nullified if it is not signed by the applicant. |

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| I attach the necessary documentary evidence and declare that all the particulars provided are to the best of my knowledge and belief correct. | | | | |
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| Signature of applicant |  | Name in block letters |  | Date |

*For office use only:*

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| *Received by:* |  |  |  |  |
| Signature of officer |  | Name in block letters |  | Date |
| *Applications should be provided in original signature to the Plant Protection Directorate. Information provided in this application is protected and used in accordance with the provisions of the Data Protection Act, 2001 (CAP. 440).* | | | | |

1. If applicable. [↑](#footnote-ref-1)
2. Include the breed / variety / strain, if applicable. [↑](#footnote-ref-2)
3. Applicants seeking to obtain GR / aTK from other users should provide copies of PIC, MAT and IRCC documents belonging to the previous users in line with the requirements of Article 4(2) and (3) of Regulation (EU) 511/2014. [↑](#footnote-ref-3)