

*Microstroma ruizii-belinii*  
from *Mimosa pigra*, Mexico



**Webinar**  
**CABI ABS negotiations for compliance with the Nagoya Protocol**

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May 2020

KNOWLEDGE FOR LIFE





## Focus of the presentation

- The Nagoya Protocol (NP)
- EU Regulation scope
- CABI compliance with the NP in the utilisation of genetic resources
- CABI documents and procedures (ABS best practice)
- ABS Assessments at CABI
- CABI Strategy
- Response to date



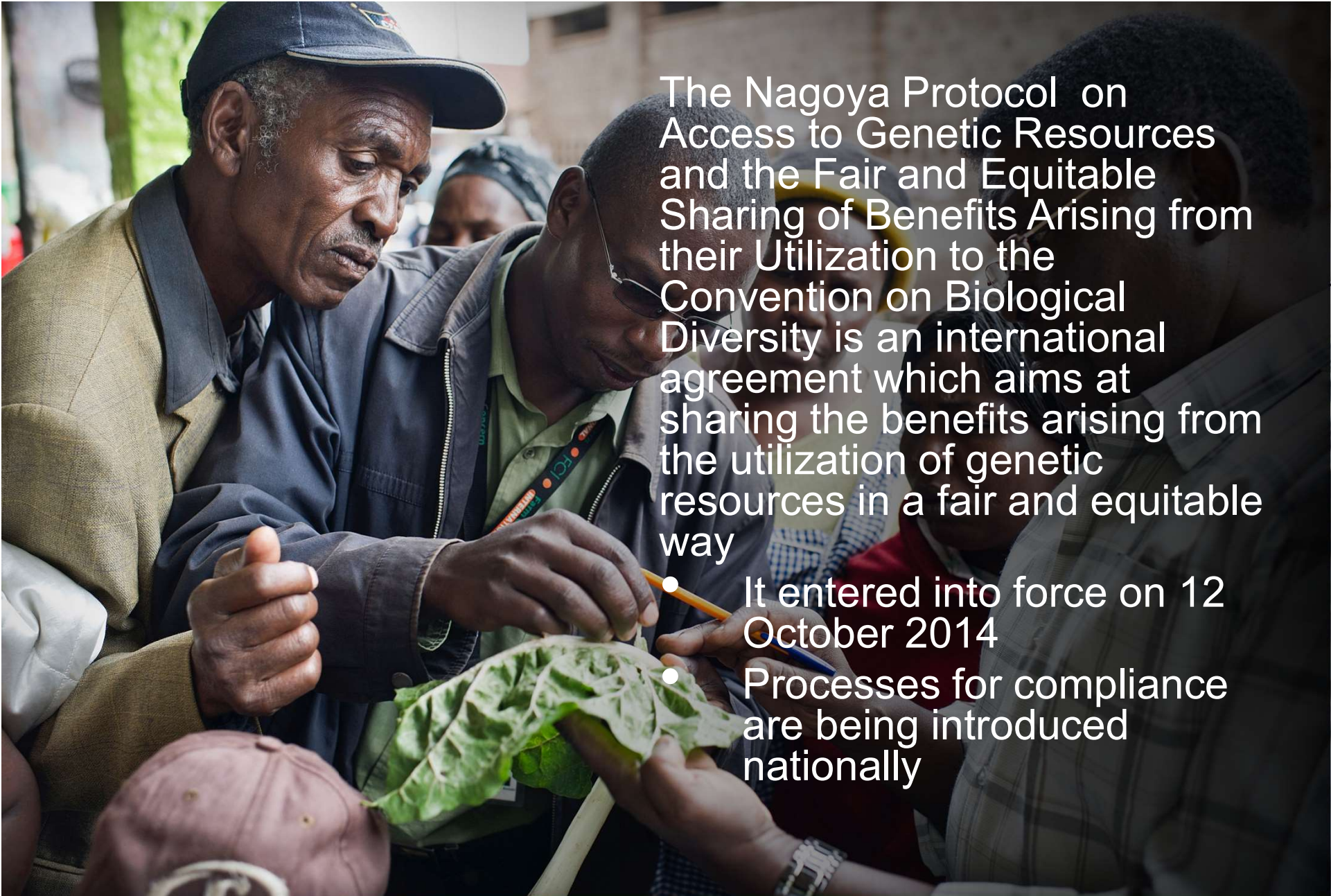


## Disclaimer

The information is presented for guidance only based on the experience of professional microbiologists working in an international organisation

We are not lawyers!

We are Microbiologists applying due diligence to comply with best practices associated with the Nagoya Protocol.

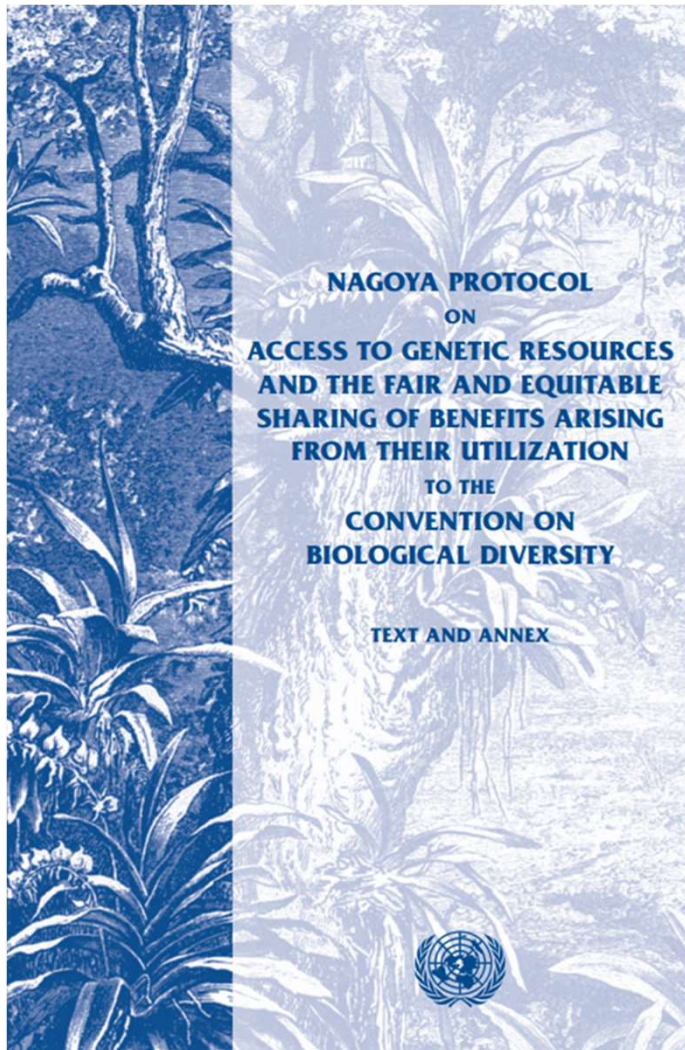


The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way

- It entered into force on 12 October 2014

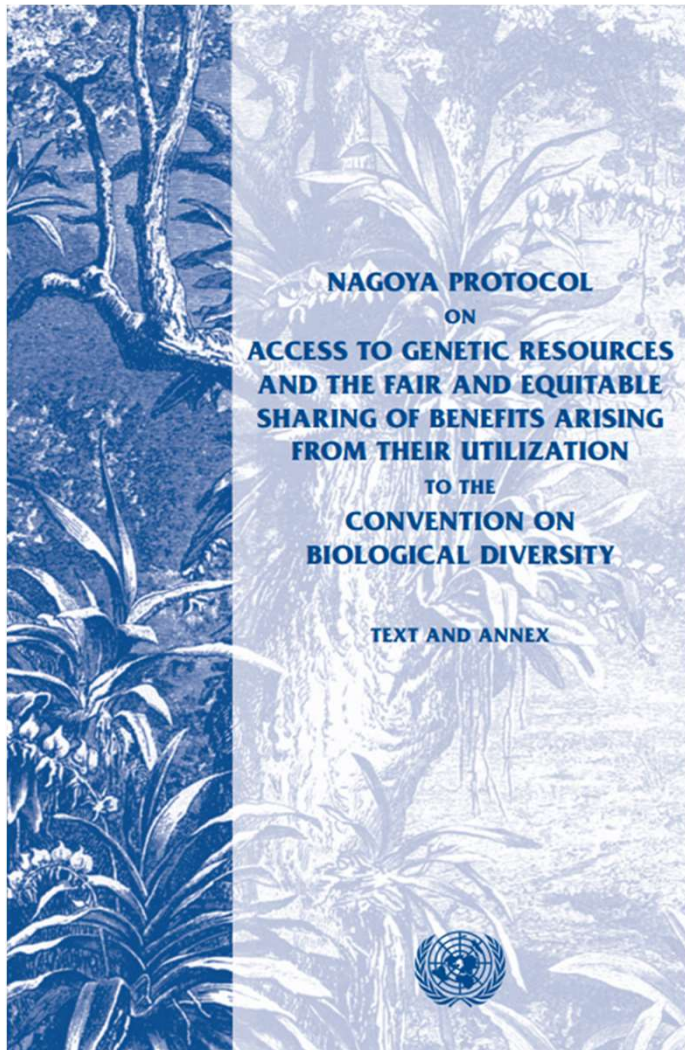
- Processes for compliance are being introduced nationally





# The Convention on Biological Diversity

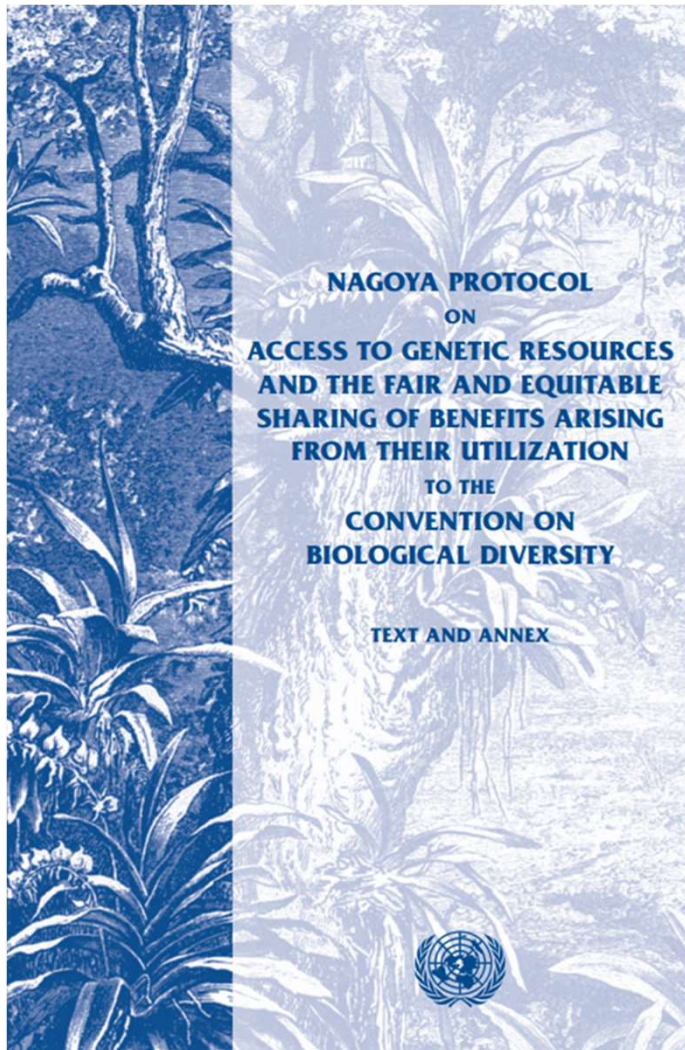
- Entered into force on 29<sup>th</sup> December 1993
- 196 parties to the CBD
- Three main objectives:
  1. The conservation of biological diversity
  2. The sustainable use of the components of biological diversity
  3. **The fair and equitable sharing of benefits arising out of the utilisation of genetic resources**



# NAGOYA PROTOCOL

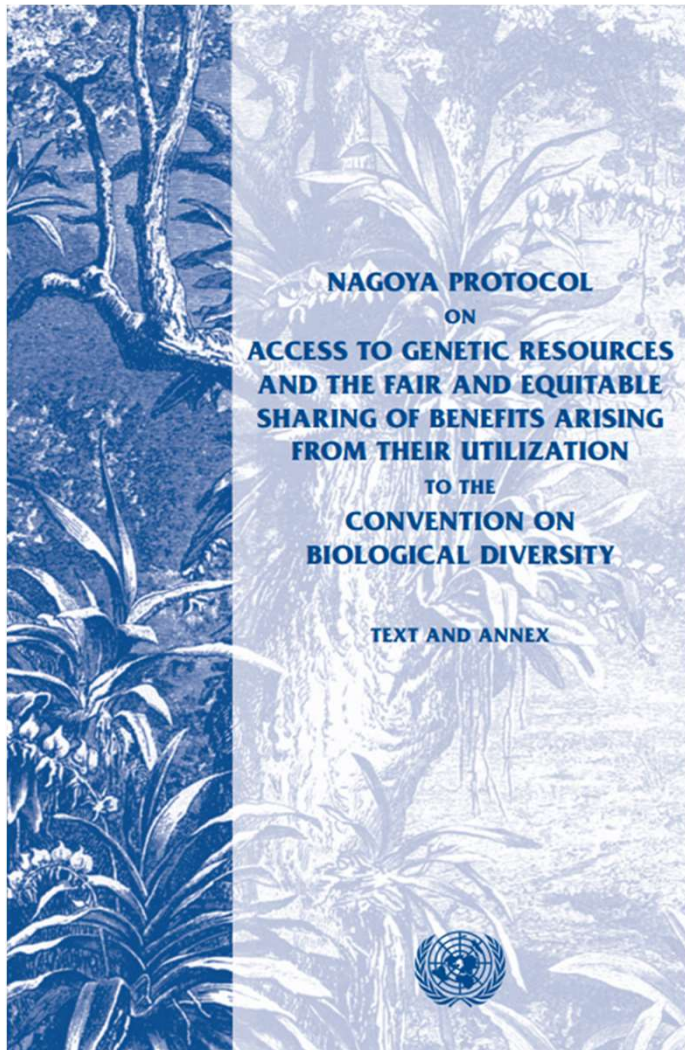
- Legal framework detailing obligations
- Includes traditional knowledge
- Requires traceability
- Implemented Nationally
- Focus here is on EU Regulation No 511/2014
- **Applies to genetic resources accessed in countries that:**
  - I. exercise their sovereign rights and have established access measures
  - II. have ratified the Nagoya Protocol
- **And where the genetic resources are:**
  - I. accessed after 12 October 2014
  - II. not already governed by specialised international instruments e.g. pandemic influenza preparedness (PIP) framework, International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)





## Activities Considered to be In-Scope of EU Legislation

- **Research** on a genetic resource leading to for example, the isolation of a biochemical compound used as a new ingredient incorporated into a pharmaceutical product
- **Creation or improvement** of organisms for example, yeasts, resulting from human action through an R&D process, to be used in manufacturing process
- **Genetic modification** – for example the creation of a genetically modified plant containing a gene from another species

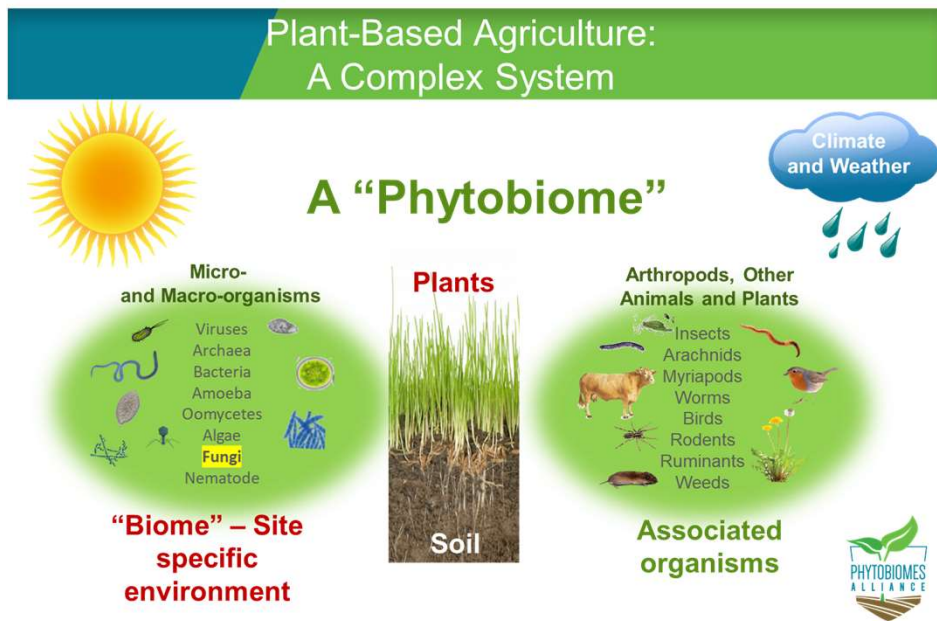


## Activities Considered to be Out of Scope of the EU Regulation

- **Maintenance and management** of a collection for conservation purposes
- **Handling and storing** of biological material and describing its phenotype
- Genetic resources (GR) as **testing tools** (GR is not the object of the research)

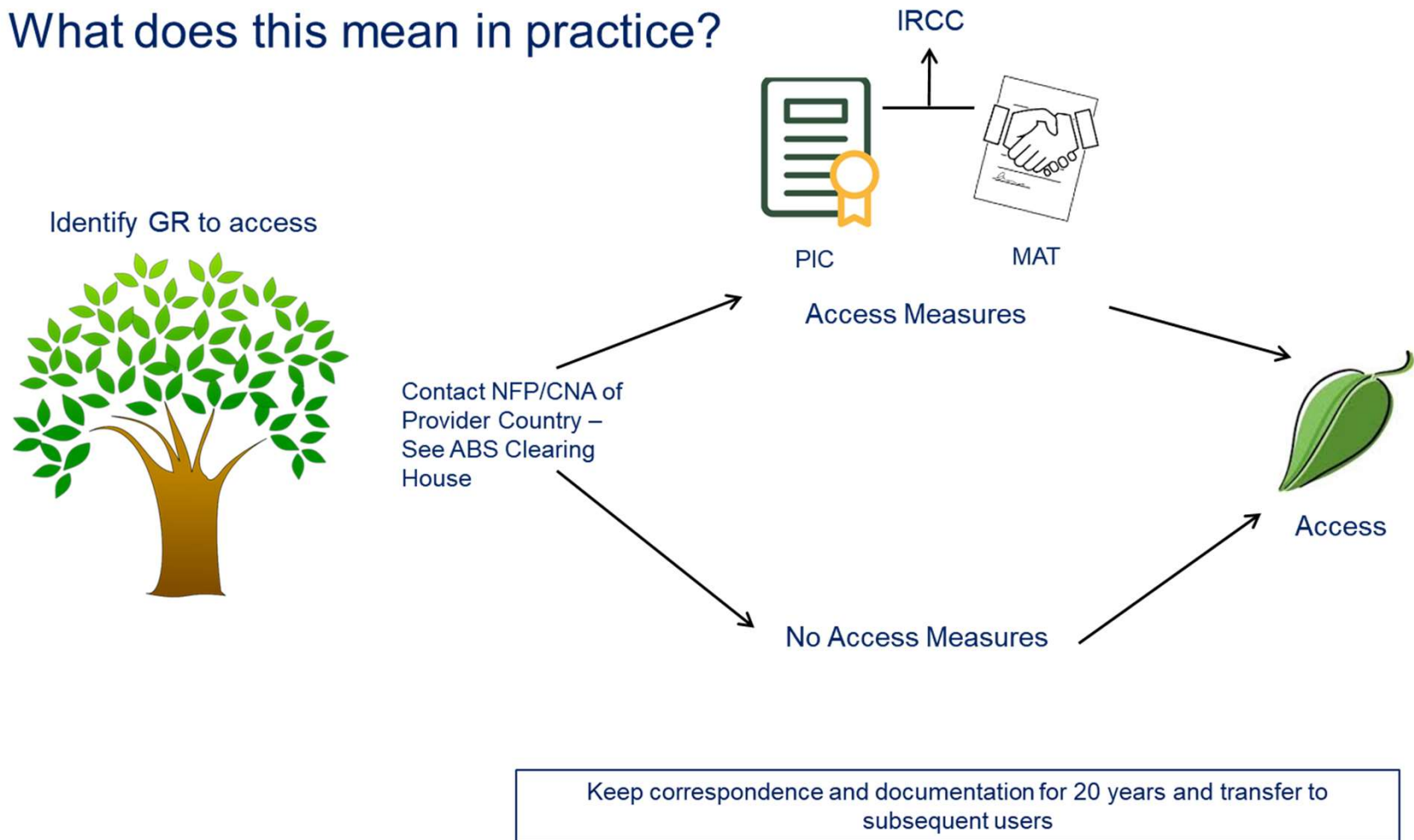


# The microbiome with respect to the Protocol



- Human microbiome within scope of Nagoya Protocol; assume other sources in scope too
- Genetic resources (GRs) are genetic material of actual or potential value which contain functional units of heredity that can be utilised
- Microbiome studies begin with an analysis of total samples, soils, plants etc. and contain GR
- Come into scope of EU regulation dependant upon utilisation and position on DSI

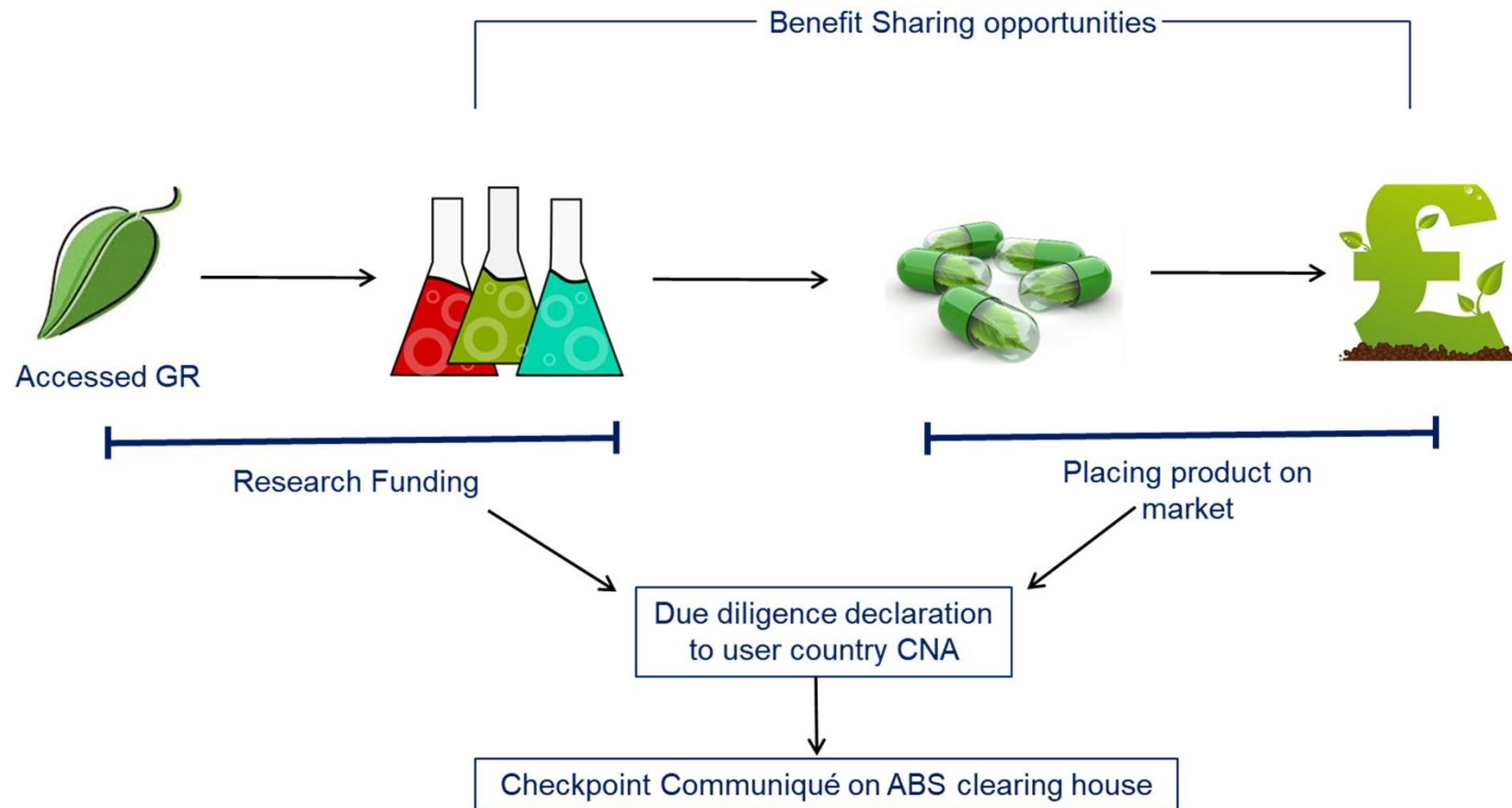
# What does this mean in practice?



By courtesy of Department for Business, Energy & Industrial Strategy (BEIS), Office for Product Safety and Standards: UK Regulator



# EU Regulation: Benefit sharing – meeting provider country commitments



By courtesy of Department for Business, Energy & Industrial Strategy (BEIS), Office for Product Safety and Standards: UK Regulator



## Outstanding issue: Digital Sequence Information

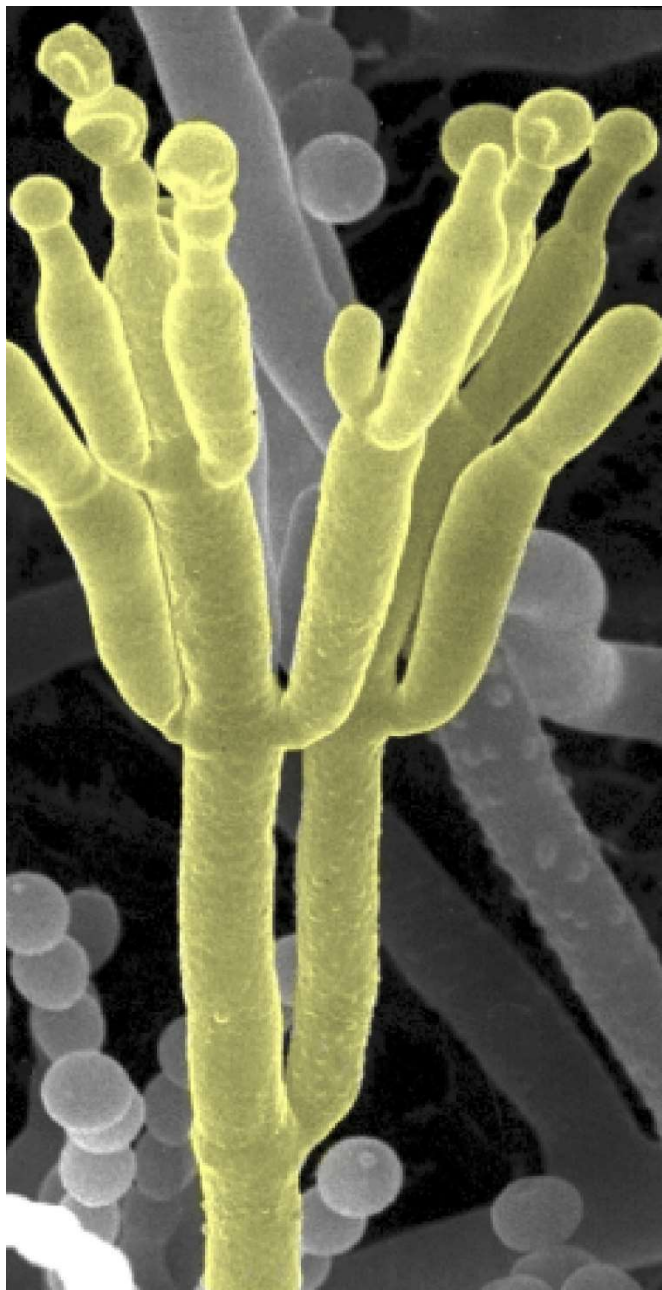
- Broad issue with many implications for ABS
- Developing countries have directly linked adoption of a post-2020 biodiversity framework with a decision on DSI
- Submissions of views and information from parties and stakeholders have been sent to the Secretariat
- The Secretariat commissioned four science-based, peer-reviewed studies: Concept and scope, traceability, databases and domestic measures – presented at the Ad Hoc Technical Expert Group (AHTEG) held on line March 2020 - <https://www.cbd.int/meetings/DSI-AHTEG-2020-01>
- Work from the AHTEG will be discussed at the 3<sup>rd</sup> Subsidiary Body for Implementation (SBI-3) and the 3<sup>rd</sup> Open-ended Working Group (OEWG) on post-2020 and CBD CoP15 originally scheduled for October 2020 in China





## EU Position on Invasive Alien Species

- Invasive alien species and Non-Invasive alien species can be treated in the same way
- Alien species once established (one or more self sustaining population in the wild) are considered *in-situ* (and therefore in scope) regardless of whether introduced or spread from another country
- PIC and MAT are required for species introduced intentionally for utilization purposes, even if before the species has become established
- IAS unintentionally brought into an EU member state prior to their establishment are considered out of scope



## Materials considered out of scope in EU

- GR governed by specialised international instruments and other international agreements
- Human GR (but human microbiome are in scope)
- Trade and exchange of GR as commodities; However, subsequent R&D on those commodities will bring them into scope
- EU ABS regs do not apply to pathogenic organisms or pests present on a human, an animal, a plant, a micro-organism, feed or any other material which were introduced unintentionally to the EU. This remains the case when such GR are transferred from one EU MS to another
- Pathogenic organisms, once unintentionally introduced into the EU and subsequently stored in a collection or passed into the research materials of a lab for utilisation for different purposes, will be within scope. This is due to utilisation for purposes other than for urgent remedial action

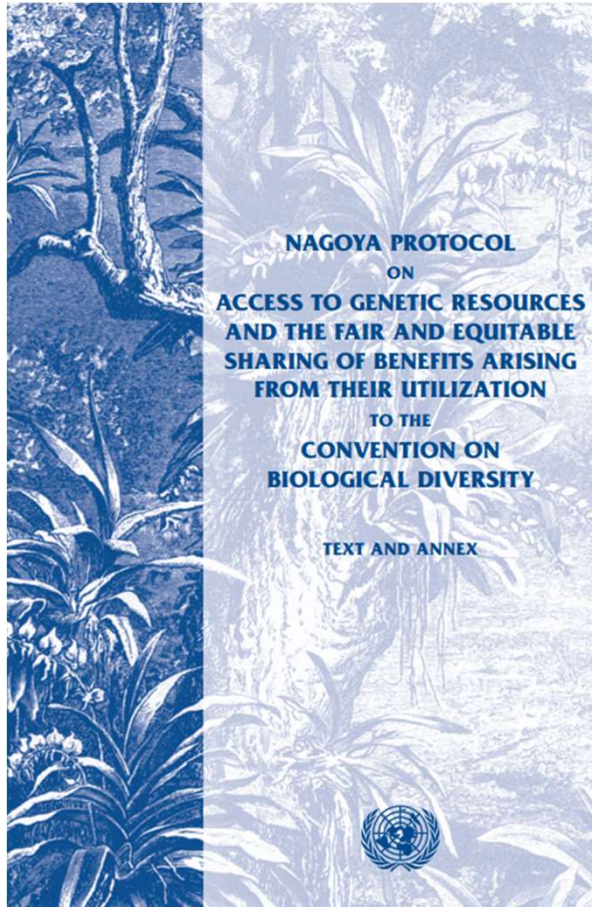




## Derivatives (EU perspective)

- Derivative is a naturally occurring biochemical compound - even if it does not contain functional units of heredity (No definition of naturally occurring)
- EU regs apply when access to a derivative is combined with access to a Genetic Resource (GR) from which that derivative was or is obtained (i.e. utilisation)
- R&D on such derivatives should be addressed in MAT when accessing the GR themselves
- R&D on derivatives (regardless of functional units of heredity) is within scope where they are derived from the GR accessed under the Protocol
- PIC and MAT will be required for the GR from which they were derived

# Receiving or collecting genetic resources



## Receiving materials

- Request a Material Transfer Agreement and/or PIC and MAT
- Compare documentation with country requirements on the ABSCH
- If the information is unavailable or is unclear contact the National Focal Point
- Culture Collections on the registered list of collections will provide legal clarity

## Obtain Prior Informed Consent (PIC) before accessing the resources

- Negotiate Mutually Agreed Terms (MAT) the benefits that will be shared and ensure all aspects of use are included
- Follow your national registration and reporting process e.g. due diligence declarations in UK & EU
- Retain information for a 20-year period after the end of the period of use





## CABI and Nagoya

- CABI is both a provider and user in the context of the Nagoya Protocol
- Also act as an intermediary – genetic resources collection

### CABI's Policy

- To perform due diligence regarding access and benefit sharing
- To put in place best practices to comply with national legislation

### CABI's negotiations to reduce administrative burden

- Participation in national stakeholder discussions
- Contacting NFP to discuss country specific best practice and overarching PIC and MAT using CABI uses and non-monetary benefits as a basis
- CDF project and ABS Champions to secure agreements with genetic resource provider countries [17 to date]



# CABI strategy

- Published ABS policy (under Environmental Policy <https://www.cabi.org/about-cabi/business-policies/>) and seeking endorsement of best practice
- Carry out ABS assessments at project design stage
- CABI appointed ABS Champions to support staff in ensuring compliant access and use
- Target countries (state of readiness as negotiations take time): primarily those we source genetic resources from; CABI Member and Partner countries
- Support initiatives to reduce administrative burden but that ensure equitable benefit sharing
- Contribute to discussions/solutions to outstanding issues:
  - Digital sequence information
  - Common understanding of what benefits are appropriate for a specific use
  - Facilitated access for uses considered to be for the "public good"

David Smith, Harriet Hinz, Joseph Mulema, Philip Weyl & Matthew J. Ryan (2018) Biological control and the Nagoya Protocol on access and benefit sharing – a case of effective due diligence, *Biocontrol Science and Technology*, DOI: 10.1080/09583157.2018.1460317 <https://doi.org/10.1080/09583157.2018.1460317>  
<https://www.tandfonline.com/eprint/4cN3Pw8Q9xtqVvd3bSe3/full>



## CABI Development Fund Project Compliance with Nagoya

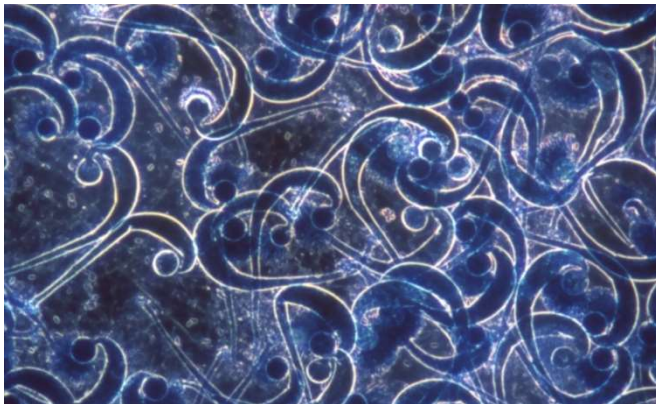
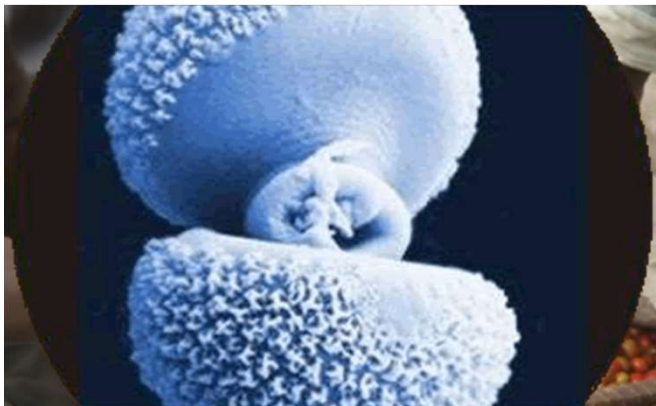
- Even after six years, many countries' policy, regulatory environment and processes for compliance remain in their infancy
- In 2019 EU revised its draft guidance, highlighting changes in interpretation
- Very few best practices are currently recognised although many are published on the CBD ABS Clearing House. The processes for recognition are not yet in place in many countries, the EU and Switzerland being rare exceptions.
- 2019, agreements were sought in five countries:
  - China has agreed an interim agreement
  - In India CABI has tested access procedures via ICAR with the National Biodiversity Authority and received samples in the UK
  - Kenya, CABI has its specific best practice adapted to national law and a clear process for access is in place
  - CABI uses do not require special agreement in Pakistan
  - CABI best practice has been redrafted to comply with Malaysian law
- CABI projects are assessed for ABS compliance





## Documents

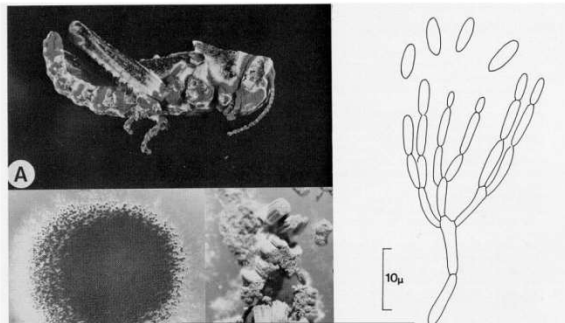
- Published ABS policy (<https://www.cabi.org/about-cabi/business-policies/>)
- CABI ABS Best Practice
- Created staff information resource (currently over 150 documents including policy, best practice and internal records on ABS)
  - Frequently asked questions
  - One page compliance assessment
  - Presentations
- CABI Development Fund Project: country resource file – country requirements and CABI status in access negotiations
- 7 publications including: David Smith, Harriet Hinz, Joseph Mulema, Philip Weyl & Matthew J. Ryan (2018) Biological control and the Nagoya Protocol on access and benefit sharing – a case of effective due diligence, *Biocontrol Science and Technology*, DOI: 10.1080/09583157.2018.1460317  
<https://doi.org/10.1080/09583157.2018.1460317>  
<https://www.tandfonline.com/eprint/4cN3Pw8Q9xtqVvd3bSe3/full>



## CABI uses of microorganisms and invertebrates

- diagnosis and identification of pests and diseases;
- rapid identification of newly introduced alien species to facilitate and management;
- studies to assess impact of land-use and climate change on biodiversity and ecosystem services;
- long-term conservation to protect investment
- microbial solutions to improve health and nutrition;
- combatting threats to livelihoods, agriculture and the environment from pests and diseases;
- biological control agents for invasive species, pests, and minimisation of pesticide use; and
- increasing and improving scientific knowledge



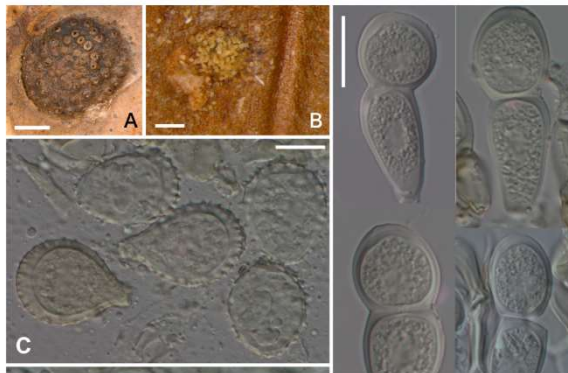


## Microorganisms as biocontrol agents

- 34 major invasive plants in UK
- Many genera utilised for biocontrol e.g. *Arthrobotrys*, *Beauveria*, *Entomophthora*, *Metarhizium*, *Paecilomyces*, *Puccinia*, *Trichoderma*, *Verticillium* (over 20 genera listed in Dictionary of Fungi)
- Over 20 countries of origin
- Including **Australia**, **Argentina**, **Brazil**, **Canada**, **Chile**, **China**, **India**, **Iran**, **Japan**, **Malaysia**, **Mexico**, **New Zealand**, **Paraguay**, **Poland**, **Russia**, **South Africa**, **Ukraine**, **Uruguay**, **USA**
- Negotiations / permissions

IMI Descriptions of  
Fungi and Bacteria  
No. 1873

Puccinia citricolor



Non-Party to NP

Party

Party with law

Non-Party with law





## CABI's non-monetary benefits and contributions to the local economy include:

- sharing of R&D results relevant to country needs;
- collaboration in education, training, research, development programmes and individual training;
- joint authorship of publications and joint ownership of intellectual property rights;
- access to *ex situ* facilities and to databases;
- transfer of scientific information, knowledge and technology; and
- institutional capacity-development to help build or maintain local collections



## The CABI offer - Mutually Agreed Terms (MAT)



Anguilla



Australia



The Bahamas



Bangladesh



Bermuda



Botswana



British Virgin Islands



Brunei Darussalam



Burundi



Canada



Chile



China



Colombia



Cote d'Ivoire



Cyprus



DPR Korea



The Gambia



Ghana



Grenada



Guyana



India



Jamaica



Kenya



Malawi



Malaysia



Mauritius



Montserrat



Myanmar



The Netherlands\*



Nigeria



Pakistan



Papua New Guinea



The Philippines



Rwanda



Sierra Leone



Solomon Islands



South Africa



Sri Lanka



St Helena



Switzerland



Tanzania



Trinidad & Tobago



Uganda



United Kingdom



Vietnam



Zambia



Zimbabwe

\* Associate Member

## our member countries

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## our member countries

9 ratified the Nagoya Protocol – the implementing legislation is enacted

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Afghanistan



Anguilla



Australia



Bahamas



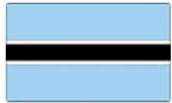
Bangladesh



Barbados



Bermuda



Botswana



British Virgin Islands



Brunei Darussalam



Burundi



Canada



Chile



China



Colombia



Cote d'Ivoire



Cyprus



DPR Korea



Gambia



Ghana



Grenada



Guyana



India



Jamaica



Kenya



Malawi



Malaysia



Mauritius



Montserrat



Myanmar



Nigeria



Pakistan



Papua New Guinea



Philippines



Rwanda



Sierra Leone



Solomon Islands



South Africa



Sri Lanka



St Helena\*



Switzerland



Tanzania



the Netherlands



Trinidad & Tobago



Uganda



United Kingdom



Vietnam



Zambia



Zimbabwe

# our member countries

Signed

Party

Ratified

KNOWLEDGE FOR LIFE 8 signed the Nagoya Protocol – expressed intention to comply with the treaty





KNOWLEDGE FOR LIFE    16 are Party to the Protocol – consented to be bound by the treaty    CABI



KNOWLEDGE FOR LIFE 9 ratified; 8 signed; 16 Party (33 of 49)







## Outreach and compliance activities

- Initiated negotiations with provider countries to cover all CABI activities – no deal: specific visits or projects
- Endorsement of best practice and project specific agreements (with CABI Centre host countries) UK/EU on hold - Brexit
- ABS assessments at project design stage
- CABI appointed ABS Champions: Kenya, Ghana, Zambia, Brazil, China, India, Malaysia, Pakistan, Switzerland, Trinidad and UK
- Target countries: primarily those we source genetic resources from; CABI Member and Partner countries
- Facilitating implementation and continuance of science
  - CABI position on Digital sequence information
  - Facilitated access for uses for the "public good"
- Outreach
  - Publications
  - Training courses
  - Project negotiations

# CABI's Best Practice for Access and Benefit Sharing Compliance

## Contents

Executive Summary .....	1
CABI ABS Policy .....	2
How CABI uses genetic resources .....	2
Benefits CABI provides from its use of genetic resources.....	2
Overview of CABI best practice .....	3
Accessing genetic resources for use .....	3
Receiving biological and genetic resources from collaborators, collections or other providers .....	5
Supplying biological and genetic material outside CABI .....	5
Monitoring sharing of benefits.....	5
Enforcement and compliance .....	6
Alignment of best practices to meet CABI Centre host country National law .....	6
Brazil .....	6
China.....	7
Ghana .....	7
India .....	7
Kenya .....	7
Malaysia.....	8
Pakistan .....	8
Switzerland .....	8
Trinidad and Tobago.....	9
UK .....	9
Zambia .....	9
Table 1. CABI Centres ABS Best Practice Regulatory Environment .....	10
Annexe 1 CABI Generic MTA for Supply of Genetic Resources.....	11
Annexe 2. Examples of community best practices that CABI adopts in its access and use of genetic resources .....	16
Annexe 3. ABS compliance decision tree that demonstrates a workflow for compliance with EU Regulation..	17

# ABS project assessment at CABI E-UK

Genetic Resources (organisms) included	How is the organism used	Provider Country	Country in which work is carried out	ABS requirement	Due Diligence Declaration	Compliant access
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- During 2019, 78 new CABI projects were assessed for ABS compliance, of which 16 may need further investigation and/or notification to the UK Regulator (a Due Diligence Declaration)
- To date total of 191 projects assessed
- 162 involved genetic resources
- Most out of scope because the provider country had no regulations in place or did not control access
- 19 project activities fell in scope of the EU Regulation
- Countries concerned were Brazil, China, India, Madagascar, Pakistan, Paraguay, South Africa
  - Agreements in place where needed or CABI's use is out of scope



# ABSCH – the source of information **BUT not always up to date**

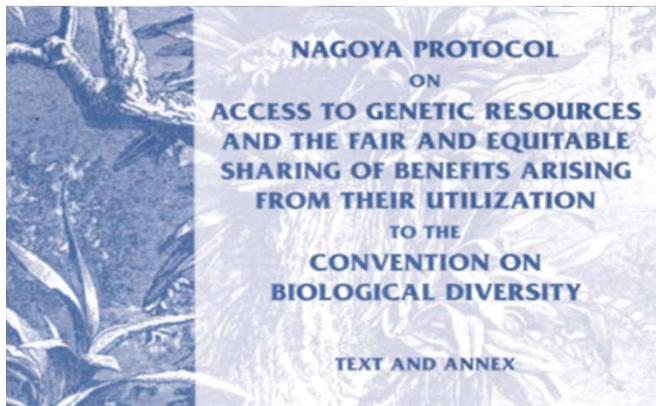
The screenshot shows the ABSCH website interface. At the top, the logo reads 'ABSCH THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE' and the Convention on Biological Diversity logo is on the right. A navigation bar includes 'About the ABSCH', 'Search', 'Submit', 'Country Profiles', 'National Reports', and 'Forums'. Below the navigation bar, a text box states: 'The Access and Benefit-Sharing Clearing-House (ABSCH) is a platform for exchanging information on ABSCH and a key tool for facilitating the implementation of the Nagoya Protocol.' A world map is displayed with a red box highlighting the EU region. At the bottom of the map area, statistics are shown: '123 Parties to the Nagoya Protocol', '1 Ratified, not yet Party', and '75 Non-Parties'. A 'National Records' section is partially visible on the right.

- 67 countries have posted Legislative, Administrative or Policy Measures
- 2017 Malaysia passed the Access to Biological Resources and Benefit Sharing Bill: [http://sullivanlaw.net/cases/D.R.24\\_2017%20\(eng\).pdf](http://sullivanlaw.net/cases/D.R.24_2017%20(eng).pdf) not on ABSCH
- Where law is in place it is not always easy to discover the process of application and negotiation for permissions
- Over 50 countries not negotiating deals until law is in place
- Should all individual scientists have to ask each National Focal Point the same questions; surely there is only one answer



## CABI Negotiations

- Only one MoU – Ghana
- Project specific Agreements in place in principle with 17 countries: Austria, Brazil, Canada, China, Czech Republic, France, Georgia, Germany, Hungary, India, Madagascar, Norway, Romania, Slovak Republic, South Africa, Sweden, Switzerland
- UK and Pakistan (unless commercial products are intended) agreements not required
- Negotiations continue with Brazil, China, Italy, Kenya, Serbia, Tanzania, Turkey, Zambia and Zimbabwe
- Awaiting/No response to enquiries Chile, Colombia, Kazakhstan, Democratic People`s Republic of Korea; No broad agreement possible with Uganda (obey law)



## Country positions differ

**Brazil** - Not Party to NP but have 2 legislative measures

- Require a permit to collect; additionally a foreign scientist must work with a partner in Brazil
- Samples sent out of the country must have a 'shipment' registration

**China** - Party to NP scheduled to put in place law in next two years

**Ghana** - CABI Memorandum of Understanding

**India** - Party to the NP and cites 30 items of Legislative, administrative or policy CABI has MoU with ICAR and is in negotiation with NBA; On line application process [projects and programmes]

**Kenya** - Party to the NP, NEMA is the only designated Competent National Authority (CNA); 11 legislative measures

**Malaysia** - Party to NP implemented Laws of Malaysia Act 795

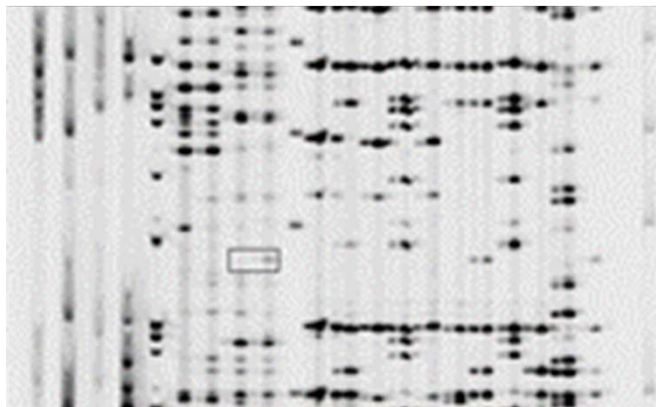
**Switzerland** - Party to the NP with 3 specific legislative, administrative or policy measures; **endorsed CABI best practice**

**Trinidad and Tobago** - Not a Party to the NP

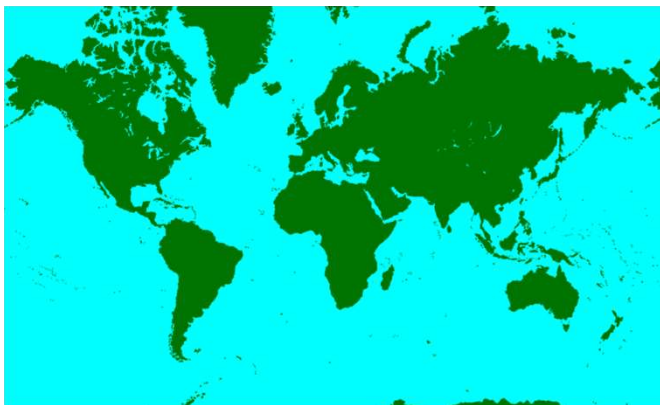
**Zambia** - Party to NP but no legislative measures on the ABSCH

**UK** - Party to the Nagoya Protocol with 3 legislative measures but does not have access control measures

- **Version of CABI best practice developed for countries without law agreeing to share benefits to engender trust**







## Summary

- Difficult to secure general agreements
- Specific project related agreements secured in several countries
- Negotiation process extremely slow particularly where laws are just developing and no precedent set for negotiation or best practice recognition
- CABI has had to find alternative access routes/agreements in several cases
- Why are there no easy routes costs CABI tens of thousands of dollars
- **Need to avoid administrative burden**

