

## **PROJECT PERIODIC REPORT**

Grant Agreement number:	312251					
Project acronym:	MIRRI					
Project title:	Microbial Resource Research Infrastructure - MIRRI					
Funding Scheme:	Combination of CP & CSA					
Date of latest version of Annex I against which the assessment will be made						
	22.07.2015					
Periodic report:	$1^{st} \square 2^{nd} \boxtimes 3^{rd} \square 4^{th} \square$					
Period covered:	from 01.05.2014 to 31.10.2015					
Name, title and organisatior Coordinator:	<b>of the scientific representative of the project's</b> Prof. Dr. Erko Stackebrandt					
	Leibniz-Institut DSMZ-Deutsche Sammlung von					
	Mikroorganismen und Zellkulturen,					
	Braunschweig, Germany					
Tel:	+49 (0) 531-2616 215					
Fax:	+49 (0) 531-2616 418					
E-mail:	erko@dsmz.de					
Project website address:	www.mirri.org					



### Declaration by the scientific representative of the project coordinator

I, as scientific representative of the coordinator of this project and in line with the obligations as stated in Article II.2.3 of the Grant Agreement declare that:

• The attached periodic report represents an accurate description of the work carried out in this project for this reporting period;

- The project (tick as appropriate)<sup>1</sup>:
  - $\boxtimes$  has fully achieved its objectives and technical goals for the period;
  - □ has achieved most of its objectives and technical goals for the period with relatively minor deviations.
  - $\Box$  has failed to achieve critical objectives and/or is not at all on schedule.
- The public website, if applicable
  - $\boxtimes$  is up to date
  - $\Box$  is not up to date
- To my best knowledge, the financial statements which are being submitted as part of this report are in line with the actual work carried out and are consistent with the report on the resources used for the project (section 3.4) and if applicable with the certificate on financial statement.
- All beneficiaries, in particular non-profit public bodies, secondary and higher education establishments, research organisations and SMEs, have declared to have verified their legal status. Any changes have been reported under section 3.2.3 (Project Management) in accordance with Article II.3.f of the Grant Agreement.

Name of scientific representative of the Coordinator:

Prof. Dr. Erko Stackebrandt

. ladehardt

Date: 18 / 12 / 2015

For most of the projects, the signature of this declaration could be done directly via the IT reporting tool through an adapted IT mechanism and in that case, no signed paper form needs to be sent



<sup>&</sup>lt;sup>8</sup> If either of these boxes below is ticked, the report should reflect these and any remedial actions taken.

## Contents

Declaration by the scientific representative of the project coordinator	2
1. Project objectives for the period	4
2. Work progress and achievements during the period	6
Workpackage 2	6
Design of the Microbial Resource Research distributed Infrastructure	6
Workpackage 3	12
Define government structure, legal status and operational practice	12
Workpackage 4	18
Financial Plan	18
Workpackage 5	26
Communication, dissemination and outreach	26
Workpackage 6	32
Development of Services, Outputs and foster interdisciplinary work programs	32
Workpackage 7	41
Capacity building, education and training	41
Workpackage 8	45
Data Resource Management	45
Workpackage 9	53
Legal operational framework for access to Microbial Resources	53
Workpackage 10	63
Innovative approaches	63
3. Project Management	67
Consortium management tasks and achievements	67
Problems and envisaged solutions	70
Changes in the consortium	70
List of project meetings, dates and venues	70
Project planning and status	71
Impact of possible deviations from the planned milestones and deliverables	72
Any changes to the Grant Agreement Number 312251	72
Development of the Project website	73
Coordination activities during the period	



### **1. Project objectives for the period**

#### Aims and objectives

As outlined in the 1st Periodic report individual partner mBRCs of MIRRI share a long history of collaboration in EU-funded research projects. As a consequence, the national collections, coined largely by national mandates and interests of their managers, learned to understand each other's individual strength and research interests. Though these mBRCs did neither change their accession policy nor agreed on common services or training programs, a platform of trust was established on which common interests in the long-term sustainability of European mBRCs were discussed. The expression of common interests and proposed long-term goals resulted in the positive evaluation of the MIRRI project and today, at the end of the third year of the Preparatory Phase, strategies have been outlined in which national interest are accepted to be aligned with the commitment as defined in the Partner Charter. National nodes and the associated national network will identify their unique place within the MIRRI infrastructure by harmonizing and fine-tuning their individual services to users with a minimum of unnecessary redundancy but a maximum partnership to foster communication and broadened portfolio elements to users.

MIRRI aims to design an open access facility with the legal status of a European Research Infrastructure Consortium (ERIC), originally made up of 5 to 6 national node centers characterized by specific tasks and local synergies by affiliating to them a national network with specific research holdings and expertise in isolation, characterization and R&D. The novelty of this infrastructure is based on the commitment of its members to coordinate and expand holdings according to collection strength and user needs, to provide a high-quality standard among partner collections, to broaden services and data offer, and to provide a common hub platform for legal and technical advice to partners and the user community.

MIRRI has outlined its goals and early strategies in the Mid-term review in 2014 to play a major part on Europeans innovation strategy to foster the bioeconomy and the meet the Great Challenges:

- To provide an infrastructure, with open access to academic, research, industry and civil services, for the provision of resources and associated data for the advancement of research in microbiology in the –omics area and exploitation of an unparalleled wealth of raw material for biotechnological application;
- To create a common technical platform for advanced screening of resource-associated data originating from MIRRI partner collections and from the literature, allowing a in depth interoperable search for new combinations of genomic, ecologic, geographic and phenotypic traits selected by the research community;
- To develop the most comprehensive European repository of microbial resources, data, protocols for standard operating procedures and best practice management, and legal advice in biosafety and biosecurity issues, intellectual property and resource traceability;
- To maximize the impact of microbial resources on European science and technology by raising the range and standard of authenticated samples and associated data for advanced experiments in basic and applied research.

The review stated that all planned milestones and deliverables were achieved for the reporting period. It also confirmed the 'great potential' of the project: 'Having a network that will supply high quality data and strains may enable scientists to perform research with well-



defined standards. In addition, it may enable bio-companies to explore databases and develop products'. The following objectives were considered 'both relevant and achievable'.

MIRRI has presented its administrative structure and its business and finance plan to national representatives in its first stakeholder meeting in October 2015. The summary of the closed discussion between the state representatives included the following points:

- The state representatives acknowledge the significant progress MIRRI made during the last years: the project has developed from a conceptual design to a workable infrastructure. The practical and operational concepts have developed very positively.
- The importance of MIRRI to support bioindustry and bioscience is visible and justifies the implementation phase.
- The next meeting of state representatives should be at the end of January 2016 in Berlin, Germany; national representatives from all countries participating in MIRRI should be invited including those who have not yet signed the Memorandum of Understanding.



## 2. Work progress and achievements during the period

### Workpackage 2

Design of the Microbial Resource Research distributed Infrastructure

#### I. Summary of progress towards objectives and details for each task

WP2 has submitted all deliverables on-time and has achieved the two milestones identified in the DoW.

In May 2014, the Deliverable 2.1 was submitted. All actions and results carried out by WP2 during the first 18 months were explained in detail, comprising mainly the development, distribution and analysis of several questionnaires to identify the needs and expectations of MIRRI stakeholders.

In April 2015, Deliverable 2.2. was submitted which is based on the *"Workshop to Agree Minimal-Maximal Function of MIRRI, the Type of Partnership and the Resources and Services to be included"*. MIRRI's operational and management structure and minimal partner requirements were discussed and mostly agreed by all participants.

Finally, in August 2015, Deliverable *2.3 Compilation report on outputs: Compilation report on outputs from WP2 tasks 1-5, final conclusions and recommendations"* was submitted. This document provides an overview of all WP2 achievements during the last 18 months of the project and presents the connections of WP2 results with Deliverables of other Work Packages.

Most WP2 actions during M18-M36 were focused on:

- Elaborating the charter of innovative services to be put forward by MIRRI and advertising the current offer through the MIRRI web page;
- Distributing the information gathered by the different surveys within the MIRRI consortium to facilitate the development of strategies of the different work packages taking into account the profiles and needs of the stakeholders;
- Participating on the development of the MIRRI Expert clusters and CWE (Collaborative working environment).

# Task WP2.1 Define the function of the research infrastructure and the resources and services to be included

During the second period of the project, the information compiled from the surveys in the first reporting period was further analysed and used by WP2, as well as by other work packages, to elaborate the strategies and deliverables (e.g. the MIRRI offer, included in D4.4 Final Draft of Business plan content).

These surveys collected data related to resources (accessibility), services (offer), adequate information (legal aspects such as biosecurity), training and outreach (awareness of all the previous). In addition, output from other WPs concerning outreach and development (WP5),



development of services, outputs and interdisciplinary work programs (WP6), education and training (WP7), data management (WP8), legal operational framework for access to microbial resources (WP9) confirmed, supported or supplemented the data obtained by the surveys. Final reports of all surveys were uploaded into the MIRRI members' area on the MIRRI website and are available upon request. Following, main achievements are highlighted:

#### User community needs

Consultation of users focused on several topics related to mBRCs in which MIRRI can make a difference and improve the present situation for both profit and non-profit respondents. The received feedback guided the design and content of MIRRI as a new concept, with goals beyond what single mBRCs can offer individually, considering that MIRRI will be a unique portal facilitating access to a broader range of microbial material, data, expertise, and services.

The improvement of the MIRRI offer falls within the scope of several deliverables (a brief overview is described in D2.3).

# Inventory of *"ex-situ"* microbial resources in Europe (maximal coverage by resource holders) and their availability. Exploring gaps in microbial resources.

D2.1 showed an overview of major groups of microbial resources conserved in European public and research collections. Although potential gaps in available microbial resources/taxa were hard to establish through the surveys, feedback from the stakeholders generated lists about microbial taxa or groups they considered as missing in public repositories. Information from these lists was used in D6.1 "List of priority groups of microorganisms to be made available via MIRRI" to identify unique holdings and to deduce priority groups in line with stakeholders needs. Alongside these lists, several approaches to enhance the MIRRI holding offer have been described in D6.2 "Report on strategies and incentives to improve accessibility of orphan cultures". These strategies propose a dialogue between providers, users, scientific publishers and public funding bodies in order to guarantee the accessibility of published key strains. MIRRI could play a key role by coordinating and leading this initiative via the Central Coordinating Unit (CCU) and compelling partner mBRCs to adhere to the MIRRI Accession Policy. This Policy is in progress and has been discussed among mBRCs Heads on several occasions (including D2.2 Workshop about minimal-maximal function). Agreed recommendations are part of D6.1 and a statement on it is included in the partner charter.

#### Inventory of services related to microbial resources in Europe (maximal coverage)

Consultation of stakeholders showed that the current service offer provided by public collections is in many cases unknown by the users (D2.1 and final surveys reports).

Strategies to improve the current situation have been discussed on several occasions during the MIRRI preparatory phase. In order to increase awareness already during this phase, a gateway into the MIRRI website named USER SERVICE was opened. It directs to a list of services offered by the current MIRRI partners and collaborating parties and provides direct access to their respective on-line catalogues. The list of services has been reviewed during the second part of the project to show the different types of services in a more structured way.



#### The MIRRI Collaborative Working Environment (CWE) to meet user needs

The envisaged MIRRI strategy focuses on the construction of a web portal as an accessible gateway for the integration of the catalogues from the different providers and tries to connect resources with as much information as possible, including links to other databases. The information exchange between MIRRI partners and (bio)-industrial partners is crucial for an adequate development of a proper service offer. Nowadays, electronic networks facilitate communication and increase visibility towards potential partners located anywhere in the world. MIRRI foresees a CWE platform (see WP10 below) with four main pillars including Project information, Resources & Data & Services, Expert Clusters and Education & Training (E&T).

The current version of the financial plan (included in D4.4) allocates part of the budget to employ an IT manager for the Central Coordinating Unit and to create and maintain an IT node and the CWE Platform.

#### Task WP2.2 Define membership criteria for MIRRI in the Construction Phase

Membership types and membership criteria have been discussed with MIRRI partners at several occasions, including the "Workshop to Agree Minimal-Maximal Function of MIRRI, the Type of Partnership and the Resources and Services to be included" (D2.2). This workshop was organized to inform and discuss with Heads of mBRCs from MIRRI Partners and Collaborating Parties, about MIRRI's operational and management structure and minimal partner requirements for the construction phase. These issues are defined in three documents, which will be the core documents for the application of a legal MIRRI status:

- **MIRRI-ERIC Statutes.** A legal binding document between the Members (States and Intergovernmental Organizations) and the MIRRI Legal Entity that describes the basic internal structure of the Infrastructure (description of the tasks and activities, definition of the governing and management bodies, formalities about acceptance and withdrawal of Members, finance mechanisms and policies about access, employment, etc.)

- **Partner Charter.** A binding document signed between the Partners (resource, training, service and expertise providers) and the National Nodes or the MIRRI Legal Entity. The partner charter takes into account requirements (i) imposed by the proposed legal structure (WP3), (ii) related to the accession policy (WP6), (iii) regarding quality management (WP3) and data interoperability (WP8), (iv) associated to the involvement in clusters of expertise and training (WP2 and WP7), (v) concerning biorisk assessment (WP9) and (vi) imposed by the regulations for compliance with Access and Benefit Sharing and the Nagoya Protocol (WP9).

- Rules of Operation. A binding document approved by the Assembly of Members that describes the "Operating Formalities" of MIRRI, its operational elements and governance structure with regards to administrative and operating structures, decision-making processes, role of stakeholders, secretariat structure, personnel issues and the role of the host. They are understood to be complementary to the MIRRI Statutes and descriptive where statutes leave space for operational freedom.



The MIRRI Statutes and the MIRRI Partner Charter were almost entirely agreed by the participants of the Workshop (D2.2). Minor details are being discussed to adapt these documents to the regulatory framework of the Infrastructure. Attached to these documents there are several policies produced during MIRRI's preparatory phase by different work packages that are also mostly completed. After finalising all details of Statutes, Partner Charter and Policies, ad-hoc designated groups will define the operating procedures related to each document in order to complete the Rules of Operation (Deliverable 3.4).

Summary of policies/documents cited in the Partner Charter and/or Statutes and/or Rules of Operation:

- Rules of operation
- Code of conduct
- MIRRI's Data Management Policy
- MIRRI Policy for compliance with the Convention on Biological Diversity (CBD) and the Nagoya Protocol.
- MIRRI Policy on biorisk assessment and biosecurity measures.
- Accession Policy.
- MIRRI mBRC Key Performance Indicators (Included in D3.6.)

# Task WP2.3 Design the operational structure for MIRRI in the Construction Phase

The essential MIRRI's operational structure was described at the beginning of the project (Deliverable 4.3 Draft short Business Plan) and assumes a non-profit distributed infrastructure. It is envisaged the creation of a central office (the Central Coordinating Unit, CCU) composed by the Director and a management team dedicated to issues such as development and maintenance of the IT knot and the Collaborative Platform, assistance to the partner mBRCs in quality / regulatory management matters, coordination of central training activities and financial / business affairs. Linked to the CCU there will be National Nodes in each participating Member Country. The National Nodes coordinate the activities and delivery of services of the different Partners (mBRCs, other service providers, experts) in each country.

This operational structure has to be supported by a solid legal framework to ensure the efficiency and the sustainability of the Infrastructure.

During months 18 to 36 MIRRI's governance structure has been discussed at several occasions including the 4th Steering Committee – Work Package Meeting (September 2014), the WP2 Workshop (D2.2, March 2015) and the 4th Annual Meeting (October 2015). As reported before, documents covering the regulatory directives have been elaborated and mostly agreed (Statutes and Partner Charter). Moreover, MIRRI partners believe that the ERIC model proposed by the European Commission meets the requirements of MIRRI as a distributed Infrastructure. Nevertheless, the final decision about these issues will be taken by MIRRI National shareholders. Accordingly, governmental representatives of MIRRI partner countries attended the 4th Annual Meeting (October 2015) and their recommendations are being considered to secure their commitment to support the Infrastructure. Next meeting has been already scheduled at the beginning of 2016.



#### Task WP2.4 Define the stakeholder community and their needs

Definition of the stakeholder community has been reported by WP5 (Stakeholder Analysis) and delivered in D4.4 Final Draft of Business Plan Content. This community integrates a broad range of players, from resource providers and users of mBRCs to governmental, regulatory or funding bodies.

As reported previously, most WP2 tasks during the first half of the project (M1-M18) consisted in producing, distributing and partly analysing four individual online questionnaires ad hoc designed targeting European public mBRCs/CCs, research collections and scientists from academia and bio-industry. During months 18 to 36 the data gathered were further analysed and other parties such as Policy Makers, National Contributors, Legal, Regulatory and Standards Institutions/Authorities, National and International patent officers, Bio-industry Associations and Biodiversity Associations were contacted directly by MIRRI partners and/or invited to several MIRRI meetings. It is to highlight the participation of Governmental representatives during the 4th Annual meeting as well as Bio-industry representatives in several meetings (e.g. R&D Expert Group Meeting on June 2014, MIRRI WP 9 and WP 3 Workshop: Biosecurity Implementation Strategies and Compliance Management in mBRCs and 4th Annual meeting).

The different needs of each group of stakeholders were considered to shape the MIRRI Infrastructure.

# Task WP2.5 Explore partner linkages and routes to harmonization, considering existing structures

A large proportion of the work carried out within this task was already delivered in D2.1 (first compilation report of WP2 actions). There, linkages in and between national consortia of CCs/mBRCs (including the description of National Nodes), Global/International directories or databases of CCs, topic-driven projects/structures and other organizations (biotech associations, other ESFRI projects, etc.) were already explored.

During the second half of the project, the definition and structure of the National Nodes was further developed in collaboration with the work packages focusing on governance structure, legal status and operational practice (WP3) and finances (WP4). Other partner linkages have been analysed within the scope of work packages 5 and 6, where several deliverables reflect on the efforts MIRRI has undertaken and/or will undertake to form strategic partnerships. Outputs from WP5 describe synergies with stakeholders and the activities which led to their identification and provides MIRRI with an outreach strategy to enhance the MIRRI reputation, expand research opportunities and bridge the gap between MIRRI and (bio)-industry.

With regard to linkages outside the MIRRI consortium, an exploratory work on the potential of joint activities with existing infrastructures, projects, initiatives and networks leading to the development of an interdisciplinary work program is described in the "Working plan for interdisciplinary activities for the MIRRI construction phase" (D6.6). This document discusses on the opportunity to create transnational clusters to address crosscutting issues such as coverage of quarantine reference materials in close collaboration with the Q-collect and Q-BaCo project. The concept to create a portal and a platform to promote this type of collaborations is defined in detail in D6.3.



### II. Significant results

Most activities during the second half of the project were conducted in collaboration with other WPs.

The most significant results can be summarized as follows:

- a) The design of the MIRRI Collaborative Working Environment (see D6.3, D10.1 and WP 10 below)
- b) The elaboration of MIRRI Statutes and MIRRI Partner Charter
- c) The advertisement of the current service offer of MIRRI partners
- d) The dialogue between Heads of mBRCs to agree on a common Accession Policy devoted to broaden the range of available reference strains
- e) The dialogue with National Governmental Representatives to finalize MIRRI's legal regulative framework and financial plan

### III. Reasons for deviations from Annex I of the DoW and impact on resources

There are no deviations from Annex I.

### IV. Explain the reasons for failing to achieve critical objectives and/or not being on schedule and explain the impact on other tasks as well as on available resources and planning

All objectives have been achieved. Final approval of the Partner Charter depends on the decision of shareholders about MIRRI's Legal Entity.

#### V. Statement on the use of resources

All resources have been used according to the DoW.

#### **VI. Propose corrective actions**

No corrective actions necessary.

### Workpackage 3 Define government structure, legal status and operational practice

#### I. Summary of progress towards objectives and details for each task

The Microbial Resources Research Infrastructure (MIRRI) is a distributed infrastructure requiring a Governance structure that facilitates its operation under an appropriate legal entity. The European Research Infrastructure Consortium (ERIC) has been selected as an appropriate legal status being designed to support entities established under the European Strategy Forum for Research Infrastructures (ESFRI). The Implementation Phase of MIRRI will be achieved through centrally coordinated activities. To do this MIRRI brings together signatory Member States in an Assembly of Members as its main decision making body. The Assembly of Members will appoint an Executive Director to implement the decisions, manage the infrastructure and report back on activities. The Executive Director will, on approval of the Assembly of Members, establish a Central Coordinating Unit (CCU) as the central element of the MIRRI governance structure providing the administration of the MIRRI-ERIC and support services for the general management; it will be the central point for communication with stakeholders and be responsible for the promotion of the infrastructure. It will be the Statutory Seat, established in one of the EU-Member States signing the MIRRI-ERIC as agreed by the founding Members of the infrastructure. The CCU will comprise a management office with appropriate staffing. The expertise will include IT Management, Communication/Customer Relations, Compliance and Quality Management expertise and a Secretary. Other skills will be required to carry out the extended functions of the CCU as it moves into its Implementation Phase including legal and regulatory guidance and support, business development, fund raising, marketing, training, education and technology use and development.

The operational structure of the MIRRI-ERIC will be a distributed model with a hub and spokes design connecting the CCU to the National Nodes (NNs) bringing together the national partners (mBRCs, experts and service providers) that meet the MIRRI requirements. Access to the MIRRI offer will be via a virtual portal, directly via mBRCs or their national nodes (NNs). All these functions require funding through revenue lines and Member State funding mechanisms. This plan addresses not only the central costs to address the MIRRI outputs but also the costs associated with running of the NNs and capacity building in the national microbial domain Biological Resource Centres (mBRCs) to meet the Partner Charter, the requirements to deliver MIRRI's objectives.

The decision on the Governance structure as well as the kind of legal status for MIRRI will be decided by the founder Member states. However, the legal entity ERIC is the first and obvious choice and the one on which this report is based. There are already a number of ESFRI research infrastructures being implemented and MIRRI has followed their lead in designing its Governance structure. It is critical that Member States are fully engaged in MIRRI's Governance but it is equally important that other stakeholders are involved in guiding the output to ensure that MIRRI delivers all it can to underpin research and development and play its role in stimulating Europe's bioeconomy.



#### Task WP3.1 Establish secretariat and governance structure

A detailed structure has been explained in the first Periodic Report and in D3.1 and in 3.4. Since then, the 1st meeting of national stakeholder recommended a simplification of the governing structure (Figure 1). European Member States will be invited to sign the MIRRI-ERIC along with EU Associated Countries, Third Countries or Intergovernmental Organizations and thus accept the MIRRI-ERIC Statutes. All can participate either as full Members or Observers. The legal minimum number of ERIC signatures from Member States to construct the infrastructure is three although the critical mass to provide financial stability may well be 5 members (see WP Financial Plan). The main obligations of Member States are to send a representative to the MIRRI Assembly of Members to provide direction in delivery of appropriate outputs and to provide funding aimed at developing capacity and quality at the national level. The two main elements of the MIRRI structure are the Central Coordinating Unit and the Assembly of members.

The MIRRI-ERIC will be steered at a number of levels. The decisions and directions from the General Assembly need to be translated into action and delivered. This will be carried out at the executive level under advice of the Advisory Bodies and executed by the CCU.

Each Member State must appoint a National Node (NN) and one National Coordinator who is responsible for the country to follow the Assembly of Member's policies. These National Coordinators come together to form the National Coordinator's Forum to maintain coherence and consistency across MIRRI in the implementation of the strategies decided by the General Assembly. The National Coordinator's Forum appoint a chair to report to the executive Director and the General Assembly. The National Nodes (NNs) will bring together the national partners (mBRCs, experts and service providers) that meet the MIRRI requirements presented in the Partner Charter. The NNs will coordinate the activities of the partners within the country, organise funding, provide or advise in training issues, enhance the development of the national mBRCs as well as expand the national network to improve the MIRRI offer. The user will have access to strains available in mBRCs as well as directories of other services, thematic clusters, facilities, expertise, data etc. via direct contact with mBRCs, National Nodes or the MIRRI portal. These services will be delivered directly from the providing institutions (e.g. mBRCs) belonging to MIRRI, which will maintain the possibility of providing services outside MIRRI.

The interests of mBRCs will be discussed in the mBRCs Directors Forum which supports the Executive Director in elaborating and the Partner mBRCs in implementing the Annual Work Plan. This Forum selects a speaker who will discuss the Work Plan with the Executive Director of the MIRRI-ERIC who will deliver the Plan to the General Assembly and transfer back the decision to the chair of the mBRCs Directors Forum.

Documents concerning membership criteria laid down in the Partner Charter will be finalized until the 2nd Stakeholder Meeting, February 2016 and will be presented in the final report. The almost latest version of the Partner Charter has been included in D3.1.





Figure 1 Schematic flow of communication channels between the elements of the MIRRI Governance

# Task WP3.2 Agreement on the choice of legal status for MIRRI and establishing Statutes

The decision to select the legal status for MIRRI according to the Council Regulation (EC) N° 723/2009 as a European Research Infrastructure Consortium (ERIC) legal entity has been explained in detail in D. 3.2. Different models of legal status have been compared, the advantages and disadvantages evaluated and the European Research Infrastructure Consortium (ERIC) as a Community law based legal form specially developed to support the ESFRI construction selected. Though the conclusion to follow the recommendation of DG Research and Innovation of the European commission is made by MIRRI the final decision will be made by the Governance Board prior to submission the document.

The 16 Partners and 20 Collaborating Parties of the EU -funded pan-European Microbial Resource Research Infrastructure (MIRRI) agreed to the temporary MIRRI-ERIC statutes as included in D3.2.

# Task 3.3 Establish a common understanding on Quality Management System (QMS) and appropriate standards and best practice models

D3.4 on the 'Internal operational policy for MIRRI' defines and summarized how MIRRI will operate, adapting the current independent, often institutional policies and managed processes by harmonized holdings, services, the training offer and accession policy and share expertise. The infrastructure coordinates the National Nodes and improves access to enhanced quality microorganisms in an appropriate legal framework and to resource associated data in a more interoperable way. The National Nodes and national mBRC's will retain their own legal entity but control of some elements of their operations will be influenced by the annual Work Plan of MIRRI-ERIC. These influences include a proportion of increased user access to mBRC facilities, services and resources, a commitment to take deposits identified in the MIRRI common accession policy and participation in the expert clusters as laid down in the Partner Charter. Most MIRRI partner mBRCs already run under a certified quality system and apply a best practice regime. Compliance with the articles of the Nagoya Protocol (NP) and of Biosafety and Biosecurity codes and laws are mandatory to apply for MIRRI partnership. It has been especially the emerging needs to follow NP requirements and national and international rules and regulations by developing a coherent working scheme for MIRRI partners that led to the extension of the MIRRI project by six month.



In order to manage harmonization the following strategies have been identified and policies will be prepared until the end of the project (Figure 2):

- Virtual platforms of expertise will be organised across the infrastructure to share access and costs.
- Duplication of holdings will be kept to a minimum, consistent with the security and diversity of microbial resources.
- Collaborations with other ESFRI consortia are underway in areas of common interests to avoid duplication and unproductive competition.
- Managing data interoperability and sharing, where appropriate, expertise in curation and analysis of different types of datasets will bring cost efficiencies and new tools. MIRRI will provide its strain metadata that will in return add value to partner data.
- MIRRI will work with partners, to develop joint standards for presenting data and providing services that effectively link phenotypic and genomic data for users. This will add significant value to the ESFRI network and the biological resources held.



## **MIRRI offers Integrated Solution**



#### Figure 2: The MIRRI Integrated Solution

#### Task WP3.4. Demonstrate the impact of MIRRI on BRCs

This D3.6 document resulted from various discussions and consultation within MIRRI, and was completed following the Foresight-enriched Research Infrastructure Impact Assessment Methodology guidelines and impact indicators. A list of measurable indicators on several topics and subtopics that fit the scope of MIRRI was produced and circulated among MIRRI



partners to obtain an indication of the perceived relevance and data availability of each indicator. Impact areas were defined which would match most activities of mBRCs such as

- Implementation of QMS
- Transparency to customers
- FAIR access to resources
- ABS Compliance
- Biorisk assessment and biosecurity
- Common accession policy
- Sustainable strategy for holdings and services
- Provision of data and information
- Participation in cluster activities
- Bio-industry interaction

Examples for measurable indicators with high perceived relevance and availability for each impact area as well as key performance indicators to measure compliance with the Partner Charter are indicated in D3.6.

All of these actions are capable of affecting the Services provided by mBRCs, either their quality, their added-value or the creation of new or expanded services. Most of the commitments made by mBRC partners will impact their operation, through the form of unified standards and Standard Operating Procedures (SOPs), or the adoption and implementation of standards. Importantly, most of the MIRRI requirements are expected to produce impacts on general topics, such as general benefits of microbiology, better distribution to place of origin, cohesion and dissemination.

As outlined in D3.6 the major shortcoming in predicting the impact the scarcity of data points that hinders the application of regression models to some datasets. To overcome this, the impact of MIRRI should take into account ex-ante and post-ante projections for as many of the measurable indicators as possible for each of the impact areas. It is crucial that mBRCs provide sufficient data to be able to assess their evolution within MIRRI.

#### **II. Significant results**

MIRRI is a distributed infrastructure which requires specific organisational features and functionalities to secure operation while optimizing return on investment and economy of scale. One of its ultimate goals, coordinating several different entities to work in synchrony has been achieved by defining common policies. The future coordination and monitoring of activities will be executed by a secretariat that is set within an agreed structure and run under simple, effective and unambiguous governance rules and a clear legal status. An appropriate communication network and rules have been set up to obtain maximum alignment and uniformity in operation controlled by a Quality Management System

MIRRI has significantly expanded the number of Collaborating Parties and countries and has increased its influence among the Research infrastructures in the biological and medical thematic area. MoUs (D3.3) have been signed by four countries forming the platform for meeting with national stakeholders. The Governance has been discussed at the first meeting of national stakeholders and subsequently simplified. Member States are fully engaged in



MIRRI's Governance and the first national stakeholder meeting has brought full support and provided important input into the improvement of documents needed to apply for a legal status. Documents to initiate the application for the legal status of an MIRRI-ERIC will be finalized until the 2nd national stakeholder meeting early 2016 and will be published in the final report. The major role of MIRRI in the landscape of microbiology has been recognized by the EC as in important and knowledgeable partner in finalizing the Guidance document on the scope of the ABS Regulation for the EU Regulation 511/2014.

#### **III. Reasons for deviations from Annex I of the DoW and impact on resources** No deviations from the DoW occurred during the reporting period.

IV. Explain the reasons for failing to achieve critical objectives and/or not being on schedule and explain the impact on other tasks as well as on available resources and planning None.

#### V. Statement on the use of resources

Partner 4 (SPP-PS) did not utilise all of the allocated funds, which will subsequently be used to partly finance the MIRRI extension period. The work of Partner SPP-PS has been executed by Partner 1 (DSMZ).

#### **VI. Propose corrective actions**

Not applicable.



### Workpackage 4 Financial Plan

#### I. Summary of progress towards objectives and details for each task

This work package developed financial plans for the operation of the future Microbial Resource Research Infrastructure based upon the estimated costs for delivery of the infrastructure as designed by the individual work packages. The first period of the MIRRI preparatory Phase resulted in the first printed version to engage Governments and potential national funders. It demonstrated possible sources of funding to be explored for the long-term functioning of the infrastructure and for the envisioned improved access to resources and services. The second period of work package 4 focused on the results of further development of the operational plans and strategies for MIRRI and the feedback received from potential national funders and users of MIRRI. Consequently two further iterations of the business case were developed revisiting mechanisms for funding the operation of the infrastructure and the consequential further development of the individual national components of this distributed infrastructure. The main goals achieved of work package 4 in this reporting period were:

- Estimation of the cost of building the RI based upon the governance structure, gap analysis of coverage, and identification of new services needed
- Evaluation of the different sources of funding available for the construction phase
- Estimation of the potential running costs of MIRRI
- Design of a financial plan for the funding of the RI utilising output from the other work packages of this proposal
- Development of structures for the management of the RI finances
- Approach national stakeholder to seek commitment of funds
- At end of preparatory phase MIRRI is ready to implement and begin the construction phase of MIRRI

#### Task WP4.1 Develop a financial plan

Within the first reporting period the task to develop the financial plan took into consideration the developments emerging from other work packages defining the rationale, costs and appropriate funding mechanisms for the establishment of the statutory seat (The Central Coordinating Unit [CCU]). The second period, months 18 to 36 defined operational costs and the investment needed to develop the distributed centres to enable delivery of the RI output (products and services). Estimations of costs at the mBRC and National Node level were discussed with Heads of Collections at a meeting in Amsterdam and subsequently made more robust resulting in the submission of the Deliverable D4.1 (D4.1.1) Financial plan. The MIRRI approach assumes a not-for-profit entity that is sustained by a mixed funding model implying long term core support by participating Member States and income generation by the MIRRI Partners, some through centrally coordinated activities.

The CCU is a central element of the MIRRI governance structure providing the administration and support services for the general management and administration of the MIRRI-ERIC; it is the central point for communication with stakeholders and is responsible for the promotion of



the infrastructure. The operational structure of the MIRRI-ERIC will be a distributed model with a hub and spokes design connecting the CCU to the National Nodes (NNs) bringing together the national partners (mBRCs, experts and service providers) that meet the MIRRI requirements. Access to the MIRRI offer will be via a virtual portal, directly via mBRCs or their national nodes (NNs). All these functions require funding through revenue lines and Member State funding mechanisms. The MIRRI financial plan addresses not only the central costs to address the MIRRI outputs but also the costs associated with running of the NNs and capacity building in the national microbial domain Biological Resource Centres (mBRCs) to meet the Partner Charter, the requirements to deliver MIRRI's objectives.

The first estimated CCU costs total almost €6.2 million over the first 5 years. The main income to cover these were outlined to come from sources including Member State contributions to the MIRRI-ERIC, partner mBRC fees, third party grants, income lines as they are developed such as access to data services and expertise and CCU host country contributions. The costs for establishment and operation of National Nodes (NNs) and the enhancement and participation of the national mBRCs is dependent upon a number of factors including the total number of mBRCs participating, the degree of development and maturation of the node, the extent to which mBRCs have devolved activities to a central unit and local costs. The funding of the mBRCs and the NNs is a national obligation outside the costings for the MIRRI-ERIC CCU and to a great extent depends on the level of involvement of national funders. Costs at the NN would include the establishment of a national mBRC network, the National Coordinator to deliver the coordination of national mBRCs and the linking out to research collections at all levels in the country. At the national levels the legal entities responsible for the NNs and mBRCs would organise their own finances to meet MIRRI needs. Some activities would be financed at national level such as mBRC participation in the common strain accession policy and some support up to 20% of physical access to facilities would be covered.

Annex 1 summarises both the costs and the project income for MIRRI as originally devised in the Reporting Period 1. Costs total almost €6.2 million and revenues to cover these are anticipated from sources including Member State contributions to the MIRRI-ERIC, partner mBRC fees, third party grants, income lines as they are developed such as data services and expertise and CCU host country contributions. The Member State contributions are calculated on the basis of country GDP (see detailed calculations in Annexe II of Deliverable D4.1).

During intensive communication with national stakeholders, MIRRI was asked in Month 26 to consider an alternative finance plan, in which in year 6 of the Construction Phase 90% of income cost for the CCU will be covered by CCU-own revenues. This requirement was matched by a combination of lowering running costs of the CCU and the broadening of income streams. The income streams are shown in Table 2 (Task WP4.2) and the revised budget is outlined in Annex 2.



#### Task WP4.2 Organise financial management

This task was to examine mechanisms for financial management for the research infrastructure and design a financial model that will enable the distributed centres to function as a coordinated infrastructure. The work to identify suitable financing sources began in the first period where analysis of different funding models (public, charity, public-private partnership or industry) that are normally used to finance the building and maintenance of research infrastructures in Europe. Evaluation of the different investment models was reflected in the first iteration business case. The second period of the preparatory phase could then focus on the controlling mechanisms to monitor performance and the final estimations of costs.

It could be anticipated that the host country would cover the CCU costs outlined above whereas the salaries will be funded through the MIRRI-ERIC and shared by Member States (Figure 1). MIRRI aims to support mBRCs to become sustainable and outlines here some of the many financial models currently in operation across the microbial resource collections world. Recent studies by the OECD and the EMbaRC project have summarised some of the working models of mBRCs. There are few collections that are self-financing but they are able to remain sustainable through a variety of routes. The mBRC or its host may have opportunities for other types of cost recovery activities and these often revolve around expertise and facilities available. The degree to which such activities may actually provide support sufficient to ensure financial sustainability of an mBRC is unproven. Other kinds of funding sources include support from industry, grants from agencies that support research, development of databases and other tools that complement the core role of mBRCs. Even funding from charitable sources, especially those associated with public health or sustainable development are sources of support. Evaluating different funding mechanisms is a core part of the MIRRI activities. Despite there not being one model for their operational and financial sustainability we can learn a lot from the experience of existing culture collections. It is difficult to estimate these costs as they vary so much dependent upon the difficulty in handling and preserving some microorganisms and the extent to which the biological material is characterised. The costs of the day to day running of the mBRC are to be met by the facility themselves and it is the additional costs needed to establish local MIRRI activities and meet MIRRI standards that the MIRRI Financial Plan is looking to cover.





Figure 1: Financing / Income sources for the MIRRI-ERIC

The level of financial contributions of the Members is to be determined by the Assembly of Members. Figure 2 shows the flow of finances through the MIRRI-ERIC and MIRRI infrastructure. These can be made through monetary contributions and in-kind contributions in the form of operating and/or capital contributions subject to payment of the minimum annual monetary contribution. The Assembly of Members will establish an accounting system and will develop rules for the acceptance of in-kind contributions and the assessment of their value.



Figure 2: Flow of finances MIRRI-ERIC and MIRRI RI



The membership fee or country contribution is calculated based on GDP per capita, and a fixed rate applicable to all. A scenario is demonstrated in Figure 3, where it is shown how the year 1 cost of  $\in$ 1 063 450 (Annex 1) would be split between France, Poland Spain, Germany and Belgium if they were the first to join. This results in a country percentage contribution split of France 31.24%, Poland 5.91%, Spain 15.52%, Germany 41.52% and Belgium 5.8% (Figure 3).



Figure 3: Financial contribution per year Belgium, France, Germany, Poland and Spain

Table 1 shows the original version in percentage terms how MIRRI saw the necessary revenue being generated. It can be seen that it was anticipated that investment by Member States in financing the MIRRI-ERIC will be reduced from 75% in year one to 50% cover of costs in year 5. Funding will be more or stable in years 6-10.

Table 1. MIRRI-ERIC Funding investment model showing percentage split between the
different sources (Original model, first reporting period

Funding source	Funding level (percentage of total cost)						
	Year 1	Year 2	Year 3	Year 4	Year 5**		
Member States (5 signatories)	75	63	58	55	50		
Third Party Grants	12.5	25	35	35	35		
Coordinating hub host country	12.5	10	2	2	2		
Bioindustry							
	0	1	3	4.5	8		
mBRC membership fees	0	1	2	3.5	5		
Total	100%	100%	100%	100%	100%		

Additionally, funding will be sought from funded projects or revenue generation from services provided by the Central Coordinating Unit (e.g. e-infrastructures support for the MIRRI



Information System). This may include licensing of any applicable intellectual property rights (IPRs). Specifically such income lines could be related to central data services or training and education programmes and tools. The partners (mBRCs, other resource providers such as culture collections (CC) and Service Providers) will also be expected to pay a fee for participation to cover some of the administrative costs. The details of this financial plan can be found in Deliverable D4.1.

Table 2 is a summary of CCU income revenues covering 90% of cost to finance the CCU income in year 6 after having received a legal status. A more substantive basis for costs of the CCU is depicted in Annex 2 and in Deliverable D4.4. The costs are based on the participation of the following member states:

# Table 2. Alternative MIRRI-ERIC funding investment model showing percentage split between the different income sources.

For the years 1-5 the GDP-based membership fees were considered for the following states: Germany, France, Spain, Poland and Greece. In year 6 Belgium as well as eight observer countries are considered.

Funding source		Funding level (percentage of total cost)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	
Expenses			•				
Costs CCU (plus statutory seat)							
	637	669	702	737	978	1060	
Devenues							
Revenues			-				
State members and observers fees							
	645€	676 €	708 €	742 €	978 €	245 €	
CCU revenues							
Partner and user fees	23€	62 €	88 €	115 €	162 €	209 €	
Sponsering by Companies	4€	14€	32 €	95 €	117 €	162 €	
Third Party Grants	-	40€	75€	110 €	150 €	405 €	
Expert and Training offer	3€	7€	15€	42€	61 €	86 €	
Total income	675€	799€	918 €	1104 €	1468 €	1107 €	
Total plus	38 €	130 €	216 €	367 €	490 €	47€	
Income versus expenses (% plus*)	5.9	19.4	30.7	49.7	50.1	4.4	

\* The income of higher than 50.000 €/ year generated is envisaged to be redistributed to member States (50%), mBRC partners (40%) and the CCU (10%) for expansion of personnel and infrastructure.



#### Task WP4.3 Engage funding bodies

Task 4.3 was arguably the most critical part of establishing a governance structure of MIRRI. It was essential that funding bodies including Ministries were brought into the discussions early. A strategy to engage potential funders and States was agreed in the first period of the preparatory phase. The key contacts identified by the partners were approached with the business case and an outline Memorandum of Understanding (MoU) with a view to signature on the MoU or securing a letter of support. This would enable Member States to be represented in further discussions to agree the process to establishment of the legal entity and secure the funding for MIRRI's construction and operation. National organisations were encouraged to trigger activity at the national level and establish national nodes. Partners were asked to contact their local funders and stakeholder to discuss National participation in MIRRI and provide resulting feedback will help design further action and provide input to the business case. Some partners were able to investigate and negotiate funding options within their own country financial sources. Based on the feedback received on these interactions the Governance Structure, Legal Entity selection, scope of the MIRRI offer and the business model to deliver this was revised.

Four countries have signed the MIRRI MoU, France, Spain, Poland and Greece. Importantly, representatives from Spain, France, Belgium, UK, The Netherlands, Poland and Romania met in Amsterdam on the 9 October 2015 to discuss the progress of MIRRI and their commitment to support its construction and operation.

#### Task WP4.4 Develop a business plan

Task 4.4 comprised the collation of information from all work packages for incorporation into the business plan. It relied on timely and detailed output from all relevant work packages WP2, which designed the infrastructure; WP3, the governance structure, legal status and operational practice; WP6 services and products; WP7 capacity building; WP8, the data management and information system; and WP9 the legal framework. Therefore the process of compilation was an iterative one and has resulted in three evolving business cases. The deliverables D4.1 Financial plan, D4.2 Financial management plan and D4.4 Final draft of business plan content the latter delivered in month 30 progressively became firmer in the cost estimations and identification of revenue sources.

Work in the second period began by producing the first iteration case case with annexed MoU as a printed product for the use by partners in the engagement of funders and stakeholders. This print version did not include the MIRRI offer which was further developed and better articulated. It was clear that this report would be a living document as partners began the engagement process and relationships developed.

The second iteration business case was drafted and circulated for input by partners taking into account the draft MIRRI-ERIC statutes and extensive changes to the Structure part and also the lessons learned from EMBRC at the evaluation meeting in Amsterdam. June 2014. This was produced in time for discussion at the September Steering Committee meeting with



work package leaders in Amsterdam (2-5 September 2014). Following strong feedback from the German Government and developments in France in particular a third iteration of the business case was initiated. Some of this input was reflected in the Deliverable D4.2 Financial Management Plan was submitted to the European Commission. UK, French and German national short business plans were produced to engage Governments and relevant elements of the 3rd iteration business case were adapted for the ESFRI assessment of the current status of MIRRI. The latter assessment went extremely well and is reported elsewhere. Discussions to engage Governments were carried out at various levels in several partner countries and to date, although there are no firm financial commitments made, very good progress is being made with four countries signing the MoU, France, Spain, Poland and Greece.

The deliverable 4.4 brought together the key content for the MIRRI business plan and contains the text of the 3rd Iteration Business Case prepared and printed in early 2015 to be use by partners to engage potential funders of the MIRRI-ERIC.. The Financial Plan included in the business case has been presented as Deliverable 4.1 Financial Plan for submission to the European Commission in April 2015. The Preparatory Phase has reached a point where the MIRRI infrastructure, governance, operations and activities are well defined. Documents needed for the negotiation of the MIRRI European Research Infrastructure Consortium (MIRRI-ERIC) are drafted including the Statutes, Partner Charter and the Rules of Operation. The cost estimates are now more robust and there is an indication of which countries are keen to establish MIRRI. The business plan content defines the problems European Research faces and provides the MIRRI offer which will deliver solutions to enable high quality research and innovation to drive microbial science and underpin the European bioeconomy.

#### II. Significant results

The following deliverables were formulated and submitted to the European Commission:

D4.1) D4.1.1Financial plan: Financial plan [month 30]

D4.2) D4.2.1 Financial management plan: Financial management plan [month 24]

D4.4) D4.4.2 Final draft of business plan content: Final draft of business plan content [month 30]

The work to bring together the costs of running Biological Resource Centres was published: Smith, D., Mc Cluskey, K. & Stackebrandt, E. (2014). Culture Collection funding models and MBRC business plans, SpringerPlus 3, 81.

http://www.springerplus.com/content/3/1/81. The publication is in Open Access and is rated highly accessed with 1189 accesses to this article in its first 2 months after publication.

Deliverable D4.3 'Draft short Business Plan' was submitted to the European Commission June 2013. Although three months delayed due to project start delays it provided stimulation for development of business models, the legal structure and operations.

A print version of the business case to take to national authorities and funders to seek commitment (with the MIRRI Memorandum of Understanding) to the further development of MIRRI will have been prepared until the end of April 2014.



**III. Reasons for deviations from Annex I of the DoW and impact on resources** None.

### IV. Explain the reasons for failing to achieve critical objectives and/or not being on schedule and explain the impact on other tasks as well as on available resources and planning

All objectives have been achieved.

#### V. Statement on the use of resources

All resource use is on track.

#### **VI. Propose corrective actions**

No corrective actions needed.

### Workpackage 5 Communication, dissemination and outreach

#### I. Summary of progress towards objectives and details for each task

The overall objective of WP 5 was to foster outreach to all MIRRI stakeholders, identified by a stakeholder analysis, and to establish a stimulating mutual communication. This dialogue needs to be specifically tailored since MIRRI has a wide range of stakeholders, each one with specific communication preferences. To develop and to implement such a customised communication and outreach strategy was the main goal of WP5 during the Preparatory Phase.

Outreach to the stakeholder community was done by all MIRRI partners according to the preliminary communication and outreach strategy outlined by WP5. A revision of the MIRRI Stakeholder Analysis in October 2015 proved the success of these outreach activities as certain stakeholders now show a higher interest in MIRRI. Based on the national contact points identified within WP5 a first meeting of the national representatives interested in signing the MIRRI-ERIC took place in October 2015. Further meetings are already scheduled.

Several MIRRI representatives are by now recognized experts regarding the Access and Benefit Sharing issues; through their activity the outreach of MIRRI to the user community, especially to industrial users, was significantly improved.

### Task WP5.1 Identify opportunities to improve communication between providers and users of microbiological material and design appropriate mechanisms

The task aimed to identify opportunities and define strategies for efficient and effective communication inside and outside the community of microbial biological material holders.



Several small surveys were performed to analyse the status quo of communication between the user community and the microbial domain Biological Resource Centres (mBRCs). Results show that there is a lack of communication especially in the following areas: accessibility of microbial resources, access to information, offer/request of services by mBRCs and training.

In detail, the actions fulfilled include:

In Deliverable D5.4 "A strategy and implementation plan to identify opportunities to improve communication between providers and users of microbial material" was developed which focused on four main steps:

- a) articulate the MIRRI offer
- b) define what MIRRI expects from its stakeholders (here: users and providers of microbial genetic resources
- c) prepare the MIRRI Business Plan as well as the MIRRI Partner Charter to become transparent for users and other collections
- d) develop the MIRRI Communication and Outreach Strategy to ensure appropriate dialogue with MIRRI stakeholders

All steps have been implemented meanwhile.

With the EU regulation 511/2014 coming into force in 2014, with some aspects of implementation still unclear, the users of microbial genetic resources request a deeper discussion of this issue. MIRRI answered this needs e.g. by organising workshops and giving lectures at several international events.

# Task WP5.2 Organise an expert group to define the policy and priorities of MIRRI in terms of support to R&D

From the very beginning MIRRI envisaged to establish several expert clusters which shall serve the users' specific needs in different fields of work. Task 5.2 aimed to compile a list of R&D experts to help to define the policy and priorities of MIRRI in terms of support to R&D. First ideas and suggestions were provided during a small workshop (see deliverable D5.5 "Organise and report on an R&D expert group meeting to define the policy and priorities of MIRRI").

In detail, the actions fulfilled include:

Based on the compiled list of experts from R&D (members are seen inter alia in sectors like Agriculture and Rural Development, Climate and Environment, Education and Culture, Energy, Maritime Affairs and Fisheries, Health Care, Nutrition and Consumers and Waste Technology) a one-day workshop was organised to discuss with them the needs of R&D and how MIRRI can serve them. The following needs were identified e.g.

- a) platforms that operate according to the requirements of bio-industry are needed: these requirements include confidentiality, reasonable time, appropriate charges, data rights issues etc.
- b) potential areas of interest for the bio-industry, e.g. predictive microbiology, data mining, courses on quality management, handling and preserving of resources



The envisaged MIRRI Collaborative Working Environment (CWE) will translate these needs into an attractive service offer for R&D. Experts who attended the workshop are willing to participate in the MIRRI expert clusters in the future.

#### Task WP5.3 Demonstration of the impact of MIRRI on society

Assessing the impact of the infrastructure is important to demonstrate that user needs are met and to show the added value of having MIRRI as part of society. This is of major interest of the policy makers who want to see a return of their (national and international) investment. These expected benefits can be knowledge, new products, processes or services and training for economic, environmental or social purposes.

An initial impact of MIRRI was calculated in deliverable D5.6 "Reporting on demonstrating the impact of MIRRI on society and describing model tools to monitor MIRRI's impact and value".

Seven major indicators, subdivided into several sub-topics, were identified:

- a) Science & Technology
- b) Networking, Communication and Collaboration
- c) Organisation & Methods
- d) Human Resources, Education & Training
- e) Service
- f) Reputation & Label
- g) Other/General

Based on the guidelines and the proposed methods from this document data collection for suggested indicators can start now.

# Task WP5.4 Establish mechanisms for connection with governing bodies and policy makers at national & European levels

During the preparatory phase each MIRRI participant is required to organise dialogue with their national governing body utilising common approaches and report to the consortium on policy matters. Partners identified relevant national contact points (for details see deliverable D5.7 "Report on linkages to governing bodies and policy makers at national and European level and common work programmes with other infrastructures both in and outside Europe").

Outreach activities of MIRRI partners resulted in the signature of the MIRRI Memorandum of Understanding in France, Greece, Poland and Spain. Representatives from these four countries as well as representatives from four additional countries (Belgium, Rumania, UK and The Netherlands) met in October 2015 to discuss the documents needed for the initiation of the legal status. Discussions revealed that some work still has to be done:

a) revision of Statutes and Partner Charter to clarify the function of envisaged boards and partnership criteria

b) simplification of the governance structure



#### c) risk assessment of expected revenues

d) external evaluation of MIRRI Business Plan

Revised documents will be provided to representatives of MIRRI partner countries in a meeting to be organised beginning of 2016 (for details see deliverable D5.3 "Final Meeting").

# Task WP5.5 Identify synergies and share common tasks and strategies with other ESFRI RIs

Task 5.5 was to elaborate synergies between the 13 ESFRI BMS RIs to avoid duplication of efforts when setting up state-of-the-art services. A comprehensive overview on synergies and options for their translation is presented in deliverable D5.7 (submitted October 2015).

Communication with other ESFRI RIs has been improved after synergies and shared strategies had been identified. Outreach was focussed on RIs from the Health & Food group since potential synergies with other projects are mainly expected in the fields of biological and environmental science.

A significant result of outreach activity is the welcomed involvement of MIRRI in several Horizion 2020 projects. By being part of these international projects MIRRI will be able to identify synergies with projects outside the ESFRI landscape, using these synergies as motor for future collaborations.

Horizon 2020 projects with MIRRI involvement:

- a) CORBEL Coordinated Research Infrastructures Building Enduring Life-science services (www.corbel-project.eu)
  - involvement: WP leader for communication (MIRRI partner DSMZ), involvement in WPs dealing with user access (MIRRI partner CABI), data access (MIRRI partner JacobsUni) and accelerating innovation (MIRRI partner KNAW-CBS)
  - participating ESFRI BMS RIs: BBMRI, EATRIS, ECRIN, ELIXIR, INFRAFRONTIER, INSTRUCT, EU-OPENSCREEN, EMBRC, EuroBioImaging, ISBE
- b) EMBRIC European Marine Biological Research Infrastructure Cluster to promote the Blue Economy (preliminary website: http://www.embrc.eu/node/612; accessed 24.11.2015)
  - involvement: WP leader for microbial pipeline from environment to active compound (MIRRI partner CABI) with DSMZ as additional task leader, access to marine organisms (MIRRI partners CABI, DSMZ [task leader]), concepts for discovery and exploitation of marine products and biomolecules (MIRRI partners CABI [task leader], CRBIP, DSMZ), mobilising RIs to foster blue technology (MIRRI partner CRBIP), training (MIRRI partner CABI), transnational access (MIRRI partner CRBIP as task leader)
  - participating ESFRI BMS RIs: EMBRC, MIRRI, EU-OPENSCREEN, ELIXIR
  - participating Integrating Activity projects: AQUAEXCEL, RISIS
  - participating SMEs: TUNATECH, SCALPRO, Xelect
- c) RItrain Research Infrastructures Training Programme (www.ritrain.eu)
  - involvement: coordination and project management, competency definition, course mapping and gap analysis, curriculum development, CPD (all MIRRI partner UMinho)



- participating ESFRI BMS RIs: BBMRI, INFRAFRONTIER, EATRIS, ECRIN, MIRRI, EuroBioImaging, ISBE
- other ESFRI RIs: DARIAH, SHARE
- other partners: EMBL-EBI, Medical University of Vienna, University of Milano-Bicocca

# Task WP5.6 Evaluate non-European participation and develop programmes of cooperation with non-European partners

Task WP5.6 was to evaluate non-European participation and develop programmes of cooperation with non-European partners seeking opportunities for cooperation beyond the European boundary. The hypothesis was that global collaboration was needed if microbial diversity was to be exploited fully to address the common challenges. This task focused on building bridges between providers and users of microbiological material from outside EU. A key aim was to facilitate access to the huge, mainly undiscovered microbial resources in the mega-diverse regions of the world.

The CABI MIRRI partner has been highly active in connecting MIRRI internationally (see Deliverable 5.7)

- a) CABI Development Funds were used to run a workshop Hands across the Atlantic in Ghana, resulting in linking South-South networks (Brazil-Kenya/Ghana) for further development
- b) Exchange of Knowledge and Technology transfer in a three way collaboration between Brazil, Kenya and CABI, UK for
  - i. Capacity building including Post Graduate Course run in country
  - ii. Exchange of scientists
  - iii. Look for African funding programmes to support a project to extend linkages and position KBRCN in Government strategy using the GEF project as leverage
  - iv. Accreditation of the Kenyan BRC should be part of the future strategy in the "business plan"
- c) In Asia there are already established Biological Resource Centre activities through the Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM, http://www.acm-mrc.asia/index.html). MIRRI is collaborating with them and the Asian BRC Network (ABRCN). The MIRRI potential Access and Benefit Sharing (ABS) compliant business model was explored with the Director General, NITE BRC, Mr Yasushi Noto, who was very interested and wanted to maintain the link with MIRRI to establish the Global BRC Network. Areas for identified collaboration were:
  - i. Promulgating common open access ABS policy
  - ii. Best practice country resource data base
  - iii. ABS compliant business models
- d) Activities in South America continued where Andres France, Instituto de Investigaciones Agropecuarias (INIA), Chile liaised with PROCISUR - the 'Cooperative Program for the Development of Agricultural Technology in the Southern Cone' to seek funding to involve MIRRI in helping in the setting up the South American mBRC infrastructure.



e) Activities also continued in the USA with the link to the US Culture Collection Network http://www.usccn.org/. The USCCN wished to continue its co-development with MIRRI and some opportunities for better collaboration were elucidated.

Work package 5 collaborated with work package 6 at a workshop in Amsterdam to bring together a MIRRI strategy for future interdisciplinary activities; this has been reported upon in Deliverable D6.6.

Once MIRRI is fully operational it will be well placed to further these links to establish the GBRCN.

#### II. Significant results

- To visualise the complex MIRRI offer a short animation film was produced. It is available via the MIRRI website (www.mirri.org); MIRRI participants can also download it from the Members Area.
- PR material like the MIRRI leaflet and MIRRI info presentation were updated regularly and are available for all participants.
- The MIRRI website was updated regularly to keep stakeholders up-to-date with latest project developments. Although only little used by the MIRRI consortium, the password secured Members Area was regularly updated with internal project information.
- The MIRRI newsletter, introduced in May 2014, was distributed quarterly to more than 1,000 recipients.
- Social media accounts (Facebook, Twitter, LinkedIn, Google+) were frequently used; an increase of followers could be recorded over time.
- The MIRRI Stakeholder Analysis has been revised and based on this analysis a Communication and Outreach Strategy for the envisaged MIRRI-ERIC was developed.
- Links to regional and national activities have been established to explore collaborative opportunities and for the future linkage to form a Global Biological Resource Centre Network (GBRCN) as envisaged by the Organisation for Economic Cooperation and Development (OECD).

### **III. Reasons for deviations from Annex I of the DoW and impact on resources** No deviation from Annex 1 (DoW).

### IV. Explain the reasons for failing to achieve critical objectives and/or not being on schedule and explain the impact on other tasks as well as on available resources and planning

Task WP5.4: In the DoW Task 2.4, "Stakeholders" are described to include providers of resources, users of resources, government, regulatory bodies, and policy makers. The MIRRI steering committee has agreed that WP2 will take care of the Providers of the resources and of the users of the resources, and will coordinate the necessary actions needed. Coordination of the communication with the other stakeholders for defining their needs with regard to mBRCs, has been allocated to WP5 (1PM). WP 5 has also been committed to cover additional work in WP 3, 4 (0.5 each) and WP8 (2.5 PM). No deviations from other objectives and tasks.



#### V. Statement on the use of resources

All resources were used as planned.

Outreach is costly - effective communication tools like face-to-face meetings require adequate travel funds. The same is true for exhibition at meetings or publications. Due to a very limited amount of money for PR activities and travelling, presentation of MIRRI at the national and international level during the Preparatory Phase was restricted. To improve this situation in the future, appropriate funds for outreach were considered in the MIRRI Financial Plan.

#### **VI. Propose corrective actions**

No corrective actions needed.

### Workpackage 6

Development of Services, Outputs and foster interdisciplinary work programs

#### I. Summary of progress towards objectives and details for each task

It is the goal of Work Package 6 to identify intrinsic features of national MRCs with respect to holdings, expertise and services. These objectives should be considered in the greater context of how to improve the management of MIRRI to better serve the stakeholder demands in academia and bio-industries. A new overarching structure for a decentralized European MRCS network with a hub-spoke structure will provide a more centralized plan to provide the authenticated biological raw material upon which high quality research and biotechnological innovation is based. The aspects of improved management refer to the central coordinating unit (CCU) as well as to the individual MRCs who have to implement the policies outlined by the CCU according to improve services within the frame of the infrastructure and to the specific demands of national nodes and their networks. The general aim is to improve MRC-user relationships to foster research and support the knowledge-based bio-economy. In order to encourage and stimulate a modification of the present situation and to create incentives for its implementation the present situation needs to be evaluated.

WP6 has submitted all deliverables described in the DoW on-time. In the following sections we summarize the most relevant outcomes of each task.

# Task WP 6.1 Define strategies on how gaps in MBRC holdings can be addressed

The vision of MIRRI is to establish a unique pan-European high-performance platform adding value to known and yet unknown microbial biodiversity and exploiting novel sources and knowledge to discover and disclose for the bio-economy and bioscience. MIRRI, during its Preparatory Phase, develops strategies to achieve this vision and one of these strategies centres around the MIRRI resource holding offer



- reduction of the overlap in holdings
- filling gaps in holding offer and in the accompanying data
- · expand the range of holdings

In achieving these goals the following steps must be initiated:

- 1. Inventoried MIRRI partner collections holdings must be compared to each other in order to determine overlap in holdings as well as individual mBRC focus on specific taxa or physiological groups, phrased 'strength' in the following context:
  - mBRC holdings must be compared to the list of validly named species, reference taxa but also with respect to the coverage of ecological, physiological and health-related (plant, animals, humans) groups to identify taxonomic gaps as first step.
  - User demands must be identified to enrich the present offer by significantly adding resources to highly demanded taxa.
- 2. Academic and other non-public collection must be evaluated and collaboration initiated to fill the gaps by transferring 'key' resources into public collections.
- 3. Authors of scientific publications, journal publishers and editors must be convinced that deposition of 'key' resources into public collections at the time of publication is as important, as the mandatory deposition of molecular sequences into public data bases. If retroactive remediation turns out to be only partially realisable, future attitudes of researchers needs to be stimulated and even stronger, should be imposed.
- 4. Public funding bodies for research should be convinced that they have an important role in stimulating the availability of the resources

#### Ad 1. Current status of mBRC holdings and future harmonization and coordination

Most of the work in this Task has been performed in the first reporting period and results were published in the periodic Report 2014. The wide range of taxa with the Prokaryotes including cyanobacteria, yeast and fungi as well as their species and strain numbers were listed and evaluated. Comparison of data allowed the recognition of mBRC-specific strength. Three categories of MBRCs could be identified, emphasizing resource holdings of medical, biodiversity and application importance. None of these three categories are exclusive but reaches over into the other two categories (see Annex WP6-1 of Periodic Report 1 [PR1])

The major goal of the second reporting period was the establishment of an expert cluster embracing the mBRCs heads and managers (H&M group) to initiate a dialogue on future coordination of holdings. The idea is to create centers of holding excellence with as little redundancy as necessary to keep the todays mBRC-customer relationship flourishing. Rather than each mBRCs acquiring a broad range of diversity, mBRC should identify those taxa, in which holding strength, resource numbers and service and identification expertise is already represented to a higher extent than in other parts of the collection. During the second reporting periods the H&M group met twice to discuss the basics of a harmonization approach. The outcome is summarized as follows:

• the idea of a harmonized accessioning strategy has been welcomed as each mBRC can acquire a higher number of resources belonging to their individual holding strength;



- national mBRCs may have to follow a national mandate which will takes several years to change;
- in order to reduce the high number of resources potentially being deposited in mBRCs, selection criteria for resources worth depositing should be published (this was done in due course by defining 'key' strain criteria by Stackebrandt et al. 2014)
- no mBRC agrees, nor will be asked to abandon presents holdings;
- heads and managers agreed to continue regular meetings to continue the dialogues on targeted accessions, also in light of the Partner Charter requirements;
- Individual mBRCs are free to establish non-public collections for exclusive industrial use. MIRRI, through its Collaborative Working Environment, is willing to coordinate such activities and to guide the customer to the proper holdings.

#### Ad 2. Evaluation of orphan and academic collections and their future fate

The 2013 survey on laboratory collections maintained in research institutes, universities, hospitals or reference centers in Europe resulted in the localization of > 1 million resources. Holdings of bacteria, yeast and fungi that are not well represented in public mBRCs were listed in Annexes WP6-2 and WP6-3 of PR 1. Several collections specialized in other kinds of microbial material that are available from only limited public mBRCs, such as Microalgae, Protozoa, consortia, phytoplasmas and plant viruses, were identified as well (Annex WP 6-4 PR 1). Needless to say that these holdings are a rich source to complement the holding of public mBRCs though a preselection of resources worth deposition must precede prior deposition.

In order to assess the ratio of 'key' strains among holdings in laboratory holdings, researchers having received grants for microbiological projects by the German Research Council (DFG) between 2001 and 2010 were asked to respond to a survey. Of 167 addressees contacted, 30 researchers (18%) indicated the presence of collections with a total of about 60.000 microbial strains. Of these, 11.000 matched the 'key' strain criteria. Using the number of 'key' strains of Germany to extrapolate these numbers in Europe at a GDP-base, the total number of resources worth depositing would be 75.000. Acquisition id such a high number of strains needs at least 12 years work for public European collection if they double their annual acquisition, without taking into account the new isolates accumulating each year. Thus, possible solutions to this problem could be:

- Distributing resources according to centers of expertise, following the MIRRI strategy for harmonization and collaboration. As some groups of microorganisms are more represented than others, mBRCs with similar taxon strength should collaborate to arrange the acquisition according to function, ecology, application, health and more;
- Tighten the 'key' strain definition, to reduce the number of resources for deposition;
- Safeguard entire collections in special collections public collections with a minimum of authentication and visibility of content in specialized catalogues.

#### Ad 3. Moving from non-mandatory to mandatory deposition of published resources

The work on surveying authors' willingness to deposit strains in public collections started between 2010 and 2012 (EU EMbaRC project) and the study was deepened and a strategy proposed within the MIRRI project.

Previous studies noted the missing cooperation of authors to share resources. This stands in contrast to the publication policy of the majority of journals which expressively states in the



Instruction to Authors that biological resources included in scientific articles need to be available to the user (though not necessarily deposited in public collections). Despite the obligation to share resources, several arguments and obstacles were put forward by the authors that prevent putting this obligation of authors into action. Once published, most resources are either no longer maintained or are not publicly available in the long run.

The only known example for obligate deposition includes the deposition of prokaryotic type strains as laid down in the Code of Nomenclature of Prokaryotes. This single example shows that a strategy could be successful if all stakeholders involved are guided by the necessity to change the present practice. A similar strategy also works with the obligate deposition of sequence data in public data repositories. Thus a strategy needs to include discussion on present strength and weakness (bottlenecks of policy implementation) of practice, possible incentives and correcting actions, resulting in a consensus strategy, also involving publishers of scientific journals.

#### Ad 4. Involve public funding bodies for research

Public funding bodies are already heavily involved in the financial support of public mBRCs. Firstly by providing funds for the long term maintenance of the daily running through direct support or indirectly through a governing organisation; secondly, by funding successful grants for taxonomy-related projects. MIRRI is advocating a higher uptake of resources from the academic environment to protect public funding and to increase the credibility of science. This can only be done successfully if mBRCs are supported financially for expansion of staff and infrastructure. Support for the acquisition of resources is part of the request each MIRRI partner is should demand from the national stakeholder. Support for additional staff and enlargement of the infrastructure is part of convincing application for MIRRI-membership to the same or other national stakeholders by third party grants. However, national funding bodies can do more. Support for the identification of resources isolated in the course of projects would help to identify 'key' resources and thus safeguarding valuable genetic material. Funding bodies are in the process of implementing Codes of Conducts to have researchers comply with the articles of the Nagoya Protocol (NP). Thus, deposition of resources together with the necessary NP documents may be advantageous as researchers can point to the receiving mBRC instead of dealing themselves with the paperwork associated with requests for a resource by peers.

#### **Major results**

The improved and coordinated acquisition policy by MIRRI embraces multiple players that need to inter-relate bi- or multilaterally to achieve a successful implementation of the strategy outlined in WP 6 (Figure 1).

The **mBRCs** need to coordinate among themselves strength of holdings. Only by following a coordinated accession policy the MIRRI mBRCs will be able to enlarge their collection by resources from academia and orphan collections in a harmonized manner, thus unravelling the hidden potential of novel strains and increasing the numbers of customers in an area of expertise. Duplication of taxa, though not at the strain level, is necessary in those taxa which are either species-rich or of importance for industrial, agricultural and food and of health. The non-mandatory abandonment of partial collection will make space for a focused realization of collection strength. mBRCs, in turn must ask for funds for expansion and compliance with the articles of the NP and biosecurity issues.



**Non-public research collection holders** must be convinced about the advantage to deposit part of their collection ('key' strains) into a public mBRC to safeguard holding, to reduce maintenance cost and to optimally comply with the articles of the NP. Resource providers should receive an mBRC incentive for deposition.

**Authors** should be obliged to deposit 'key' strains into public mBRCs to protect public investment in the original isolation and subsequent research.

**Publishers** should reinforce this obligate deposition policy by a respective record in the 'Instruction to Authors'.

**National funding bodies of MIRRI partner mBRCs** will be asked to invest in the expansion of mBRCs for strain acquisition, and new staff to handle the higher number of resources and the demanding compliance policy of the NP.

**National funding bodies of research projects** should include in their project guidelines the need of researchers to deposit 'key' strains and to allocate part of the grants for their preliminary identification.

**The central hub of MIRRI** will coordinate all the above mentioned activities. It will provide the platform for heads of mBRCs to harmonize their holdings. It will serve as a communicator between researchers and authors, respectively, about the definition of 'key' strains and their optimal deposition in one of the MIRRRI partner mBRCs. MIRRI will actively contact the European Publisher Association to address the needs for mandatory deposition of strains included in publication.



Figure 1. Interaction linkages between the multiple players involved in a harmonized and cooperating MIRRI accession policy
#### Task WP6.2 Facilitate access to expertise in microbiology

The original list of about 500 putative target names of taxonomic experts in Europe has been crosschecked with public publication records such as Scopus and other databases in order to complete their affiliations, and electronic addresses. The original bacteriologist list has been enlarged during the second phase of the project with cyanobacteriologists, protistologists and mycologists. In conclusion, the survey on the current census of microbial taxonomists in Europe produced a list of 297 taxonomists of prokaryotes, 69 of Cyanobacteria (treated differently from the rest of prokaryotes given that most of the descriptions are based on the botanical code instead of the bacteriological code), 106 of fungi and 123 for protists. The lists have been reported in Deliverable D6.4). A strategic approach is being developed to make these lists dynamic.

Future developments within MIRRI included the creation of topic-driven platforms. Deliverable 6.3 focussed on the creation of the concept for such a portal and/or a platform that will allow an interlinkage between experts in taxonomy and methods, and new users from academia, the bio-industry and other research infrastructures. During the Preparatory Phase the MIRRI consortium collated a comprehensive list of stakeholders from academia and bio-industry who are willing to participate in the Expert Cluster (Deliverable 6.4 and Innovative survey report), indicating that a high quality platform for knowledge transfer in the field of microbiology is in high demand.

Utilisation of available virtual techniques allows almost boundless chances of knowledge transfer and collaborations. One of the pillars of the envisaged Collaborative Working Environment (CWE) platform is a communication gateway allowing like-minded users to meet virtually, to exchange knowledge and to link to offered services (Figure 2). Another element of such pillar consists of the link to MIRRI Expert Clusters. These clusters are implemented to support MIRRI partners and users in dedicated issues to respond to user and stakeholder demands. The final thematic content of the clusters will develop during the maturation of the MIRRI-ERIC. Deliverable D6.4 elaborates more in detail on this subject.



Figure 2: Example of the taxonomy element of the CWE Expert Cluster



#### Task WP6.3 Assess and define services required from MIRRI

The services of mBRCs extend beyond expertise in isolation, growth and use of microorganisms as better services and economic benefits are well recognized by MIRRI users. The more precise and compelling the service offer, the higher the possible value for bio-industrial applications and academic research. For MIRRI and partner mBRCs improved and expanded services have the potential to generate user loyalty through building and maintaining good relationships. In order to strengthen the service offer, it is essential to not only understand the user/stakeholder environment but also the current MIRRI offer. Deliverable 6.5 outlines strategies to fulfil the user's demands. The compilation presented in this document is the result of strong inter-WP collaborations (surveys conducted and information gathered by several work packages WP2, WP5, WP6, WP7 and WP8) that provides insight on the current status of the service offer and service-related issues.

Though the bio-industrial partner is one of the main user clientele of mBRCs, little is known about their demands in terms of holding spectrum, expertise, and added value offer. MIRRI therefore organised a workshop to identify elements that impede communication between the public collections and the bio-industry. Analyses, conclusions and recommendations from this workshop were reported in Deliverable 6.7.

The development of the CWE as an innovative platform envisages the creation of so called "Fast Track Engineering Pipelines" to convert the non-transparent distributed information to logically connected components specifically designed for complex tasks in science and research and development (Deliverable 6.5). The transformation process of bringing distributed information and knowledge to a systematic and exploitable level creates added value for bioscience and biotechnology. More specifically, the intention of a fast track engineering system focusses on saving valuable time in research, extending potentials, gaining time to the market.

#### Task WP6.4 Foster interdisciplinary work programs

Task WP6.4 discussed the potential of joint activities with existing infrastructures, projects, initiatives and networks to develop an interdisciplinary work program. The work was based upon already established relationships prior to MIRRI and those established through participation in the Biological and Medical Sciences (BMS) group of ESFRI Research Infrastructure Coordinators. Partner relationships with other project consortia were also explored to initiate collaborations. Interaction was at various levels, for example through the coordinator, the outreach team at DSMZ and other work package teams. These interactions resulted in several activities which have been reported in Deliverable D6.6 Work plan for interdisciplinary activities for the MIRRI construction phase; key activities in the period this report are summarised here.

Several MIRRI partners had links to specific European Commission funded projects and were able to form links with some key projects. Collaboration with BioMedBridges was extended and formalised; this relationship being especially relevant to the development of the MIRRI Information System and most of the interaction was through the Work Package 8 team involvement. MIRRI was accepted as an associate partner to BioMedBridges in March



2014. BioMedBridges is a joint effort of twelve biomedical sciences research infrastructures on the ESFRI roadmap. Together, the project partners develop the shared e-infrastructure, the technical bridges, to allow data integration in the biological, medical, translational and clinical domains and thus strengthen biomedical resources in Europe.

MIRRI has also established strong links with Q-collect particularly through its partner UGent. Q-collect envisages the establishment of a European network that supports European plant quarantine policy in its control of existing and emerging plant pests in Europe by increasing the availability and accessibility of qualified reference and recent biological materials as well as data for diagnostic and curating purposes. Q-collect benefits from MIRRI's microbiology experience while MIRRI gains information from the Q-collect knowledge of quarantine reference material. A joint approach to make a broader offer available for users is being elaborated in-depth within the scope of strategies on how gaps in mBRCs holdings, identified by users and collections, can be addressed (D6.1/D6.2).

Additionally, initiatives like Q-Bacco-net in which three EU bacteria collections (NCPPB, CFBP and BCCM/LMG) collaborate in close relation with EPPO (European Plant Protection Organisation) to facilitate access to high quality reference organisms for bacterial quarantine pests has to be seen in the context of MIRRI activities such as the coordinated accession policy and the MIRRI Information System (MIRRI IS) i.e. encouraging the complementarity of mBRCs in their holdings of guaranteed authenticity and high quality.

MIRRI participated in project proposal writing and submission with the BMS coordinators group which has resulted in three projects being funded through Horizon 2020 calls for proposals.

The MIRRI partner MUM-UMinho represents MIRRI in Research Infrastructures Training Programme (RItrain), an INFRASUPP-3-2014, H2020 project which will help MIRRI initiate training programmes for the skills and abilities needed in mBRC management and the characterisation and use of microorganisms that will enable discovery and development of microbial solutions. RItrain will develop a transversal training programme to increase capacities in governance, organisation, financial and staff management, funding, IP, service provision and outreach in an international context. This project will engage senior RI managers and experienced professionals to design and implement a Bologna-compliant degree and a Master in Research Infrastructure Management for individuals working in RIs, management teams, and recent graduates wishing to increase their employability.

MIRRI is also represented in the CORBEL - Coordinated Research Infrastructures Building Enduring Life-science Services (INFRADEV-4-2014/2015) project. CORBEL coordinates the implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives and is funded from 2015 to 2019. MIRRI is represented by CABI, CBS – KNAW, DSMZ and JACOBS UNI to establish a collaborative and sustained framework of shared services between the ESFRI Biological and Medical Research Infrastructures.



A third H2020 project in which MIRRI is represented is EMBRIC – European Marine Biological Research Infrastructure Cluster to promote the Blue Bioeconomy. MIRRI participation is through CABI, CRBIP, DSMZ, INRA and UGent. The overarching objective of EMBRIC is to build interconnectivity along three dimensions: science, industry, and regional RDI policies. The expected endpoint is the formation of a perennial cluster of RIs, which will foster innovation in marine biotechnologies. Further information on this and the two previous H2020 proposals can be found in Deliverable D6.6 Work plan for interdisciplinary activities for the MIRRI construction phase.

MIRRI organised a workshop to define a working plan for interdisciplinary activities for the MIRRI construction phase. The workshop provided the basis for Deliverable D6.6 Work plan for interdisciplinary activities for the MIRRI construction phase. The efforts MIRRI has undertaken to meet the demand for interdisciplinary engagement were outlined in this deliverable and provided an overview on the work done to date, i.e. how existing connections with the identified stakeholders were transformed into strong interactions and where there is room for improvement. It focussed on rationale and strategies to deliver a work plan for interdisciplinary activities in the MIRRI construction phase. Its general conclusion was that organisational structures often act as barriers to develop an efficient interdisciplinary work program. For this reason, it was considered critical that interdisciplinary engagement activities were led by a committed team in MIRRI's Central Coordinating Unit (CCU). They will strategize, manage and eventually implement the interdisciplinary activities through the expert cluster approach. In addition, the CCU will ensure that the budgeting process supports interdisciplinary work. A strategy for long-term stability of funding over the next several years has already been considered and elaborated in depth in the latest version of the Business and financial plan.

#### **II. Significant results**

The MIRRI offer is a complex system to foster innovation and economic growth in Bioindustry and Bioresearch. The complexity of the inter-coordinated and complementary service structure can only be served through a network of links to mBRC-internal and external databases and to experts and organizations with a high level of knowledge, experience and skills. MIRRI translates its distributed network structure into a distributed and dynamic environment in which partners and users of MIRRI from various stakeholders and stakeholder communities share knowledge, exchange experience and collaborate to achieve common goals in research and development. Collaborative work and learning are of particular importance in our global economy, which is increasingly based on knowledge production and fast innovation cycles. In a networked world, such collaborative processes can only be executed efficiently through a dedicated virtual platform.

The open and to be continued discussion on the future development of individual mBRCs marks a new step in the mode of communication among mBRCs and demonstrates the political power of the MIRRI consortium to move the MIRRI mission forward. The first initiatives demonstrate the beginning of a new phase and form the basis for building trust on which the national self-centred acquisition policy is subordinated to the spirit of a cooperate MIRRI identity.



The presentation of the MIRRI offer via the CWE is virtual but the resulting services and outputs are real microbial resources, expertise (via experts and expert clusters), data, and new collaborations/projects. MIRRI Partners are encouraged to explore their potential to serve bioscience and bio-industry by using this innovation platform. The tools and possibilities of the CWE allow the creation and implementation of new innovative services to fil market gaps, achieve knowledge transfer, address new ideas/projects and create new collaborations within distributed communities in a faster, easier and cheaper way.

#### III. Reasons for deviations from Annex I of the DoW and impact on resources

The coordinator has worked 0.5 PM more than anticipated in Annex 1. The reason has been the additional workload caused by writing several MIRRI-related publications.

#### IV. Explain the reasons for failing to achieve critical objectives and/or not being on schedule and explain the impact on other tasks as well as on available resources and planning

All objectives have been achieved.

#### V. Statement on the use of resources

All resources have been used prudently and according to the DoW.

#### **VI. Propose corrective actions**

No corrective actions needed.

### Workpackage 7 Capacity building, education and training

#### I. Summary of progress towards objectives and details for each task

Task leaders and contributors have gathered information from the literature, available legal and administrative documents, surveys, and interaction with other projects such as Lifetrain. This information was integrated and discussed among project members to produce a coherent strategy for Education and Training (E&T) activities, including an innovative program to implement in MIRRI, aiming to bridge identified offer-demand gaps, update, harmonize, establish accreditation and coordinate the E&T offer.

Briefly, a strategy and mechanisms for implementation of the MIRRI E&T offer were discussed, designed and described in the five workpackage deliverables, all submitted between M19 and M35. The prominent role of not only the individual microbial domain Biological Resource Centres (mBRC) but also of the Central Coordinating Unit (CCU) in coordinating liaisons with stakeholders and Higher Education Institutes (HEI) was established. The Collaborative Working Environment (CWE) will be responsible for compiling, organizing and advertising the E&T offer. Appropriate steps will be taken to assign European Credit Transfer System (ECTS) credits for achievements or ECVET (European Credit System for Vocational Education and Training) points for qualifications, aiming to



standardize certification of the E&T offer and promote knowledge and staff transfer between mBRCs, academia and industry.

In this second reporting period, all tasks in WP7 were successfully finalized, all deliverables were submitted, the corresponding milestone was concluded and all objectives for the workpackage were achieved.

# Task WP7.1 Design innovative learning programmes and tools, e.g. e-learning and virtual laboratories

An analysis on the offer and demand of E&T within the MIRRI consortium was carried out from the extensive surveys conducted as part of WP2 and WP7. This, combined with results from Task 7.2 has permitted the identification of key issues that need to be addressed to design a strategy for E&T in MIRRI: the current offer is dispersed through the different mBRCs in several different countries; it is heterogeneous both in terms of structure (training courses, staff visits, organization of workshops and seminars) and in terms of content (various different topics on offer, focusing on different groups of organisms); and fragmented (mBRCs do not all contribute to a common E&T catalogue, and differ in their maturity and reputation in providing E&T). Importantly, there is a gap between the topics on offer and the demand of MIRRI users, which accordingly outsource a small fraction of their E&T from MIRRI mBRCs. Not only are profit (10%) and non-profit (25%) users unware of the E&T service of mBRCs, over half of the respondents do not perceive a need for training.

Currently available innovative tools such as e-learning as well as the future trends in learning tools (immersive and augmented reality) were compiled from various sources. Their characteristics, delivery methods, advantages and disadvantages were listed and described to provide a wide knowledge of available tools and approaches that could be applied to the MIRRI offer. This resulted in D7.1 'Report on available and potential new tools for training'.

To consolidate the success of E&T throughout the mBRCs and to harmonise and organize the MIRRI offer, an innovative learning programme for Continuing Professional Development (CPD) was designed, that builds on knowledge drawn from other tasks and deliverables, and also on the input received from contributors through informal discussions. This was presented as part of Deliverable D7.2 'Report on a strategic concept for innovative learning programmes and tools'. The general structure of the programme is described in Figure 1.



Figure 1: General structure of a typical Continuing Professional Development course with a theoretical and a practical component.



Briefly, prospective trainees apply for a given course through the CWE, submitting their application that is evaluated against a set of pre-established criteria. After selection of the trainees, they each pay the course fees before they are given login credentials by the CWE to access a set of e-learning modules. All administrative processes and advertising is processed by the CWE. After completion of the e-learning modules that run in a set time period to allow close communication with the trainers thus reducing procrastination and increasing completion rates, the trainees can proceed to on-site learning modules. Having gained the theory-based knowledge before attending the on-site learning modules at the host mBRC, trainees cut spending on travel and accommodation whilst courses become more cost-efficient also for mBRCs. After completion of the on-site modules, a final assessment will permit both the evaluation of the trainees and of the course itself, for continuous improvement of contents. An accredited CPD certificate will be issued, that contains detailed course information and hence permits the transfer of credits or qualifications between academia and industry. Variations of this structure to accommodate different kinds of E&T offer (mentoring, Small Private Online Courses - SPOCs - and Massive Open Online Courses - MOOCs) are detailed in deliverable D7.2.

The CCU will coordinate the E&T offer, implementing the MIRRI label and distributing fees to the appropriate mBRCs. The CWE will compile, advertise and organise the whole MIRRI offer through a set of drop-down menus that apply filters in various layers: course branch (Culture, Preservation and Management or Specific courses), course topic, level of expertise for learning outcomes, course structure, and, if applicable, the organism(s) targeted.

This E&T strategy will first be applied to bridge the gap between the E&T offer and demand, in designing new courses on the topics corresponding to the top training needs, to increase impact and add value to the MIRRI E&T offer.

# Task WP7.2 Coordinate education and training programmes and facilitate knowledge transfer

Questionnaires were designed and surveys conducted to obtain information on the current E&T offer of mBRCs, and results were compiled with those obtained on E&T as part of WP2 services surveys. The analysis of the results permitted the characterization of the E&T offer itself, its topics, structure, content types, delivery methods and current challenges in implementation and design of new courses. The topics on offer were confronted with the demand from users of MIRRI and compared to the offer of competitors such as HEI and Research Institutes. A gap between offer and demand was detected, and particularly topics such as 'Legal aspects related to the microbial/genetic resources', 'handling of hazardous microorganisms', 'Genotyping' and 'Phenotyping' are completely lacking from E&T services offered by responding training providers. Importantly, some of these topics contained subjects in demand by users. From those users that outsource training, over half of those surveyed do not perceive they need to acquire training from mBRCs, and a significant percentage stated they were not aware that mBRCs had training services. Therefore, a coordinated effort must be put in place to revise and adapt the training offer and also increase its visibility through advertising. Continuing Professional Development itself is not currently a mandatory requirement by professional bodies or by mBRCs for staff



specialization and knowledge update, and MIRRI should liaise with the appropriate parties to further encourage training of staff.

To enable the transfer of qualifications and achievements of trainees between industry and academia, an appropriate harmonization and accreditation of the E&T programmes across MIRRI must be put in place. After a wide review of the existing mechanisms for credit accumulation and transfer that promote mobility and comparability of learning contexts, the European Credit Transfer System (ECTS) and the European Credit System for Vocational Education and Training (ECVET) are particularly appealing. By abiding to specified rules on these systems, implementing appropriate Quality Management Systems (QMS) and organizing the training offer accordingly, the allocation of ECTS credits or ECVET points to the MIRRI E&T offer will be achieved. This will involve liaising with HEI for incorporation of selected E&T in university curricula to obtain ECTS credits and with the suitable stakeholders (including bioindustry associations) to obtain the necessary Memoranda of Understanding for acknowledgement of ECVET points in the CPD offer.

#### II. Significant results

Important links were forged with the Lifetrain project European Medicines Research Training Network (EMTRAIN), for which MIRRI became a signatory, and which allowed for valuable discussions for the design of the E&T strategy. MIRRI was integrated into an E&T consortium aiming to develop a strategy and programme for capacity building in Research Infrastructure management, as part of the recently funded EU project RITrain (EU project 654156).

A report on available and potential new tools for training was compiled and submitted to the EU in M19 as Deliverable D7.1.

A strategic concept for innovative learning programmes and tools in MIRRI was designed and submitted to the EU in M32 as Deliverable D7.2.

Milestone 7.1. 'Create a strategic concept for innovative learning programmes and tools including expertise, facilities and technologies needed for tools for training and E&T programmes' concluded.

A report on the current E&T programmes in MIRRI mBRCs was prepared and submitted to the EU in M26 as Deliverable D7.3.

A report on the strategy and mechanisms for harmonization and accreditation of the MIRRI E&T offer was compiled and submitted to the EU in M35 as Deliverable D7.4.

### **III. Reasons for deviations from Annex I of the DoW and impact on resources** Not applicable.

### IV. Explain the reasons for failing to achieve critical objectives and/or not being on schedule and explain the impact on other tasks as well as on available resources and planning

The submission of deliverables D7.3 and of D7.4 was delayed. This delay resulted from a combination of facts beginning by the delay accumulated for D7.3 due partly to the long absence of the appointed post-doc scientist for maternity leave. Moreover, a person could not be recruited to do the work and the person in charge could not work through sufficiently long periods of time to be efficient. Although the delay in submission of D7.3 was partly responsible for the delay in submission of D7.4, no further effects were produced in the other tasks or deliverables, and the objectives were all achieved in due time.



#### V. Statement on the use of resources

A post-doctoral scientist was not appointed at UMinho-MUM from December 2014 to mid-January 2015; this has not negatively impacted the tasks, deliverables or milestones in the project.

#### **VI. Propose corrective actions**

No corrective actions needed.

### Workpackage 8 Data Resource Management

#### I. Summary of progress towards objectives and details for each task

The objectives of work package 8 wwere to define concepts and strategies to improve the quality, quantity, interoperability and usage of data associated with biological material in mBRCs.

Most mBRCs are acting as proprietary entities with respect to data acquisition, data quality management, data exchange and interoperability. Despite the fact that 'OECD Best Practice Guidelines for Biological Resource Centers and CABRI guidelines for minimal datasets exists, standardized protocols for submission and insertion of strain specific associated data (metadata) to mBRCs have not been commonly implemented. Heterogeneous and incomplete datasets in mBRC are the consequence. Furthermore, the lack of commonly agreed exchange formats as well as heterogeneous and often insufficient Information and Communication Technology (ICT)-competences hamper data exchange and interoperability between mBRCs as well as third party databases. As a consequence, the usage of the accumulated knowledge stored in mBRCs is hampered for stakeholders in academia and industry. Improved access to biological materials and its metadata is clearly needed.

Discussions to date have set the target to establish the MIRRI Information System (MIRRI-IS) and deploy an integrated, high-quality, manually annotated, non-redundant microbiological resource database which provides all relevant information data and associated contextual data (metadata) about a particular biological resource as part of MIRRI's the common working environment. MIRRI will work with its partners including other ESFRI research infrastructures, to link its mBRC data to other relevant data sets to facilitate the generation of knowledge from data. It will provide high quality well curated strain data to enable discovery of new products and properties and drive innovation in microbiology. Innovative links to ecological (substrate and habitat), genomic and chemical properties and metabolic pathways to taxonomic and environmental relationships will facilitate the user finding microbial resources to enhance their studies and find new leads and products.

The current status as well as the strategy to move forward has been detailed in the strategy paper "MIRRI WP8 strategy paper about data resource management". The paper summarizes the current status of data management in mBRCs as well as the vision for the MIRRI Information System as an integrated, high-quality, manually annotated, non-redundant micro-biological resource database.



The detailed summary (review) paper: "An Information System for European Culture Collections: the way forward" was submitted on the 24th of August and handled by Springerplus on the 28th of August 2015; still under review as of November 15th. The paper lists and discusses informatics infrastructure needs for mBRCs, their curators, associated technicians, researchers, clients and end-users.

To force the implementation of a common working environment among mBRCs the WP8 charter "Commitment to a FAIR (Findable, Accessible, Interoperable and Reusable) provision of data and information to meet MIRRI's data management (WP8) and delivery need" have become part of the Partner Charter.

#### Task WP8.1 Provide strategies for consistent acquisition of data

Task WP8.1 was to provide strategies for consistent acquisition of data and ran from month 1 to month 18. It focused on defining clear requirements and standards for data acquisition at the point of deposit. The available minimal standards for common data requirements available were assessed, analysed and enhanced in Deliverable D8.1 "Report on minimum standards for data acquisition and data management and mechanisms to incentivize the deposit of quality data." The principles laid down in this task have been taken forward in the further design of the MIRRI Information System and used to help shape its structure, operation and output. This is seen in the MIRRI Information System policy, part of the MIRRI Partner Charter and outlined as part of the submitted publication entitled "Information System for European culture collections: the way forward".

The first step in the setting of minimum standards for data acquisition and data management for MIRRI was to assess the current status in European collections and a paper was drafted by Vincent Robert to assess software options and mechanisms in place in microbial resource centres. This is summarised in the first section of Deliverable 8.1 submitted month 18. The assessment of the European Collections data sets and feedback from this community on the requirements of both the collections and their user communities was reported in Deliverable 8.5 Report on users' requests, desired features, and meta-analyses of the integrated platform. Minimum data sets have been the topic of previous European Commission funded projects including the Common Access to Biological Resources and Information (CABRI) which were adopted by the OECD Best Practice Guidelines for Biological Resource Centres (OECD, 2007); these continue to be the basis for microbial resource centre data management as the MIRRI information system develops. As we understand the data relationships that MIRRI needs to make with other data holders these data standards will continue to develop. The minimum data sets (MDS), recommended data set (RDS) and full data set (FDS) defined by these best practices are a good basis for now while MIRRI focusses on how to get added value to its data. At the MIRRI project meeting in Amsterdam November 2013 the metadata that should be provided for strains and that could be a basis for negotiation with publishers and authors for deposits were defined. Mechanisms were explored to incentivize the deposit of quality data and a number of incentives were suggested in Deliverable 8.1:

• Furthering the work of EMbaRC in influencing Journal policy to set data provision requirements with deposit of microorganisms cited in publications



- Working with funding agencies to require minimum standards for data associated with strains used in the research projects for which they support and its deposit in MBRCs
- Promulgation of the benefits of deposition of data to encourage data provision
- Mechanisms for improving data acquisition processes for MBRCs including:
- Re-evaluation of the system for unique identifiers across MBRCs, currently provided by WDCM

• Development of standard operation procedures (SOPs) to be implemented across MIRRI The goal is to define a concept to maximize the guality management of storage of metadata

#### Task WP8.2 Strategies for data evaluation and validation

Task 8.2 was concerned with the development of strategies to evaluate and curate the present and future data in MIRRI to guarantee a continuous exchange and integration of data without extensive manual intervention. Hereby, central accessibility and comparability of strain metadata are a precondition for the use of microbial resources and hence represent key components of an mBRC network. Although MIRRI is not designed to provide individualized, specific ICT solutions to single member mBRC, by establishing the necessary integrated portal MIRRI will support all participating mBRCs by presenting and linking their data in a standardized manner. The idea of a centralized approach and the first steps towards a MIRRI Information system have been outcomes of a workshop on strategies for data evaluation and validation, which was held at "La Sapienza" University in Rome on February, 25th 2014. At this workshop a cross-section of European collections, different in size and focus, participate and presented their data management, evaluation and validation procedures.

In 2015, ten design principles were elaborated for an integrated portal in order to improve the basic concept of a central MIRRI Information system presented in the Mid-Term report and to provide the basis for robust data evaluation and curation:

- i. One common standard will be used for exchanging information about microorganisms already kept or later deposited in mBRC. Within the preparatory phase of MIRRI the consortium agreed on the Microbiological Common Language (MCL).
- ii. A MIRRI repository will be established to collect recent dumps of the catalogues of all mBRC, formatted in the common exchange format (MCL).
- iii. The MIRRI portal will provide information on all biological resources within Europe or even worldwide.
- iv. Suppliers of software that manage data about individual mBRCs will be encouraged to provide support for the common exchange format
- v. The MIRRI portal will supply high-quality information to the users of biological resources; quality control and quality assurance measures are applied to all intermediate layers on which a common portal is built.
- vi. The MIRRI portal will integrate or link to all relevant external national- and international data and service providers in particular sequence databases, publication databases, taxonomic databases, patent repositories, and standards organisations.
- vii. Training will be provided to 1) enable all mBRCs establishing a common portal 2) enable the users to make effective use of the data provided.



- viii. A central index with up-to-date administrative information will be maintained about all mBRCs.
- ix. One central index mBRCs and one integrated common portal of the organisms kept in these mBRCs will be established.

x. User acceptance and satisfaction of the service provided by MIRRI will be monitored. Collaboration at many different levels is needed in order to realize this integrated common portal of mBRCs. Therefore, a central, multinational, ICT team will be established to support all stakeholders involved in formalizing design decisions for establishing such a common portal, coordinate actions and create momentum to bring it into practice, oversee the management of standards development, coordinate the development of appliances and organize training sessions for all stakeholders involved in the process.

#### Task WP8.3 Provide strategies for data Integration and Interoperability

In the context of the desired IT architecture for the Microbial Resource Research Infrastructure (MIRRI), the assessment of best implementation methods for data integration and systems interoperability for the MIRRI Information System (MIRRI-IS) was the objective of task T8.3. The two task-related project deliverables D8.3 and D8.4 present the results and achievements of all activities carried out through the whole project for the task.

The analysis of a survey among mBRCs showed that the vast majority of curators knows data structure and format standards, but only ca. half of them apply any such standard to its database. The use of taxonomic sources and of shared controlled vocabularies is also limited and much work is needed to enforce the adoption of shared terminologies. The majority of catalogues may then be included into a MIRRI common repository, but often only after conversion procedures, which may also require changes in the original mBRC databases.

Annexes A and B of deliverable D8.3 present the results of a comparison of CABRI guidelines for microbiological data sets with the Microbiological Common Language (MCL) in order to define a proper standard for interoperability both among mBRCs and with external information resources. An analysis of current bacteria data sets, of their contents and of a possible improved definition was performed, and possible curation activities were outlined. This analysis led to the definition of new MCL tags that allow incorporating the full contents of a CABRI catalogue into an MCL file. A revised version of the MCL, able to express the full contents of catalogues, has been proposed as MIRRI reference standard.

A possible Minimum Data Set (MDS) for MIRRI has been discussed as a useful core, but it was agreed that for application oriented data more data is often mandatory to satisfy end user demands. An effort is needed to examine strain data in the context of their application domains with the aim of identifying proper data structures (data type, values, syntax, best reference lists / terminologies / ontologies). This analysis may support the definition of software objects and related analysis methods, leading to the creation of software models and libraries which can improve interoperability and support the development of application oriented software.

Many databases can be interconnected with catalogue data and a first list has been provided starting from information sources that are already linked to some of the microbial domain databases. A comprehensive analysis of all databases of possible interest is however almost impossible. Ontologies and other semantic sources have proven to be essential for data



integration as shared terminologies. As for external data sources, a first list has been provided. In any case, the analysis of external and semantic sources of interest is a continuous task, due to their continuous evolution.

As reported in D8.4, the MIRRI-IS platform will allow the exploitation of all available information from mBRC catalogues, together with various databases and tools which are maintained outside the MIRRI infrastructure but are tightly interconnected. It will be a portal for accessing all mBRC catalogues represented in a uniform format and should also include extended annotations on strain characteristics, beyond information that is usually included in catalogues, as they can only be provided by specialized information systems. This information should be of high-quality and it should be linked to many relevant data and service providers, external to MIRRI.

Data exchange between mBRCs and MIRRI, as well as catalogue data archiving in MIRRI-IS, will be based on an extended version of the Microbiological Common Language (MCL) able to represent the whole contents of mBRCs catalogues. The information from mBRCs will only constitute a data core of the MIRRI-IS: information from StrainInfo, BacDive, BioloMICS and SILVA will provide additional highly characterized data. Associated information on sequence, literature, and taxonomic data will also be linked, either statically or on-the-fly according to users requests.

The MIRRI-IS user interface will be flanked by Application Programming Interfaces (APIs) which will also be used to integrate the strain and associated data within the MIRRI Collaborative Working Environment (CWE), thus enabling an integrated view of all MIRRI services, including expert clusters, specialized services, and training. MIRRI-IS APIs will then constitute the natural way to make access and retrieve data from the MIRRI-IS in an effective, yet flexible, way. Availability of adequate APIs for software platforms like BioMart, Taverna and Galaxy will increase the awareness of researchers regarding the availability of high quality information on microorganisms as well as the effective access to integrated mBRC catalogues.

All activities have been conceived and carried out in collaboration and synergy with WP8 task leaders.

The ideas and results related to this task have been presented as posters and oral communications in various meetings, both at National and International levels.

#### Task WP8.4 Provide strategies for access

Task 8.4 was concerned to provide strategies for data access to the integrated data in MIRRI and the general schema for construction of MIRRI-IS. The schema was presented and discussed on four conferences/workshops and finally reported in D8.5.

First we discovered interdependence of desirable MIRRI-IS components:

- 1. Information problems to be solved
- 2. Data contents, data structures
- 3. Data standards, vocabularies
- 4. Ontologies
- 5. User interfaces, algorithms, interchange protocols
- 6. Software
- 7. Information system as a final product



- I. Information services for mBRCs personal:
  - 1. Unification of Standard Operational Procedures (SOP), data structures, software tools.
  - 2. Construction of integrated MBRC knowledge system
- II. Information services for external users:
  - 3. Presentation of and search for MBRC services
  - 4. Content search of microorganisms based on their properties.
  - 5. Navigation in information space of microbiology, bioinformatics, biotechnology, agriculture, medicine.
  - 6. Content search of microorganisms experts based on user problems

The only non-trivial subjects for MIRRI Task 8.4 "Provide strategies for access" were the tasks II.4. and II.5. Task II.5. was changed to "An integration with microbial data of microbiology, bioinformatics, biotechnology, agriculture, biomedicine". For this task we inspected 870 life science databases and information systems, ABCD, DwC, MINE, OECD BPG and Straininfo MCL data standards, 575 ontologies, as well as data transfer and software tools in these practical areas. The most detailed analysis was done in EBI biomedical solutions. In databases that we inspected, EBI was the biggest databases producer and the key partner in ELIXIR. The least detailed - in agriculture. The pharma field - in between. For other fields of biotechnology we did not find good data holdings and infrastructures yet.

In task II.4., "Content search" means the search based on the meaning of the user request. The search methods are based on ontologies. In the case when the search is done on the mBRC holdings only (no data integration task II.5.), we collected an optimal data standards (level 3 in interdependence list), but did not convert it to vocabularies format having no approval from microbiologists yet. Ontologies (level 4) were the problem. Only 136 ontologies were applicable to microorganisms, they were not optimised to mBRC data standards structure, the content needed additional curation before they are used in MIRRI. The general advice from the producers - they should be done from the scratch for MIRRI. Section "Human access" of D8.6 report presents popular formats of this access collected in 870 life science information systems that we inspected (level 5 User interfaces).

In task II.5., mBRC microbial data must be accessible by the databases and information systems of the integrated areas, from EBI biomedical system first. This system is done with Semantic Web tools and presented in LOD cloud. The most natural for MIRRI is to follow the same schema. Necessary components up to software tools (level 6) and the links to additional descriptions are collected in section "Programmatic access" of D8.6 report.

#### **II. Significant results**

Discussions to date have resulted in the MIRRI WP8 vision to establish MIRRI-IS. MIRRI-IS intends to deploy an integrated, high-quality, manually annotated, non-redundant microbiological resource database which provides all relevant information, data and associated contextual data (metadata) about a particular biological resource (Figure 1). Such a harmonized integrated system will facilitate locating a particular biological resource for the customer. The exchange of (meta-)data of the holding mBRCs and the alignment of all available information connected to the biological resource form a comprehensive repository of high quality content. The MIRRI-IS serves as a knowledge resource, a research tool and a



shopping guide within the virtual MIRRI Collaborative Working Environment, and is in consequence a unique selling point and attraction pole. It is expected that major scientific databases will link directly to the biological resources in great extent resulting in a higher visibility of affiliated mBRCs. Such a harmonized system will also ensure correct and up to date taxonomic assignments to all biological resources. Furthermore, by providing curated strain histories, each resource within an associated mBRC becomes easily traceable and transparent according to the Nagoya protocol.



# Figure 1: Flowchart showing the integration and interplay of existing resources providing access to integrated, quality controlled information and associated contextual data (metadata) about a particular biological resource.

To allow MIRRI-IS to become operational, MIRRI partners need to comply with:

1. Machine-readable mBRCs catalogues.

In case information is not digitally available yet, proper digitalization of key information needs to be undertaken.

2. Provision of accurate data.

The MIRRI Minimum Data Set (MIRRI MDS) of descriptors include 1) Strain Number, 2) Other Strain Number, 3) Present Name, 4) Organism Type, 5) Restrictions, 6) Status, 7) History of Deposit, 8) Growth conditions, 9) Form of supply, 10) Geographic Origin and 11) additional accession number(s) to link the data to the International Nucleotide Sequence Database Collaboration (INSDC), in case this is available. Besides these fundamental fields, specific "data packages" and additional subfields will be added over time to enrich the MDS. This will be extended towards a recommended and finally full data set (RDS/FDS).



The content of the fields is expected to follow the guidelines, data model, controlled vocabularies and ontologies specified by the MIRRI consortium.

The final set of fields, including their expected content, will be consolidated in the Minimum Information about Biological Resources (MIaBRe) standard and checklist.

Curation level and quality of data needs to be assured by unified Standard Operating Procedures in mBRCs.

 Provision of the data in a structured electronically available format.
For each biological resource, data need to be made available in machine-readable format and in regular time intervals. Over time, each mBRC in MIRRI should provide their data by Web Services in an XML based exchange language, e.g. based on the Microbiological Common Language (MCL) and its extensions.

Finally a timeline (Figure 2) has been sketched depicting how the implementation of the different MIRRI-IS components and resulting added value services for the users can be archived.



Figure 2: Schematic overview of MIRRI-IS implementation steps in a projected five year implementation phase. MDS: Minimal Data Set, RDS: Recommended Data Set, FDS: Full Data Set, MIaBRe: Minimum Information about Biological Resources.

**III. Reasons for deviations from Annex I of the DoW and impact on resources** Not applicable.



### IV. Explain the reasons for failing to achieve critical objectives and/or not being on schedule and explain the impact on other tasks as well as on available resources and planning

Not applicable.

#### V. Statement on the use of resources

The amount of person months used in this WP, to month 18, are commensurate with the achievements by all partners working in this WP.

#### **VI. Propose corrective actions**

Not applicable.

### Workpackage 9 Legal operational framework for access to Microbial Resources

#### I. Summary of progress towards objectives and details for each task

Since the delivery of the minimal requirements for enhanced compliance to CBD and IP issues (D9.1), the activities under **Task 9.1** have focused on developing a MIRRI Policy and Best Practice on Access and Benefit-Sharing (ABS) and organizing the International Workshop on ABS. (D9.2).

The International Workshop, "MIRRI WP9 Workshop on Best practice for Access and Benefit Sharing (ABS)" of September 15th, 2015 was attended by 25 persons representing the European Commission, national competent authorities and NFP, CBD Secretariat, MIRRI partner mBRCs and several international stakeholders. The aim of this workshop was to discuss the implementation of the Nagoya Protocol in mBRCs, with a special focus on the basic EU Regulation 511/2014. The programme included an update by the EC on the state of affairs, a round table discussion on the EU Register of collections, initiatives on development of codes of conduct, best practices and other tools to implement ABS, databases and practical ABS implementation in mBRCs. As far as possible, the foreseen consequences of the unpublished Commission Implementing Regulation ('Implementing act') on user obligations, compliance monitoring and user checks, were also taken into account. The main conclusions and a MIRRI roadmap for ABS were included in the D9.2 document, which was submitted early December 2015. The MIRRI Policy on ABS was finalized, and considerable progress was made with the MIRRI Best Practice. Activities will continue during a 6-month extension of the Preparatory Phase of MIRRI granted to take account of the implementing act and guidance from the EU delivered after the official end date of the MIRRI preparatory phase when the Best practice Manual can be delivered.

Under **Task 9.2**, the **Workshop** "Biosecurity Implementation Strategies and Compliance Management in mBRCs" in Braunschweig, Germany, on 1-3 December 2014, was attended by 21 experts representing the user community, governments, industry and MIRRI partners. To announce this workshop and draw attention to MIRRI's activities on biosecurity implementation strategies and compliance management, a **Biosecurity Compliance** 



**Brochure** was compiled and circulated (Annex 1). Aims of this workshop were to discuss key-issues such as education and awareness-raising on biosecurity, and to make steps forward in designing a MIRRI policy on risk assessment and an overall compliance strategy. The input of the external experts proved extremely valuable, and was included in the Report of the Workshop (D9.4). A Policy statement was formulated and approved, and will be taken up to deliver D9.3 in the extension period of the MIRRI Preparatory Phase.

# Task WP9.1 Define a MIRRI policy on IPR and Access and Benefit Sharing (ABS) in compliance with the Convention on Biological Diversity (CBD)

#### MIRRI Policy and Best Practice on Access and Benefit-Sharing (ABS)

WP9 provided the key-elements from the policy on ABS and biosecurity for the Partner Charter. A Policy Statement on ABS was finalized and agreed upon among the partners during the workshop in Amsterdam (Appendix X). During the reporting period, the Best Practice was continuously updated according to new information on the interpretation of the EU basic Regulation 511/2014 via contacts with national and EC representatives at various meetings, on other occasions, and through the implementing acts which have now been published (Commission Implementing Regulation, http://eur-lex.europa.eu/legal-content/FR/TXT/?uri=uriserv:OJ.L\_.2015.275.01.0004.01.FRA; see also next section).

#### Organise an international workshop (D9.2, M32)

Given the fact that the publication of the Commission Implementing Regulation, dealing with detailed measures on user obligations, compliance monitoring and user checks, was still pending, and many concerns regarding the implementation of the basic EU Regulation 511/2014 also persisted, the MIRRI partners strongly felt that the International Workshop (D9.2) should address these issues. This resulted in a workshop with a broad focus on ABS in the microbial domain (so much broader than originally envisaged and the title of D9.2 in the DOW suggested).

**The International Workshop**, "MIRRI WP9 Workshop on Best practice for Access and Benefit Sharing (ABS)", was held in the Van der Valk Hotel Schiphol A4, Hoofddorp near Amsterdam on September 15th 2015. It was attended by 25 persons representing the European Commission, several national competent authorities and national focal points (NFP), CBD Secretariat (via skype), the MIRRI partner mBRCs and collaborating parties and relevant user associations working on ABS implementation, viz. the World Federation of Culture Collection (WFCC), the Global Biological Resources Centre Network (GBRCN), and the Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM). The aim of this workshop was to discuss the implementation of the Nagoya Protocol in mBRCs, with a special focus on the basic EU Regulation 511/2014. As far as possible, the foreseen consequences of the unpublished Commission Implementing Regulation (Implementing act) on user obligations, compliance monitoring and user checks, were also taken into account.

**Session 1** focused on the requirements coming from these legal instruments, and to come to a clearer understanding of what due diligence entails. A **round table discussion** focused on the EU Register of collections (EU basic Regulation Art. 5). The Register still needs to be put in place, so the discussion and conclusions concerning potential benefits and liabilities for



collections listed on the Register mainly reflected what the participants of the workshop were expecting from such a register. None of the mBRCs represented in the audience indicated that they have decided to apply for admittance to the Register at that time, but several indicated to at least consider it. Session 2 presented a number of initiatives for developing codes of conduct and best practices for mBRCs, and finding common approaches to promote compliance and reach compatibility under various ABS regimes. The Network of International Exchange of Microbes in Asia (NIEMA) system and Code of Conduct proposed by the Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM) were presented as an interesting example of an ABS compliant transfer and exchange system for mBRC strains for non-commercial purposes. MIRRI envisages that through the MIRRI network its partner mBRCs should collectively take their responsibility to support the bio-economy and discovery in general for the benefit of society (and its global users) and refrain from posing a priori (and unnecessary) restrictions on commercial use. The more restrictive approach presented by the NIEMA system would not work in this regard and therefore would not be appropriate for MIRRI. In Session 3 possible database solutions for appropriate and compliant data management for mBRCs were presented. Of particular concern were the functions of the Access and Benefit-sharing Clearing House (ABSCH) as a principle source of information for the user community, and its current lack of information. Participants discussed how the needs of mBRCs could be better served, and the possible role of other global database initiatives that could support the successful implementation of ABS.

Back-to-back WP9 organized a **second one-day workshop** on September 16th, aiming to finalize the discussions among the MIRRI partners on the Policy and Best Practice. These essential documents will feed activities on ABS during the six-month extension period of the MIRRI Preparatory Phase. After the end of the Preparatory Phase, these products could guide European mBRCs in ABS implementation and serve as a solid basis for MIRRI's continued ABS activities in the interim period towards the establishment of MIRRI as a legal entity. D9.2 provides the programmes, the main conclusions and the list of participants of these workshops.

#### **EU level activities**

**Task-coordinated activities and communications**. The CBD communique dated July 14 2014 announcing the entry into force of the NP on October 12, 2014, was mailed to the MIRRI WP9 participants (all MIRRI partners) on July 15, 2014.

Several MIRRI partner representatives including Heads of collection attended the Workshop "Working out ABS", 24-25 November 2014, in Paris, organized by the International Chamber of Commerce (ICC). As input for the discussions during the workshop, MIRRI WP9 partners compiled a list of questions which was submitted to the organizers prior to the meeting. EC representative, Mrs Alicja Kozlowska (EU- NFP) and Hugo-Marie Schally provided answers to questions on the scope and more precise interpretation of several articles in the EU Regulation 511/2014 and presented a discussion paper on the draft Regulation Implementing Acts. Representatives of industry provided their view on implementation issues, and several national authority officers presented plans and described progress in national implementation of ABS legislation. It was clear from the discussions that the user community expects more guidance on the implementation of the Regulation, and the EC recognized the need for this.



The EC organized an ABS-stakeholders meeting on December 9, 2014 in Brussels. For MIRRI it was attended by the Coordinator and a few other partners. In preparation for the First Committee Meeting on the Implementing Acts, a written response to the discussion paper was compiled with input from several MIRRI partners, and sent by the coordinator to the EC on January 9, 2015.

#### International outreach activities - other ABS initiatives, symposia and meetings

## "TRransparent User-friendly System of Transfer for Science & Technology" (TRUST) of the World Federation for Culture Collections (WFCC)

On behalf of MIRRI, Gerard Verkley attended the TRUST/WFCC meeting on 15-16 May, 2014, at Belspo, Brussels, Belgium. TRUST is an initiative based on the MOSAICC project, for which an updated draft version that would comply with the Nagoya Protocol was presented at this meeting. During the meeting the consequences of the final text of the ABS regulations for the Union, and various approaches to support implementation of the Nagoya protocol were discussed. The progress in the design of the ABS Clearing House was presented by Chris Lyal, Natural history Museum, London, UK, and possibilities to improve its design and functionality in order to better meet the needs of microbiology were discussed. MIRRI WP9 provided feedback on the draft TRUST code of conduct.

#### **European Culture Collection's Organisation (ECCO)**

Gerard Verkley chaired the symposium "Microbes and bioeconomy: regulation and legal aspects", during the 33rd ECCO Annual Meeting on June 12, **2014**, in Valencia, Spain. He delivered a lecture entitled: "Nagoya Protocol at the doorstep – how collections in the Microbial Resource Research Infrastructure (MIRRI) prepare to comply". During a round table discussion access and benefit-sharing and related IPR issues were discussed. Other contributors were Alejandro Lago (UNESCO, Spain) and Ewald Glantschnig (WIPO, Geneva, Switzerland).

A MIRRI WP9 and WP3 Workshop "The new Regulation for the use of genetic resources – the impact of the actual regulatory development on Access and Benefit-Sharing" was organized by DSMZ in collaboration with the WP9 team. The opportunity was taken to schedule this meeting on May 27, 2015, just before the 34th ECCO Annual Meeting, which was held at Institut Pasteur, Paris, on May 28-29. Sixty participants from all over Europe attended the workshop. BRCs in Japan and Thailand also sent delegates. The main workshop conclusions form this workshop included the following:

- The EC statements concerning the interpretation of "research and development "as cumulative requirements appear to have been misunderstood. There is again more confusion on what it actually entails.
- A strong declaration is immediately needed from MIRRI and ECCO collections to the EC on the urgent need to clarify the definition of "research and development"
- The legal uncertainty for users of genetic resources especially in industry persists almost seven months after the Nagoya Protocol and the ABS Regulation 511/2014 entered into force. The EC has announced the delivery horizontal guidance (on scope) and sector-



specific guidance for users but these will probably not be issued before the articles Reg. 4, 7 and 9 will apply (as of 12 Oct 2015) and the implementing acts to the Regulation have entered into force.

- The bioindustry sector is expected to increasingly outsource preservation of their genetic resources collections to the BRCs, while they may also use more genetic resources from the BRCs, and less from their own collecting activities in situ (or only in "the back yard").
- Those present at workshop were asked to provide information after the workshop to build case studies which can be communicated to the EU legislators and national authorities for discussion and clarification.
- The mBRCs staff and affiliated researchers (working in the same institute or legal entity) should always act with due diligence, i.e., check the ABS status of all biological material received, and collect information and relevant documentation required under applicable ABS legislation and the Regulation.

#### MicroB3

Gerard Verkley attended the IUCN-MICRO-B3 stakeholders meeting "At the crossroads of Open Access to Data with access and benefit-sharing requirements – promoting precompetitive scientific research", 25-26 September 2014, at the Fondation Universitaire, Brussels. Because of similarities in the practical aspects of sampling activities with legal access to genetic resources in many different jurisdictions, distribution of samples and genetic resources contained therein to research facilities in several countries, and the pool of data generated and released in the public domain, these activities are of particular interest for the MIRRI partners and public microbial collections in general. The nain purpose of the meeting was to discuss the data policy with regard to ABS, and practical aspects of governing use of data generated by the MICRO-B3 Ocean sampling days. The IP Model agreement for pre-competitive access to large-scale microbial genomic research databases was also discussed.

Gerard Verkley delivered a lecture at the Second International Ascomycete Workshop, held at the KNAW Trippenhuis, Amsterdam, on April 23, 2015. The title of his talk was "The Nagoya protocol: how do we proceed with fungal systematics?" This workshop was attended by 150 mycologists from all over the world, including 50 Postdocs and students, who have to become aware of the impact of the Nagoya Protocol, and how ABS requirements will affect their daily work (and careers) in taxonomy and phylogeny of fungi. A recording of the talk is available on you-tube (http://www.cbs.knaw.nl/index.php/pr/616-youtubecbs2015).

#### Federation of European Microbiological Societies (FEMS)

At the Sixth Congress of European Microbiologists FEMS in Maastricht (7-11 June, 2015), MIRRI in collaboration with ECCO organized a session on ABS on June 9, 2015, entitled: "The Nagoya Protocol on biological diversity and its impact on microbiology" (Annex 2, abstract & programme). Speakers in this session were Dunja Martin (MIRRI, DSMZ), Gerard Verkley (MIRRI, CBS-KNAW), and Ricardo Gent (Association of the German Biotechnology Industry). The workshop aimed to present, analyse and discuss key aspects of the EU Regulation and the draft Implementation Act, in particular the impact of these instruments on research and development activities and the possible implication on the bio-economy and the preservation of biodiversity. The legal aspects of sovereign and intellectual property, the



transactions associated with the use of biological material in scientific research as well as in early stages of commercial research and development and the governmental control and monitoring mechanisms of the complex regulatory ABS regime in the EU were introduced. The session also highlighted the value of MIRRI in offering expertise to assist microbiologists in Europe by advising best practices and implementation strategies for an institutional ABS policy.

#### **Q-Collect project**

Several MIRRI partners are also partner to the Q Collect project, which aimed at improving the status of reference collections important to plant health (pro- and eukaryote pests). At the second project workshop ("Q-Collect Workshop for Collections and users of biological material"), held in Rome, September 8-9, 2015, the main findings of the Q-collect European project were presented to its stakeholders (i.e. representatives of collections and Heads of national plant protection laboratories within the EPPO region), Paul de Vos (MIRRI, BCCM-LMG - UGent) presented the MIRRI approach to implementing the Nagoya Protocol in collections.

#### European, Middle Eastern & African Society for Biopreservation & Biobanking (ESBB)

Raquel Hurtado et al. presented a poster on "The Nagoya protocol and its implications for users of Microbial Resources" on behalf of the MIRRI consortium at the ESBB's 2015 Annual Conference, 29th September to Friday 2nd October, London, UK. David Smith, CABI presented the talk entitled MIRRI common approaches to compliance at the same ESBB conference including the implications of the Nagoya Protocol and how MIRRI through its networked activities were supporting microbiologists in compliance.

#### **National activities**

Throughout this reporting period, MIRRI partners had regular contact with their competent national authorities and provided feed-back to MIRRI WP9 and during workshops on ABS where appropriate, on the developments at national level, including national responses to the draft Implementing Acts (UK, France), and also on meetings with competent authorities (Belgium, UK, Netherlands, France, Italy, Spain), and national stakeholder workshops (Belgium, Italy, France, UK).

In the Netherlands, Gerard Verkley presented a lecture "Implementation of the Nagoya Protocol in the practice of public collections of living micro-organisms" (in Dutch) during the seminar workshop "Gebruik van biodiversiteit in onderzoek na 12 oktober 2014", at Universiteit Utrecht, 27 January, 2015. Representatives of Dutch Ministry of Economic Affairs, The Dutch Centre of Genetic Resources (also ABS-NFP, plant resources), Dutch University departments, botanical gardens and other biological collections, and agro-industry attended this meeting. One of the most important topics in the discussions was the interpretation and scope of "research and development". David Smith, CABI presented the talks International Outreach with a focus on MIRRI at the UK Biological Resource Centre Network annual meeting in London on the 7th October 2015 and Towards a South American BRC Network at the meeting Amazing Amazon held at the Millennium Seed Bank, Wakehurst Place, UK. The advantages of networked approaches to compliance with ABS regulation and the MIRRI approach were discussed.



# Task WP9.2 Develop a common approach for mBRCs on risk assessment and evaluate the practical implementation of the Biosecurity Code of Conduct for BRCs

## Organise an international workshop on Biorisk assessment and Biosecurity measures (D9.4, M24)

An international expert Workshop "Biosecurity - Implementation Strategies and Compliance Management in mBRCs" was held at the Steigerberger Park Hotel, Braunschweig, Germany, 1-3 December 2014. To announce this workshop and draw attention to MIRRI's activities on biosecurity implementation strategies and compliance management, a **Biosecurity Compliance Brochure** was compiled and circulated (Annex 1). Seven non-MIRRI invited speakers and 14 MIRRI partners attended the workshop in Braunschweig. The programme and list of participants are provided in the Workshop Report (D9.4).

One of the main aims of this workshop was to discuss key-issues for biosecurity, such as education and awareness-raising, and to make steps forward in designing a MIRRI policy on risk assessment and an overall compliance strategy. The input of other experts and important stakeholders from the user community, governments and industry proved extremely valuable.

The main conclusions from the Workshop are: Education, training and specific meetings was considered to be very crucial as an ethical basis for implementing biosecurity demands, this may or should include curricula modules for academia/universities. Establishing defined programmes for this aim was mentioned to be desirable. In this context, it is fundamental to "understand the others". Furthermore, communication between institutions in the broader sense, but between the BRCs in the narrow sense was noted to be an important issue. To fill the existing gaps, the role of the deputies in the institutions (i.e. staff with designated responsibilities for biosecurity at various mBRCs) is of outstanding relevance. The office dedicated to biosecurity issues beeing established in the Netherlands was viewed as an exemplary and commendable model. New approaches should be created to define pathways with guidance regarding biosecurity and compliance questions.

Laboratory biorisk assessment and the active processes were mentioned to be a difficult facet of biosecurity in daily practice. Help is needed in this field. The specific "GMO issue" was more precisely reduced to be a "GOF issue" (gain of function). It was questioned whether laboratory biosafety/biosecurity must by definition include the transport chain.

Providing quality to the recipients of bioresources was raised to be fundamentally important, this requires proper risk assessment and useful standards and regulations guidance. Highly pathogenic bacteria allocated to the RG 3 will necessarily or probably have to receive more attention in the future. It remains a matter of importance that research shall not be restricted, it would be contra productive. The "DURC dilemma" issue was received with interest, also related to the most recent development towards the current discussions on establishing a new ISO Standard (ISO/TC 212) on the basis of CWA 15793 on Laboratory biorisk management. In this regard, a broad dialogue seems highly relevant. It was stated that MIRRI not only has a chance, but indeed has a role, in alleviating the biorisk issue. Broader alliance and transparency seem necessary. In connection with biosecurity and compliance, MIRRI has an important role. It was criticised that governments are hardly aware of what is done and brought forward by BRCs.



The surprising diversity of the themes addressed by the Workshop was positively expressed. It was elucidated that a roadmap is definitely necessary involving all authorities and communities involved in biosecurity and compliance issues, with a particularly clear message that scientists and all relevant actors shall debate in a much tougher, courageous manner than usual when it comes to negotiations on the political or regulatory levels. Finally, a link between the political arena and all actors should be sustainably established. Touching this aspect, it was suggested to check the output of this Workshop against a stakeholder's analysis.

To help develop guidance for the scientific community, the existing Code of Conduct on Biosecurity for BRCs should be used, but an introductory proactive ethical element seems necessary (Rhode et al., 2013). Finally, for the contemporary development of a roadmap resulting from this MIRRI Workshop, it was said that the exact way on how to support further steps was not yet clear. All positive actions should be drawn together to reduce individual work. In conclusion, the compilation of what was raised would be used in the development of the MIRRI Charter."

The concerte outsome of the Workshop was not only a document on MIRRI perspectives and workshop resolutions, but a MIRRI Biosecurity Roadmap (Fig. 1). These outputs from the workshop have been incorporated into Deliverable 9.4 Report on the Workshop, which was submitted on April 15, 2015.

At the WP2.2 Workshop on minimal-maximal function (Partner charter) 5-6 March 2015, in Amsterdam, the outcome of the Biosecurity Workshop and a Roadmap for further action on Biosecurity by MIRRI and stakeholders, was presented to the partners and approved.



Figure 1: MIRRI Biosecurity Roadmap



The "MIRRI Policy statement on biorisk assessment and biosecurity measures" to link to the Partner Charter, was approved by those present in Amsterdam. This will be taken to compile D9.3.

The key elements of the MIRRI policy on Biorisk Management in mBRCs are:

- I. Follow the relevant national law
  - a. adhere to the Code of Conduct on Biosecurity for BRCs
  - b. other comparable recognized standards
  - c. 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.

Taken into account that Biorisk assessment is a crucial part of the Biorisk management in mBRCs and need to be complemented by a solid Biorisk prevention program based on legal, normative, ethical and organizational requirements, MIRRI developed an implementation scheme for Biosecurity measures as a result of these two complementary elements. The strategy for the implementation of Biosecurity measures is based on the determination of risk levels (profiles) as a result of the risk assessment and the establishment of an institutional Biorisk policy as a result of the risk prevention. Both elements lead to measures in Biosecurity, which need to be implemented via harmonized procedures and monitored within a continuous improvement process.





Figure 2: MIRRI Biosecurity implementation strategy

#### Other activities

MIRRI attended the first National Workshop on Biosecurity organized by Bureau Biosecurity in the Netherlands, held on Oct 30, in Utrecht. During this workshop the topic of Biosecurity was introduced to a mixed audience of lab managers, biosafety officers, curators and other scientific staff. The opportunity was taken to meet and discuss with the speakers of the Dutch Bureau for Biosecurity who were invited for the MIRRI WP2 and WP9 Biosecurity workshop.

Since January 2015 MIRRI is participating in the ISO/TC 212 WG 5 Laboratory Biorisk Management Standard, which converts the outdated CEN Workshop Agreements CWA 15793 and 16393 into an international standard ISO 35001.

#### **II. Significant results**

The deliverable D.9.2. was submitted in November, 2015. Deliverable 9.4 was submitted on April 15, 2015. In addition, a MIRRI Best Practice for ABS for BRCs in the microbial domain is in an advanced state, and will be completed before the end of the extension period of the MIRRI Preparatory phase (11/2015 - 5/2016).

#### III. Reasons for deviations from Annex I of the DoW and impact on resources

No deviations from the DoW occurred during the reporting period. WP 9 is on schedule with achieving its main critical objectives.

### IV. Explain the reasons for failing to achieve critical objectives and/or not being on schedule and explain the impact on other tasks as well as on available resources and planning

The International Workshop on ABS had to be postponed in order to have more information on the advance text of the European Commission Implementing Regulation (the "implementing acts"). Due to the presence of the EC representative at this workshop, and



close communication on national and EU level regarding progress made with the guidance documents (which are expected end of 2015 and 2016), the Workshop did get sufficient information to have useful discussions and exchange of views. Thus it addressed all key issues regarding ABS implementation in mBRCs. D9.3 is delayed but will be finished and submitted soon, within the extension period of the MIRRI Preparatory phase (11/2015 – 5/2016).

#### V. Statement on the use of resources

All resources were consumed as planned.

#### **VI. Propose corrective actions**

Not applicable.

### Workpackage 10 Innovative approaches

#### I. Summary of progress towards objectives and details for each task

MIRRI has laid down strategies to change the current independent, often institutional policies and managed processes which will be adopted by partner mBRCs to harmonize holdings, services, the training offer and accession policy and share expertise. Better managed resources coupled with improved interaction with stakeholders will lead to further discovery in all areas of the Life Sciences. Influenced and directed by user needs, the MIRRI Partners will coordinate National Nodes of unparalleled depth and breadth of microbial resources; the infrastructure will improve access to enhanced quality microorganisms in an appropriate legal framework and to resource-associated data in a more interoperable way. The MIRRI Central Coordinating Unit will function as the core of MIRRI established through a European Research Infrastructure Consortium (ERIC). The National Nodes and national mBRCs will retain their own legal entity but control of some elements of their operations will be transferred to the MIRRI-ERIC. These functions include a proportion of user access to facilities, services and resources; a commitment to take deposits identified in the MIRRI common accession policy and participation in the expert clusters. mBRC participation in the MIRRI National Nodes will be governed by commitments made in the Partner Charter which will include delivery of high quality data to agreed standards, participation in capacity building programmes and a commitment to deliver the MIRRI communication and outreach strategy to stakeholders particularly to bio-industry. MIRRI is putting in place an associate partner scheme to help those wishing to join MIRRI but need assistance in meeting the Partner Charter.

The MIRRI offer to science and bioindustry will remove fragmentation in resource and service availability and focus on fundamental needs and challenges and thus will:

a. facilitate legally protected and regulative compliant access to resources in mBRCs and associated data to maintain a comprehensive supply of biological material in keeping with the demands of the research community;



- implement a common acquisition policy to increase capacity and engender trust in order to facilitate access to materials from countries of mega diversity
- link member mBRC holdings with contextual data and publicly available data generated on these microorganisms
- ensure that key reference strains from publications are available for the furtherance of science;
- b. improve the interoperability between mBRCs and overarching, as well as complementary data offers;
- c. implement quality management including standardised procedures, best practices and appropriate tools to increase the quality of the resources collected and their associated data as well as performed services;
- d. establish relationships with other European research infrastructures and Pan-European organisations in related fields;
- e. perform research to add value to strains, match and pool services for public and private institutions and launch joint activities;
- f. provide coordinated external user access to the research infrastructure;
- g. engage the internal researcher and technologist community to implement common standards, share technologies and knowledge and coordinate to resolve operational problems and address user community needs.

# Task WP10.1 Draw together all innovative approaches from previous work packages

All individual offers projected in work packages 2 through 9 will be managed through a single access entry point. The underlying knowledge-based platform, the Collaborative Working Environment (CWE), to be established in the MIRRI Transition Phase, will guide the user to state-of-the-art microbial biological services, to experts and training and this technical platform will enable researchers to carry out in-house research on mBRC holdings. Detailed information on the CWE is given in Deliverable 10.1.







The ultimate goal of a functional platform includes access to all of its areas, no matter from which individual point of interest a user approaches. Moreover, based upon certain query key words the user has the option to retrieve information on related topics beyond which they had originally anticipated.

# Task WP10.2 Design a implementation plan for each of the innovative approaches for consideration in the construction phase of MIRRI

The implementation plan has been outlined in Deliverable 10.2.1. The MIRRI project faces an Interim Phase, the length of which is uncertain as a Governing Board has not yet been established and documents for applying an ERIC status has not yet been submitted to the EC. MIRRI is planning to submit a proposal for funding a Preparatory Phase 2 project to the INTRADEV 2 call to the EC in June 2016 in which the CWE will be designed and its functionality tested.

The MIRRI Interim Phase will focus on reducing the fragmentation in resource and service availability and focus on fundamental needs and challenges and thus will:

- facilitate legally protected and regulative compliant access to resources in mBRCs and associated data to maintain a comprehensive supply of biological material in keeping with the demands of the research community;
- implement a common acquisition policy to increase capacity and engender trust in order to facilitate access to materials from countries of mega diversity
- link member mBRC holdings with contextual data and publicly available data generated on these microorganisms
- ensure that key reference strains from publications are available for the furtherance of science;
- h. improve the interoperability between mBRCs and overarching, as well as complementary data offers;
- i. implement quality management including standardised procedures, best practices and appropriate tools to increase the quality of the resources collected and their associated data as well as performed services;
- j. establish relationships with other European research infrastructures and Pan-European organisations in related fields;
- k. perform research to add value to strains, match and pool services for public and private institutions and launch joint activities;
- I. provide coordinated external user access to the research infrastructure;
- m. engage the internal researcher and technologist community to implement common standards, share technologies and knowledge and coordinate to resolve operational problems and address user community needs.



# Task 10.3. Produce specific information and publicity material for dissemination and feedback through work package WP5 communication, dissemination and outreach

Work Package 5 through its 7 Deliverables provided high amount of valuable information to foster the cooperation among MIRRI partners, to address the needs of users and to respond to stakeholder's specific request to the business and financial plans. The short 'MIRRI video' highlights the vision and mission of MIRRI and is available to the public via the MIRRI website. The linkage with other European ESFRI infrastructures led to the acknowledgement of MIRRI by more mature infrastructures in joint projects such as BioMedBridges CORBEL, EMBRIC and RiTRAIN. The closer involvement of the European MIRRI counterpart with other international infrastructures existing in North and South America and in East Asia has been achieved by intensified dialogue concerning ABS matters (Nagoya Protocol), biosecurity issues and renewed discussion in establishing a Global Biological Resource Center network.

#### **II. Significant results**

Individual mBRCs cannot present global solutions to microbiological needs; this requires a coordinated approach by a consortium of national mBRCs guided by their stakeholders. No single country currently offers a complete coverage of microbial diversity and associated services and therefore an overarching European organisation of the national distributed infrastructures is required to make best use of current capacity, bridge gaps and address the needs of biotechnology today. Together, MIRRI

- can afford the full range of often expensive technologies needed to explore biodiversity; offer a more integrated spectrum of equipment, data, background knowledge and services
- provides access to the entire spectrum of microorganisms accessible via a single "entry"-point
- · sets European standards of collection, curation and analysis
- · sets ambitious, collaborative research goals over extended periods
- can share best practices, standards, data and personnel; can exchange personnel for sabbaticals, organize courses together, offer vocational and professional training and education

MIRRI will set the framework for mBRCs to change their operations so that they can underpin and improve the microbiological sciences more effectively and efficiently. This will enable users to access the microorganisms' yet unrecognized potential, deliver regulatory compliance and facilitate knowledge and technology transfer. Thus they will have impact on the bioeconomies of Europe, providing integrated solutions to the Grand Challenges and facilitate the generation of knowledge from data. MIRRI will work with other ESFRI infrastructures providing the essential microbial strain data and expertise to facilitate the use of microorganisms in research and development.

#### III. Reasons for deviations from Annex I of the DoW and impact on resources

No deviations from the DoW occurred during the reporting period.



IV. Explain the reasons for failing to achieve critical objectives and/or not being on schedule and explain the impact on other tasks as well as on available resources and planning

None.

#### V. Statement on the use of resources

All resources were used as planned.

#### **VI. Propose corrective actions**

Not applicable.

## 3. Project Management

#### Consortium management tasks and achievements

Objectives:

The project management of the Preparatory Phase (PP) project of MIRRI ensures an adequate flow of all activities within the project to guarantee successful implementation. This comprises the provision of comprehensive general coordination, proper administration and a legal and financial management according to the rules set by the European Commission and the Consortium Agreement as well. This enables fair and transparent decision-making processes, constant monitoring of the progress of the PP project and steering of all activities and implementation of corrective actions where necessary. The organisation of meetings on a regular basis (e.g. General Meetings, workpackage meetings, Steering Committee Meetings, Advisory Board Meetings, workshops, mBRCs Heads meetings) ensures a profound communication flow on all levels within and outside the PP consortium. These provisions guarantee efficient and timely reporting to the European Commission as well as enabling MIRRI to address ethical and gender issues.

#### Task WP1.1 Scientific and general coordination

The main objective of the project management was to carry out and to guarantee the effective coordination and management of the project: focusing especially on the day-to-day administration, coordination, and monitoring of the project's progress.

The task implies the coordination of the overall project and related activities. The achievements of the project's objectives, such as the deliverables, milestones, and periodic reports including their timely provision, was constantly reviewed and traced. Where necessary, corrective actions were implemented e.g. to keep the management up date with the latest developments in all tasks of the workpackages, three months activity reports were introduced. This implemented the possibility to immediately start any corrective action, if necessary. All decision-making processes were made on a fair and transparent basis and



were in line with the rules defined in the collateral established Consortium Agreement between all Partners. Another part of the Management Workpackage comprises a proper consideration of ethical and gender issues also as well as the analysis of events that may impact on the project and finding of alternative solutions. The issues of reinforcement of the relevance of existing tasks or workpackages or topics were thereby considered in particular.

The Coordinator acted as the intermediary between the Consortium and the European Commission and executed the project management by taking over the responsibility for the MIRRI Preparatory Phase project. The extensive contacts to ESFRI and especially to the Health & Food Domain (former BMS-RI) as well as to CoPoRI (Communication and Policy Development for Research Infrastructures in Europe) were further strengthened, their activities were intensively traced to participate successful in the Horizon 2020 programme of the EC (successful participation of MIRRI in H2020: CORBEL, RITrain, EMBRIC). The Coordinator and the Management Team were supported by the MIRRI Steering Committee as an auxiliary body for the execution of the project. It is composed of the Coordinator Erko Stackebrandt (DSMZ), Chantal Bizet (IP) and David Smith (CABI).

A high level Advisory Board consisting of Iain Gillespie (UK) (resigned 2014), Lodovica Gullino (Italy) (resigned 2014), Indrikis Muiznieks (Latvia), Janet Thornton (UK), Daniel Ramón Vidal (Spain), and Wiebe Kooistra (Italy) (convened 2014) closely followed the progress of the project and gave relevant advice on the general strategy to help to improve MIRRI's impact at several stages. Therefore different meetings, like the Mid-Term Review Meeting (June 2014), the 4<sup>th</sup> General Meeting (October 2015) and the Steering Committee-Workpackage Leader Meeting in Amsterdam (September 2014) were organised. Experts and stakeholders were also involved at the General Meetings to provide further input to several workpackages. The first national stakeholder meeting with participants from six European countries was organised in October 2015 to provide the stakeholders with an overview of achievements of MIRRI as well as future strategies to pass the Interim Phase until an application for a legal MIRRI structure can take part.

#### Task WP1.2 Administrative, legal and financial management

In this task the day-to-day management of the Preparatory Phase issues was processed. One main objective was to monitor the project costs and predicted costs to control both, the overall costs incurred and EC support granted. Certain attention was set to the distribution of the Central Budget, to the budget of the different workpackage meetings, and to third party contracts. This tracing and verification of different financial resources of the consortium budget was reconciled with the Steering Committee and handled in direct cooperation with the financial department, which is assigned to all financial issues regarding this project for internal adjustment of how to proceed with different financial approaches. For example different subcontracts with external experts were established.

As specified in March 2013 within the Consortium Agreement (based on the DESCA model for FP7 projects) for the Preparatory Phase a confidentiality agreement (Non-Disclosure Agreement) was signed by all subcontractors and new affiliated Collaborating Parties as well.



#### Task WP1.3 Meetings and Communication

This task comprised the management related communications and meetings. The Coordinator and the management team were in close contact with the European Commission's representatives e.g. the project officer, the legal officer and the administrative officer, which guaranteed a productive communication flow at all levels of the project: between Partners, Collaborating Parties, Workpackages and activities (e.g. General Meetings and workshops). The progress of the project was summerised by the Coordinator by collecting 3-month activity reports from each workpackage leader, as well as the status of deliverables and milestones, and information concerning upcoming events and tasks. These reports, including their summary and outcome, were published on the secured internet site of MIRRI which is accessible for all participants of the consortium. During the reporting period the Steering Committee met on a regular basis by conference telephone calls as well as face-to-face meetings in parallel to the general meetings or separate meetings.

The development and update of the MIRRI website (www.mirri.org) was further advanced as this site represents a key tool in both, internal and external communication strategies. Within the MIRRI website the internal password protected area was used, in addition to face-to-face meetings, phone or video conferences and email, as the main communication and archive tool within the consortium. It stores all information relevant for implementing the project Agreement, (deliverables, milestones. contracts (Grant Consortium Agreement, Memorandum of Understanding), reports (3-months-reports, financial status (of Workpackage Meetings), joint documents (guidance notes on special topics: e.g. ABS and the Nagoya Protocol), events, project meetings, minutes of meetings, contact persons etc.). This comprehensive management platform also contains online document for the preparation of the different reports and also provides the possibility for the users to upload documents for internal use within specific workpackages.

The Mid-Term Review Meeting with 57 participants (Amsterdam), the 4<sup>th</sup> General Meeting with 57 participants (Amsterdam) as well as several Workpackage (Amsterdam, Braunschweig, Hanover, Paris) and the Workpackage Leader-Steering Committee Meetings (Amsterdam), the Steering Committee Meetings (Braunschweig), the Workshop on Communication Approaches to Bioindustry and in-house meetings (Braunschweig) on a regular basis were thereby key management tools in drawing together key information and control points for delivery. All meetings, except the Workpackage Meetings, were completely organised, executed, and supervised by the Coordinator and the management team. The execution of Workpackage Meetings was supported by supporting the organization and financial issues. All kinds of information regarding these meetings (programmes, flyers, lectures, and protocols) and post-processing procedures were directly published on the MIRRI webpage. Besides these meetings an expert meeting was organised in Amsterdam, including the directors of 11 leading European mBRCs that met the second time organsised by MIRRI to discuss future perspectives of a pan-European infrastructure like MIRRI and its requirements for implementation.



#### Task WP1.4 Reporting

The Coordinator and his management team collected, merged and checked three-monthly internal progress and financial reports of all workpackages (shortened from six-monthly reports) from the specific workpackage leaders, which were reviewed by the Steering Committee and published on the internal website of MIRRI at www.mirri.org to be available for all Partners and Collaborating Parties. The Coordinator and his team were also responsible for timely collection, review, consolidation, and preparation of the second periodic report P2 (M19 - M36) according to the provisions of the Grant Agreement. Financial statements were collected and will be approved by an external auditor. These aspects ensured that the project's output, such as deliverables, milestones, periodic reports and financial statements were punctually delivered to the European Commission. The status of the deliverables and milestones were constantly monitored by the Coordinator and the management team. During the second reporting period (P2: M19 - M36) 38 deliverables in total were submitted to the European Commission via the ECAS system. The full list is available within the ECAS version of the P2 report.

The submission of Deliverable 6.7 "Workshop to identify improved services, the priority actions and implementation mechanisms" and Deliverabe 7.3 "Report on current E&T programmes" that were postponed after reconcilement of the EC project officer Ann Uustalu from month 15 to month 25 (D6.7) and from month 18 to month 23 (D7.3) were now successfully submitted to the EC: D6.7 (24.03.2015) and D7.3 (19.12.2014).

#### Problems and envisaged solutions

No problems encountered.

#### Changes in the consortium

No changes in the consortium were implemented.

#### List of project meetings, dates and venues

TABLE 1.2. LIST OF PROJECT MEETINGS						
No.	Meeting	Number of Participants	Venue	Date		
General Meetings						
01	Mid-Term Review Meeting: 3 <sup>rd</sup> MIRRI General Meeting	57	Amsterdam	18 20.06.2014		
02	General Meeting: 4 <sup>th</sup> MIRRI General Meeting	57	Amsterdam	08 10.10.2015		
Steering Committee Meetings						
03	Steering Committee Meeting: 4 <sup>th</sup> SC Meeting	3	Braunschweig	06 07.05.2014		
04	Steering Committee Meeting: 5 <sup>th</sup> SC Meeting	2	Braunschweig	04.12.2014		



05	Steering Committee Meeting: 6th SC Meeting	2	Braunschweig	20 23.07.2015		
06	Steering Committee Meeting: 7 <sup>th</sup> SC Meeting	2	Braunschweig	30.11 02.12.2015		
Steering Committee - Workpackage Leader Meetings						
07	Steering Committee - Workpackage Leader Meeting: 4 <sup>th</sup> SC-WP Meeting	13	Amsterdam	01 05.09.2014		
Workpackage Meetings						
08	Workpackage Meeting: 3 <sup>rd</sup> WP2 Meeting	24	Amsterdam	05 06.03.2015		
09	Workpackage Meeting: 2 <sup>nd</sup> WP3 Meeting	12	Paris	10.07.2014		
10	Workpackage Meeting: 3 <sup>rd</sup> WP3 Meeting (together with 1 <sup>st</sup> WP9 Meeting)	18	Braunschweig	01 03.12.2014		
11	Workpackage Meeting: 1 <sup>st</sup> WP5 Meeting	9	Amsterdam	20.06.2014		
12	Workpackage Meeting: 1 <sup>st</sup> WP6 Meeting	10	Amsterdam	01 02.07.2015		
13	Workpackage Meeting: 3 <sup>rd</sup> WP8 Meeting	12	Hanover	14.04.2015		
14	Workpackage Meeting: 1 <sup>st</sup> WP9 Meeting (together with 3 <sup>rd</sup> WP3 Meeting)	18	Braunschweig	01 03.12.2015		
15	Workpackage Meeting: 2 <sup>nd</sup> WP9 Meeting (together with 4 <sup>th</sup> WP3 Meeting)	65	Paris	27.05.2015		
16	Workpackage Meeting: 3 <sup>rd</sup> WP9 Meeting	6	Hanover	20.07.2015		
17	Workpackage Meeting: 4 <sup>th</sup> WP9 Meeting	25	Amsterdam	15 16.09.2015		
Other Meetings						
18	Microbial Resource Centers Heads Meeting: 2 <sup>nd</sup> mBRCs Heads Meeting	18	Amsterdam	11.12.2014		
19	Workshop on Communication Approaches to Bioindustry	22	Amsterdam	12.12.2014		

#### Project planning and status

The preparatory phase project MIRRI is subdivided into 10 Work Packages with independent Milestones and Deliverables. The main requirement for their successful completion are intense interactions between the individual tasks, which includes the Project Management (WP1) and Definition of Innovative Approaches (WP10) which merge all work packages, but also for all those work packages that handle the design of the infrastructure (WP2), its governance, legal status, and operational practice (WP3) and the legal operational framework for access (WP 9). These three WPs define the rationale for operational cost of the central coordinating unit and the governance structure of the distributed infrastructure. The MIRRI offer to users is defined in WP5 to WP8 which effects elements of the financial plan of the next phase. One essential aspect is the interaction between management /



steering committee and the task leaders of WP5 to WP8 to guarantee the timely preparation of strategies to address synergies and complementarity. The resulting services and processes must ensure a profound coordination, harmonization, integration and interoperability of data, applications and other services between MIRRI partner collections whereas these activities must be translated into actions for which funding mechanisms must be explored and applied. The two main elements are the basis for the financial component (WP4) of an envisaged ERIC legal structure for the MIRRI implementation phase.

All WPs are highly advanced, having reached all anticipated Milestones and submitted the Deliverables completely.

# Impact of possible deviations from the planned milestones and deliverables None.

#### Any changes to the Grant Agreement Number 312251

The third amendment was accepted by the EC and came into force at 24.04.2014. This amendment comprises the introduction of three additional Collaborating Parties: 1. Culture Collection of Industrial Importance Microorganisms (CMII, Romania), 2. Scandinavian Culture Collection of Algae & Protozoa (SCCAP, Denmark), 3. Public Health England (PHE, United Kingdom). The MIRRI Grant Agreement (Annex I) was revised and replaced any former versions.

The fourth amendment was accepted by the EC and came into force at 22.09.2014. This amendment comprises the introduction of one additional Collaborating Party: 1. University of Helsinki, Faculty of Agriculture and Forestry, Division of Microbiology and Biotechnology (HAMBI, Finland). The MIRRI Grant Agreement (Annex I) was revised and replaced any former versions.

The fifth amendment was accepted by the EC and came into force at 10.03.2015. This amendment comprises the introduction of six additional Collaborating Parties: 1. The Culture Collection of Algae and Protozoa (CCAP, United Kingdom), 2. The National Collection of Plant Pathogenic Bacteria (NCPPB, United Kingdom), 3. The National Collection of Yeast Cultures (NCYC, United Kingdom), 4. The National Institute for Biological Standards and Control (NIBSC, United Kingdom), 5. Banco Español de Algas (BEA-Spanish Bank of Algae, Spain), 6. The Biological Resource Centre Toxoplasma (BRC Toxoplasma, France).

The sixth amendment was accepted by the EC and came into force at 14.10.2015. This amendment comprises two main modifications of the Grant Agreement: firstly the introduction of one additional Collaborating Party: 1. UNIMORE Microbial Culture Collection (UMCC, Italy).

Secondly the Modification of the duration of the preparatory phase project. The extension of the project centres on WP 9, Task 9.1 covering aspects which could not been foreseen during the writing of the project in 2010. The EU Regulation 511/2014 scheduled for 15 October 2014 was not fully delivered and regulation articles 4 (user obligations), 7 (monitoring user compliance) and 9 (checks on user compliance) are only applicable from 12 Oct 2015. The implement act is still being worked upon and this includes the final details on the 'Registered Collections'. It was expected that guidance documents and the implementing act will be published by the EU in October 2015, making the request for a project extension highly timely. As the additional workload for mBRCs to become a 'registered collection' will be demanding, MIRRI was planning to spend the amount of about 200,000 Euros, expected


to be still available at the end of October 2015, for devising a workflow-based Manual for curators of mBRCs to comply with the various obligations as laid down in the Nagoya Protocol. Work to be done in WP 9 will be accompanied by the MIRRI Management and Coordination (WP1). The final reports will be executed by partner 1 in WPs 1 and 10.

## **Development of the Project website**

Directly at the beginning of the MIRRI project, the website was established in November 2012. The webpage is available at <u>www.mirri.org</u> and is divided into two main areas:

The first one is a free accessible public area, that is structured in different main categories "About MIRRI", "Work Packages", "Consortium", "News and Events", "User Service", "ESFRI", "Links", and "Downloads". These webpages provide general information on the project and the consortium as well as beneficial contact data.

The second one is an internal area that is accessible for members of the consortium only by entering an appropriate password. This area provides internal information for download and is subdivided into different folders e.g. "Documents & Co.", "Workpackages", "Deliverables", and "Meetings & Conferences". One substancial aspect of this area is the possibility for members of the consortium to upload files and share these ones with other participants.

The contents of both areas are constantly updated and adapted under the prevailing requirements.

MIRRI is also represented at different social media. Links to the relevant profiles are also provided at the webpage and are set to Facebook, Twitter, LinkedIn, and Google+, respectively. A short MIRRI movie (04:50 min.) was uploaded in October 2015 to present more information about the MIRRI service offer and the benefits users can gain from the research infrastructure.

## Coordination activities during the period

In this part activities will be described that were not mentioned in the "Consortium management tasks and achievements".

One of the most important aspects during the preparatory phase period was the establishment of a Memorandum of Understanding (MoU) within the Consortium. The compilation of a final document that can be adjusted or amended for specific national concerns, allows for sending to the national stakeholders. In parallel a detailed Business Case (third iteration) has been finalized which was submitted along with the MoU. The objective was to receive an approval by the stakeholders by sending a "Letter of Intent" to receive non-binding support at the current state of MIRRI's development.

The following national Authorities sent a signed MoU to the MIRRI coordination bureau:

- France: Ministère de L'Enseignement et de la Recherche (10.12.2014)
- Greece: General Secretariat for Research and Technology (31.03.2015)
- Poland: Ministry of Science and Higher Education (13.02.2015)
- Spain: Ministry of Economy and Competitiveness(25.09.2014)

Additionally the MoU was signed by the following Authorities, Universities, and Associations:

- Greece: Agricultural University of Athens (03.12.2014)
  - National and Kapodistrian University of Athens (11.12.2014)
- Italy: SIMTREA (10.06.2014)



## - Spain: - Generalitat Valencian General Directorate of European Funds and Projects (23.06.2014)

To guarantee a good communication flow within the management team and the DSMZ MIRRI members of the coordination bureau participated regularly in in-house meetings, together with the director of the DSMZ, Prof. Overmann is thereby directly involved in MIRRI-related issues e.g. the Nagoya Protocol, Training & Education, German collection network, and Finances.

Following the intermediate Review Meeting by the European Commission at June 18<sup>th</sup> 2014, by the evaluator Dr. Leo Schouls, it was stated that "Considerable progress has been made in this project. Most of the work packages are well underway and virtually all objectives and goals have been reached."

In December 2014 an assessment of implementation of all projects that were added to the ESFRI roadmap in 2008 and 2010 was executed by ESFRI's Working Group on Implementation (IG). The assessment was intended to update the understanding the project's progress and enable adequate follow-up by ESFRI in general and the IG in particular to support the project as it moves towards full implementation and to stay on the "active list" of projects in the 2016 ESFRI Roadmap. The decision of the ESFRI Plenary Forum of 12<sup>th</sup> June 2015 regarding the status of MIRRI and its position on the 2016 ESFRI Roadmap was that of MIRRI is "feasible" and it will thus be added to the list of active projects in the 2016 ESFRI Roadmap.

## Cooperation with other projects/programmes

- Participation at the EMBRC meeting to prepare the EMBRIC proposal under H2020 in Lisbon, May 7-8, 2014
- Lecture at the meeting on Genetic Resources Repository for Plant Metabolic Engineering and Synthetic Biology (PlantEngine) in Helsinki, May 8-9, 2014
- Participation in the TRUST/WFCC meeting in Brussels, May, 15-16, 2014
- Participation at a meeting to prepare the EMBRIC proposal under H2020 in London, June 2, 2014
- Presentations and posters at the ECOO XXXIII meeting in Valencia, June 11-13, 2014
- Presentation at the BioMedBridges Standards Workshop in Amsterdam, June 24-25, 2014
- Participation in the Extraordinary ESFRI BMS RI meeting to define H2020 BMS RI Cluster project(s) in Berlin, June 26-27, 2014
- Participation in the DIN Workshop ISO/TC 276 Biotechnology in Berlin, July 8, 2014
- Participation in the CABI Development Fund Hands across the Atlantic Workshop in Accra, July 14-18, 2014
- Poster at the International Union of Microbial Societies Congress in Montreal, July 27– August 1, 2014
- Participation in the EMBRIC project writing meeting (H2020) in Roscoff, August 13-15, 2014
- Participation in the EMTRAIN Strategic Coordination Board Meeting in Berlin, September 9-10, 2014
- Participation in the 7th Global Identifier Meeting in York, September 11-12, 2014



- Participation in the MicroB3 Stakeholder Workshop on Data-Sharing and ABS Compliance in Brussels, September 25-26, 2014
- Participation in the joint workshop A Common Vocabulary to Classify Resources in the Life Science Domain by ELIXIR, BioMedBridges and RDA in Brussels, October 16, 2014
- Participation in the RDA Europe Workshop about Data Sharing and Interoperability in Brussels, October 17, 2014
- Poster at the ESBB Annual Meeting: Biobanking A Choral Symphony of Science, Technology and Human Rights in Leipzig, October 21-24, 2014
- Participation in the ESFRI @ Leibniz Association Workshop in Berlin, November 6, 2014
- Lecture at the First Q-collect Dissemination Workshop in Kleinmaschnow, November 27-28, 2014
- Lecture at the Workshop on Italian-German Cooperaton in Biomedical Research Infrastructures in Berlin, December 16-17, 2014
- Participation in the ESFRI BMS Group Meeting in Amsterdam, January 27, 2015
- Poster at the 3rd Annual General Meeting of BioMedBridges in Munich, February 17-18, 2015
- Participation in the BioMedBridges Workshop on Data Strategies for Research Infrastructures in Munich, February 19, 2015
- Poster at the 4th LifeTrain Workshop Achievements and Challenges in Lifelong Learning for the Biomedical Sciences in Brussels, March 2-3, 2015
- Participation in the DIN Workshop ISO/TC 276 Biotechnology in Berlin, March 12, 2015
- Participation in the ELIXIR Collaboration Workshop on Marine Informatics in Hinxton, March 16-17, 2015
- Presentations and posters at the ECOO XXXIV meeting in Paris, May 27-29, 2015
- Poster, exhibition and workshop at the 6th Congress of European Microbiologists in Maastricht, June 7-11, 2015
- Participation in the DFG International Workshop on ABS in Bonn, July 2-3, 2015
- Participation in the ESFRI BMS Coordinators Meeting in Brussels, July 15, 2015
- Pre-CORBEL meeting to discuss communication issues with the CORBEL project management unit in Hanover, July 17, 2015
- Lecture at the Regional Conference on Culture Collection in Putrajaya, August 17-18, 2015
- Participation in the RItrain Kick-Off Meeting in Vienna, September 3, 2015
- Participation in the EMBRIC Kick-Off Meeting in Paris, September 17-18, 2015
- Presentation at the 2nd ICC Conference on Working out ABS in Paris, September 28-29, 2015
- Poster at the ESBB Conference 2015 in London, September 30 October 2, 2015
- Presentation at the US Culture Collection Network Fall Meeting in Fort Collins, October 12-13, 2015
- Participation at CORBEL meeting as MIRRI representative in the Executive Board in Hinxton, 15.10.2015
- Participation in the CORBEL WP5 Kick-Off Meeting in Munich, October 16, 2015



# ANNEXES



	Year 1	Year 2	Year 3	Year 4	Year 5	TOTAL			
CCU infrastructure investments									
Membership fees	949,984.87 €	922,668.70 €	1,034,756.81€	1,037,468.28€	1,037,468.28€	4,982,346.94 €			
Observer fees	76,073.10€	103,389.27 €	96,518.04 €	42,276.19€	49,776.19€	368,032.79 €			
Partner fees mBRCs	25,000.00€	30,000.00€	35,000.00€	45,000.00€	60,000.00€	195,000.00€			
Partner fees other	5,000.00€	7,000.00€	9,000.00€	12,000.00€	15,000.00€	48,000.00€			
partners									
Third grants	24,000.00€	49,000.00€	69,000.00€	69,000.00€	69,000.00€	280,000.00 €			
Host country input	171,000.00€	182,925.00 €	195,717.38 €	209,441.37 €	224,493.83 €	983,577.58 €			
Income data access	-€	2,000.00€	5,500.00€	9,000.00€	16,000.00€	32,500.00€			
and expert clusters									
TOTAL Income	1,251,057.97€	1,296,982.97 €	1,445,492.22€	1,424,185.84 €	1,471,738.30€	6,856,957.30 €			
CCU infrastructure costs	- host country								
Accommodation	20,000.00€	20,600.00€	21,218.00€	21,854.54 €	22,837.99€	106,510.53 €			
Running costs	11,000.00€	11,825.00€	12,711.88 €	13,665.27 €	14,690.16 €	63,892.30 €			
Communication and	40,000.00 €	43,000.00€	46,225.00 €	49,691.88 €	53,418.77 €	232,335.64 €			
Outreach									
Annual meeting,	100,000.00€	107,500.00 €	115,562.50 €	124,229.69 €	133,546.91 €	580,839.10 €			
stakeholder meeting									
CCU infrastructure costs									
Advice	30,000.00 €	32,250.00€	34,668.75€	37,268.91€	40,064.07 €	174,251.73 €			
Advisory Board	20,000.00€	21,500.00€	23,112.50€	24,845.94 €	26,709.38 €	116,167.82 €			
Travel and	140,000.00€	150,500.00 €	161,787.50 €	173,921.56 €	186,965.68 €	813,174.74 €			
accommodation									
IT node	50,000.00€	53,750.00€	57,781.25€	62,114.84 €	66,773.46€	290,419.55 €			
Expert platforms	100,000.00€	107,500.00 €	115,562.50 €	124,229.69€	133,546.91 €	580,839.10 €			
CCU costs for									
personnel									
Director	152,400,00€	156.972.00 €	161.681.16 €	166.531.59 €	171.527.54 €	809.112.30 €			

## Annex 1 Investments and costs for the MIRRI- ERIC Central Coordinating Unit and its operations as defined in the first reporting period

Secretary	63,500.00€	65,405.00€	67,367.15€	69,388.16€	71,469.81€	337,130.12€
IT Manager	127,000.00€	130,810.00€	134,734.30€	138,776.33€	142,939.62€	674,260.25€
Communication, public	82,550.00€	85,026.50€	87,577.30€	90,204.61€	92,910.75 €	438,269.16€
relation						
Compliance Officer –	127,000.00€	130,810.00€	134,734.30€	138,776.33€	142,939.62€	674,260.25 €
legal, QMS						
Business development,	-€	-€	-€	-€	127,000.00€	127,000.00€
grants						
Technology Transfer	-€	-€	-€	-€	82,550.00€	82,550.00€
Officer						
Training and education	-€	-€	-€	-€	76,200.00 €	76,200.00€
TOTAL CCU expenses	1,063,450.00€	1,117,448.50€	1,174,724.08 €	1,235,499.34 €	1,586,090.68 €	6,177,212.60 €

## WP4-Annex 2. Detailed costs of the MIRRRI-CCU, alternative proposal.

ltem	Details	Costs year 1*	Costs year 2*	Costs year 3*	Costs year 4*	Costs year 5*	Cost year 6
CCU Costs for statuary seat at host country							
Head office	Office, equipment for 5 persons (75m <sup>2</sup> at 12 €/m <sup>2</sup> /Month)	20.000,00€	20.600,00€	21.218,00€	21.854,54€	22.837,99€	23.865,70€
Consumables	Consumables and communication €7.000/Year	11.000,00€	11.825,00€	12.711,88€	13.665,27€	14.690,16€	15.791,92€
Communication and Outreach	Printing, poster, fair, booths	40.000,00€	43.000,00€	46.225,00€	49.691,88€	53.418,77€	57.425,17€
Subtotal: Indirect Costs CCU - stat	tuary seat at host country	71.000,00€	75.425,00€	80.154,88 €	85.211,68 €	90.946,92 €	97.082,80 €
CCU Operating Costs							
Annual meeting Shareholder + Advisory Board + National Coordinators	1 annual meeting/year, connected to National Coordinators Forum meeting/year; each €50.000	30.000,00€	32.250,00€	34.668,75 €	37.268,91€	40.064,07€	43.068,88€
Consultancy/Agency	Financial and legal agency (€20.000/year), consultancy in ethics and socio- economic matters (€10.000)	30.000,00€	32.250,00€	34.668,75€	37.268,91€	40.064,07€	43.068,88€
Advisory Board	5 members, travel costs	20.000,00€	21.500,00€	23.112,50€	24.845,94 €	26.709,38€	28.712,59€
Travel and accomodation	5 persons (meetings and conference visits, individual travels to stake- and shareholders)	90.000,00€	96.750,00€	104.006,25€	111.806,72€	120.192,22€	129.206,64 €
IT Knot	Data Management, costs for upgrade and licences (€50.000/year)	50.000,00€	53.750,00€	57.781,25€	62.114,84€	66.773,46€	71.781,47€
Subtotal: Operating Costs CCU		220.000,00€	236.500,00€	254.237,50 €	273.305,31€	293.803,21 €	315.838,45 €
CCU Personnel costs							
Director	Year of appointment: 1	125.730,00€	129.501,90€	133.386,96€	137.388,57€	141.510,22 €	145.755,53€
Assistant & Back Office	Year of appointment: 1 (year 1-5 halftime)	31.750,00€	32.702,50€	33.683,58€	34.694,08 €	35.734,90 €	73.613,90€
Communication - customer relationship, training and education (year 1-4)	Year of appointment: 1	82.550,00€	85.026,50€	87.577,30€	90.204,61€	92.910,75€	95.698,07€
Financial & Legal Officer – finance, legal, compliance, risk, QMS	Year of appointment: 1	106.680,00€	109.880,40€	113.176,81€	116.572,12 €	120.069,28€	123.671,36€
Business development	Year of appointment: 5					127.000,00€	130.810,00€
Training and education	Year of appointment: 5					76.200,00€	78.486,00€
Subtotal: Personnel CCU		346.710,00€	357.111,30€	367.824,64 €	378.859,38 €	593.425,16 €	648.034,87 €
TOTAL costs CCU		637.710,00€	669.036,30€	702.217,01€	737.376,37€	978.175,29€	1.060.956,12€
TOTAL costs CCU for statuary seat at host country		71.000,00€	75.425,00€	80.154,88€	85.211,68€	90.946,92 €	97.082,80€
TOTAL costs CCU for MIRRI CCU infrastructure and personell		566.710,00€	593.611,30 €	622.062,14€	652.164,69€	887.228,37€	963.873,32€

Funding source	Funding level (percentage of total cost)				
	Year 1	Year 2	Year 3	Year 4	Year 5**
Member States (5 signatories)	75	63	58	55	50
Third Party Grants	12.5	25	35	35	35
Coordinating hub host country	12.5	10	2	2	2
Bioindustry					
	0	1	3	4.5	8
mBRC membership fees	0	1	2	3.5	5
Total	100%	100%	100%	100%	100%

Funding source	Funding Period					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Expenses						
Costs CCU (plus statutory seat)						
	637€	669€	702 €	737€	978€	1060€
Revenues						
		T		I	I	I
State members and observers fees						
	645 €	676€	708 €	742 €	978 €	245 €
	1					
CCU revenues						
Partner and user fees	23 €	62 €	88 €	115€	162 €	209 €
Sponsering by companies	4€	14 €	32€	95 €	117€	162 €
Third Party Grants	-	40€	75€	110€	150€	405 €
Expert and Training offer	3€	7€	15€	42€	61€	86 €
Total income	675€	799€	918€	1104 €	1468€	1107 €
Total plus	38 €	130€	216€	367€	490 €	47€
Income versus expenses (% plus*)	5.9	19.4	30.7	49.7	50.1	4.4

#### Annex WP9-1

## Compliance Management

Microbial Biological Resource Centres are facing a growing regulatory environment, a higher complexity in their operations, seemingly limitless requirements by user communities and an increased focus on accountability. Hence a broad range of governance, risk, quality and compliance initiatives across the organization of a mBRC seems to be necessary to cope with global development. The impact on the compliance spectrum is manifold and can mainly be identified as internal and external determinants.



The main support can consequentially be given by a management system fostering this balance. A support platform offering applicable and customizable solutions as a model kit would build the bridge to a sustainable and beneficial management system.

## The MIRRI Policy Compliance Management System



The layered system structure recommended by MIRRI shows a dedicated Quality Management mapping the compliance policy as the overarching priority in any effort for performance excellence.

## Biosecurity: Towards a New Governance Paradigm

The **MIRRI Expert Cluster Workshop** brings together stakeholders and experts to discuss the possibilities for a science based, evidence-led and harmonized biosecurity gaining

- reliable tools, methods, systems and techniques
- data mining, improved analysis and knowledge sharing
- forward looking legal framework and shared ethical principles.

### Talks and Sessions

- An Integrated Approach to Biosecurity: The Role of Education and Awareness-Raising
- Reflecting Legal Requirements and Political Expectations within Organisations and Codes
- Risk Assessment: Basis for the Creation of Risk Profiles and for Implementation of Biosecurity Demands
- Perspectives from a Governmental Authority
- Managerial Perspectives and Models for the Implementation of Legal and Normative Requirements and Assessed Profiles
- Standardisation and Harmonisation of Requirement
  Assessments and Profiles

The workshop will reflect that safeguarding responsibilities must be embedded in a harmonized Biosecurity regime to increase the degree of awareness, to promote a culture of responsibility, to be aware of and engage in the debate on biosecurity issues and to be capable of estimating the potential for risks and misuse.

COORDINATION & CONTACT Leibniz Institute DSMZ - German Collection of Microorganisms and Cell Cultures Inhoffenstraße 7b, 38124 Braunschweig, Germany www.mirri.org | info@mirri.org

## BIOSECURITY IMPLEMENTATION STRATEGIES AND COMPLIANCE MANAGEMENT IN MICROBIAL BIOLOGICAL RESOURCE CENTRES

MIRRI Expert Cluster Workshop Braunschweig 01. - 03. December 2014





opean Strategy Forum Research Infrastructures

ESFRI

## **MIRRI in Europe**



Microbial Resource Research Infrastructure MIRRI

MIRRI builds a Pan-European distributed research infrastructure that provides microorganisms services facilitating access to high quality microorganisms, their derivatives and associated data for research, development and application. It connects resource holders with researchers and policy makers to deliver the resources and services more effectively and efficiently to meet the needs of innovation in biotechnology.

MIRRI was established on the European Strategy Forum on Research Infrastructures (ESFRI) road map and is now an EU funded project with the goal to improve access to the microbial resources and services that are needed to accelerate research and discovery processes.

The existing but fragmented resources, distributed across Europe, need to be coordinated and operated to common standards with facilitating policy. This can help focus activities to resolve key problems and address the big challenges in healthcare, food security, poverty alleviation and climate change.

#### United in Microbial Bio-Diversity!



## Facing the Global Deficits

One of today's most complex global security challenges is how to protect and promote rapid advances in the life sciences to improve global public health and quality of life, while preventing the misuse of these advances.

The successful management of biosecurity relies on a sustainable regime in place to ensure compliance with the legislation and broader biosecurity requirements. This regime should be based on internationally binding biosecurity standards and a common understanding of Bioethics.

Thus the most provoking deficit in the life sciences is a coherent regulatory system that aims directly at minimizing and preventing misuse of research and the results of research.

## **MIRRIs** Approach

Biological weapons proliferation and the insecurity of biological weapons-related materials constitute a multifaceted problem that requires a multifactorial, holistic approach to address the full spectrum of human, animal, plant, and environmental health risks. MIRRI seeks to strengthen biosecurity and the international norms, especially the BTWC, and to establish an international biosecurity code of conduct for

- responsible research,
- securing biological materials and
- foster the integrity of the individuals who have access to the material and the related knowledge.

Biosecurity is a shared responsibility of government, science, industry and the community. Bringing together the stakeholders of Biosecurity issues and establishing a unifying biosecurity culture as well as compliance understanding lays the foundation for the implementation of strategies and best practices to minimize the risks and dangers that can arise from any use of pathogenic biological material in any stage of hanaling. With the potential threat of biological weapons proliferation and bioterrorism, there is a critical need for constructing a solid global governance system that is capable of addressing the complexity and multiplicity of the topics related to various aspects of biosecurity.

MIRRI outlines a new biosecurity governance model that is integrative, network-based, flexible, cross-cultural, transparent, and multi-disciplinary. The model emphasises the need to engage all stakeholders ranging from governments and non-profit organisations to private industry, science, and academia.

## Safeguard Public Health and Environment

The term 'biosecurity' relates to the risks associated with potential dual uses of the life sciences and applies to an internal and external environment, where legitimate research may have malicious applications and implications beyond its intended use and thus endanger community health, agriculture, food safety and biodiversity.

Delivering a sound Code of Conduct, a harmonized Risk Assessment and validated Best Practices will increase the impact of the Bioeconomy on todays Grand Challenges.

## The Importance of MIRRI as an European Research Infrastructure

International research infrastructures can play a unique role in bringing scientists together not only to address the most challenging scientific questions, but above to bridge legal, cultural, developmental and governmental gaps on a politically neutral platform.

## The Nagoya Protocol on biological diversity and its impact on microbiology

Organized by the European Culture Collections' Organisation (ECCO) and Microbial Resource Research Infrastructure (MIRRI)

#### 12:30-14:25

Hall H

The workshop will present, analyze and discuss key aspects of the EU Regulation and the draft Implementation Act. A particular focus of the workshop session will be on their impact on research and development activities and their possible implication on Bioeconomy and the preservation of Biodiversity. The legal aspects of sovereign and intellectual property, the transactions associated with the use of biological material in scientific research as well as in early stages of commercial research and development and the governmental control and monitoring mechanisms of the complex regulatory ABS regime in the EU will be introduced. The European ESFRI project MIRRI offers experts to assist microbiologists in Europe and around the world to cope with global and EU based ABS regulation by advising best practices and implementation strategies for an institutional ABS policy. The MIRRI experts introduce the various legal instruments, offer approaches for an appropriate implementation and show the threshold of legal compliance and obstruction of the use of genetic resources and the development of innovative products.

## 12:30 Presentation:

The new EU Regulation for the use of genetic resources- the impact of the actual regulatory development on science and research in the European Union

13:10: Q&A

Case Studies:

- 13:30 Impact on researchers
- 13:40 Implementation approach for a BRC
- 13:50 Implementation approach for a R&D company
- 14:00 Discussion

#### Speakers:

- Dunja Martin (MA, Quality Manager), Leibniz Institute DSMZ-German Collection for Microorganisms and Cell Cultures GmbH, Braunschweig, Germany
- Gerard Verkleij, Centraalbureau voor Schimmelcultures (CBS) Fungal Biodiversity Centre- Royal Netherlands Academy of Arts and Sciences, Utrecht, The Netherlands
- Ricardo Gent, Association of the German Biotechnology Industry, Frankfurt Germany