



# Output from MIRRI WP9, the Code of Conduct on BRCs and subsequent activities

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# Microbial Resource Research Infrastructure

## MIRRI

- builds a **pan-European distributed research infrastructure** that provides facilitated **access** to high quality **microorganisms**, their derivatives, associated **data** and **services** for research, development and application
- connects public resource centres with researchers and policy makers as well as other stakeholders to **deliver material and services** more effectively and efficiently to **meet the needs of innovation** in biotechnology

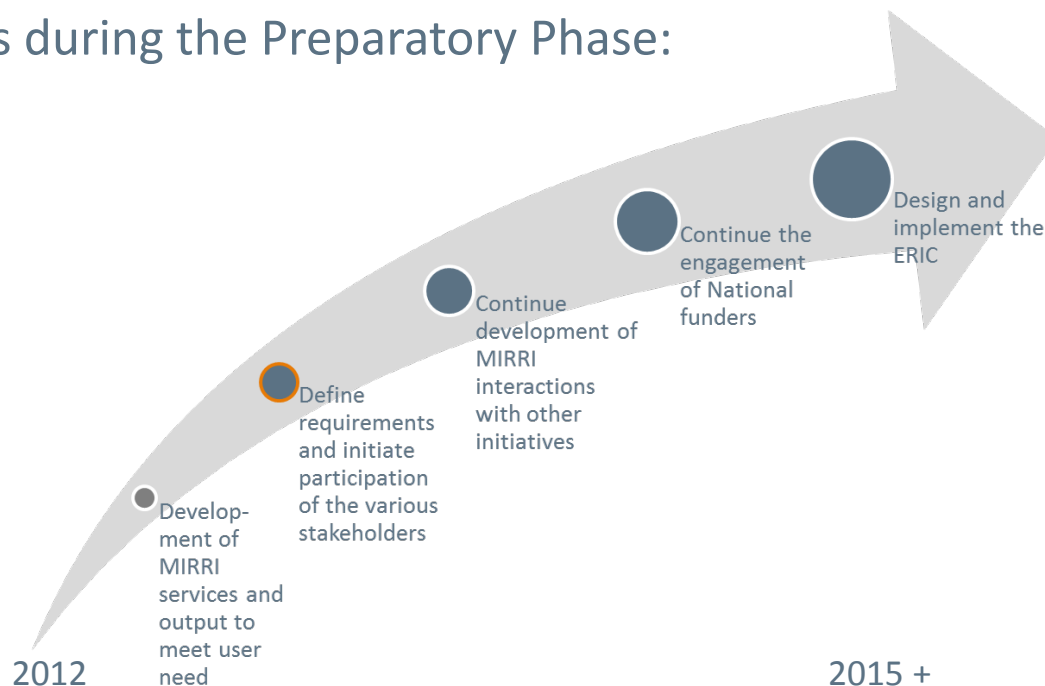


# Background

During the **Preparatory Phase** (2012-2015) the MIRRI consortium comprises **16 Partners** (dark orange) and **20 Collaborating Parties** (light orange), representing 19 countries throughout Europe.



Objectives during the Preparatory Phase:



# MIRRI – our vision and values

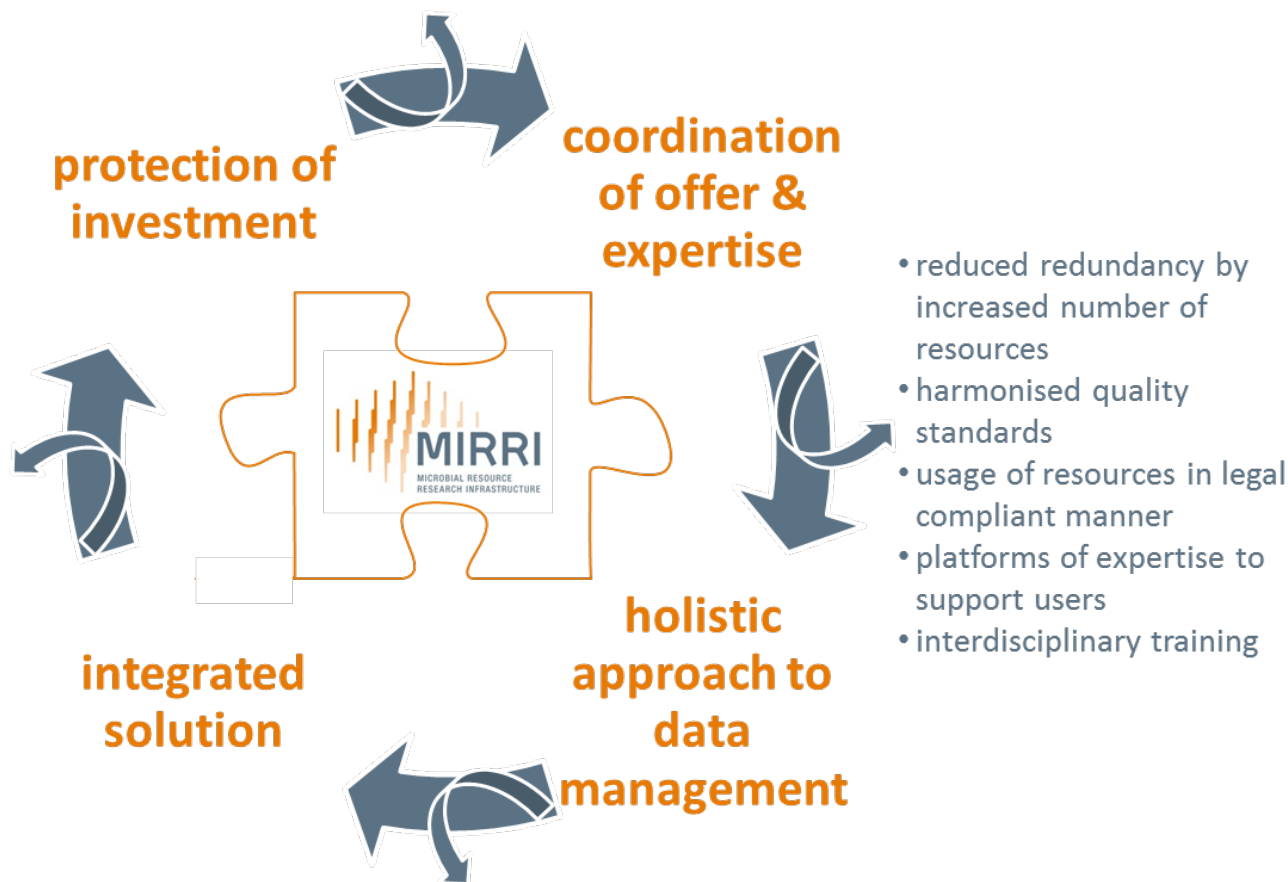
- MIRRI is part of the Biological and Medical Research Infrastructure (RI) ESFRI landscape
- MIRRI vision is to be a unique pan-European high-performance platform
  - adding value to known and yet unknown microbial biodiversity
  - exploiting unknown sources and knowledge
  - to accelerate discovery for the bioeconomy and bioscience
- MIRRI will generate solutions to societal challenges by stimulating interaction between academia and bioindustry



# MIRRI offers Integrated Solution

- improvement of credibility of science
- consistency with research council policy by return of investment
- establishment networks of interdisciplinary collaborations

- foster innovation through excellence in science
- stimulation of economic growth by supporting the bio-economy
- solutions to the Grand Challenges via the MIRRI integrated solution
- job development



- interoperability of databases
- add value by consolidation of as yet scattered data
- setting standards by facilitating data mining

# What makes MIRRI different?

What is the special thing about being an infrastructure?

- **Together**, MIRRI can afford the full range of often expensive technologies needed **to explore biodiversity**: an integrated spectrum of equipment, data, service, knowledge etc.
- **Together**, MIRRI provides **access to the entire spectrum of microorganisms** accessible via a single entry point
- **Together**, MIRRI sets **European standards** of collection, curation and analysis
- **Together**, MIRRI sets ambitious, collaborative **research goals** over extended periods
- **Together**, MIRRI can **share** best practices, standards, data, personnel, knowledge etc.

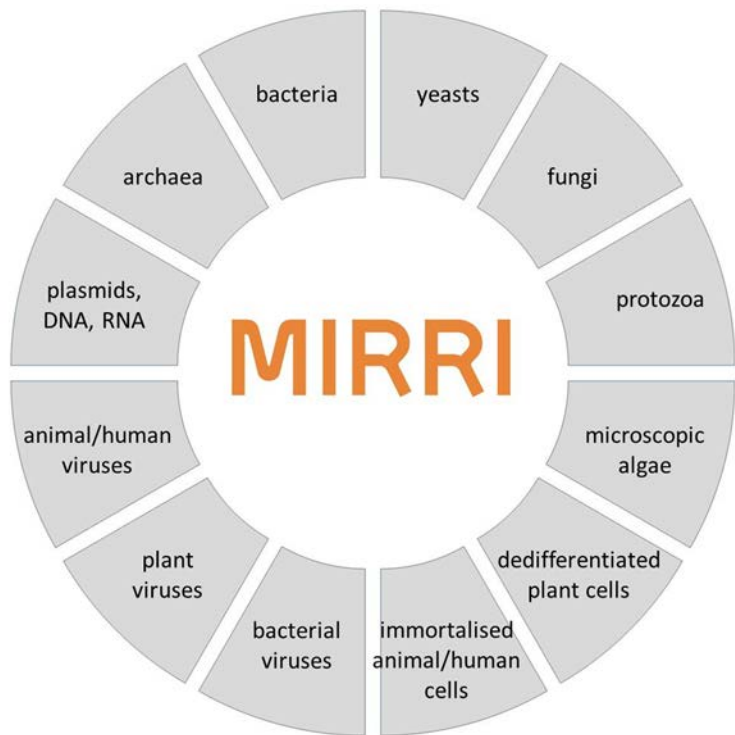


# Compliance management

- Quality of science and business
- Standard of services and products
- Legally compliant operational framework
- MIRRI supports best practice in all these areas but specifically through its work packages:
  - Access and Benefit Sharing (ABS)
  - Biosecurity
  - Business models
  - Stakeholder relationships and partnerships
  - Governance
- MIRRI policy must operate at the national, regional and global levels



# MIRRI Biosecurity Policy



MIRRI is preparing a policy statement on Biorisk assessment and implementation of Biosecurity measures based on analyses of the results obtained from the Biosecurity questionnaire and risk assessment trials, and the outcome of the MIRRI Workshop Biosecurity implementation strategies and compliance management in mBRCs, of 1-3 December 2014 (D.9.4).



# The key elements of MIRRI Biosecurity Policy

- i. Follow the **relevant national law**
  - adhere to the Code of Conduct on Biosecurity for BRCs
  - other comparable recognized standards
  - OECD Best Practice Guidelines on Biosecurity for BRCs;
- ii. **Follow the development of biosecurity implementation strategies** and adjust practice accordingly;
- iii. Work in collaboration with MIRRI- and external partners towards developing and **implementing protocols for adequate biosecurity risk assessment** of holdings and normative compliance in MIRRI-mBRCs;
- iv. Offer available specific expertise to the **MIRRI biosecurity expert cluster**
- v. Work with national authorities to increase competence and advocate the establishment of national biosecurity offices and their international cooperation;
- vi. Work in collaboration with MIRRI- and external partners to **strengthen the ethical basis for biosecurity** in the scientific community;
- vii. Adopt existing or develop new **educational tools** to raise awareness among mBRC staff.

# The Code of Conduct on Biosecurity

## **(1) Biorisk management**

- Integrate biorisk management throughout the organization and seek its continuous improvement.
- Assign adequate resources and responsibility to guarantee compliance with legal requirements, communication to staff and relevant third parties, and carry out reliable and appropriate risk assessment.

## **(2) Raising awareness**

- Devote specific attention in the education and further training of all staff on:
  - the dual use dilemma i.e. the risks of misuse of biological material, information and life sciences research
  - the requirements of regulations in this context.
- Provide regular training and carry out auditing to maintain up to date knowledge on biosecurity.
- Raise awareness of related third parties on their responsibilities.

# The Code of Conduct on Biosecurity

## **(3) Reporting misuse**

- Encourage a culture of reporting misuse.
- Report any finding or suspicion of misuse of biological material, information or technology directly to competent persons or commissions.
- Protect persons reporting on misuse and ensure that they are not targeted for retribution as a consequence.

## **(4) Internal and external communication**

- Prevent access by unauthorised persons to internal and external e-mails, post, telephone calls and data concerning information about potential dual-use research or potential dual-use materials.
- Regulate the communication of sensitive information.

# The Code of Conduct on Biosecurity

## **(5) Research and sharing knowledge**

- Assess possible dual-use aspects of research during the application for and the execution of research projects.
- Minimize the risk that publication of results on potential dual-use organisms will contribute to misuse of that knowledge.
- Consider biosecurity implications when sharing knowledge.

## **(6) Accessibility**

- Ensure physical security of and access control to stored potential dual-use material in accordance with its risk classification.
- Implement access control for staff and visitors where potential dual-use biological materials are stored or used.

# The Code of Conduct on Biosecurity

## (7) Supply, shipment and transport

- Screen recipients of potential dual-use biological materials, in consultation with the relevant authorities and parties.
- Select transporters suitable to handle potential dual use biological materials.
- Perform export control in accordance with applicable regulations.

Christine Rohde, David Smith, Dunja Martin, Dagmar Fritze, and Joost Stalpers (2013). Code of Conduct on Biosecurity for Biological Resource Centres: procedural implementation. *International Journal of Systematic and Evolutionary Microbiology* 63, 2374-2382.  
[http://ijs.sgmjournals.org/content/63/Pt\\_7/2374.long](http://ijs.sgmjournals.org/content/63/Pt_7/2374.long)

*International Journal of Systematic and Evolutionary Microbiology* (2013), 63, 2374–2382 DOI 10.1093/ijs/63.051901-0

### Code of Conduct on Biosecurity for Biological Resource Centres: procedural implementation

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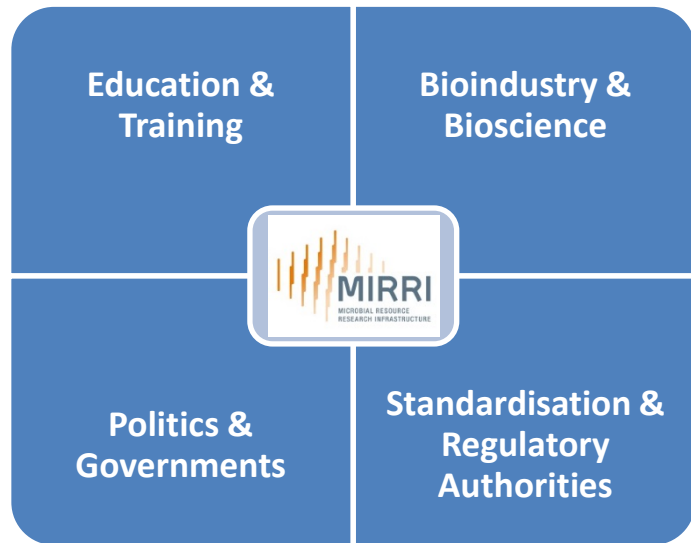
<sup>4</sup>CBS-KNAW Fungal Biodiversity Centre, Utrecht, Netherlands

A globally applicable code of conduct specifically dedicated to biosecurity has been developed together with guidance for its procedural implementation. This is to address the regulations governing potential dual-use of biological materials, associated information and technologies, and reduce the potential for their malicious use. Scientists researching and exchanging microorganisms have a responsibility to prevent misuse of the inherently dangerous ones, that is, those possessing characters such as pathogenicity or toxin production. The code of conduct presented here is based on best practice principles for scientists and their institutions working with biological resources with a specific focus on micro-organisms. It aims to raise awareness of regulatory needs and to protect researchers, their facilities and establishments. It affects global activities in this area in response to legislation such as that in the USA, the PATRIOT Act of 2001, Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, the Anti-Terrorism Crime and Security Act 2001 and subsequent amendments in the UK; the EU Dual-Use Regulation; and the recommendations of the Organisation for Economic Co-operation and Development (OECD), under their Biological Resource Centre (BRC) initiative at the beginning of the millennium (OECD, 2001). Two project consortia with international partners came together with experts in the field to draw up a Code of Conduct on Biosecurity for BRCs to ensure that culture collections and microbiologists in general worked in a way that met the requirements of such legislation. A BRC is the modern day culture collection that adds value to its holdings and implements common best practice in the collection and supply of strains for research and development. This code of conduct specifically addresses the work of public service culture collections and describes the issues of importance and the controls or procedures that should be in place. However, these best practices are equally applicable to all other microbiology laboratories holding, using and sharing microbial resources. The code was introduced to the Seventh Review Conference to the Biological and Toxin Weapons Convention (BTWC), United Nations, Geneva, 2011; the delegates to the States parties recommended that this code of conduct be broadly applied in the life sciences and disseminated amongst microbiologists, hence the publishing of it here along with practical implementation guidance. This paper considers the regulatory and working environment for microbiology, defines responsibilities and provides practical advice on the implementation of best practice in handling the organism itself, associated data and technical know-how.

**Abbreviations:** BRC, biological resource centre; BTWC, Biological and Toxin Weapons Convention; CBSN, chemical, biological, radiological and nuclear; ECRI, European Commission of Microbial Resource centres; EBCN, Global Biological Resource Centre Network; GMI, genetically modified organisms; IUIS, International Union of Microbiological Sciences; NGO, non-governmental organization; OECD, Organisation for Economic Co-operation and Development; WHO, World Health Organization; WHOCC, World Collection for Culture Collections; WHO, World Health Organization.   
Three authors are available as supplementary material with the online version of this paper.

# MIRRI Biosecurity Workshop

## Braunschweig December 2014



**MIRRI brought together stakeholders to find common solutions**

- Education is paramount - use existing training modules (see <http://www.brad.ac.uk/bioethics/TraintheTrainer/20CreditBiosecurityModule/>)
- Creation of Biosecurity Offices e.g. similar to the Netherlands
- MIRRI should influence policies and practices
- Ensure the Biosecurity Code for BRCs is dynamic
- Help develop the absolutely essential risk assessment best practice
- Ensure high quality, high risk group organisms are available
- Creation of an expert cluster
- Establish minimal requirements for mBRCs



# MIRRI Workshop defined next steps

- A roadmap to implement best practice
- Establish the expert group and support network
- Seek sources of further information and use existing tools – a more connected approach
- Stepwise work flow for legal certainty and best practice
- Assess changes since GBRCN, EMbaRC and OECD best practice
- Establish a suitable mBRC risk assessment
- Lobby policy makers to establish Biosecurity Office, tools to help
  - OECD
  - EU
  - National
  - Organisations – WHO, ISU, CBD (CHM), Institutions
- Outreach to stakeholders, media
- Workshops (MIRRI and attendance of others e.g. Interpol)

# Next steps continued

- Overcome hurdles:
  - Lack of coherent legislation
  - Fragmented communication;
  - Weakness of BTWC
  - Acceptance: awareness in the lab; commitment of management; Resistance to new regulation;
  - Codes are not pragmatic; Changing mind sets; Need to follow the advances in science (dynamic approaches)

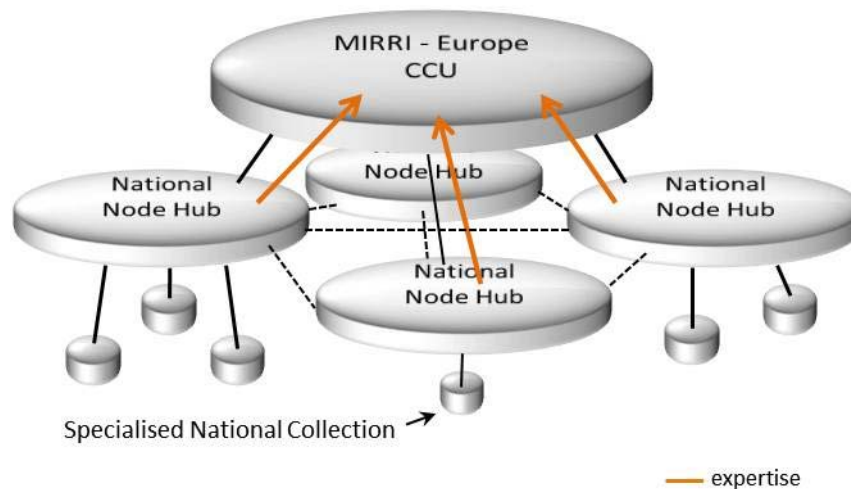
# Next steps continued

- Education/Awareness of : Tools; dual use; restricting sensitive information; finances to fund this
- Knowledge: Lack of; Expertise; Community needs and expectations
- Support: Legal, advice, finances; networks to help in compliance measures; lack of experts (sufficient staff) in mBRCs; help in the biorisk process
- Stepwise approach to mBRC compliance management incorporating

- Biorisk management
- Quality management
- Training
- Business operation
- Funding



# Summary



## MIRRI to:

- support mBRCs to implement best practice
- to work with science and bioindustry communities on common approaches
- to work with policy makers to get practical solutions
- Support the implementation of the Biosecurity Code of Conduct for BRCs

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