Department for Business, Energy & Industrial Strategy

Regulatory Delivery

The Nagoya Protocol on Access and Benefit Sharing: Why is it relevant and how to comply

Natural Compounds and Drug Development Day

Mercure Holland House Hotel, Cardiff

16th May 2017

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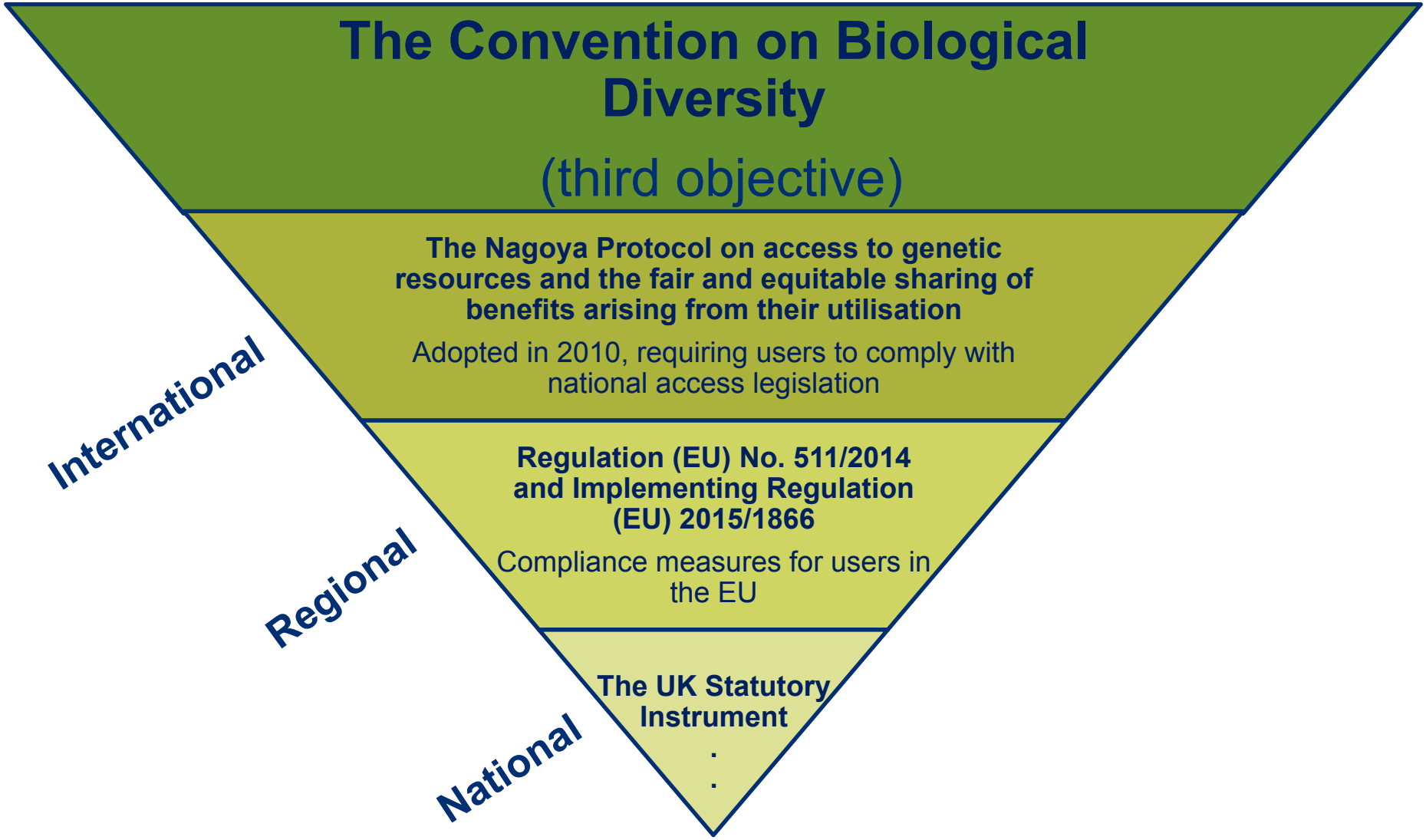
Who we are

Regulatory Delivery (RD)

- Enforcement authority for Access and Benefit Sharing (ABS) in the UK
- Technical and product-based Regulations with environmental focus
- Expertise in risk-based market surveillance, supporting compliance and addressing non-compliance in a proportionate and pragmatic manner

Defra

- Policy lead on Access and Benefit Sharing
- National Focal Point (NFP)


The Convention on Biological Diversity
(third objective)
The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation
Adopted in 2010, requiring users to comply with national access legislation
Regulation (EU) No. 511/2014 and Implementing Regulation (EU) 2015/1866
Compliance measures for users in the EU
The UK Statutory Instrument
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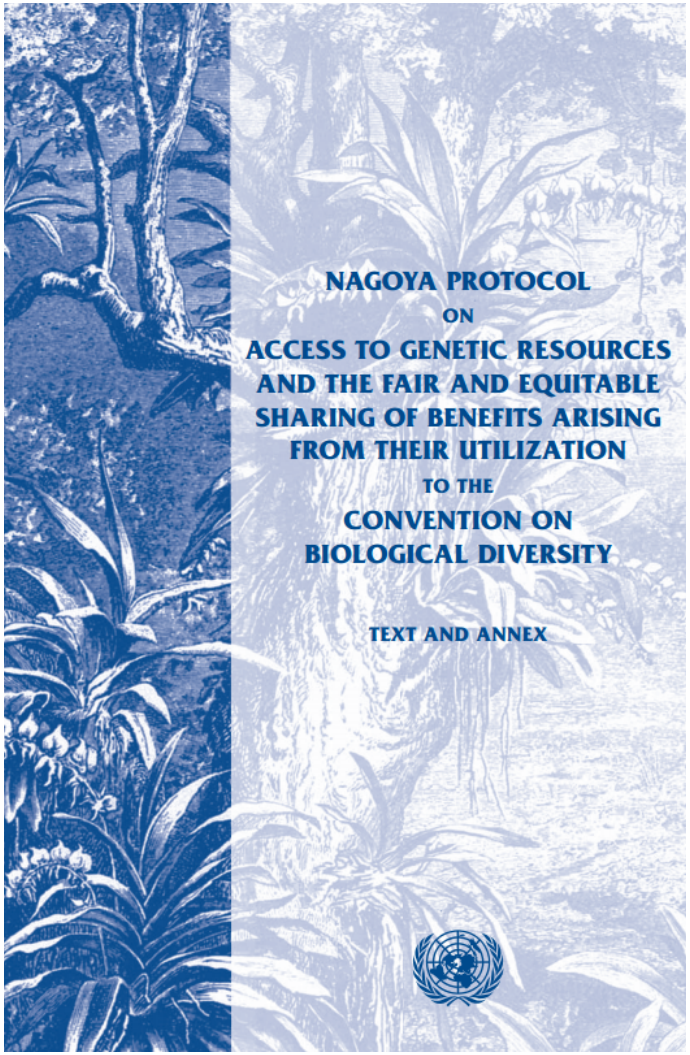
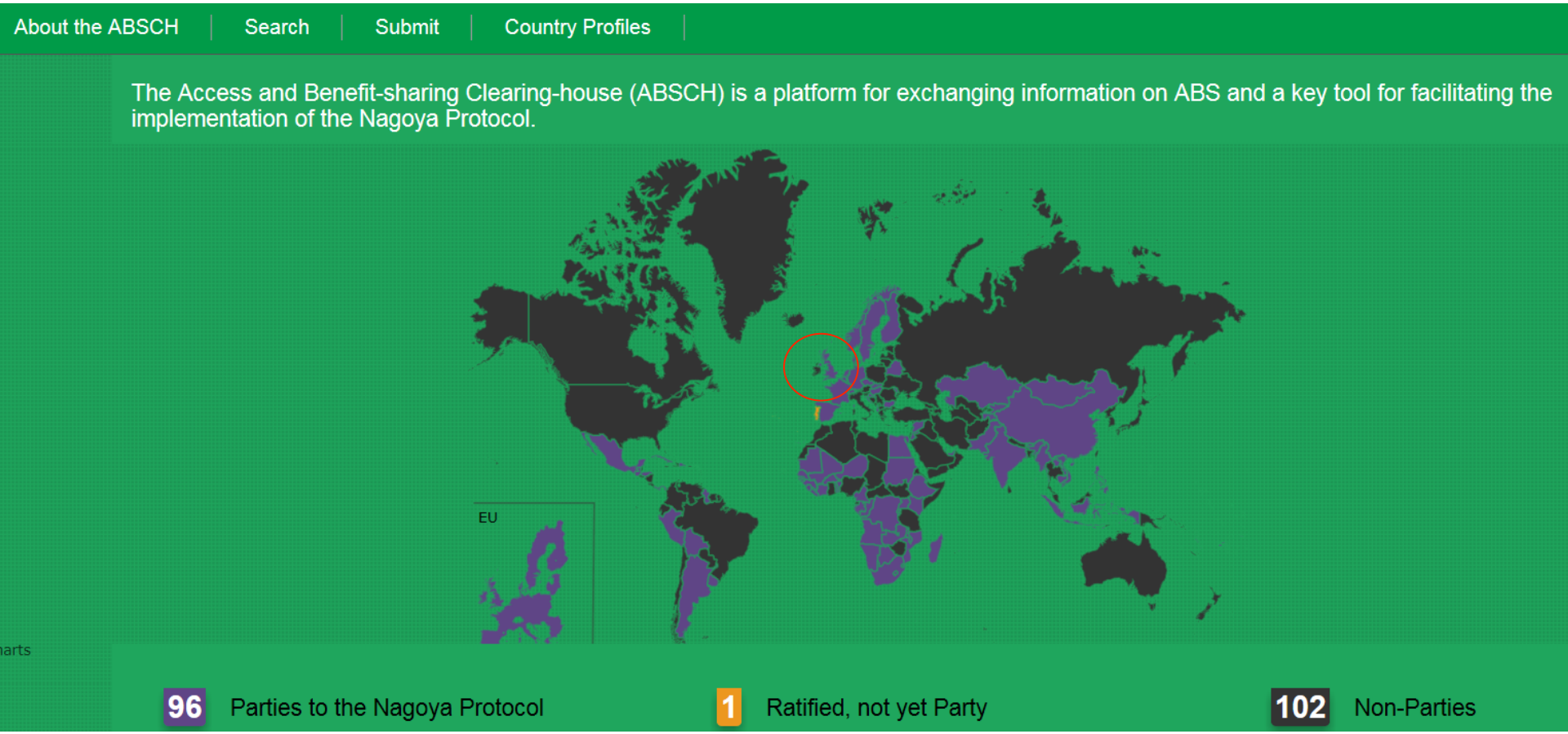
International
Regional
National



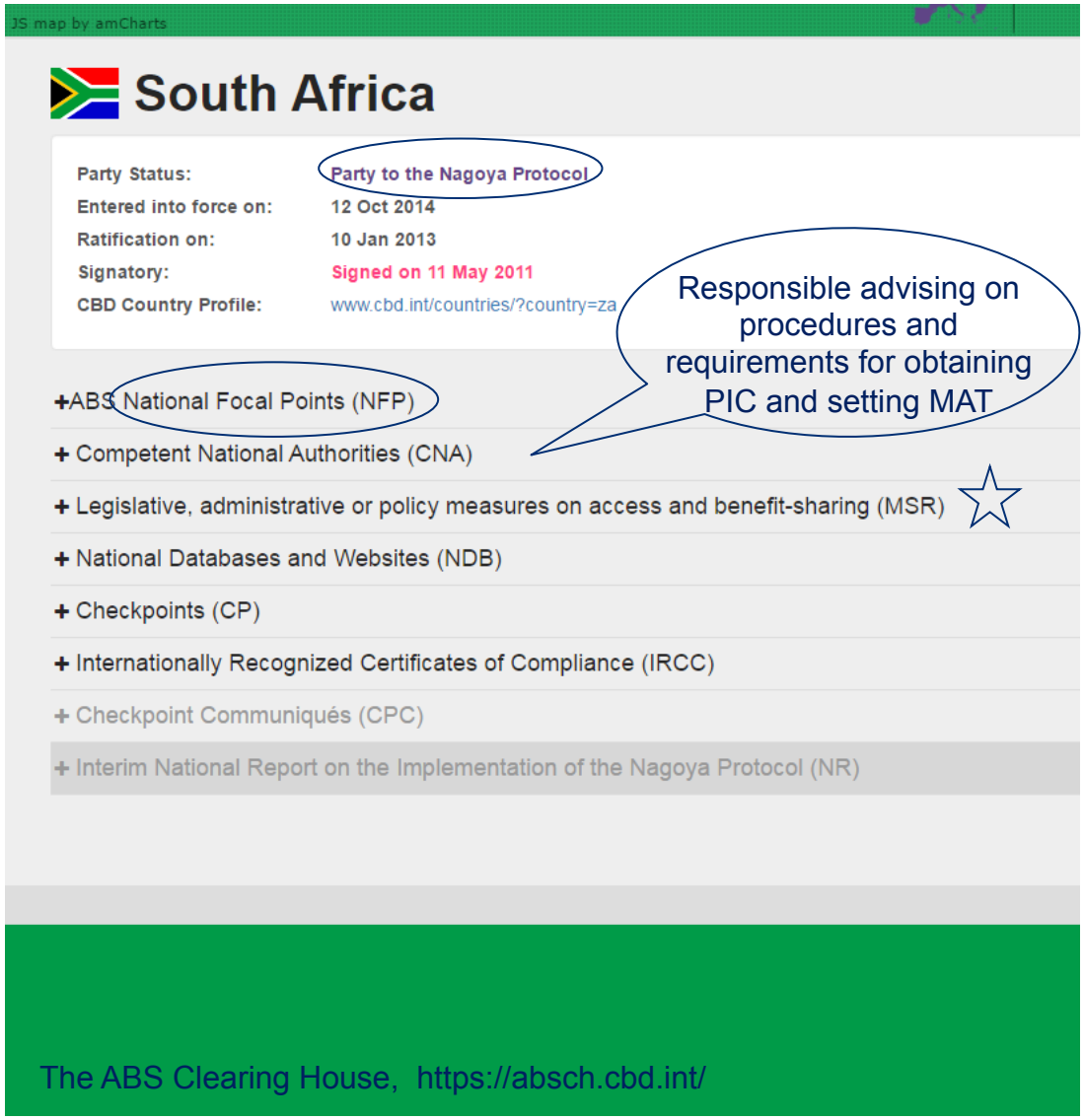
NAGOYA PROTOCOL

- Supplementary to CBD
- Legal framework for implementation of the fair and equitable sharing of benefits arising from utilisation of genetic resources
- More predictable conditions for access to GRs
- Help ensure benefit-sharing when GRs leave the country of origin
- Traditional knowledge associated with GRs
- Tools: Access and Benefit Sharing Clearing House

Access and Benefit Sharing Clearing House (ABS-CH)



https://absch.cbd.int/



The ABS Clearing House, https://absch.cbd.int/

ABS Clearing-House

- Platform to exchange info
- Connecting users and providers
- Country profiles and summaries
- Helps countries monitor utilisation of genetic resources
- Publically available
-

https://absch.cbd.int/

Implementation in the UK

- Regulation (EU) No. 511/2014 (user compliance)
- EU Implementing Regulation (due diligence, best practices, registered collections)
- UK Statutory Instrument (powers to enforce)
- Regulatory Delivery – UK Competent Authority

STATUTORY INSTRUMENTS

2015 No. 821

ENVIRONMENTAL PROTECTION

The Nagoya Protocol (Compliance) Regulations 2015

Made - - - - 17th March 2015
Laid before Parliament 23rd March 2015
Coming into force in accordance with regulation 1

CONTENTS

Regulation (EU) No 511/2014 on compliance measures for users

- Entered into force on 12th October 2014
- Access in accordance with applicable legislation of the provider country
- Research and development
- Genetic material (plant, animal, microbial, other) and traditional knowledge
- Due diligence
- Does not address access to genetic resources in Europe

Assessing scope (EU Legislation)

The EU Regulation applies to genetic resources that meet all of the following conditions:

I. from countries that **exercise sovereign rights**

II. where countries have **established applicable access measures and ratified the Nagoya Protocol**

III. if **accessed after 12 October 2014**

IV. those that are not already **governed by specialised international instruments**

Why is it of relevance?

Activities considered to be in scope of the EU Regulation

- Research on a genetic resource leading to the isolation of a biochemical compound used as a new ingredient incorporated into a product
- Breeding programme to create a new plant variety based on naturally occurring plants
- Genetic modification – creation of a genetically modified animal containing a gene from another species

Activities considered to be out of scope

- Handling and storing of biological material and describing its phenotype

- Genetic resources as testing tools (GR is not the object of the research)

- Supply and processing of relevant raw materials for incorporation into a product (no new research)

Due diligence

- …'*exercise due diligence to ascertain that the genetic resource which they utilise have been accessed in accordance with the applicable legislation'.*

- Seek, keep and transfer information along the value chain

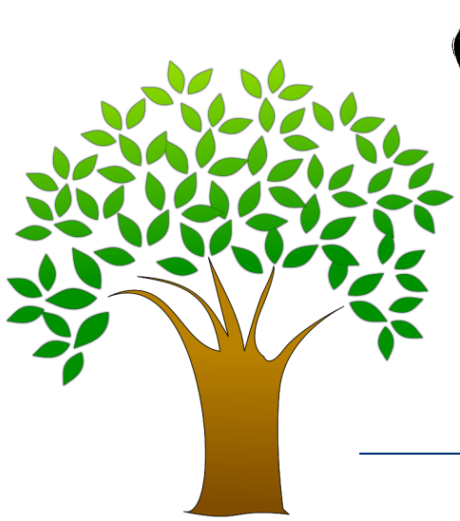
- ABS Clearing House and contacting NFP

- IRCC or equivalent

- Best practices and Registered Collections (Implementing Act)

- EU Checkpoints:
  - Stage of research funding and / or placing a product on the market
  - DECLARE – EU IT Tool

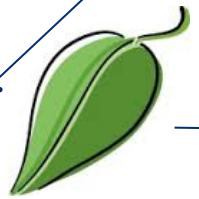
Provider country	European User country

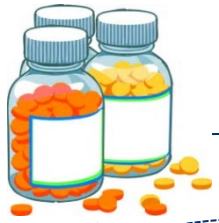


PIC

MAT

Benefit Sharing opportunities





Research funding

Placing product on market

Due diligence: seek, keep & transfer

Due diligence declaration to EU CNA

IRCC	Checkpoint Communiqué

ABS Clearing House

UNEP | Convention on Biological Diversity

ABSCH-IRCC-IN-204353-1
Internationally recognized certificate of compliance constituted from information on the permit or its equivalent made available to the Access and Benefit-sharing Clearing-House

In accordance with Article 17, paragraph 2, of the Nagoya Protocol on Access and Benefit-sharing, a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

General Information

Issuing country

INDIA

Verification link (view latest version)

http://absch.cbd.int/database/ABSCH-IRCC-IN-204353

ABS-CH Unique Identifier (UID)

ABSCH-IRCC-IN-204353-1

Issuing Authority

Competent National Authority

National Biodiversity Authority (NBA)
5th Floor, TICEL Biopark, CSIR Road, Taramani
Chennai, Tamilnadu
600 113, **India**
Phone: +91 44 2254 2777
Fax: +91 44 2254 1200
Email: secretary@nbaindia.org, chairman@nba.nic.in, secretary@nba.nic.in
Website: http://www.nbaindia.org

Details of the permit or its equivalent

Reference number of the permit or its equivalent

India/NBA/App/9/684

Additional national references or identifiers

Application in Form-I for accessing ethno-medicinal knowledge of the Siddi community from Gujarat for research

Date of issuance of the permit or its equivalent

27 Mar 2015

Date of expiry of the permit or its equivalent

26 Mar 2018

Prior Informed Consent (PIC) Information

Confirmation that prior informed consent (PIC) obtained or granted

YES

Provider The person or entity that holds the right to grant access to the genetic resources in accordance with domestic legislation.

CONFIDENTIAL INFORMATION

Entity to whom PIC was granted

Ms Seema Solanki

Mutually Agreed Terms (MAT) Information

Confirmation that mutually agreed terms (MAT) have been established

YES

Additional information about the mutually agreed terms

1. The user shall not obtain any form of IPR based on the biological resources and /or associated knowledge accessed under this agreement in any manner without obtaining the prior approval of NBA under provisions of the Biological Diversity Act, 2002.

2. The applicant shall submit a report to NBA on the outcome of the research work.

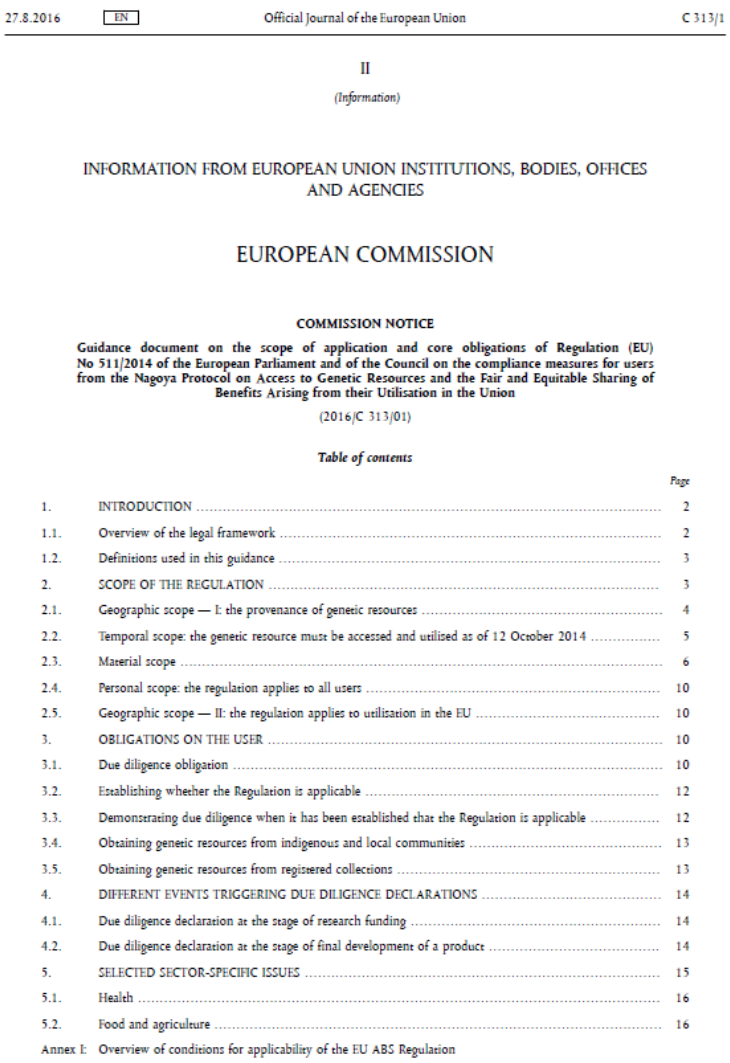
Subject-matter

Subject-matter or genetic resources covered:

Accessing ethno-medicinal knowledge of the Siddi community from Gujarat for research

Support for users: EU Guidance

- Horizontal – published cross-sector guidance
- Sector specific – in preparation
  - Cosmetic
  - Pharmaceutical
  - Bio-control
  - Plant breeding
  - Animal breeding
  - Food & feed
  - Biotechnology
  - Collections and research institutions



27.8.2016 EN Official Journal of the European Union C 313/1

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(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

COMMISSION NOTICE

Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union

(2016/C 313/01)

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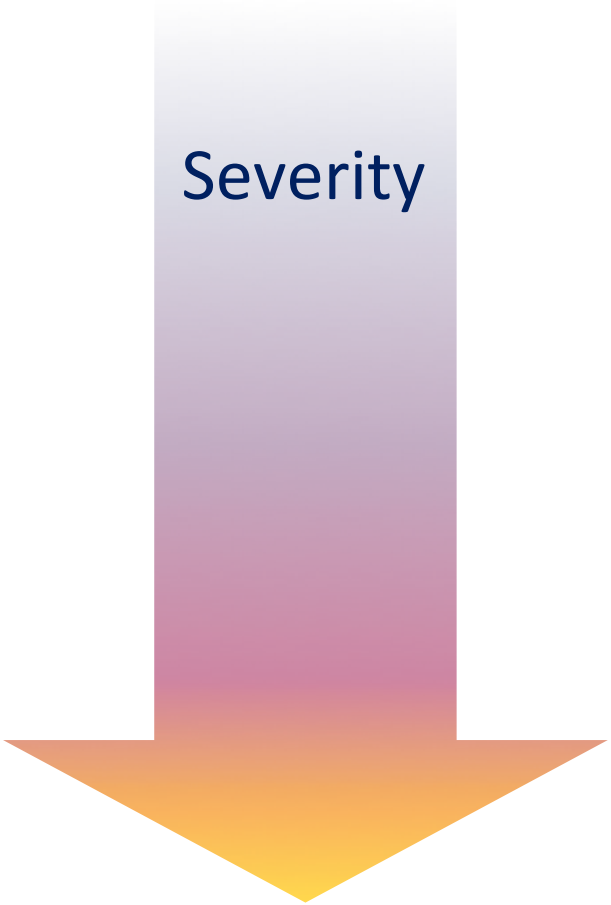

Thank you for your attention