



XXXVI ECCO Meeting
Brno, Czech Republic
13-15 September 2017

Nagoya Protocol EU Regulation 511/2014 & ECCO

Philippe Desmeth



OUTLINE

Incorporate legal obligations into daily work

Legal Context - Change of paradigm

Culture Collections proactive solutions

Future developments - ECCO



COLLECTIONS' MISSION

Customer oriented

To propose **solutions**

by providing **services of quality**

in microbial and genetic resources

for **academia and industry**.



FIT FOR PURPOSE – FIT FOR USE SOLUTIONS

GREAT AT SMALL THINGS

Scientific & technical package



Biological Resources



Data



Services + after sales

Legal & Administrative package



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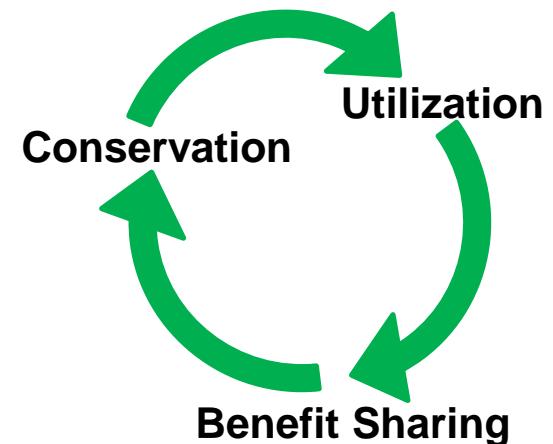
Future developments - ECCO



Convention on Biological Diversity

CBD Article 1: 3 Objectives

1. Conservation of biological diversity
2. Sustainable use of its components
3. Fair and equitable sharing of the benefits



Entry into force: 29 December 1993

Change of paradigm

From **free access** to **sovereign rights** (CBD article 15)

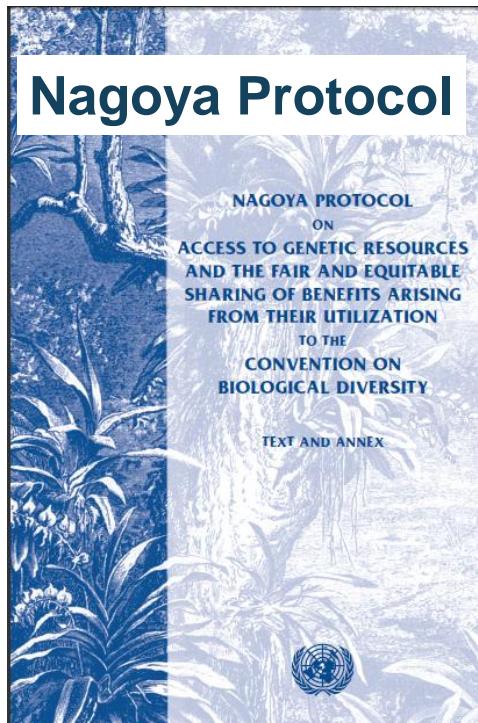
[...the authority to determine access...] (CBD article 15.1)

[...to create conditions to facilitate access...] CBD art. (15.2)

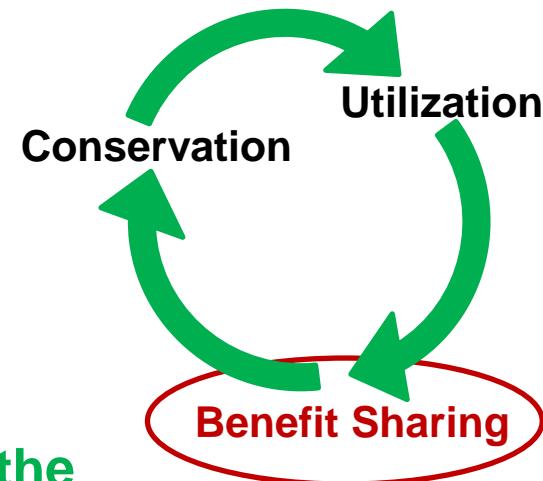


Nagoya Protocol

Article 1 : Objective fair and equitable sharing of the benefits



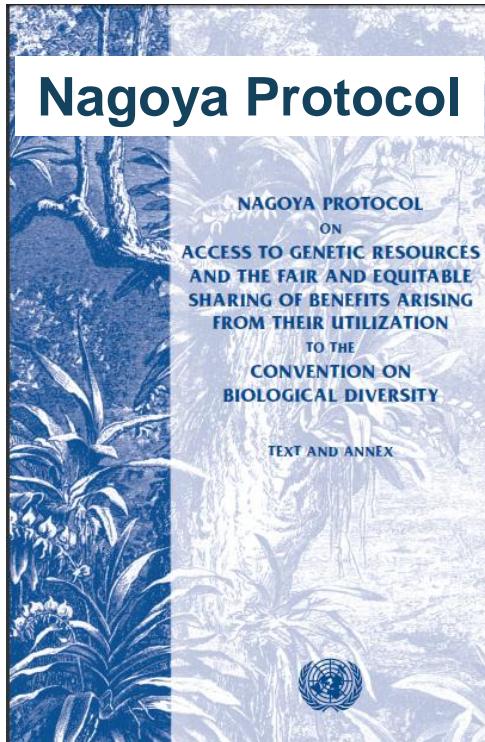
by appropriate **access to genetic resources**
by appropriate transfer of relevant technologies
by appropriate funding



thereby contributing to the
1. conservation of biological diversity
2. sustainable use of its components



Convention on
Biological Diversity



Nagoya Protocol

ABS - Access and Benefit Sharing

or **Access to Genetic Resources**

Quid pro Quo

and the Fair and Equitable
Sharing of Benefits Arising from their Utilization

Entry into force 12 October 2014



NEW RULES – NEW PRACTICES



Applicable on R&D
ng
eed Terms – MAT
MTA

CONTROL OF ACCESS

Prior to any collecting

Obtain **authorization of sampling**

=>>>



Obtaining Prior Informed Consent – PIC⁽¹⁾

Exercise Due Diligence⁽²⁾

(1) Nagoya Protocol Article 6

(2) European regulation EU 511/2014

OBTAINING PIC

Microbiologists inquire on the official website of the ABS Clearing House (ABSCH)

<https://absch.cbd.int>



- About the Competent National authority (CNA)
- Check the information with the National Focal Point (NFP)
- Make efforts to get a **PIC** from the CNA and other authorization from possible rights holders.

The Access and Benefit-sharing Clearing-house (ABSCH) is a platform for exchanging information on ABS and a key tool for facilitating the implementation of the Nagoya Protocol. [1](#)

**100**

Parties to the Nagoya Protocol

1Ratified, not yet Party [1](#)**98**

Non-Parties

<https://absch.cbd.int/>

Czech Republic

PARTY TO THE NAGOYA PROTOCOL

SIGNATORY

ENTRY INTO FORCE: 04 AUG 2016

ABS NATIONAL FOCAL POINTS (NFP)

Ms. Eliska Rolfova

Unit of International Conventions Ministry of the Environment Vrsovicka 65 C, Prague 100 00, Czech Republic

ABS NATIONAL FOCAL POINT

CZECH REPUBLIC | 27 APR 2017

COMPETENT NATIONAL AUTHORITIES (CNA)

Ministry of the Environment

Only designated competent national authority for the country

COMPETENT NATIONAL AUTHORITY

CZECH REPUBLIC | ABSCH-CNA-CZ-202046-4 | SINGLE CNA FOR THE COUNTRY | 18 JUN 2017

LEGISLATIVE, ADMINISTRATIVE OR POLICY MEASURES (MSR)

Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the application of Regulation (EU) No 511/2014 as regards best practices

On the basis of powers granted in Regulation 511/2014 (the "basic" EU ABS Regulation)

LAW (MSR) | CZECH REPUBLIC | ABSCH-MSR-EU-204508-6 | REGIONAL / MULTILATERAL | LAW | LEGALLY BINDING | COMPLIANCE

EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Arising from their Utilization in the Union

This Regulation establishes rules governing compliance with access and benefit-sharing for genetic resources and traditional knowledge.

LAW (MSR) | CZECH REPUBLIC | ABSCH-MSR-EU-201808-6 | REGIONAL / MULTILATERAL | LAW | LEGALLY BINDING | COMPLIANCE | 20 SEP 2016

Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 as regards best practices and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union

This document is intended to provide guidance on the provisions and implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council.

NATIONAL OR DOMESTIC GUIDELINES (MSR) | CZECH REPUBLIC | ABSCH-MSR-EU-208044-1 | REGIONAL / MULTILATERAL | NATIONAL OR DOMESTIC GUIDELINES

NATIONAL WEBSITES OR DATABASES (NDB)

CBD Clearing House Mechanism - national website

CBD Clearing House Mechanism - national website

NATIONAL WEBSITE OR DATABASE

CZECH REPUBLIC | ABSCH-NDB-CZ-202244-1 | 12 JAN 2015



Czech Republic

Convention

Party since: 1994-03-03

By: Approval

Cartagena Protocol

Party since: 2003-09-11

By: Ratification

Nagoya Protocol on Access and Benefit-sharing

Party since: 2016-08-04

By: Ratification



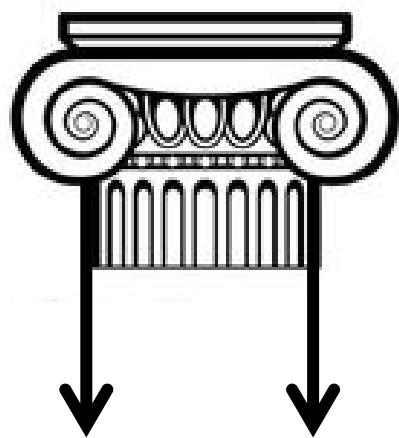
ABS implementation in EU



GREAT AT SMALL THINGS

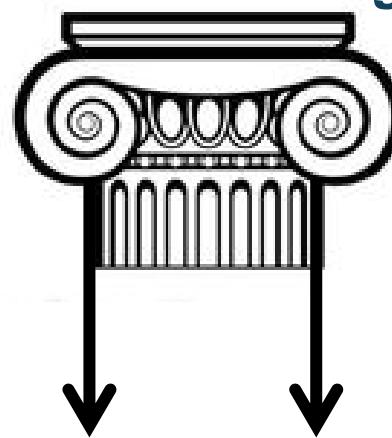
Pillars of the Nagoya Protocol - the ABC of ABS -

Access



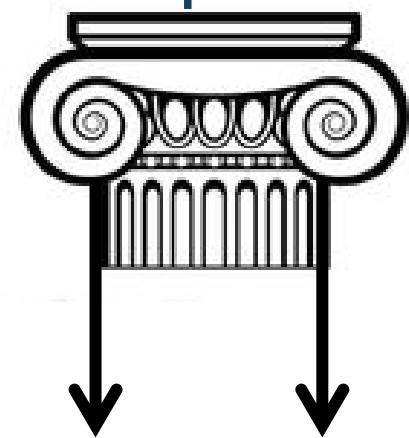
Implemented at
Member States level
Not EU level

Benefit Sharing



Subject to
contractual
agreement

Compliance



EU Regulation
511/2014
& concomitant



EU Law

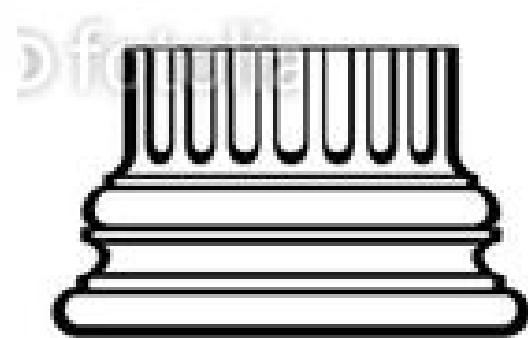


EN

Official Journal of the European Union

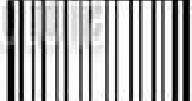
REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014

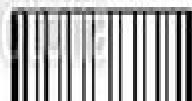
on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

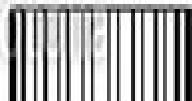




Knowledge Based Bio Economy

 **Sectorial guidance documents & ABS Consultation Forum**

 **European Commission Notice (2016/C 313/01) - Guidance document**

 **Commission Implementing Regulation (EU) 2015/1866**

 **Regulation (EU) No 511/2014**

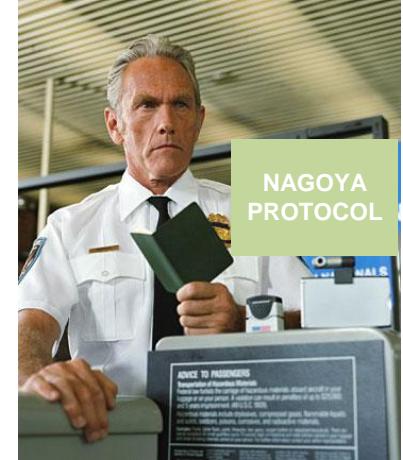
EXERCISE DUE DILIGENCE

Microbiologists inquire on the official website of the ABS Clearing House (ABSCH)

<https://absch.cbd.int>

- About the Competent National authority (CNA)
- Check the information with the National Focal Point (NFP)
- Make efforts to get a PIC from the CNA and other authorization from possible rights holders.

In absence of any contact point or information,
apply sectoral codes of conduct



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PROACTIVE STRATEGY

December 1993 CBD comes into force

MOSAICC (1999) Basic procedures

Standard contracts

April 2002 BCI

MOSAICS (2005)

Facilitating
Access & legitimate use

Transparency
, Microbial Commons

Nagoya Protocol comes into force

Global Catalogue of Microorganisms

Linkage with ABS Clearing House (ABSCH)

Updated Model contracts MTA & MDA

Specific procedures (basic research, emergencies,
regularization)

SOLUTION DRIVEN STRATEGY

Nagoya Protocol

Article 17c Use of cost-effective communication +

=> Global Catalogue of M

Article 19 Model contractual

=> MDA, M

Article 20 C Best Practices

Facilitating
Access & legitimate use
of genetic resources, IUST, NIEMA
BCCM Capacity building programme

GREAT AT SMALL THINGS

BCCM • CC



TRUST

TRansparent Users-friendly System of Transfer

Belgian
Science
Policy
Office



Sector-based Conveyance System for ABS

- **Simple, support legal certainty**
Compatible with different legal framework (common & civil law)
- **Cost-effective**
Attractive system enforceable without constraints
- **Efficient, fast**
Easily applicable in all conditions = flexible
- **Multipurpose, multi-users**
Fulfilling the needs of all stakeholders

Features for efficient administrative system

- **Minimal set of documents** (no paperwork overload)
Material Deposit Agreement - MDA
Material transfer Agreement - MTA
- **Minimum Data Set to be registered**
Minimum necessary information for science and management
- **Standard procedures**
- **Decentralised management with same rules of implementation**
 - Persistent identification linked to updated information
 - Information Technology based

TRUST



BCCM/ITM mycobacteria catalogue



- Search the BCCM/ITM catalogue by using the [search form](#) below or the [table of contents](#)
- [Price list](#)

BCCM/ITM search form

Read also the [instructions of use](#) which explain how to optimise your search.

Field

Free text boxes

(select a field and type your query)

All Fields	<input type="button" value="▼"/>	<input type="text"/>
Species name	<input type="button" value="▼"/>	<input type="text"/>
Species name	<input type="button" value="▼"/>	<input type="text"/>
Accession number	<input type="button" value="▼"/>	<input type="text"/>
Accession number	<input type="button" value="▼"/>	<input type="text"/>

Catalogue

Combine multiple queries with OR AND

Instructions of Users

1 information

{ WHAT
WHEN
WHERE
FROM WHOM
TO WHOM

Choice of technical solutions

Feasibility imposes

- Use of Global Unique Identifiers – GUID for tracking

Cost effectiveness requires

- Electronic thread rather than paperwork path

Flexibility needs

- Built in system,
which allows instant and ex post checks

TRUST

TRUST

Two parts system



Administrative Guidelines, Documents & Procedures

= Legal processing (MOSAICC based)

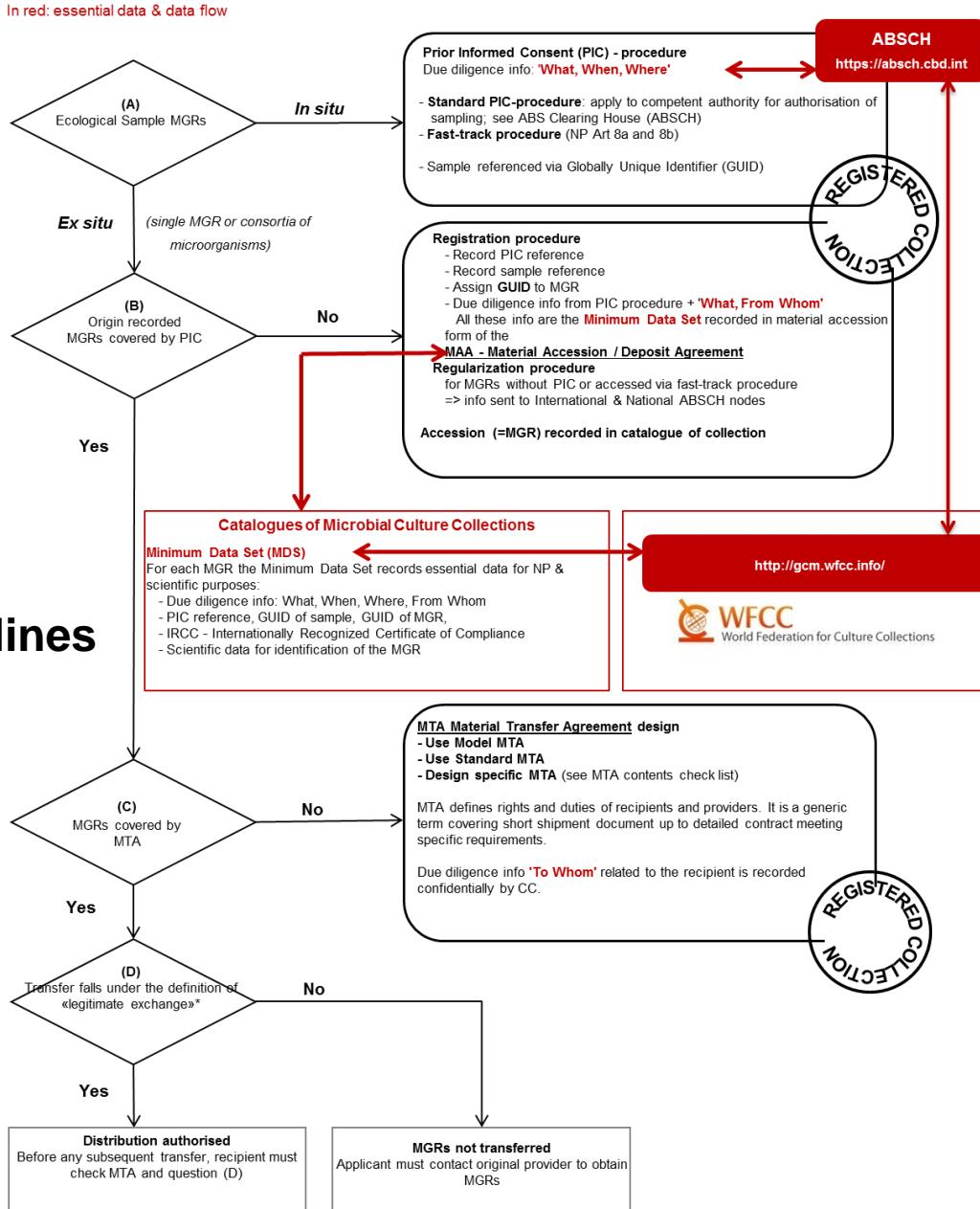
Global Catalogue of Microorganisms (GCM)

= Technical processing

ADMINISTRATIVE PATHWAY

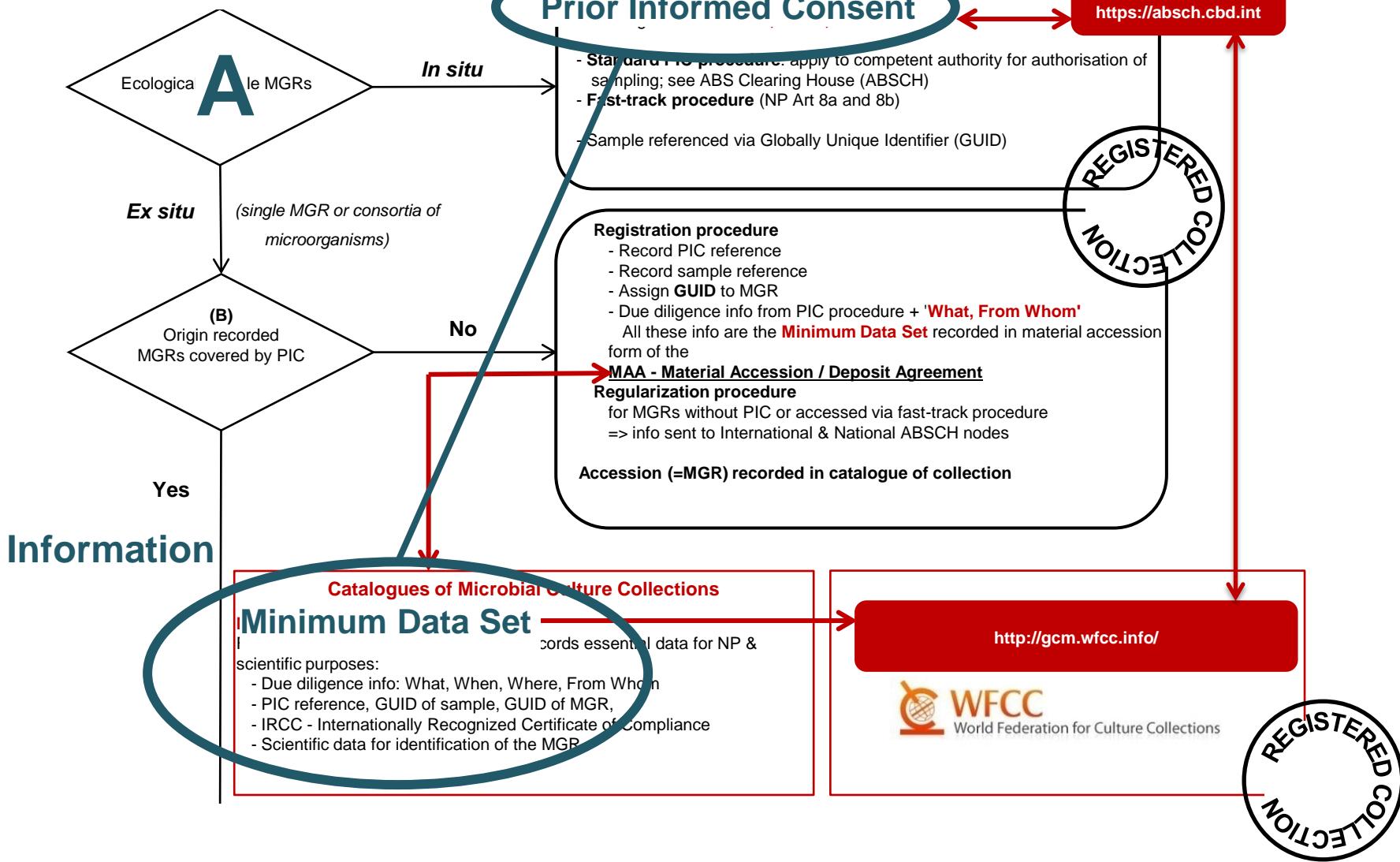
Operating Nagoya Protocol in Microbiology

MOSAICC & Guidelines TRUST

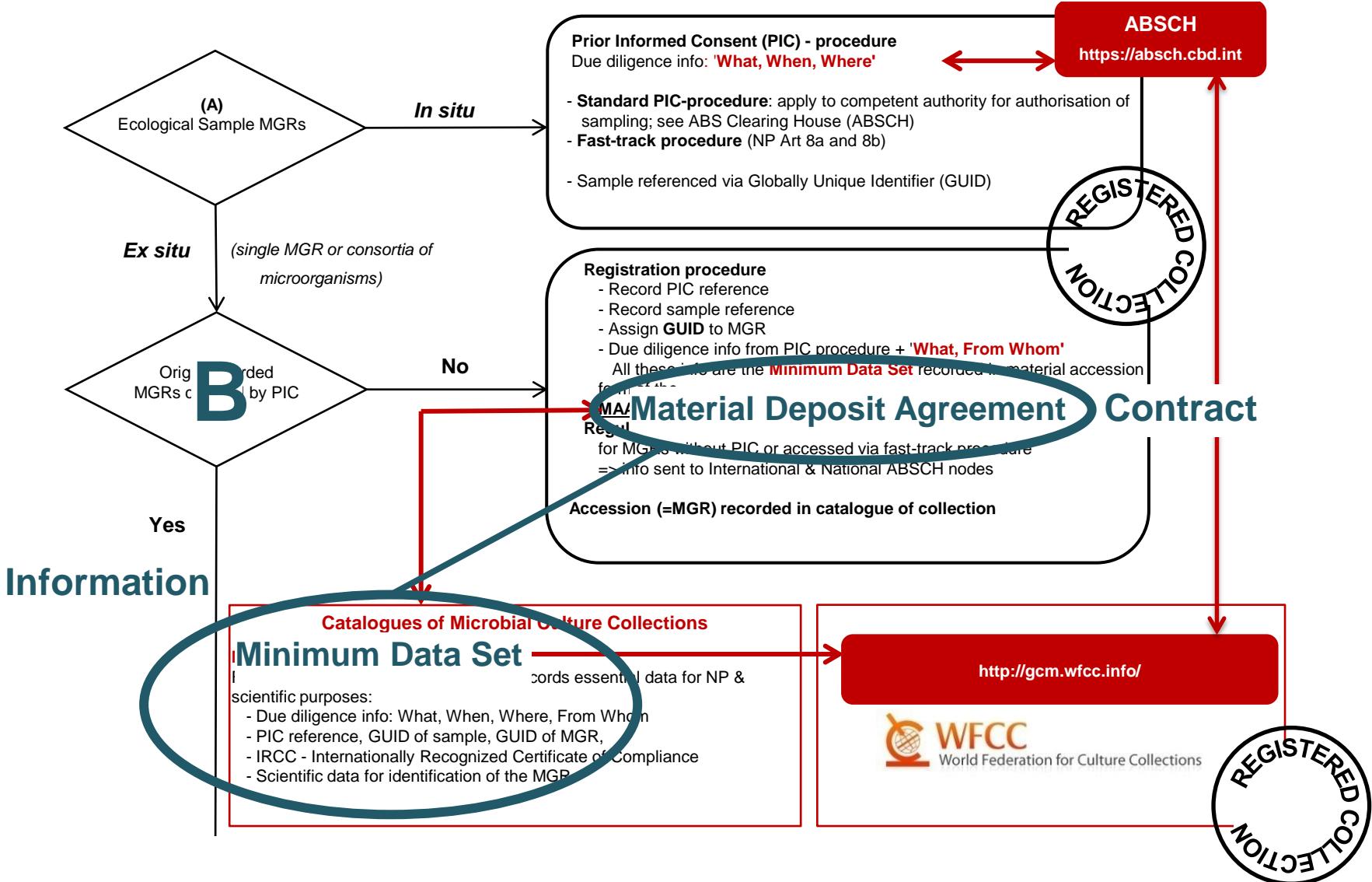


A. Access *in situ*

Access regulation in the country of origin

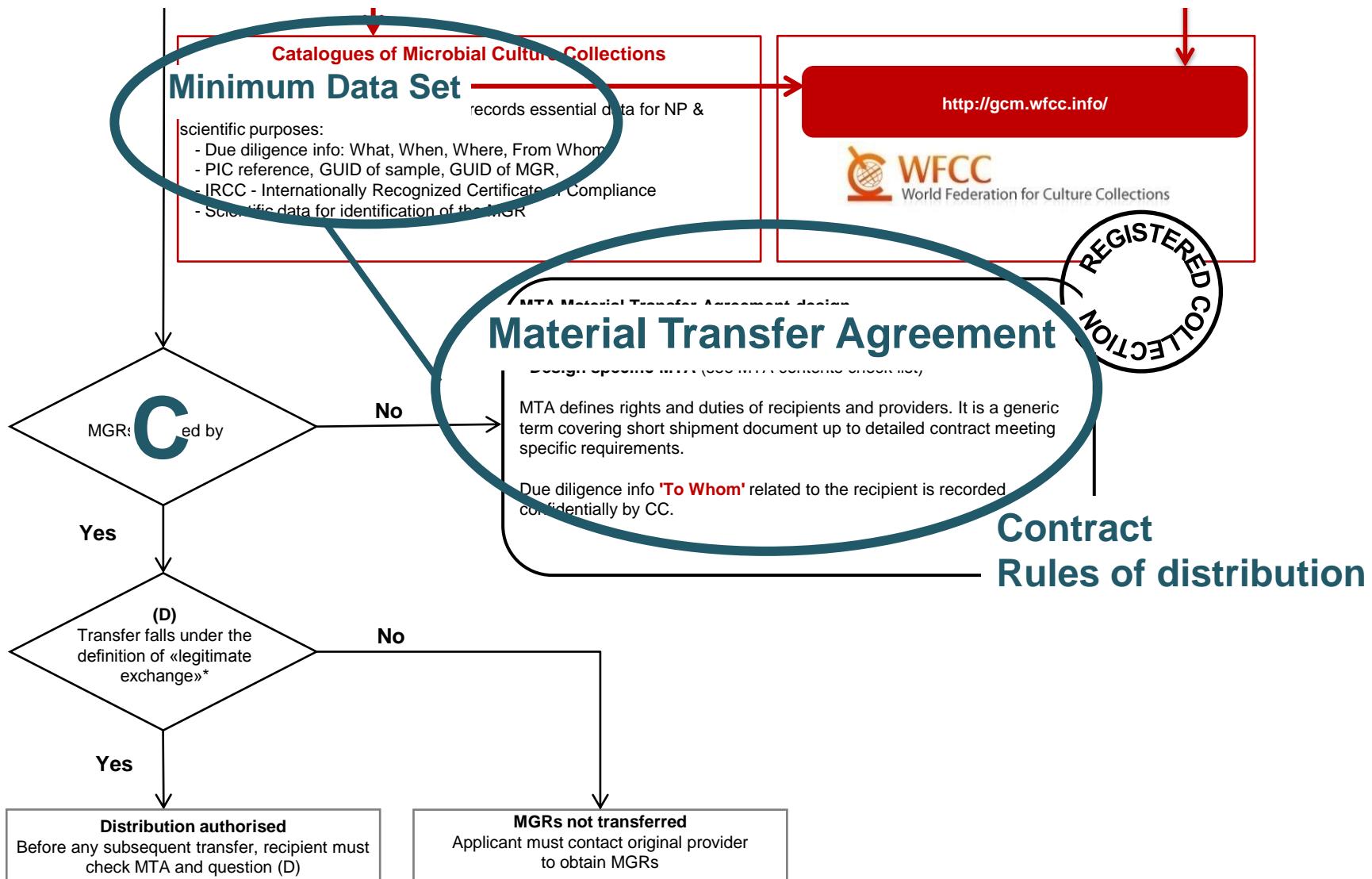


B. Deposition ex situ



Minimum Data Set in Material Deposit Agreement (MDA)
WHAT, WHEN, WHERE + FROM WHOM

C. Distribution - Transfer



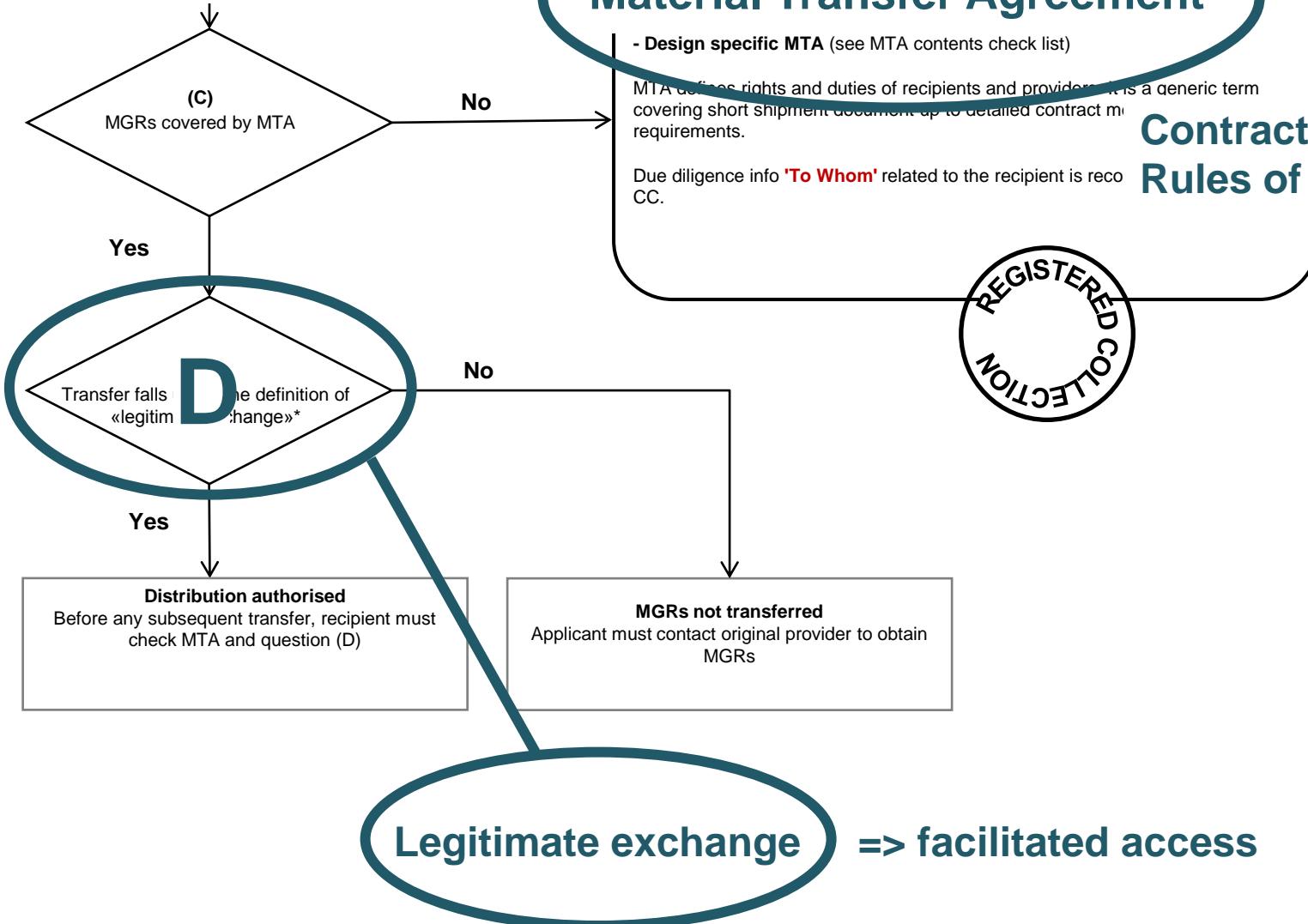
Minimum Data Set in Material Deposit Agreement (MDA)

WHAT, WHEN, WHERE, FROM WHOM + (TO WHOM Confidential)

D. Publication of Novel species / Type strains

Information

> Recommended Data Set



Reference records

101 Virtual Library Records 

09 FEB 2017

Biodiversity and culture: exploring community

43 Capacity-building Initiatives 

06 FEB 2017

PALAU: Support of Implementation of ABS Roadmap

17 Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards 

2 Community protocols and procedures and customary laws 

11 AUG 2016

MOSAICC - Micro-Organisms Sustainable use and Access regulation International Code of Conduct (2011)

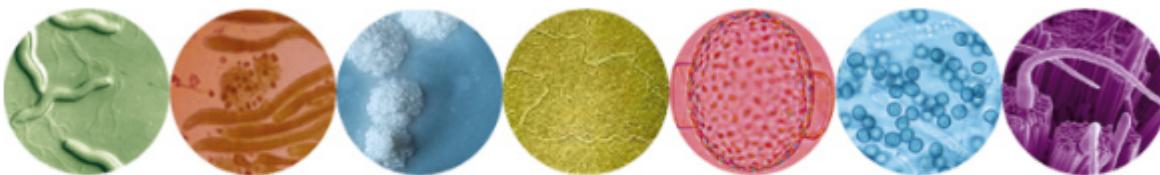
INTRODUCTION SECTION I. TERMS OF ACCESS TO MGRS I.1. Prior Informed Consent: definition and contents I.2. Procedure for access to in situ

MODEL CONTRACTUAL CLAUSES, CODES OF CONDUCT, GUIDELINES, BEST PRACTICES AND/OR STANDARD | ABSCH-A19A20-SCBD-207283-1 | **CODES OF CONDUCT** | 17 JUN 2016

TRUST - TRansparent Users-friendly System of Transfer (2016)

TRUST is a system having as backbone the Global Catalogue of Microorganisms (<http://gcm.wfcc.info/>) and using the expertise of MOSAICC, MOS/

MODEL CONTRACTUAL CLAUSES, CODES OF CONDUCT, GUIDELINES, BEST PRACTICES AND/OR STANDARD | ABSCH-A19A20-SCBD-208170-1 | **BEST PRACTICES** | 18 OCT 2016

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TRUST - TTransparent User-friendly System of Transfer, implementing the Nagoya Protocol in microbiology

TRUST aims at managing the incidence of the CBD and Nagoya Protocol on the scientific, technical and administrative activities of culture collections and, more generally, incorporating the Nagoya Protocol into the daily life of microbiologists.

- **TRUST guidelines March 2016 Version**
- **TRUST handbook March 2016 Version**

[Search catalogues](#)[Order material](#)[Deposit material](#)[Analyses](#)[Training](#)[Collaboration](#)

<http://bccm.belspo.be/projects/trust>

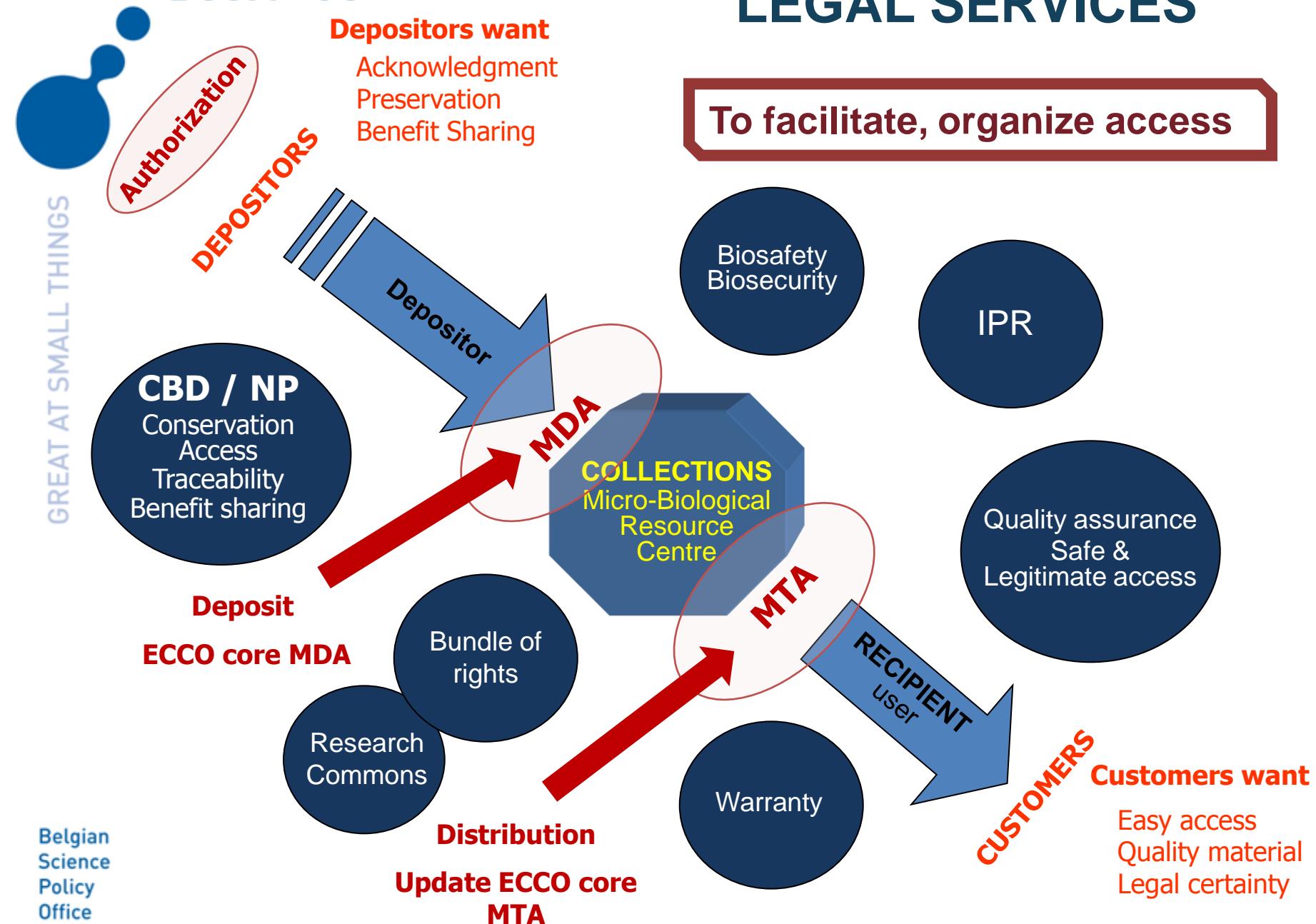
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Scientific & technical package



Biological
Resources



Data



Services +
after sales

Legal &
Administrative
package



customs clearance customs export
customs clearance customs import
export import customs import
customs
customs clearance customs export
import import customs clearance
customs clearance customs export
export import customs customs



NO WAITING





Thank you

