

Nagoya Protocol – UK processes for submitting Due Diligence Declarations, applying for Best Practice and registering a Collection in the UK

1. Introduction

From 1 January 2021, UK stakeholders involved in accessing genetic resources (GR) from Parties to the Nagoya Protocol are required to follow new, UK processes in the following areas:

- 1. Submitting Due Diligence Declarations
- 2. Applying for a Best Practice
- 3. Registering a Collection

The purpose of this document is to provide simple to follow instructions to meet each of those processes. Note that it is only the process of submitting, applying or registering that has changed.

Users of this document should refer to the specific detail which can be found in the Access and Benefit Sharing (ABS) legislation¹.

Further resources are available at https://www.gov.uk/abs. Help and advice is also available from the Defra policy advisor and UK National Focal Point (NFP) on the Nagoya Protocol – email abs@defra.gov.uk - and the UK's Competent National Authority (CNA), the Office for Product Safety and Standards (OPSS) - email Opss.enquiries@beis.gov.uk.

2. Submitting Due Diligence Declarations (DDD)

Who is to submit a DDD? The obligation to submit a DDD applies to all users of GRs falling within the scope of ABS legislation. This is independent of the user's size, or whether they are profit or non-profit entities, or of the intent of the utilisation (commercial or non-commercial). Users may include the individual (e.g. researcher) utilising the GR or the organisation (e.g. university, research institute, company etc) to which the individual is affiliated with and/or employed by.

Those who have submitted previous DDD via the EU DECLARE system will not need to re-submit these as they have been uploaded to the <u>Access and Benefit Sharing Clearing House</u>.

DDD requirement. There are two 'checkpoints' at which a DDD is to be submitted by the users of GRs:

- 1. at the stage of research funding, and
- 2. at the stage of final development of a product.

Submitting a DDD

1. Complete the required fields of the DDD form which can be downloaded from the OPSS website (https://www.gov.uk/abs).

- 2. Submit the completed form to Defra at abs@defra.gov.uk.
- On behalf of Defra, the UK NFP will upload the relevant information contained in this
 document to the <u>Access and Benefit Sharing Clearing House</u>, with the exception of
 information marked as confidential.

For support in completing the DDD form, please contact Defra via abs@defra.gov.uk.

¹ 'ABS legislation' means legislation implementing the requirements of the Nagoya Protocol (on Access and Benefit Sharing (ABS)) in the UK, comprising The Nagoya Protocol (Compliance) (Amendment) Regulations 2015 (1691) and retained EU direct legislation (Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 and Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015), as amended by the Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 (SI 2018/1393) and the Environment and Wildlife (Legislative Function) (EU Exit) Regulations 2019 (SI 2019/473)).

3. Applying for Best Practice

Who can apply for Best Practice? Associations of UK users or other interested parties may apply to have a combination of procedures, tools or mechanisms, developed and overseen by them, recognised as a Best Practice.

An interested party is one that does not represent users but is involved in the access, collection, transfer or commercialisation of GRs or in developing measures and policy related to GRs.

Best Practice requirement in the UK. Note that EU-recognised Best Practices will not automatically be recognised by the UK after 31 December 2020. Therefore, UK entities that have had their Best Practice recognised by the EU are required to re-submit their application if they wish to have their Best Practice recognised in the UK.

UK entities who wish to apply for Best Practice must apply as per the process laid out below.

Application process for Best Practice.

- An email application must be submitted to the Defra Secretary of State via this email address

 abs@defra.gov.uk
 and include the information stipulated at Annex IV of the Commission Implementing Regulation (EU) 2015/1866.
- 2. The submitted information will be reviewed by OPSS and Defra and further details may be requested.
- Those Best Practices recognised by Defra SoS will be made available on a publicly accessible, internet-based register which will be accessible via the OPSS website https://www.gov.uk/abs.

For support in applying for Best Practice, please direct your query to abs@defra.gov.uk.

4. Registering a Collection

Registering a Collection in the UK. Note that EU-registered Collections will not automatically be recognised by the UK after 31 December 2020. Therefore, entities within the UK who have had their Collection registered by the EU will be required to re-register in the UK if they desire their Collection to continue to be recognised in the UK.

UK entities who wish to apply to register a Collection in the UK are to follow the process set out below.

Information and evidence required for registering a Collection. The information and evidence to be provided with a request for inclusion in the register of Collections is to be found at Annex I, Parts A and B of the Commission Implementing Regulation (EU) 2015/1866.

Application process for registering a Collection. For those collections that meet the criteria and wish to gain Registered Collection status in the UK, entities are requested to:

- 1. Complete the application form which can be downloaded from the OPSS website https://www.gov.uk/abs.
- 2. Submit the completed form to Defra at abs@defra.gov.uk.
- 3. Those Collections recognised by Defra SoS will be uploaded to a publicly accessible, internet-based register which will be accessible via the OPSS website https://www.gov.uk/abs.

For support in registering a Collection, please direct your query to abs@defra.gov.uk.