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**Due Diligence Declaration (Final Stage of the Development of a Product)**

The University of Cambridge is committed to compliance with the [Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity](https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf) and the EU’s Nagoya Protocol Implementation Regulation ([Regulation (EU) No 511/2014](http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm)).

As part of the compliance process, a declaration of due diligence must be made to the Office for Product Safety and Standards, the UK’s Competent Authority for the Protocol at the final development stage of any product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources that are subject to the Nagoya Protocol.

This form is designed to be submitted to the Office for Product Safety and Standards. The Office for Product Safety and Standards will also transmit some of the information provided to the Access and Benefit Sharing Clearing House (ABSCH). The ABSCH will publish the information it receives unless it is indicated as confidential (according to the definition of confidentiality set out in Article 7(5) of Regulation (EU) 511/2014)[[1]](#footnote-1) on this form. To indicate confidentiality, tick the relevant box and provide a justification at the end of the form. If you mark as confidential essential information without which the record cannot be published on the ABSCH, this information will not be shared with the ABSCH by Office for Product Safety and Standards, but may be passed directly to the competent authorities of the provider country.

If the utilisation has involved more than one genetic resource or any traditional knowledge associated with genetic resources, please provide relevant information for each genetic resource or any traditional knowledge utilised.

This form is based on the template provided in Annex II of Commission Implementing Regulation (EU) 2015/1866.

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| **A. Information to be transmitted to the ABSCH** | | | |
| I declare that I have fulfilled the obligations under Article 4 of Regulation (EU) No 511/2014. I am making this declaration for the utilisation of:  *Please tick the appropriate box or boxes* | | | |
| Genetic Resources  Traditional Knowledge associated with genetic resources | | | |
| Name of the product, or description of the result of the utilisation[[2]](#footnote-2), or description of the outcome of utilisation[[3]](#footnote-3): | | | |
|  | | | |
| Confidential? Yes  No | | | |
| Contact details of the user: | | | |
| Name |  | | |
| Address |  | | |
| Email |  | | |
| Telephone |  | | |
| Website (where available) |  | | |
| The declaration is made on the occasion of the following event:  *Please tick the appropriate box:* | | | |
| a) market approval or authorisation is sought for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;  b) a notification required prior to placing for the first time on the Union market is made for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;  c) placing for the first time on the Union market a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources, for which no market approval, authorisation or notification is required;  d) the result of the utilisation is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);  e) the utilisation has ended in the Union and its outcome is sold or transferred in any other way to a natural or legal person outside the Union. | | | |
| Information on exercise of due diligence | | Yes | No |
| An internationally recognised certificate of compliance (i) was issued for my or my entity's access or (ii) covers the terms of this access to the genetic resource(s) and traditional knowledge associated with genetic resources. | |  |  |
| If ‘Yes’ please provide the unique identifier of the internationally recognised certificate of compliance and then go to Part B (2): | | | |
| If ‘No’ please provide the information below | | | |
| 1. Place of access: | | | |
|  | | | |
| Confidential? Yes  No | | | |
| 2. Description of the genetic resources or traditional knowledge associated with genetic resources utilised; or unique identifier(s), where available: | | | |
|  | | | |
| Confidential? Yes  No | | | |
| 3. Date of access: | | | |
| Confidential? Yes  No | | | |
| 4. Identifier of access permit or its equivalent[[4]](#footnote-4), where available: | | | |
|  | | | |
| Confidential? Yes  No | | | |
| 5. Person or entity who granted prior informed consent | | | |
|  | | | |
| Confidential? Yes  No | | | |
| 6. Person or entity to whom prior informed consent was granted: | | | |
|  | | | |
| Confidential? Yes  No | | | |
| 7. Is the utilisation of genetic resources and traditional knowledge associated with genetic resources subject to mutually agreed terms? | | | |
|  | | | |
| Confidential? Yes  No | | | |
| Please go to Part B (1) | | | |

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| **B. Information not to be transmitted to the ABSCH** | | |
| 1. Information on exercise of due diligence: | | |
| a) Direct source of the genetic resource and the traditional knowledge associated with genetic resources: | | |
|  | | |
| b) Are there any restrictions in the mutually agreed terms limiting the possible utilisation of the genetic resource(s) or the traditional knowledge associated with genetic resources, e.g. allowing for non-commercial utilisation only? | | |
| Yes | No | Not applicable |
| c) Have there been rights and obligations agreed regarding subsequent applications and commercialisation in the mutually agreed terms? | | |
| Yes | No | Not applicable |
| 2. If the genetic resource(s) was(were) obtained from a registered collection[[5]](#footnote-5), please provide the registration code of the collection: | | |
|  | | |
| 3. If you are implementing a best practice recognised under Article 8 of Regulation (EU) No 511/2014, please provide the registration number: | | |
|  | | |
| 4. Which category best describes your product (optional)? | | |
| a) Cosmetics  b) Medicinal products  c) Food and beverage  d) Biological control  e) Plant breeding  f) Animal breeding  g) Other, please specify: | | |
| 5. Member State(s) in which the utilisation of genetic resources and traditional knowledge associated with genetic resources takes place or has taken place: | | |
|  | | |
| 6. Member State(s) in which the product is to be placed on the market, following the procedure for approval, authorisation or notification referred to in Article 6(2)(a) and (b) of Commission Regulation (EU) 2015/1866 or placed on the market in accordance with Article 6(2)(c) of that Regulation: | | |
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| **C. Confidentiality** |
| If you have declared that some information is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please state the reasons for each piece of information for which you have declared that confidentiality applies: |
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| Date: |  |
| Place: |  |
| Signature of the person legally responsible for the stage of final development of a product: |  |

1. To be confidential, information must be “commercial or industrial information where such confidentiality is provided for by Union or national law to protect a legitimate economic interest, in particular concerning the designation of the genetic resources and the designation of utilisation”. Regulation (EU) 511/2014, Article 7(5). [↑](#footnote-ref-1)
2. ‘Result of the utilisation of genetic resources and traditional knowledge associated with genetic resources’ means products, precursors or predecessors to a product, as well as parts of products to be incorporated into a final product, blueprints or designs, based on which manufacturing and production could be carried out without further utilisation of the genetic resource and traditional knowledge associated with genetic resources. [↑](#footnote-ref-2)
3. Where the utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union. [↑](#footnote-ref-3)
4. Evidence of the decision to grant prior informed consent or approval for access to genetic resources and traditional knowledge associated with genetic resources. [↑](#footnote-ref-4)
5. A ‘registered collection’ is a verified collection of ABS-compliant genetic resources that meets the criteria set out in the [EU ABS Regulation](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511) (Article 5) e.g. DSMZ. The register of collections is available [here](http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm) [↑](#footnote-ref-5)