ESFRI European Strategy Forum on Research Infrastructures

MIRRI MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE

Nagoya Protocol at the doorstep – how collections in the Microbial Resource Research Infrastructure (MIRRI) prepare to comply

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CAPACITIES

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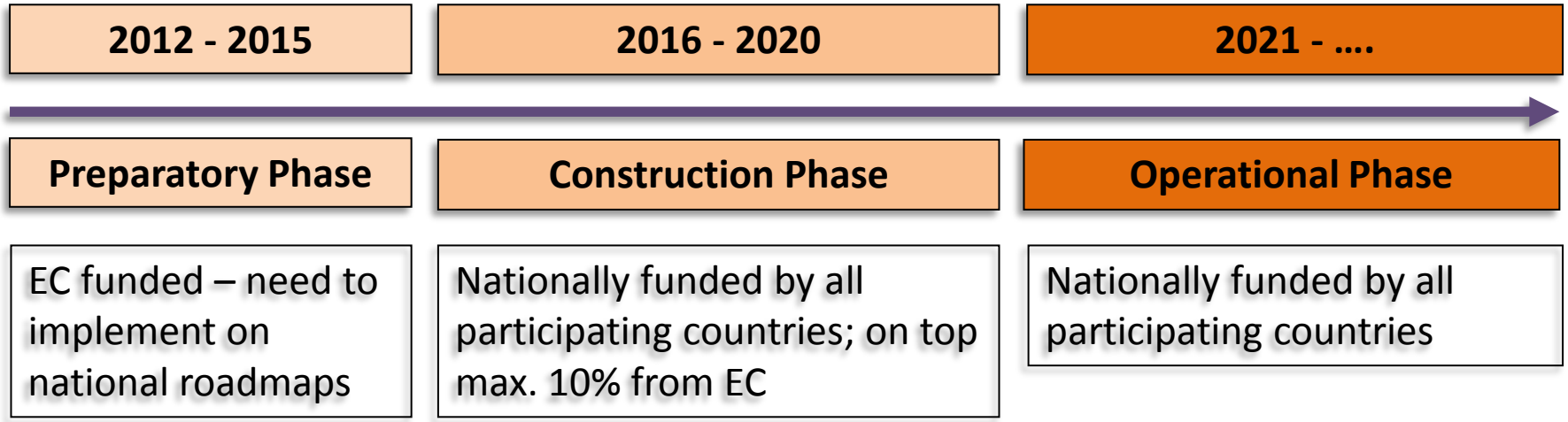
CBS-KNAW Fungal Biodiversity Centre

Microbial Resource Research Infrastructure

MIRRI' s aim: to build a pan–European distributed, yet coordinated infrastructure

Now in the preparatory phase:

- Focus on **governance and structure**, technical, legal and financial issues for entity
- Establish **links** within the RI, with the users, policy makers, potential funders
- Establish **operational policy and legal operational framework**
- **Engaging states** – to fund the Construction Phase to enable resource centres to deliver the infrastructure services



- 16 partners collections, 20 collaborating parties
- Project Coordinator: Erko Stackebrandt, DSMZ
- Also involved: European and non-EU experts

MIRRI Partnership is strongly based on ECCO Collections

MIRRI is strongly based on previous International Project Collaborations of BRCs:

'99 – '07

GBRCN GLOBAL BIOLOGICAL RESOURCE CENTRE NETWORK DEMONSTRATION PROJECT

’08-’11

EMbaRC

'09 – '12

MIRRI Workpackage 9 – Legal operational framework for BRCs

A focus on IPR, ABS and Biosecurity

Task 9.1 objective

Define a MIRRI policy on Intellectual Property Right (IPR) and Access and Benefit Sharing (ABS) in compliance with the Convention on Biological Diversity (CBD)

Key to our activities:

MIRRI partners need to comply to the CBD in a transparent and cost-effective way, while minimizing administrative burdens and avoiding more restrictive access

Work planned includes:

- Analyse **problems** and **deficiencies** on matters of IP and ABS in currently used **MTAs**
  - for supply of strains
  - for deposit of strains
- Report on **minimal requirements** for enhanced **compliance** to CBD and IP issues
- **International Workshop** (date to be determined)

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Nagoya, Japan 2010

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MIRRI
MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE

The Nagoya Protocol - Access and Benefit Sharing (ABS)

Access provided to GR is subject to **Prior Informed Consent (PIC)** of the Country of Origin, and under **Mutually Agreed Terms (MAT)** by provider and user

How could it work?

1) The Collector searches the ABS Clearing House for information on national ABS legislation and CNA in the Country of Origin
2) Collector contacts the Competent National Authority (CAN) and the local counterparts (i.e., provider) in the Country of Origin to request for a Prior Informed Consent (PIC) and agree on the terms (MAT) for access and use of the genetic resource (GR)
3) If a Permit is issued, the collector can start collecting *in situ*
4) The CNA submits PIC and MAT to the National Publishing Authority for the Clearing House (CH), and then it is formally published as the Internationally Recognized Certificate of Compliance (IRCC , a “national record” in the ABS CH database)

➢ Once published, national records are unchangeable

Recent developments at EU-level

- The EU ratified the Nagoya Protocol on May 15, 2014
- Most EU Member States will still have to follow suit
- Almost all EU-member states grant free access to their GR – harmonized EU access measures therefore not needed
- Legally binding EU-level intervention only on user-compliance
- The European Commission designed a **Regulation on ABS**, presented October 2012
- The Regulation has been negotiated and the final text* recently formally approved by the European Parliament (March 11) and the Council (April 14)
- Regulation no. 511/2014 published on May 20, 2014 in EU OJ
- Regulation entered into force on June 9, 2014

* http://register.consilium.europa.eu/doc/srv?l=EN&f=PE%20131%202013%20INIT

Recent developments at EU-level

- Regulation will not be applicable until the Nagoya Protocol enters into force
- Regulation articles 4 (*user obligations*), 7 (*monitoring user compliance*) and 9 (*checks on user compliance*) are applicable one year after the date of entry into force of the Nagoya Protocol for the Union

  Caution: a GR may have been collected at a time that applicable ABS legislation was already in place in the Country of Origin
- Guidance documents from EC to be expected next year
- Consultation forum to be established in the 2nd half of the year

EU Regulation on ABS in the Union: Scope (art 2)

- (1) ..applies to GR over which States exercise sovereign rights and to TK associated with GR **that are accessed after the entry into force of the Nagoya Protocol for the Union**. It also applies to the benefits arising from the utilisation of such GR and TK associated with GR.

- (2) ..does **not apply** to GR for which access and benefit-sharing is governed by **specialised international instruments**[(A)] that are consistent with, and do not run counter to the objectives of the Convention and the Nagoya Protocol.

- (3) This Regulation is without prejudice to Member States' rules on access to GR over which they exercise sovereign rights within the scope of Article 15 of the Convention, and to Member States' provisions on Article 8(j) of the Convention concerning traditional knowledge associated with genetic resources.

- (4) ..applies to GR and TK associated with GR **to which ABS legislation or regulatory requirements of a Party to the Nagoya Protocol are applicable**.

(A) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

EU Regulation on ABS in the Union: Definitions (art. 3)

- (3) "**access**" = the acquisition of GR or of TK associated with GR in a Party to the Nagoya Protocol

  so,

  - wider than just the Country of Origin (where the GR was collected from *in situ* conditions)
  - including acquisition of GR from *ex-situ* collections

- (5) "**utilisation of GR**" = to conduct research and development on the genetic and/or biochemical composition of GR, including through the application of biotechnology as defined in Article 2 of the CBD

Handling of microbial resources by MRC s

The handling of microbial resources typically done by most MRCs can be divided into two categories:

(i) MRC management activities, including handling for purpose of accession, preservation, supply of samples, quality control, and for pursuing correct and up-to-date identification;

(ii) Research, viz.:

(a) activities generating data on the microbial resources that will be placed in the public domain and constitute added value to these resources;

(b) activities that can be seen as conducting "research and development" on GRs, for various purposes (non-commercial or commercial)

- ***Which of these activities will be seen as conducting "research and development" (= "utilisation") on GRs?***

MIRRI advocates: recognize (i) and (ii a) as "accepted uses", to be treated as outside the Regulation's definition of "research and development", for which reporting to check-points should not be required

EU Regulation on ABS in the Union: Obligations of users (art. 4)

- exercise due diligence to ascertain that GR were accessed in accordance with ABS legislation and regulatory requirements
- share benefits fairly and equitably
- utilise and transfer of GRs and traditional knowledge (TK) only in accordance with MAT
- seek, keep and transfer to subsequent users all information and documents relevant for ABS
- in case of uncertainty about legality of access or utilisation, the user shall obtain additional information/evidence or obtain a proper access permit and establish Mutually Agreed Terms (MAT)
- keep ABS relevant information for minimum of 20 years after the end of the period of utilisation

EU Regulation on ABS in the Union: Register of collections (art. 5)

Requirements for registered collections :

- Apply standardized procedures for exchanging GR with other collections and supplying to third persons
- Supply GR and related information to third persons only with documentation providing evidence that they were legally accessed and, where relevant, with Mutually Agreed Terms (MAT)
- Keep records of all GR and related information supplied to third persons
- Establish and use unique identifiers , where possible, for samples of GR supplied to third persons
- Use appropriate tracking and monitoring tools for inter-collection exchange

Competent National Authority will decide if a collections can be included in the Register

➢ **Users obtaining a GR from a registered collection shall be considered to have exercised due diligence** (Art. 4, par. 7)

EU Regulation on ABS in the Union: Monitoring user compliance (art. 7)

Declarations of due diligence and/or compliant utilisation will be required upon:

- receiving grants for research involving utilisation of GR or TK
- at the stage of final development of a product developed via the utilisation of GR or TK (the *exact* stage will be further elaborated in implementing acts)

And based on the NP (and Regulation):

- each country will put in place methods of monitoring compliance by users; e.g., when GR 'utilized' or submitted to the market
- one or more 'Checkpoints' may be involved and will collect appropriate information
- Checkpoint will notify Providing Country through 'Checkpoint Communiques'
- This does not replace any communication required between the user and the providing country

Elements for the MIRRI policy statement

MIRRI MRCs are (i.a.) committed to:

(iii) deliver, in compliance with the Nagoya Protocol and applicable legislation or regulatory requirements, well-identified, authentic and high-quality genetic resources that are preserved in the public collections of the MRCs to third parties for microbiology research , education and biotechnology, to the benefit of public health, food security, and social and economic development especially in developing countries. In doing so, the MRCs also contribute to the Nagoya Protocol's wider objective of supporting the conservation and sustainable use of biological diversity;

(iv) present clarity on permitted use to recipients of *ex situ* MGRs , considering that these resources are the essential raw materials that drive the bio-economy, and while fully recognizing the sovereign rights of the Country of Origin over their MGRs, to refrain from posing unnecessary restrictions upon the use of these resources in research with commercial intent, while reminding users of applicable benefit sharing obligations through transfer agreements;

Elements for the MIRRI policy statement

(v) cooperate with relevant associations of users and other interested parties in the EU and globally to develop procedures, tools or mechanisms that can facilitate the implementation of the Nagoya Protocol, stimulate the use of *ex situ* MGRs, and lead to an increase in transparency and legal certainty or a reduction in costs for both provider MRCs and the users of the MGRs;
Note: Special arrangements will be urgently needed for genetic resources preserved in MRCs that currently lack an internationally recognized certificate of compliance or other documentation to prove that these resources were legally accessed;

(vi) design a light and transparent legal framework that includes transfer agreements with model clauses, and best practices under which all MIRRI-MRCs can operate;

(vii) respect, where appropriate and permitted by law, the confidential nature of user information, documentation and administration associated with the transfer of MGRs;

Elements for the MIRRI policy statement

(viii) share benefits arising from the utilization of the MGRs by the MRCs themselves, with the Country of Origin and other rightful stakeholders, in accordance with the provisions of the Nagoya Protocol and applicable legislation or regulatory requirements, where appropriate and possible, including, but not limited to,

(a) adding value by generating new information on the characteristics of the genetic resources preserved in the MRC's collections, and where appropriate make this information publicly available through scientific and popular publications and by adding information to open access data repositories;

(b) providing support to initiatives for the establishment of new *ex situ* collections in developing countries through collaborative research programs, training and other means of sharing expertise.

Minimal Requirements for MIRRI - Material Accession Agreement (for deposits)

Acceptance of GR for a new deposit only:

with a Material Accession Agreement (MAA) including a minimum set of terms agreed upon in MIRRI

or

an Accession Form used by the MRC and which includes an equivalent minimum set of terms, with all obligatory fields completed, and signed by the depositor

and, if so required by applicable law and regulations,

PIC and MAT (Permit) or reference to an IRCC in the CH

Minimal Requirements for MIRRI - Material Accession Agreement (for deposits)

The depositor should also provide:

- *the date and place of original collecting in situ* (including Country of Origin, if applicable)
- *date and place of isolation* (if different), *name* of the individual that has isolated the strain from *in situ* conditions and/or the name of the institution (legal person) that employed the individual at the time of the isolation of the strain
- As complete as possible list of all transfers that took place between the *in situ* access and the current deposit ('history of the GR")

Minimal Requirements for MIRRI - Material Transfer Agreement (for supply)

General considerations:

- No supply of GRs by the MRC without a Material Transfer Agreement (MTA)
- A standard MIRRI MTA may suffice for most GR supplied. Specific MTAs may be used where appropriate or required. If available, the MAA (dating from the time of deposit in the Provider MRCs) should also be part of the package of documents that is provided to third parties along with the GR.
- Third Party transfer by the recipient will not be allowed.
- "Legitimate exchange" most likely needs to be more restricted than under the definition in the ECCO Core MTA, namely to only include:
  - exchange between collections (using compatible MTAs)
- A statement from MRCs that charge fees for furnishing GRs is desirable, to explain what these funds are used for (i.e., not for profit); underpin the non-monetary benefits provided by the MRC!

Minimal Requirements for MIRRI (for MRCs own activities)

Some general considerations:

- The ABS policy should be inclusive for all GRs accessed *in situ* or acquired otherwise by staff or visitors of the MRC, regardless whether these GRs will be accessioned into the public collection or not
- The conditions for internal use of GRs lacking PIC and MAT should be clear (as for supply!)
- For GRs accessioned into the public collection, it should be clear that the MRC is allowed to release data (e.g., sequence data for reference and essential for clarifying the taxonomy of a GR) in their open access database or other publications after release of the GR for distribution

Some challenges to be addressed…

- Reach **sufficient coverage** of all microorganism groups in collections that will be **in the Register**
- How to assure that **simplified *in situ* access for non-commercial purposes** will be possible
- Availability of **type strains** for non-commercial research should not be restricted or hindered due to negative (side-)effects of legislation
- Likewise, availability of **reference strains** (used in international standards, e.g. ISO) should not be restricted or hindered

Outlook

- At the national level MRCs will have to settle details on important issues with the competent authorities, regarding, i.a.,
  - Assessment and support of Registered collections
  - reporting requirements for MRCs (new deposits, supply)
  - user compliance measures and their effect on the scientific community and MRC operation
- In coordination with other initiatives in the global MRC community, MIRRI is also committed to develop tools that can facilitate the implementation of the NP.
- The MRC community should suggest tools that are difficult to establish centrally, viz. unique strain identifiers (GUIDs) and their linking to IRCC records in the CH
- MIRRI will propose best practices that will be required to avoid high costs and unnecessary administrative burden for MRCs.
- The scientific community will depend on the competent authorities and the ABS Clearing House to provide crucial services, such as the speedy approval and publication of Internationally Recognized Certificates of Compliance.

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Thank you for your attention !