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Executive summary

In Europe there are a considerable number of well-established, mature Microbial Resource Centres (MRCs) and Culture Collections (CCs) which differ in many aspects such as size, focus, quality assurance, information and communication technology (ICT) development, etc. but have in common their status as service collections that accept, maintain and provide microbial raw material. In addition, most public MRCs/CCs provide microbial services and contract research related to microbiology. However, at present the European public MRCs/CCs preserving this important resource potential operate in a fragmented, uncoordinated and disharmonized way. The integration of all or part of this resource, knowledge, services and research in a sustainable multipurpose platform will be a major step forward with respect to their visibility, transparency, access and use, and will provide significant added value for all stakeholders involved, be they academic or industrial end-users, policy makers or funding bodies.

To design the "Microbial Resource Research distributed Infrastructure", henceforth MIRRI, the resource providers and users have been consulted through four questionnaires *ad hoc* designed. The feedback from MRCs/CCs will be used to determine which services and resources to include in the infrastructure and to lay down the requirements for resource/service providers. The design of MIRRI should be in accordance with the needs of the different user communities (academics, profit sector). Therefore, users' feedback on their profiles and their needs and expectations regarding the use of microbial resources and associated services has been compiled, analysed and evaluated. The questionnaires directed to the (potential) users have fulfilled a double function by gathering their feedback and, at the same time, spreading the MIRRI outreach and raising the awareness of the user community to the broad coverage and diversity available in European MRCs/CCs.

The needs of resource/service providers and users have been studied using the data from the surveys, to guide decisions on the final content and functionality of MIRRI. The main providers of resources in Europe can be divided into two groups, those public collections belonging to the European Culture Collection Organization (ECCO) and those research collections that conserve microbial strains currently not accessible to the community. They all expressed the need of financial support for their activities although they have different demands in terms of equipment or training to improve their functioning. With regard to users, two groups, academic and industrial, were also distinguished having different needs and expectations, although they generally confirmed the necessity for broadening public MRC/CC holdings and services

improving access to microbial expertise and data, and for mechanisms to optimize the MIRRI offer.

The survey results showed that the MRCs/CCs, public and non-public, greatly differ in holdings, size, scope, and services offered to third parties. Bacteria, yeasts and filamentous fungi, and their genomic DNA, are the main scope of most of the public MRCs/CCs in Europe, as well as the highest demanded resources by current users, and will be the core of MIRRI holdings. Identifying existing gaps in the microbial resources and services offered by public MRCs/CCs through the surveys has been proven difficult, but some recommendations can be drawn from the users' feedback. Nevertheless, several of the surveyed non-public CCs preserve and have expertise with organisms that are rare or difficult to maintain, such as phytoplasmas, consortia, viroids, microalgae, or viruses. These microbial types are considered valuable for MIRRI as they harbour resources and expertise that are currently not sufficiently covered by the public MRCs/CCs, and thus not available to the research community under quality standards.

To define the MIRRI consortium structure, draft exploratory models have been depicted about the operational, governance and portal structures and are intended to promote discussion. Moreover, a first effort to map existing networks and structures among microbial resource holders/providers was made using the information provided by the surveys. They will be the base to propose routes of harmonization and cooperation models among resource holders.

Last but not least, preliminary ideas about the criteria for MIRRI membership are outlined based on the Organisation for Economic Co-operation and Development (OECD) best practices guidelines (BPGs) for Biological Resource Centres (BRCs)¹. Additional requirements will be defined in the second half of the project, covering aspects such as (i) requirements imposed by the proposed legal structure (ii) proposed requirements regarding quality management, data interoperability, etc. (iii) regulations concerning Access and Benefit Sharing and the Nagoya protocol.

Content

1. Consultation of Stakeholders	5
2. The Stakeholder community and their needs	9
2.1. Resource and service providers	
2.2. 03013	
3. The MIRRI offer: Resources, services and expertise	18
3.1. Resources & services to include	
3.2. Exploring gaps	
3.3. Clusters of expertise	
4. MIRRI consortium structure	28
4.1. MIRRI operational structure	
4.2. MIRRI governance	
4.3. MIRRI portal	
4.4. Partner linkages and routes of harmonization	
5. Membership criteria	36
Abbreviations	42
References	42
Annexes	
Annex 1: ECCO-Culture Collection questionnaire	43
Annex 2: Non-ECCO Culture Collection questionnaire	53
Annex 3: User questionnaire	58
Annex 4: Innovative Services questionnaire	64
Annex 5: Correlation between OECD BPGs for BRCs and	
questions in the MIRRI survey of ECCO CCs	73

1. Consultation of Stakeholders

To design MIRRI, two stakeholder clientele being resource providers and users have been consulted in order to analyse their needs and expectations regarding quality, range of offer, etc. of microbial resources and associated services.

The European microbial resources are mainly preserved in public MRCs that are members of ECCO, which about half are not involved in MIRRI but would benefit from MIRRI upon future membership. In addition, there are vast numbers of laboratory collections (e.g. research, reference, or hospital collections) distributed in Europe, some of which might harbour important taxa and expertise not well covered by public MRCs/CCs. These non-public CCs represent important stakeholders as (potential) providers of needed microbial resources/expertise for MIRRI.

Regarding users, both current and potential have been considered as MIRRI stakeholders, with special emphasis on the bio-industry sector to present the innovative functions and services that MIRRI will offer.

Consultation has been carried out by means of four individual online questionnaires *ad hoc* designed targeting scientist from academia and the bio-industry and to European MRCs/CCs:

- a. the "ECCO-CC" questionnaire: Survey of the public MRCs/CCs that are members of ECCO (Annex 1)
- b. the "**non-ECCO-CC**" questionnaire: Survey of the non-public CCs within laboratories of European research institutes, public health centres, universities, national reference laboratories and hospitals (Annex 2)
- c. the **"User"** questionnaire: Survey of the current and potential users of microbial resources and related services (Annex 3)
- d. the "Innovative Services" questionnaire: Survey about the interest of current and potential users of microbial resources and services in the innovative aspects of MIRRI (Annex 4)

In Table 1.1, an overview including the target groups, distribution channels, response rate and feedback received is given for the four surveys. The surveys directed to microbial resource users are ongoing, but the first main results are included in the present report.

Table 1.1 Overview of the targets, expected outputs and feedback received through the different surveys

Microbial Resource HOLDERS/PROVIDERS			Microbial Resource USERS		
Survey Name	a. ECCO-CC questionnaire	b. non-ECCO-CC questionnaire	c. USER questionnaire	d. INNOVATIVE SERVICES questionnaire	
Target	Public MRCs/CCs that are member of ECCO	Non-public CCs within laboratories of European research institutes, public health centres, national reference laboratories, hospitals, etc.	Current and potential users of microbial resources and services	Current users of microbial resources and services and potential users from industry (Bio-, Food & Health industry)	
Distribution of questionnaires	 to ECCO collection managers to compiled list of contacts partners and collaborating p 		 to customers of MIRRI collections* to members of scientific microbiology associations in Europe via the European Federation of Biotechnology (EFB, email to members + link on EFB website) via MIRRI website and social media 	 to customers of MIRRI collections* to (bio-)industry contacts identified by MIRRI partners and collaborating parties via EEN via MIRRI website and social media 	
Number of respondents	60	173	1146 (until May 21 st , 2013) - ongoing	865 (until March 20 th , 2014) - ongoing	
Response rate	80%	Approx. 30%	Unknown (overlapping distribution channels)	Unknown (overlapping distribution channels)	
Main categories of respondents	of Other ECCO collection (26) ts MIRRI collection (34) Other ECCO collection (26) Mational Reference Laboratory (13) Hospital and Public Health Laboratory (11) Other (6)		non-profit (875) profit (271)	non-profit (572) profit (293)	
Geographical coverage	France (8) Belgium (7) UK (6) Italy and Russian Federation (4) Czech Republic, Germany, Greece and Portugal (3) Denmark, Finland, Poland and Spain (2) Bulgaria, Estonia, Hungary, Latvia Sweden, Switzerland, Slovakia, Slovenia, The Netherlands and Turkey (1)	Spain (43) Italy (27) Russian Federation (17) Belgium (14) France (11) Czech Republic, Germany and Greece (9) Finland and Portugal (8) United Kingdom (4) Latvia and The Netherlands (3) Slovak Republic and Sweden (2) Georgia, Hungary, Norway and Slovenia (1)	Spain (256) Germany (129) Italy (86) Portugal (80) France (54) United Kingdom (52) The Netherlands (44) Belgium (40) Czech Republic (31) Switzerland (24) Sweden (20) Denmark and Russian Federation (17) Austria (14) Ireland (10) Other** (58) Outside Europe (214)	Spain (278) Germany (108) Italy (57) France (31) The Netherlands and Portugal (30) Belgium and Switzerland (27) United Kingdom (20) Denmark (17) Czech Republic, Greece and Sweden (13) Austria (11) Other** (73) Outside Europe (126)	

*Public MRCs/CCs that are a full partner or collaborating party in the MIRRI preparatory phase. **Other European countries with less than ten respondents in the survey.

Profiling of European public MRCs/CCs and their users

The ECCO-CC (a) and the User (c) surveys were conducted in parallel, with the main goal of comparing the offer and demand in microbial resources, services, associated data, quality assurance, etc., to define the future function and content of MIRRI.

For the ECCO-CC survey the response rate was high (80%), suggesting a high level of interest of this stakeholder group in the MIRRI initiative. Furthermore, the obtained profiles from the 60 ECCO-CCs of various sizes and scope well represent the European public MRC/CCs' community, enabling inventory of the resources and services they cover, and comparison of their current practices. The latter is important in view of the development of MIRRI membership criteria in line with standards specified by the OECD for BRCs¹ (see section 5).

For the User survey nearly 1200 replies were received for the first period of the consultation (until 21st May 2013), providing user details on sector, institute type, use, origin and application of microbial resources, outsourcing of microbial analysis, problems encountered in obtaining the required microbial resources, etc. Participation of the non-profit sector was significantly higher than the profit sector (resp. 76% and 24%), which reflects the general representation of both sectors in the customer databases of most MRCs/CCs. Although most participants filled in the questionnaire anonymously, about 300 users (of which 22% from profit) provided contact details allowing further direct communication for MIRRI outreach and potential involvement in the future MIRRI design. This questionnaire was reopened together with the launch of the Innovative Services (d) survey. In this report only the feed-back from the first term is evaluated.

Mapping of microbial resources preserved in non-public laboratory CCs

The questionnaire addressed to the non-ECCO-CCs (b) contains several similar or identical questions as for the ECCO-CC questionnaire, e.g. on available resources, quality standards and data, for comparative purposes, since they might become part of MIRRI in the future.

An extensive list of approximately 500 contact persons from different EU countries maintaining laboratory collections was compiled in collaboration with all MIRRI participants. Information was retrieved from 173 laboratories in different types of institutes maintaining a non-public (research) CC. Valuable data were obtained about their microbial resources, services and expertise, and about their interest to associate with MIRRI. The latter will be considered for the establishment of the national nodes; especially in countries where there is no formal national network among resource holders (see section 4.4).

Assessment of the interest of users in innovative MIRRI aspects

A fourth questionnaire (d) was designed which aimed to evaluate the degree of interest of current and potential users, especially from the bio-industry, in putative innovative functions and services of MIRRI, beyond what is offered by public MRCs/CCs individually. Through this survey, the proposed new MIRRI functionalities and the portal concept were introduced to the user stakeholder group.

The questionnaire was distributed among current customers of MIRRI CCs, bioindustry contacts gathered by MIRRI participants (e.g. companies retrieved from public directories or associations) and the European Enterprise Network (EEN). These approaches were successful in increasing the share of respondents from the profit sector compared to the previous User survey, from 1/4 to 1/3 in the new survey. Also many potential MRC/CC users were reached, since 1/3 of respondents using microbial resources for their professional activities (both in the profit and non-profit user group) indicated not to be a current customer of public MRCs/CCs.

Geographical coverage of users consulted

Through the "User" and "Innovative Services" surveys around 2000 answers were recovered representing 60 countries; 30 countries were European and 30 were from other continents (Asia, America, Africa and Oceania). Europeans represent 83% of the respondents. The top three countries outside Europe in terms of number of respondents were USA, China and India (166 responses). These figures reflect the international profiles of MRCs customers with an outreach far beyond the frontiers of Europe that should be kept in mind while designing the infrastructure.

Approximately 91% of the profit organizations are located in Europe and are mainly represented by countries that are MIRRI partners (Table 1.1). This bias (also observed for non-profit users) emerges from the work done by the national coordinators in contacting their customers themselves. A more realistic representation of the distribution of stakeholders in Europe will be achieved in near future through other forms of dissemination like participation in events, trade fairs (business community) or scientific conferences (academic users).

As a result, the consultation of the users provided valuable feedback on users' needs and their appreciation for the novel functionalities and harmonization MIRRI will offer, for which the main conclusions and recommendations are presented in section 2.2. In addition, the surveys had greatly contributed to the dissemination to the MIRRI infrastructure since around 45% of respondents declared to have learnt about it through this medium.

2. The stakeholder community and their needs

MIRRI has a broad range of stakeholders, from governmental, regulatory or funding bodies to resource providers and users. Here, we present the needs of resource/service providers and users, as they should be the main players in the definition of the final content and functionality of MIRRI.

2.1. Resource and service providers

Sustainability of the providers is a key issue to consider for the construction of MIRRI. Twelve ECCO-CCs (20%) indicated that they expected a decrease in their main source(s) of income in the next five years. Regarding non-ECCO CCs, nearly half of the respondents (46%) believe that the future of their collection is in danger. Most of them (92%) pointed out the lack of funding as the main reason for being at risk and about 1/3rd mentioned issues related to human resources, such as retirement of the scientist responsible for the collection or lack of dedicated personnel. If these providers have relevant resources/services for the MIRRI strategy (strains with new potential functions, missing taxa/expertise/service, etc.), MIRRI and/or their host countries should develop common strategies to guarantee their maintenance.

In relation to preservation of the biological material, 63% of the ECCO-CCs declared their wish to implement additional methods to improve the conservation of the collection, for which they expressed the need for equipment, human resources and infrastructure (in this order of priority). With the combined expertise held in MIRRI, preservation methods for the different microorganisms groups will be established to secure the viability and stability of the strains in a harmonized and coordinated way. Improvements in CCs under MIRRI should be reflected in the Business Plan taking into account the information retrieved from the surveys.

Regarding training, as reported in Table 2.1 both ECCO-CC and Non-ECCO-CC declared necessities in dealing with microbial resources. Training in quality management is demanded by more than half of both groups; characterization of the biological resources is mostly required by ECCO-CCs, while preservation of the biological resources is mostly required by non-ECCO-CCs, which is in accordance with the concrete aims of each of them. In addition, a clear demand of non-ECCO-CCs in legal matters and international regulations has been identified which should be highlighted since the implementation of the Nagoya Protocol is close to be approved in the European Community (EC).

Needs for job-specific training	ECCO-CC	non-ECCO-CC
No training needed	9%	16%
Quality Management	58%	53%
IT	39%	19%
Characterization of the biological resources	60%	42%
Preservation of the biological resources	46%	58%
Legal matters and international regulations	ND*	52%

 Table 2.1. Percentage of ECCO CCs and non-ECCO CCs that expressed needs in training regarding specific

 BRC/CC issues (data from ECCO and non-ECCO-CC surveys)

*Not determined in the ECCO-CC questionnaire.

2.2. Users

Users' input is crucial to shape and tailor the services that MIRRI will offer to support life sciences and bioeconomy in Europe. Data recovered from the "User" and "Innovative Services" surveys (2011 answers) have been analysed in an effort to better identify the needs of current and potential users of MRCs, their level of interest in the envisaged coordinated operation of MRCs and in the new microbiology-related services and functionalities MIRRI wants to establish.

Most users (72%) belong to the non-profit sector and work mostly in Academia & Education. Regarding the profit sector, about 43% of respondents work in small to medium enterprises (between 10 and 250 employees, Figure 2.1) and have their field of activities in different sectors such as Food & Feed, Pharma & Medical or Quality Analyses, among others (Figure 2.2b).



Figure 2.1. Size of profit organizations in which users developed their activities

More than 10% of users from both profit and non-profit organizations work in the Food & Feed area (Figure 2.2), which should be considered when designing the MIRRI offer.

Moreover, various and unexpected domains of activity were also identified, including cultural heritage, petrochemical or shoe factories, representing a huge diversity of knowledge areas.





User needs - High quality, diverse and original microbial resources

As shown in Figure 2.3, microbial resources mostly used in the last five years were bacteria (used by 85% of the respondents), yeasts (42%), filamentous fungi (41%), and genomic DNA (39%). Yeasts and fungi are more frequently used by profit than non-profit users, whereas genomic DNA, plasmids, cell lines, archaea and phages are mainly demanded by non-profit users. Besides, a slight increase in the use of archaea, viruses, cyanobacteria, and microalgae is anticipated for the future. It has to be highlighted that these microorganisms are also cited as gaps in the Innovative Services questionnaire. In addition, extremophiles, actinobacteria, lactic bacteria, some pathogenic or symbiotic groups of microorganisms and fastidious or recalcitrant "non culturable" microorganisms (ex. anaerobes, phytoplasms) are among the resources cited as gaps. Other users' demands learned from the questionnaires concern the availability of more reference strains per species than only the type strain, genome sequenced strains, genetically modified organisms and strains from recently described or emergent species. Many requests are related with possible applications, emphasizing the importance of including this kind of information in the strain-associated data.



Figure 2.3. User needs for microbial resources. Percentage of users that use, or intend to use, each type of microbial resource

Among the MIRRI proposals, the improved access to a broad range of standardized and high quality microbial resources in a harmonized way using the "one-stop shop" model is regarded as major improvement by more than half of the users, with a slightly higher interest for users belonging to non-profit organizations.

One of the main features linked to microbial resources is the supply of the living biological material. It was inquired in the survey if "alternative formats of supply" are necessary. Less than 50% of respondents considered this useful, which corroborates that shipping lyophilized strains (usual practice of most MRCs) or genomic DNA is preferred by users. However, a standardized inoculum supply was requested by almost 70% of users. The less demanded alternative formats proposed in the questionnaire were large-scale inoculum, strain specific purpose panels, mixed cultures with known composition and permanent microscopy slide

sets. Nevertheless, more than 30% of the profit sector demands large scale inoculum which together with standardized inoculum could be included in the future by the MIRRI offer.

Globally (profit and non-profit), users prefer that the suppliers of microbial material are formally certified or accredited according to 79% of respondents, but 55% do not consider it mandatory. Considering this is one of the potential criteria for MIRRI membership (see section 5) it is recommendable that MRCs/CCs willing to join MIRRI implement or maintain quality certificates.

User needs – integrated database for microbial resources

One of the main aims of MIRRI is to create a unique and integrated search tool for MRC catalogues and to provide an integrated and curated database. This fits perfectly to the demands of the users of which the vast majority (about 77%) considers that these tools can be a major improvement for their activity. In Figure 2.4 the types of information more relevant to the users' work are listed, showing a higher demand in most of the fields from the non-profit organizations. Information about growth conditions and requirements is the most demanded field by both sectors. The need for information on pathogenicity correlates with the demand of services related to pathogenicity test and risk assessment in the service section of the questionnaire and the interest on biosecurity and biosafety topics. Additional information requested by users refers to identification-detection methods (specific PCR primers, availability of MLST schemes, antibodies, photos) denoting the interest for integrated databases dedicated to identification tools.

Furthermore, in an attempt to make the MIRRI platform adapted to users' needs it was asked to which of the existing databases MIRRI should establish a direct link. The responses clearly show that users would like to have a direct link to the major European MRCs and to the American collection ATCC. Hence, the construction of an integrated catalogue of the collections belonging to MIRRI is of interest to the users. Moreover, users suggest useful links to service platforms that manage data of genomics, proteomics, metabolomics, and taxonomy,e.g. Enzyme database-Brenda Gold, genomes OnLine Database, Mycobank, NCBI (BLAST, GenBank, PubMed), Straininfo, Swiss PROT and LPSNbacterio.net.



Figure 2.4. Relevant data on microbial resources that would be a major improvement for the users' activities

User needs - services associated to microbial resources

According to the User questionnaire, the analyses mostly outsourced by users of microbial resources (to any third party, not only to MRCs/CCs) are DNA sequencing (60%) and identification (44%). Other analyses outsourced by over 20% of users are isolation of pure cultures, microbial count, real-time PCR and gene/whole genome sequence data analysis. Users have been less committed in proposing new services than in expanding the range of available resources, as only 86 answers were gathered regarding the gap in services compared to the 242 answers about gaps in resources. This is in accordance with the fact that current users of the collections (63% of respondents) are satisfied with the services provided by MRCs. However, still 35% are interested in innovative services. Figure 2.5 lists the relative relevance for both profit and non-profit organisations of the innovative services envisaged by MIRRI. Noteworthy is the high demand for customized isolation, cultivation (including media optimization) and preservation of microorganisms in accordance with user need to enlarge the scope of available microbial resources. Less relevance is given to the genomic subset.



Figure 2.5. Users' demand on the innovative services envisaged by MIRRI

Original propositions, supported by multiple respondents, about new services currently not or hardly provided by MRCs, have emerged from the Innovative services survey. Some of them were already proposed by MIRRI collaborators:

- Development of methods to enhance cultivation of fastidious or actually non-culturable microorganisms.

- Supply of artificial or natural microbial communities (ex. gut microbiota). This need might correspond to a small niche as mixed cultures were not evaluated as very useful when proposed as innovative format of supply.

Others were newly indicated by the respondents:

- Taxonomy and Identification/Detection methods: users ask for an easier access to information and new methods.

- Genetic: several users expressed the need for procurement of mutants (ex. antibiotic resistant strains), genetically modified microorganisms (tailor made or available as libraries) or genes.

- Pathogenicity tests and risk assessment: users from bioindustries need this information to guarantee the safety use of microorganisms in biotechnology. This gap is seen as a constraint for the use of new strains by bioindustries. Moreover, this information is also requested to guarantee the pathogenic status of pathogens of interest.

Regarding the main goal of MIRRI, the integrated search tool and one-stop shop for MRC services together with a uniform service agreement are considered major improvements by above 50% and 60% of profit and non-profit organizations, respectively. Thus supporting the construction of MIRRI as a pan European distributed infrastructure working in a harmonized and coordinated way.

User needs - Consultancy and Training on microbial related topics

One of the main aims of MIRRI is to provide consulting services and access to expertise in specific microbial- or technical-related issues. Both profit and non-profit end-users (63%) consider this service very relevant for their activities. The top three subjects of interest for establishing expert platforms, favoured by 50-60% of respondents (profit and non-profit), are (i) microbial taxonomy and identification, (ii) isolation and cultivation of microorganisms and (iii) preservation of microbial resources. These subjects represent the core expertise of MRCs staff. Moderate interest is shown in training about legal issues. However, the user questionnaire reveals a limited knowledge of users on their obligations related to the CDB.

In view of organizing expert-platforms for training and consultancy, it has to be emphasized that the interest expressed by users is in both directions, *i.e.* to contribute to and to utilize the expertise made available by MIRRI. The data clearly indicate that there is room for all modes of counselling/training formats, with a clear preference for online guides, documents, presentations and searchable databases with individual experts per subject. To access to MRCs' expertise, the survey revealed that collaboration with MRCs through fundamental or applied research projects is preferred by non-profit users, as it was quoted "very useful" by 68% of users from non-profit but only by 45% of users from profit organizations.

Conclusions and recommendations about the stakeholder community and their needs

In this section, the needs of providers and users of microbial resources have been evaluated.

Among providers, there are two well-differentiated groups, i.e. public ECCO CCs and research laboratories non-ECCO CCs. The majority of ECCO CCs (80%) seem to be confident about their sustainability although nearly half of the non-ECCO CCs believe that the future of their collections is in danger. States members of MIRRI will have to coordinate the collections participating in the infrastructure and ensure their maintenance. Another issue expressed by most collections is related to training needs. In this aspect, ECCO and non-ECCO CCs also differ, being characterization of microbial resources the highest demanded

by public collections and preservation of microbial resources the most required training topic by research collections. Therefore, training demands can be complemented, as ECCO CCs are experts in preservation of their resources and non-ECCO CCs provide more services related to characterization of microbial resources (see next section, Figure 3.4).

The responses to the questionnaires clearly indicate that the MIRRI research infrastructure is very interesting for both non-profit and profit users who want to be continuously informed of the progress of the project. The core activities of MRCs/CCs revolve around isolation, cultivation, characterization, preservation and delivery of microbial resources and associated data. All five pose significant issues and challenges, as revealed by the user needs expressed in the surveys. Besides, broadening of the scope of available microbial resources and standardization on quality management are also appreciated by the users. On the other hand, end users would clearly benefit from having a single portal to search for microbial resources and needs specified by users are clearly due to lack of information. The idea of having an integrated curated database of microbial resources and the expert platforms to facilitate consultancy and training in microbiology-related issues, are in line with user demands.

Some respondents barely know the services currently provided by MRCs, as they demand services already offered (see also section 4.3). This fact reinforces the necessity to construct MIRRI and provide a user-friendly portal integrating all available material, services and information.

This analysis has provided a global view of major and common user needs, but also specific requirements by the different sectors (profit and non-profit).

3. The MIRRI offer: Resources, services and expertise

Based on the feedback from the resource holders in the surveys, information on expertise, resources and services of public MRCs/CCs (ECCO members), but also from institutions maintaining laboratory (research) collections in Europe was compiled in a database. A large diversity in scope and size, offered services, research areas, compliance to basic BRC guidelines, etc., exists for both public and non-public CCs. Public MRCs/CCs range from very large facilities offering a broad portfolio of microbial resources and services, to small, general collections not offering any other service besides deposit and supply of microbial material. Although the laboratory collections are generally smaller in terms of number of holdings, some of them are very elaborate, highly specialized, or contain microbial material not available in public MRCs. Furthermore, several of these laboratories offer microbial services to third parties, including consultancy and training. Their association with MIRRI would add considerable value for the user community, and would give currently endangered non-public CCs opportunities to consolidate their future by establishing networks and national nodes supported by MIRRI and their government.

The compiled CC database will be used as a tool to work on strategies for improving complementarity of and increasing publically available microbial resources, and to identify expert clusters among resource holders willing to associate with MIRRI. The contacts made through the surveys between the MIRRI partners and other interested resource holders and microbial experts will be reinforced in the frame of the MIRRI outreach strategy.

3.1. Resources and services to include

Geographical coverage of microbial resource/service providers

Information on microbial resources and services in European Culture Collections (CCs) were gathered surveying 60 ECCO member public Microbial Resource Centres (MRCs) and CCs from 24 different countries¹ and 173 laboratories maintaining CCs in different types of institutes (primarily Universities and Government Research Institutes) (so-called non-ECCO-CCs) from 19 countries (see Figure 3.1 and Table 3.1). A good representation of the European CC landscape was obtained with the study, especially for countries with partners actively involved in the MIRRI preparatory phase.



Figure 3.1. Number of individual MRCs/CCs per country participating in the WP2-surveys targeting microbial resource holders in Europe (data from ECCO and non-ECCO-CC surveys)

¹Of which 18 countries with ECCO-MRCs/CCs collaborating in the MIRRI preparatory phase as full partner or associated party: Belgium (4), Czech Republic (1), Finland (1), France (6), Germany (2), Greece (2), Hungary (1), Italy (4), Latvia (1), the Netherlands (1), Poland (2), Portugal (2), Russia (2), Slovakia (1), Spain (1), Sweden (1), UK (2).

Inventory of *ex-situ* microbial resources and their availability (maximal coverage by resource holders)

A comparison of the holdings of public MRC/CCs and non-public laboratory CCs per type of microbial/genetic resource is shown in Table 3.1 and Figure 3.2. Filamentous fungi, bacteria, and yeasts are the main *ex-situ* preserved microbial resources, making up >90% of the holdings in both groups. However, thirteen ECCO-MRCs/CCs (22%) focus exclusively or primarily on the preservation and distribution of other microbial/genetic resources within the scope of MIRRI, such as microalgae, cyanobacteria and/or protozoa (9 CCs), cell lines (2), plasmids & DNA libraries (1), or human viruses (1). Also several laboratory CCs were

identified maintaining these types of resources that are currently offered by only a limited number of public MRCs/CCs in Europe (Table 3.1).

Resource type	Total number of items in ECCO-CCs	Number of ECCO-CCs involved	Total number of items in non- ECCO-CCs	Number of non-ECCO- CCs involved ¹	Total number of items
Filamentous fungi	212,389	28	58,234 ²	60	270,623
Bacteria	180,328	33	230,474	99	410,802
Yeasts	58,796	33	24,408	41	83,204
Micro-algae	8,741	9	4,835	13	13,576
Protozoa	6,483	5	13,277	5	19,760
Plasmids	3,286	7	823	10	4,109
Cyanobacteria	2,744	9	1,885	11	4,629
Phages	1,249	8	165	7	1,414
Cell lines_human	793	4	439	3	1,232
Archaea	772	7	6,335	9	7,107
Viruses_plants	741	2	2,195	10	2,936
Viruses_human	734	3	313	7	1,047
Cell lines_ plants	674	1	-	-	674
Cell lines_animal	312	4	57	5	369
Hybridomas_animal	89	2	50	1	139
Viruses_animal	35	1	41	2	76
Totals for CCs providing numeric data on their resources	478 166	59	343 531	151	821 697

 Table 3.1. Total number of holdings per resource type conserved in European MRCs/CCs participating in the

 WP2-MIRRI surveys (data from ECCO and non-ECCO-CC surveys)

¹Including those laboratories that did not provide exact numeric data for the resource types in their CC; ²For filamentous fungi, one outlayer was excluded from the table, being a single national reference collection for Mycology in the UK of 1,240,000 items of herbarium material.

Especially bacteria, protozoa, archaea and viruses are better represented in the laboratory collections compared to the public MRCs/CCs (Figure 3.2). Furthermore, a number of laboratories were identified preserving microbial resources that are not or hardly available from public MRCs/CCs, such as phytoplasmas (5 CCs), consortia (4), oomyctes (2), viroids (2), and microalgae viruses (1). Furthermore, several non-public CCs hold microbial resources that require specific expertise for preservation, belong to species/genera not well represented in public MRCs/CCs, have particular applications or microbial function, etc. Some of these research collections harbour valuable and well characterized resources that are currently difficult to access by the broad research community.



Figure 3.2. Comparison of the total numbers of microbial resources preserved in ECCO and non-ECCO MRCs/CCs (data from ECCO and non-ECCO-CC surveys)

In the questionnaires, only numbers of available items per type were requested. Detailed information on genus/species/strain level is currently not available for analysis, but will be gathered in the second term of the preparatory phase. This additional data on the taxonomic level will be needed to determine complementarity and missing taxa in the publically available resources, so that priority groups can be identified and a strategy for a more coordinated MIRRI accession policy can be proposed.

Further analysis of the non-public holdings in laboratory collections should determine if some of the priority groups could potentially be covered by the interested laboratories. In the next term of the preparatory phase, selection criteria and strategies for integrating unique holdings in MIRRI to complement those already available to the user community, in compliance with criteria developed for MIRRI membership, will be proposed.

Accessibility of microbial resources

The online catalogue of public MRCs/CCs should present most to all of the available biological material, although for 24 ECCO members less than 75% of the available material is presented online (Figure 3.3). Consequently, not all of their content is that visible and thus easily accessible to the user. In this respect, MIRRI could improve visibility, by imposing a minimum of online presented material, and providing common IT services in database management and catalogue editing to member MRCs/CCs.





Regarding the accessibility of the inventoried non-public resources, only 38% of the surveyed laboratories claim to supply samples to third parties upon simple request. Others share resources in specific cases only (36%), such as in collaborative research, or not at all (24%). Nonetheless, the research laboratories support initiatives for opening their collection to the broader scientific community, since 86% are willing to associate with networks such as MIRRI to make material from their collections available to third parties. Furthermore, 76% of the laboratories are interested in letting established public MRCs/CCs foster their most important strains/items, opening possibilities for MIRRI to attract new depositors.

Inventory of services related to microbial resources in Europe

Public ECCO-MRCs/CCs largely vary in service capacity, from offering only deposit and supply of microbial material, to a whole range of microbial analyses, consultancy and/or training. Figure 3.4 gives a comparison of which services are provided by ECCO and non-ECCO-CCs. In general, the surveyed laboratories have similar expertise as available in the public MRCs/CCs, but offer it on a service basis to a lesser extent. In total, 70% of ECCO-CCs and 54% of laboratories offer microbial analysis as a service to third parties, and respectively 68% and about 25% provide training and/or consultancy. Of the ECCO-

MRCs/CCs, 16% has a broad service portfolio including more than ten different microbial analyses, compared to 7% of the laboratories.





The services covered least by ECCO-CCs are whole genome sequence data analysis, serotyping, pathogenicity tests, sequence analysis of non-characterized plasmids and polar

lipid determination. These and other services, such as real-time PCR, PFGE, and DNA sequencing, are better represented in non-public CCs (Figure 3.4).

Another service in line with the biotech applications of microbial resources is the preservation of patent-linked strains, offered by 25 ECCO-CCs. These CCs are recognized by the World Intellectual Property Organization (WIPO) as International Depositary Authorities (IDA) competent to accept deposits for patent purposes under the Budapest Treaty.

The survey results allow mapping the availability of microbial services in Europe, providing the basis for an integrated MIRRI directory. Innovative services covered by non-public CCs could also become part of the Infrastructure. Strategies to improve existing MRC services and to design the common MIRRI service output will be elaborated in the next term of the project.

3.2. Exploring gaps

User needs for microbial resources

Potential gaps in available microbial resources/taxa were hard to establish through the surveys. None came forward from the first User survey although participants were given ample opportunity. In the Innovative Services survey, a second attempt was made and 30% of profit and 27% of non-profit respondents listed at least one microorganism group important for their work that is according to them not offered by public MRCs at present. Microorganism groups that are hard to obtain according to multiple users included viruses, cyanobacteria, microalgae, extremophiles, mycobacteria, mycoplasma, environmental or clinical isolates, pathogenic/multidrug-resistant/toxin-producing strains, and fastidious organisms.

Currently three lists are available with feedback from the stakeholders about microbial taxa or groups they consider as missing in public holdings:

- List of microorganism groups that are important for the user's work but are not offered by public MRCs at present (Innovative Services survey).
- List of holdings conserved in the laboratory collections belonging to species/genera not well represented in public MRCs/CCs (non-ECCO survey).
- List of specializations of laboratory collections in particular taxa, environments, microbial function or applications (non-ECCO survey).

To deduce priority groups in line with user needs and to identify unique holdings, these three lists will be further analyzed and compared with the holdings available in public collections.

Page 24 of 82

Need for services related to microbial resources

In the ongoing Innovative Services survey, 65% of users indicated that the services currently offered by MRCs/CCs suffice for their work. However, several respondents specified new services that would be valuable for them, e.g. supply/preservation of microbial communities, virus propagation, training in bio-informatics software, on-line microbiology courses, and a phytoplasma database. It is noted that several "new" services proposed by respondents are already offered by public MRCs/CCs, such as plasmid typing, provision of microbial DNA, lipid analysis and species identification, indicating a lack of awareness of the availability of such services.

Other needs respondents mentioned concerned easy access to MRC/CC material and services, e.g. the development of a culture deposit system accessible at any time, and the possibility for rapid information search and ordering by direct contact (e-mail) were suggested. Nearly half of the respondents also mentioned customized isolation, cultivation and preservation as very useful services. These specific needs will be taken into account when designing the MIRRI portal. Further analysis of the data provided by users in the surveys and at face-to-face meetings will guide MIRRI to map user needs and to prioritize on specific services. Furthermore, the MIRRI outreach strategy should tackle the lack of awareness that seems to exist among part of the microbial resource users about the various services offered by MRCs.

3.3. Clusters of expertise

Generally, the non-ECCO respondents have similar expertise as in public MRCs/CCs regarding microbial analyses (Figure 3.5). However, the majority of the surveyed laboratories are specialized in particular environments (46%) and/or taxa (42%), and some of them have expertise that is not (well) represented in public MRCs/CCs, such as phytoplasma identification, analysis of symbiotic properties, phage typing, and fungal virus detection. The knowledge associated with the resources in these non-public CCs can complement the expertise available in public MRCs/CCs, and would add value to the MIRRI Infrastructure in the form of consultancy services.



Figure 3.5. Expertise in microbial analyses in ECCO and non-ECCO-CCs (data from ECCO and non-ECCO-CC surveys)

Through the last survey dedicated to the MRC/CC users and the bio-industry, the expertise in the user community was also registered. Moreover, the respondents were explicitly asked if they were willing to act as an expert for MIRRI and nearly 250 agreed (of which 30% are profit users). Their fields of expertise include, e.g. agri-food, pharmaceutical microbiology, (industrial) biotechnology, proteomics, plant pathology, virology, fermentation, mycology, bioenergy, vaccines, microbial genomics, taxonomy, and enzymes.

Based on the feedback received from the surveyed stakeholders and other relevant aspects that should be covered by the infrastructure:

- taxonomic expert databases,
- R&D expert groups,
- experts on legal issues related to microbial resources,
- experts on risk assessment,
- experts on quality management and MRC standards,

microbial expertise in European MRCs/CCs, institutes, universities and companies with interest in MIRRI can be grouped into broad thematic clusters (Figures 4.1 and 4.2, see section 4).

Conclusions and recommendations about the MIRRI offer (resources, services and expertise)

MIRRI needs to integrate microbial resources and associated data, services and expertise.

With regard to resources, additional data on the taxonomic level of the publically available resources will be gathered in the next term of the project to identify complementarity and missing taxa. Based on this more detailed information, a workshop will be organized to decide on the minimum coverage that MIRRI should have to start as a RI and to elaborate plans to enlarge this offer. Priority groups will be ranked and a strategy for a more coordinated MIRRI accession policy developed. Further analysis of non-public holdings will determine if some of the identified priority groups could be covered by these laboratories in compliance with criteria developed for MIRRI membership.

The survey results allow mapping the availability of microbial services in Europe, providing the basis for an integrated MIRRI directory. Strategies to improve existing services and to design the common MIRRI service output need to be elaborated. Further analysis of the data is necessary to decide which services covered by non-public CCs could become part of the Infrastructure, and the kind of membership that is eligible for those laboratories willing to collaborate in MIRRI.

Clusters of expertise will be organized to cover the range of different important aspects including fields of research, regulations related to the use and access to microbial resources, biosafety and biosecurity, management, etc.

4. MIRRI consortium structure

4.1. MIRRI operational structure

MIRRI will be an organized network of resources based on the model of ERIC (European Research Infrastructure Consortium). There will be a Central Coordinating Unit (CCU) responsible for the following activities:

- Managing the technical aspects of MRCs
- Coordinating the infrastructure with other international initiatives
- Providing an intergovernmental forum on MRC issues
- Project development and management
- Technical issues for membership
- Outreach and publicity
- Organisation and delivery of capacity building programmes
- Central financing issues

The CCU will be linked to the National Nodes that bring together the participant MRCs/CCs in each country (Figure 4.1). In addition, functional transnational clusters (Figures 4.1 and 4.2) composed by expert groups will carry out different projects on behalf of MIRRI or will serve as consultancy platforms for users.







Figure 4.2. MIRRI National networks and clusters of expertise

4.2. MIRRI governance

In Figures 4.3 and 4.4 diagram representations of MIRRI governance are depicted.

EU member states, associated countries, third party countries and intergovernmental organizations can become MIRRI members after signing the MIRRI-ERIC MoU. The main obligations of member states are to provide direction in delivery of appropriate outputs and to provide funding aimed at developing capacity and quality at the national level.

The interaction between MIRRI-ERIC and the Partners (MRCs, CCs, experts, etc.) will be defined in a Partner Charter that has to be agreed between National Nodes and Partners. Similarly, users will have to comply to the terms of use in order to benefit from MIRRI resources or services.

The composition of the CCU will depend on the financial contribution of members and other funding sources but will have, at least, an Executive Director which, together with the Heads of the MIRRI MRCs/CCs, will constitute the executive secretariat. This body will coordinate the activities of the National Nodes and the institutions of associated members. Still to be decided is how these institutions of associated members from states that have not signed the MIRRI-ERIC can participate in the RI.

The activities of the CCU/executive secretariat will be defined and governed by a decision making Governing Board consisting of the MIRRI members (see above) and the Steering

Committee and guided by an Advisory Board. The Governing Board approves the budget and decides on membership issues.



Figure 4.3. MIRRI structure as ERIC. Financial implications and agreements

Page 30 of 82

4.3. MIRRI portal

The "User questionnaire" revealed that users request services that are already offered by public MRCs/CCs, indicating a lack of awareness of the availability of such services. Moreover, about 1/3rd of the participants responding to the "Innovative services questionnaire" declared to use microbial resources for their professional activities, but currently not order them from public MRCs/CCs. These are good indicators for the need to create an integrated portal including resources, data, services, legal framework and expertise in a higher level quality to better serve the user communities. To assess the level of interest of current and potential users in this envisioned MIRRI portal the "Innovative services" questionnaire was performed. This survey was designed in a specific way, informing the participants of the shortcomings and fragmentation of the current situation in Europe regarding accessibility of microbial resources, services and associated data, and presenting the improvement that MIRRI could offer in these respects (Annex 4).

A summarized diagram showing the main aspects of the portal is depicted in Figure 4.5. The user will have a unique access point to a broad range of microbial resources, their associated data and related services and expertise available in European MRCs/CCs and institutes. These will be delivered directly from the providing institutions belonging to MIRRI, which will have to comply with high quality standards and legal requirements. The national nodes will coordinate the activities, training and financial support to broaden and improve the offer.



Figure 4.5. MIRRI portal

4.4. Partner linkages and routes to harmonization

As explained above, MIRRI aims to be a distributed research infrastructure enabling resource holders to function together in a structured way. Existing partner linkages have been evaluated to identify their added value and study their participation in MIRRI or use them as models to create the different structures (CCU, National Nodes, etc.). Three different levels have been considered:

- National consortia of CCs/MRCs for coordinated function.
- Global/International directories or databases of CCs.
- Topic-driven projects/structures.
- Others.

National consortia of CCs / MRCs for coordinated function

The envisaged MIRRI distributed model will be a hub and spokes design consisting of the CCU as a central unit with national nodes bringing together the MRCs in each Member State (Figures 4.1 and 4.2). The CCU will provide a common access portal to resources available in Member States as well as directories of other services, thematic clusters, facilities, expertise, etc. The National Nodes will be the units to coordinate the activities of the MRCs/CCs within the country, to organise funding, to enhance the development of the national resource centres as well as to expand the national network. Establishing national nodes as a mandatory intermediary between interested microbial resource holders and the envisaged legal Infrastructure is a priority for MIRRI. In some countries, such nationally coordinated consortia already exist, in other countries, initiatives to build such networks of microbial resources holders are on going.

Several networks to coordinate the function of national MRCs/CCs in several countries were identified through the surveys (Table 4.1) although for some of them it was not possible to determine if they are still active. Experience from these existing networks will facilitate the establishment of the CCU and the National Nodes. From the networks listed in the table, the most active and coordinated ones seem to be the Belgian co-ordinated collections of micro-organisms (BCCM), the French Biological Resources Centres for Microorganisms (FBRCMi) and the United Kingdom National Culture Collection. In their respective countries, these networks can provide the fundamentals for the construction of the national nodes. For countries where this kind of consortia do not exist, they can be the mirror to look in.

It is worth highlighting the FBRCMi as a highly coordinated structure of French microbial resource holders. They have an integrated catalogue and the possibility of on-line ordering which are desired features for the MIRRI portal. The experience from this network can be used as a model for the design of the MIRRI portal.

Country	Name (Acronym)	Involved ECCO collections	Size of the network	Web page	Status
Belgium	Belgian co-ordinated collections of micro- organisms (BCCM)	BCCM-LMG; BCCM- IHEM; BCCM-LMBP; BCCM-MUCL; BCCM- DCG; BCCM-ITM; BCCM- ULC	7 CCs	bccm.belspo.be/	Currently active
Czech Republic	Federation of Czechoslovak Collections of Microorganisms (FCCM)	CCF; CCM; CNCTC	22 CCs	web.natur.cuni.cz/fccm/	Active?
Finland	Finnish Microbial Resource Centre Organisation (MICCO)	VTTCC; HAMBI	5 CCs	www.micco.fi/in-english	Active?
France	French Biological Resources Centres for Microorganisms (FBRCMi)	CIP-CRBIP; CRB- Oenologie; CRB-Leish; CIRM-BIA; CIRM-BP; CIRM-CF; CIRM-CFBP; CIRM-Levures	10 CCs	www.fbrcmi.fr/?lang=en	Currently active
	International Centre of Microbial Resources (CIRM)	CIRM-BIA; CIRM-BP; CIRM-CF; CIRM-CFBP; CIRM-Levures	5 CCs	www.inra.fr/en/crb-cirm	Currently active
	Biobanques	CIP-CRBIP; CRB-Leish; CIRM-BIA; CIRM-BP; CIRM-CF; CIRM-CFBP; CIRM-Levures	77 biobanks		Currently active
Italy	Italian Network of Genetic Resources (BioGenRes)		17 microbial CCs and other genetic resource centres	www.biogenres.cnr.it/	Currently active
UK	The United Kingdom National Culture Collection	CABI; CCAP; NCIMB; NCPPB; NCYC; NCPV	9 CCs	www.ukncc.co.uk/	Currently active

Table 4.1 National	networks of microbial	CCs identified through	iah the	nroviders surveys
	networks of microbia		agir the	

Global/International directories or databases of CCs.

At present, many CCs are members of international associations such as the European Culture Collections' Organization (ECCO), the World Federation of Culture Collections (WFCC), the Global Biodiversity Information Facility (GBIF), the Genomic Encyclopedia of Bacteria and Archaea (GEBA), etc. which promote the global integration of microbial biodiversity. They basically consist of strains, genomes and/or CCs directories accessible on line. They constitute a reservoir of information related to microbial resources where MIRRI can search for missed microbial resources, potential new members, etc.

Topic-driven projects/structures.

As explained in previous section 3.3, MIRRI foresees the creation of transnational clusters to address issues such as coverage of quarantine reference materials, perform geno- and phenotyping of resources or provide expertise at different levels (particular taxa or environment, methods, etc.). Looking at existing projects and networks can be the basis to harmonize or develop these kinds of clusters. Listed below are examples of several already existing structures and projects identified through the surveys:

Related with human and plant infections:

- German Centre for Infection Research (DZIF)
- Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens (QUANDHIP)
- Eva Virus Archive (EVA)
- European Plant Protection Organization (EPPO)
- Comprehensive database on quarantine plant pests and diseases (Q-bank)

Related with specific groups of microorganisms:

- International Phytoplasmologists Working Group (IPWG)
- The International Bank for the Glomeromycota (BEG)
- Spanish Network of Lactic Acid Bacteria (RedBAL)
- Réseau de Collections Françaises de Microorganismes d'Intérêt Laitier (Résomil)

Related with specific environments:

- Cryostress mechanisms of cellular adaptation to extremely low temperatures (KALT)
- Microbiome Influence on Energy balance and Brain Development-Function Put into Action to Tackle Diet-related Diseases and behaviour (MYNEWGUT)

Related with molecular and/or phenotypic carachterization of microorganisms:

- European Network of Laboratories for Sequence Based Typing of Microbial Pathogens (SeqNet)
- North-German Centre for Microbial Genome Research (NZMG)
- Réseau de Systématique, outil de caractérisation moléculaire et phénotypique d'organismes d'intérêts (R-SYST)

Others

To disseminate the surveys a database of microbial scientific associations was compiled and can be used to approach current and potential users for MIRRI outreach.

We also identified biotech networks like the European Federation of Biotechnology (EFB) or the European Enterprise Network (EEN) that provide a good link to connect with the bioindustry, a relevant sector with many MIRRI potential users.

Connections with other closely related ESFRI projects (EU-Openscreen, EMBRC or ELIXIR, ISBE, EMBRC, ERINHA, ELIXIR, EMTRAIN) are also being evaluated to determine potential common services and to look for synergies in view of applications for Horizon 2020 calls.

Conclusions and recommendations about the MIRRI consortium structure

Waiting only for a formal final decision it is anticipated that MIRRI will be implemented with a legal status under the ERIC regulation. With this basis, general operational and governance structures have been proposed and they are currently under discussion.

The MIRRI portal will be designed according to the needs and expectations of the users. Decisions on the holdings, data and services to include in MIRRI will be made in the second half of the project.

Compilation and study of existing networks, projects and associations that are related with microbial resources can be useful to build the national nodes, establish collaborations or develop clusters of expertise. Close interactions with the most relevant ones are recommended as they will help in the construction of the different MIRRI structures.

5. Membership criteria

As MIRRI will probably be constructed as an ERIC, EU Member states, associated countries, third countries, and intergovernmental organisations will constitute its legal entities. To participate in the consortium they must sign an agreement and contribute to the MIRRI budget. Nevertheless, there are other membership/partnership types, each related to the different types of stakeholders – other than States – involved in this Research Infrastructure. These may encompass e.g. the depositors who chose to deposit their microbial materials in a MIRRI resource centre, the academic or industrial users who chose to procure from a MIRRI resource centre the microbial material needed for their work, the experts who commit to contribute to the MIRRI expert platforms, the institutes who chose to offer their specialized laboratory microbial materials through MIRRI, etc. They all will have to comply with the MIRRI operational and legal framework for deposit and/or access to microbial resources by agreement with the terms of use.

However, the core of MIRRI will be the group of public MRCs/CCs willing and able to operate in a coordinated platform, and to offer high quality materials, services and expertise through the MIRRI portal. In this section, we will present the first steps to define the membership criteria for participant MRCs/CCs to reach the level of quality, sustainability and efficiency that will make the Infrastructure the desired tool for underpinning life sciences and biotechnology.

Criteria for MIRRI participant MRCs/CCs

Different sections of the "ECCO-CC questionnaire" were dedicated to determine the degree of compliance with the guidelines for the operation of a public MRC/CC as formulated by the WFCC² and especially by the OECD¹. Annex 5 documents the correlation between OECD guidelines and questions in the survey, and the corresponding tentative internal MIRRI criteria numbers.

The replies received from the 60 responding MRCs/CCs were evaluated in order to search for a balance between requirements imposed and the envisaged critical mass (in partners and in coverage), without jeopardizing quality, sustainability and efficiency.

From the full set of criteria given in Annex 5, a limited number of requirements are of core importance:

Regarding the quality of the microbial material

- 1. Checks for viability, purity, identification and authentication are performed
- 2. Accreditation/Certification
Regarding the sustainability of the collection and the securing of the material

- 3. Sustainability of the collection
- 4. Resources are preserved by two different methods
- 5. Maintenance of a duplicate collection in a separate building
- 6. Secured access to the collection stocks

Regarding biosafety and biosecurity issues

7. Risk assessment is performed on all material

Regarding digitized data and online catalogue

- 8. Standardization of the database structure and data formatting
- 9. An online catalogue in place, including most to all publically available resources from the collection

Regarding criteria resulting from CBD implementation

- 10. Material Accession Agreements include the Prior Informed Consent of the country of origin of the material
- 11. Information on depositor, geographical origin, and growth conditions are mandatory fields for each new deposit
- 12. Material Transfer Agreements refer to the country of origin of the biological material with respect to fair and equitable Benefit Sharing in case the recipient uses the material supplied for commercial purposes

Regarding traceability of the material

13. CC keeps record of distributed biological material and the respective recipients

In the present intermediate Deliverable, some particular cases of criteria versus partners and coverage are presented.

The number of ECCO CCs holding each organism type and the total number of items was compiled in Table 3.1. Table 5.1 summarizes the impact of some selected criteria on the content of MIRRI with relation to microbial material coverage.

Criteria number and content	Organism type Impact on MIRRI content	Filamentous fungi	Yeasts	Bacteria	Protozoa	Archaea	Micro-algae	Cyanobacteria	Phages	Viruses_animal	Viruses_human	Viruses_plants	Cell lines_animal	Cell lines_human	Cell lines_ plants	нувлаотаs_ animal	Genomic DNA	Plasmids
1 Quality checks after	Number of CCs complying	18	20	22	4	4	8	8	5	1	2	2	4	4	1	2	9	4
preservation	% of items retained	91	76	60	100	84	88	64	94	100	32	100	100	100	100	100	89	30
2 Certification and/or	Number of CCs complying	13	15	17	1	4	1	2	4	0	2	1	2	2	1	1	10	5
	% of items retained	71	44	75	4	93	20	36	20	0	95	87	77	94	100	51	89	98
	Number of CCs complying	9	9	10	1	2	1	2	2	0	1	1	2	2	1	1	7	3
Combined 1 and 2	% of items retained	69	41	43	4	77	20	36	16	0	27	87	77	94	100	51	87	29
5 At least part of	Number of CCs complying	13	17	22	1	6	5	5	5	0	2	1	2	2	1	1	9	6
collection in separate building and 6 secured access to stocks	% of items retained	73	56	62	4	100	33	49	23	0	95	87	77	94	100	51	87	98
8 Structured database	Number of CCs complying	17	23	26	3	7	6	8	8	1	3	2	3	3	1	2	12	7
and formatted data and 9 more than 1/2 of items online	% of items retained	22 - 44	36 -72	47 - 93	2 - 4	50 - 100	42 - 83	48 - 95	50 - 100	50 - 100	50 - 100	50 - 100	47 - 93	49 - 98	50 - 100	50 - 100	47 - 93	50 - 100
10 MAA refers to PIC	Number of CCs complying for each organism type	19	19	19	2	6	5	6	6	0	1	1	1	1	1	1	10	1
or country or origin	% of items retained	57	63	72	4	99	61	50	91	0	27	87	45	69	100	51	66	16
																<u> </u>	<u> </u>	<u> </u>
12 MTA refers to country of origin for	Number of CCs complying for each organism type	17	21	18	3	4	6	7	4	0	2	1	1	1	1	1	10	5
commercial use	% of items retained	71	65	67	4	74	83	91	17	0	95	87	45	69	100	51	87	31
Combined 10 and 12	each organism type	12	13	10	2	3	5	5	2	0	1	1	1	1	1	1	6	3
	% of items retained	38	42	48	4	74	61	46	8	0	27	87	45	69	100	51	52	13

 Table 5.1. Impact of combined tentative criteria on the content of MIRRI. Red: Below 33% of items retained.

Orange: 33-67% of items retained. Green: Above 67% of items retained.

The quality of the microbial material (criteria 1 and 2, Table 5.1)

For most microbial resources, best guarantee for good quality of the material to be supplied, is to check viability, purity, and authenticity or identity, after preservation (criteria 1). *If this set of criteria is imposed, 39 out of the 60 ECCO CCs comply, encompassing the majority of each of the different microbial resource types available, except for the human viruses, plasmids and DNA libraries.* For the latter two material types, the relevance of these controls should be discussed among experts.

Quality management is considered today as a standard investment. For MRCs/CCs, the most frequently implemented third party assessed quality systems are ISO 9001 certification of the quality management (24 CCs), and/or ISO 17025 accreditation of specific analyses (11

CCs). Since accreditation encompasses to some extent the quality management as well, the MRCs/CCs can be scored for either (criteria 2). *If certification or accreditation is imposed, less than half (27) of the ECCO CCs comply, excluding half of the yeasts and hybridomas, the majority of protozoa, microalgae, cyanobacteria and phages, and all animal viruses.*

It should be noted that 10 CCs are certified/accredited, but do not perform viability, purity or authenticity/identification controls of their material after preservation.

If the above aspects dealing with quality (quality controls and certification/accreditation, criteria 1 + 2) would be required in combination, only 17 ECCO CCs comply, excluding in addition CCs keeping bacteria, yeast, fungi, and human viruses.

The sustainability of the collection and the securing of the material (criteria 5 and 6, Table 5.1)

Twelve ECCO CCs anticipate that their current main funding source will significantly decrease in the next three years, whereas an additional 8 CCs do not know. The other 40 CCs are confident about their sustainability for at least the coming three years. As support by the respective governments will be a major aspect of the MIRRI legal structure (ERIC), *this criterion is left out of the assessment at this stage of the project.*

Storing a duplicate collection in a separate building (criteria 5) is one of the measures CCs can take to secure their material. *If this way of working is imposed, only 13 out of the 60 ECCO CCs fully comply as they currently apply this on their whole collection, whereas an additional 21 CCs apply this on at least a specific part.*

All of these 34 CCs have also installed a secured access to their stocks (criteria 6). *Excluding the remaining 26 CCs would affect quasi half of the yeasts, bacteria, cyanobacteria and animal hybridomas, most of the protozoa, microalgae and phages, and all animal viruses.*

Applying more than one preservation method is advised to assure viability of the stored microbial material over time. *Most (52) ECCO CCs invest in this effort. Of the other 8 CCs, 6 maintain material that is probably not suitable for preservation by more than one of the current techniques, hence probably only 2 CCs would be excluded by this criterion.*

Digitized data and online catalogue (criteria 8 and 9, Table 5.1)

Standardized database structure and data formatting (criteria 8) are conditions for easy data search and eventual data integration, and the majority (48) of the ECCO-CCs implement these today.

All except 1 of the 60 ECCO CCs have an online catalogue (criteria 9), but in only 44 cases this online catalogue contains more than half of the microbial materials of their public collections.

If the above criteria (8 + 9) are considered as requirements for CCs setting up MIRRI in an early stage, 37 CCs comply, excluding mainly yeast, filamentous fungi and protozoa.

Criteria resulting from CBD implementation (criteria 10 and 12, Table 5.1)

For MRCs/CCs membership/partnership, compliance with the CBD/Nagoya protocol will be one of the requirements. Although translation of CBD/Nagoya protocol into European directives is ongoing, MRCs/CCs can already be assessed in this respect, by their current practice with regard to Access and Benefit Sharing (ABS).

The majority (50) of the ECCO CCs indicate to use a Material Accession Agreement (MAA), but only 32 apparently refer in this document to the Prior Informed Consent (PIC, criteria 10) issued by the country of origin of the material to be deposited (it should be noted that for some material types this is not a relevant criterion). Of these 32 CCs, 6 claim not to accept deposits without this PIC. *Without considering material type and validity of this criterion, today, this criterion would exclude mainly collections of animal cell lines and hybridomas, animal and human viruses, protozoa, and plasmids, but would affect also filamentous fungi, microalgae and cyanobacteria collections.*

Referring customers to the fair and equitable Benefit Sharing with the country of origin of the microbial material procured, in case of its commercial use (criteria 12), is effectuated by the Material Transfer Agreement (MTA) of 30 of the 60 ECCO CCs, and whereas 14 CCs consider this is not applicable. *Without considering material type and validity of this criterion, today, this criterion would exclude mainly collections of animal cell lines and hybridomas, animal and human viruses, protozoa, and plasmids, but would affect also filamentous fungi, microalgae and cyanobacteria collections.*

If the above combined criteria (10 + 12) are considered as a requirement, today only 19 ECCO CCs comply. Except for animal viruses, all other material types are covered, although most only to a limited extent.

Conclusion and recommendations about membership criteria

The OECD BPGs for BRCs provide elements for criteria for MRCs/CCs that apply for MIRRI membership/partnership.

For this report, only a limited number of possible criteria for MIRRI membership/partnership, as extracted from these OECD guidelines for BRCs, have been considered. Even so, today several ECCO-CCs do not yet comply with one or more of this limited set of tentative criteria, resulting in only 4 CCs with overall compliance. Nevertheless, some of the criteria that are not yet fulfilled by more than half of the CCs are easy to implement, like those related to risk assessment or CBD implementation, which can be achieve following recommended protocols and introducing changes in related documents, respectively. Taking out these criteria 12 additional CCs would easily comply with the most relevant requirements.

There are 2 relevant criteria (quality management and separated duplicate of the collection) not implemented in most CCs that would have financial implications. Regarding Quality management, at least most collections have a Quality Management Policy, although more than half are not accredited or certified and do not have a quality manager. MIRRI can help in the implementation of Quality Management Systems in these collections but they or their respective countries will have to assume the costs related to the external audits and maintenance of the System. In relation to the preservation of a copy of the collection in two separated buildings, at least most collections declared to comply for a specific part of the collection, but there are not many that fulfill with this requirement for the vast majority of the strains. There has to be considered that many resources are already duplicated in different collections, as for example the type strains of newly described bacteria that have to be deposited in two different CCs to be accepted for publication. Other examples are the reference strains for quality control, which are part of the catalogues of many MRCs. One important challenge for MIRRI will be the harmonization and rationalization of the resources held by different partners, which may include preserving duplicates in different collections, instead of having the duplicate in different buildings of the same institution.

In the second half of this preparatory phase, a workshop will be organized to discuss the tentative criteria, to agree on their respective importance, and to select the mandatory ones for MRCs/CCs applying for MIRRI membership/partnership, in collaboration with all other WPs of the project. In addition, protocols for risk assessment need to be elaborated to help partners comply with this specific set of criteria. MIRRI should also provide harmonized templates for documents such as MTA, MAA, deposit form, etc. in order to ensure compliance with regulations like ABS and CBD.

Abbreviations

- ABS Access and Benefit Sharing
- BPG Best Practice Guidelines
- BRC Biological Resource Centre
- CC Culture Collection
- CCU Central Coordinating Unit
- EC European Community
- ECCO European Culture Collections' Organization
- EEN European Enterprise Network
- EFB European Federation of Biotechnology
- ERIC European Research Infrastructure Consortium
- ICT Information and Communication Technology
- IDA International Depository Authority
- MIRRI Microbial Resources Research Infrastructure
- MRC Microbial resource centre
- OECD Organization for Economic Co-operation and Development
- PIC Prior Informed Consent
- WFCC World Federation of Microbial Collections
- WIPO World Intellectual Property Organization

References

1. OECD BPGs for BRCs. http://www.oecd.org/sti/biotech/38777417.pdf

2. WFCC guidelines for the establishment and operation of collections of cultures of microorganisms. <u>http://www.wfcc.info/guidelines/</u>

Annex 1: ECCO-Culture Collection questionnaire

MIRRI Statement on use, access and protection of collected data

1. Do you accept the MIRRI Statement on use, access and protection of collected data? [Y; N]

General information

2. Give the full name and address of your Culture Collection (CC). [Full name; Acronym; Address; City/Town; State/Province; ZIP/Postal Code; Country]

3. Give the webpage of your CC.

4. Give the name, email address and telephone number of the managing director of your CC. *[Name; Email Address; Phone Number]*

5. Give the name, email address and telephone number of the person of your CC authorized to discuss the function and the content of MIRRI and the possible participation of your CC in the MIRRI Infrastructure. [Name; Email Address; Phone Number]

6. Give the registration number of your CC at the World Data Centre on Microorganisms (WDCM), if applicable.

7. Give the name of the Institution hosting your CC, if applicable.

8. Indicate the kind of institution hosting your CC, if applicable. [University; Government; Hospital; Company; Other (specify)]

9. Indicate the legal authority over your CC's biological material and activities. [The CC itself; The host Institute; Do not know; Other (*specify*)]

10. Give the name, email address and telephone number of the person authorized to represent your CC to discuss legal aspects with regard to possible participation of your CC in the MIRRI infrastructure. *[Name; Email Address; Phone Number]*

11. Is your CC recognized by the World Intellectual Property Organization as an International Depositary Authority for patent purposes? [*Y*; *N*]

Biological resources - general

12. Indicate the scopes applicable for the biological material present in your CC. [Broad-scope; Agronomy; Bioremediation; Chemical; Environmental; Food & Feed; Pharma & Medical; Taxonomy; Veterinary ; Other (specify)]

13. For each type of biological material present in your CC specify the total number of holdings. [Archaea; Bacteria; Cell lines_animal; Cell lines_human; Cell lines_ plants;

Cyanobacteria; Filamentous fungi; Genomic DNA; Hybridomas_animal ; Hybridomas_human; Lichens; Micro-algae; Phages; Plasmids; Protozoa; Viruses_animal; Viruses human; Viruses plants; Yeasts; Other (specify)]

14. For each type of biological material present in your CC estimate the portion isolated from sources/substrates in the EU (including associated countries and overseas territories). [Archaea; Bacteria; Cell lines_animal; Cell lines_human; Cell lines_ plants; Cyanobacteria; Filamentous fungi; Genomic DNA; Hybridomas_animal ; Hybridomas_human; Lichens; Micro-algae; Phages; Plasmids; Protozoa; Viruses_animal; Viruses_human; Viruses_plants; Yeasts; Other (specify)]

- > None
- Some
- About half
- > Most
- ≻ All

15. If your CC is specialized, e.g. in particular taxa and/or habitats, please list these specializations.

Biological resources – Preservation and storage

16. To what extent are the listed preservation methods used by your CC to preserve the biological material present in your CC (during the past five years)? [Agar culture; Freezedrying; Freezing above -70°C; Freezing between -70 and -140°C; Freezing in liquid N₂; Liquid-drying; Mineral oil; Water; Other (specify)]

- Not used
- Occasionally used
- Frequently used
- Nearly always used

17. In order to improve the maintenance of the biological material of your CC, which additional preservation method(s) would you like to implement in the future? [None; Freezedrying; Freezing above -70°C; Freezing between -70 and -140°C; Freezing in liquid N_2 ; Liquid-drying; Other (specify)]

18. What do you need to implement the required additional preservation techniques? [Human Resources; Infrastructure; Equipment; Expertise; Other (specify)]

> Very low priority

- Low priority
- Moderate priority
- > High priority
- Very high priority

19. Does your CC apply more than one preservation technique on the biological material in your CC? [Yes, on all holdings; Yes, on the vast majority of holdings; Yes, on a specific part of holdings; No]

20. Does your CC maintain in a separate building duplicates of the biological material? [Yes, for all holdings; Yes, for the vast majority of holdings; Yes, for a specific part of holdings; No]

Biological resources – Deposit

21. Are conditions for deposit of biological material at your CC determined, agreed and laid down in an agreement with the depositor? [*Y*; *N*]

22. Does this agreement with the depositor refer to the Prior Informed Consent (PIC) of the country of origin of the biological resource as described in the Convention on Biological Diversity (CBD)? *[Y; N]*

23. Does your CC currently accept new deposits without PIC or any other proof of permission by local authorities in the country of origin of the biological resource for collecting the material from nature? [Yes, always; Yes, only if the name of the country of origin is provided; No]

24. Has your CC ever experienced that requirements are imposed by the depositors with regard to the supply of samples by the CC? If yes, please specify. *[No; Yes (specify)]*

Biological resources – Supply of samples

25. Are conditions for the supply of samples by your CC determined, agreed and laid down in a material transfer agreement with the recipient of the samples (MTA for supply of samples) [Yes, always; Yes, for some holdings or in specific cases; No]

26. If your CC uses an MTA for supply of samples, is this MTA complying with the ECCO core MTA? [*Fully; Partially; Not at all (specify)*]

27. In case the recipient uses the biological material, supplied by your CC, for commercial purposes, does your CC refer the recipient to the country of origin of the biological material with respect to fair and equitable Benefit Sharing? [Yes ; No; Not applicable (specify)]

28. In case of commercial use of the biological material supplied by your CC, does your CC consider to negotiate participation in the benefit? [Yes ; No (specify); Not applicable (specify)]

29. Did your CC experience problems in relation to the following topics of the MTA? [Intellectual Property Rights (IPR); Commercial use; Benefit sharing; Jurisdiction; Other (*specify*)]

30. Does your CC keep record of which biological material is distributed, and of the respective recipients? [*Y*; *N*]

Finances

31. Please estimate the portion of the total funding that your CC received from different funding sources to cover all operational aspects (on average over the past five years). [Government; Private; Host institution; Own revenues; Research grants; Other (specify)]

- > None
- > Some
- About half
- > Most
- > All

32. For each funding source, what are your expectations for the coming three years? [Government; Private; Host institution; Own revenues; Research grants; Other]

- Increase
- Maintain
- > Decrease
- > Don't know

33. Estimate the portion of total funding spent to cover the different operating costs (on average over the past five years). [Consumables; Personnel; Equipment (including maintenance costs); Infrastructure]

- > None
- > Some
- About half
- > Most
- > All

Personnel

34. How many Full Time Equivalents are currently allocated to your CC for the different job types? [CC manager; Curators; Researchers; Technicians; Administratives; IT; Quality manager; Other (specify)]

35. What is the education level of the personnel allocated to your CC? Please indicate the Full Time Equivalents for each level. [No training in microbiology; Laboratory technician; University degree; PhD degree; Other (specify and give the number)]

36. How many persons are working exclusively for your CC activities?

37. How many of the persons working exclusively for your CC have indefinite contract or permanent position?

38. Do you consider that external job-specific training is necessary for some of the personnel currently allocated to your CC? In which areas? [No training needed; Quality Management; IT; Characterization of the biological resources; Preservation of the biological resources; Other (specify)]

Quality management

39. Does your CC have a Quality Management Policy? [Y; N]

40. Does your CC measure satisfaction levels of the users? [Y; N]

41. Does your CC have a documented procedure about user complaint management? [*Y*; *N*]

42. Which accreditation(s) does your CC have? [*None; ISO 17025; ISO Guide 34; Other (specify)*

43. Which certification(s) does your CC have? [None; ISO 9001; ISO 14000; Other (specify)]

44. Which quality control checks are carried out upon receipt of the biological material at your CC? [*Viability; Purity; Identification (to confirm genus and species); Authentication (to confirm some original features or properties)*]

45. Which quality control checks are carried out after preservation of the biological material at your CC? [*Viability; Purity; Identification (to confirm genus and species); Authentication (to confirm some original features or properties)*]

Informatics

46. To what extent are the daily operations of your CC computerized? [Catalogue editing; Customers data; Order processing; Sample stock management; Invoice editing; Other (specify)]

Not yet

- > Hardly
- Partially
- ≻ Fully

47. For the following tasks, has your CC access to a specialist? [For hardware-software maintenance; For CC databases management; For website management; For software development]

- > Yes, in own CC staff
- > Yes, in host Institution
- Yes, outsourced
- > No

48. Is there a backup procedure in place for the database(s) of the CC? [Y; N]

49. Which guidelines/standards regarding database structure and/or data formatting does your CC take into account? [*No standard is followed; Standardized but not following a specific guideline; Microbial Information Network Europe (MINE); OECD Best Practice Guidelines; CABRI guidelines for catalogue production; Access to Biological Collections Data (ABCD); Microbiological Common Language (MCL); Other (specify)]*

50. Does your CC perform regular curation of the data concerning the biological resources? [*No;* Yes, using standard operating procedures (SOPs); Yes, using controlled vocabularies (agreed unambiguous terms); Yes, considering inconsistencies with other CCs' data; Yes, using other approaches (specify)]

51. In which format(s) is the information on the biological resources presented to the CC's users? [Hardcopy; CD-DVD; Online]

52. If the information on the biological resources is presented online, which of the following tools do you implement? [Display online (no download or applications); Download from website_open access; Download from website_restricted access (user account required); File Transfer Protocol (FTP-server); Web services (REST, SOAP); Workflows (Taverna, Galaxy); Application Programming Interface (API); Semantic Rich Technologies (e.g. Semantic Web, Linked Open Data); Other (specify)]

53. If applicable, estimate the percentage of the publically available biological material that is presented in your online catalogue. [0%; 1-25%; 26-50%; 51-75%; 76-99%; 100%]

54. If the information on the biological resources is presented online, is your online catalogue integrated into other public web tools? [No; Common Access to Biological Resources

and Information (CABRI); StrainInfo; Global Biodiversity Information Facility (GBIF); World Data Centre for Microorganisms (WDCM); Global Catalogue of Microorganisms (GCM); Other (specify)]

55. Which subjects regarding the biological material are covered in the CC database(s), which ones are displayed online and which ones are mandatory to accept a deposit? [Scientific name; Authors of the scientific name; Year of publication of scientific name; Type strain status; Isolator; Depositor; History (from isolation to arrival at the CC); Accession number(s) in other CC(s); Geographic origin; Substrate from which the biological material was isolated; Date of sampling; Date of isolation; Growth conditions; Pathogenicity; Quarantine status in Europe; Dual-use status; Patent references; Date of deposit in the CC; Gene sequences; Literature References; Morphology; Photos, images, pictures; Physiological and biochemical properties; Applications; Other (specify)]

- In the database
- Displayed online
- > Mandatory for acceptance of a deposit

Biosecurity

56. Is the physical access to the collection stocks secured (locked storage / access control / telesurveillance...)? [*Y*; *N*]

57. Does your CC host microorganisms for which the use and/or distribution are governed by (inter)national regulations? [*No* ; *Dual-use; Quarantine; GMO; Not aware*]

58. Are you aware of the Code of Conduct on Biosecurity for Biological Resource Centres (BRCs)? [*Y*; *N*]

59. Does your CC conduct risk assessments of the biological material present in the collection to implement appropriate biosecurity measures? [No; Yes, on all material; Yes, on specific material; Not applicable]

60. Does your CC conduct a risk assessment to assign the biological material present in the collection to the biosecurity risk levels "high", "moderate", "low" or "negligible", according to the OECD Biosecurity guidelines? [*Y*; *N*]

Biosafety

61. Does your CC have a deputy/expert/responsible person who keeps the CCs export control regimes up-to-date? [*Y*; *N*]

62. What is the highest containment level implemented in your CC? [L1, L2, L3, L4]

63. Indicate which of the following package regulations your CC applies. [None; IATA PI 650 - ADR P 650 (UN 3373 for biohazard group 2, human & animal); IATA PI 602 - ADR P 620 (UN 2814/UN 2900 for biohazard group 3, human & animal); Other (specify)]

64. For which biological material does your CC ask a certificate/declaration/permit from the end-user, regarding the use of the material and/or the suitability of the infrastructure for handling the material ordered? [Biohazard group 1; Biohazard group 2; Biohazard group 3; GMO; Quarantine; Dual Use]

- Always
- In some cases
- > Never
- Not applicable

Networks

65. Is your CC member of national networks/associations? If yes, please specify (avoid acronyms) and, if possible, provide URL.

66. Is your CC member of international networks/associations? If yes, please specify (avoid acronyms) and, if possible, provide URL.

Operational guidelines

67. Is your CC aware of the existence of the World Federation for Culture Collection (WFCC) 'Guidelines for the establishment and operation of Culture Collections of Microorganisms'? *[Y; N]*

68. If your CC is aware of the existence of the WFCC guidelines, to what extent does your CC comply? [*Fully; Partially; Hardly; Not yet*]

69. Is your CC aware of the existence of the OECD 'General best practice guidelines for Biological Resource Centres'? [*Y*; *N*]

70. If your CC is aware of the existence of the OECD best practice guidelines for biological resource centres, to what extent does your CC comply? *[Fully; Partially; Hardly; Not yet]*

71. Is your CC aware of the existence of the CABRI guidelines? [Y; N]

72. If your CC is aware of the existence of the CABRI guidelines, to what extent does your CC comply? [*Fully; Partially; Hardly; Not yet*]

73. If your CC complies with other international operational guidelines, please specify.

Users (average over the last five years)

74. Concerning your CC users from the non-profit sector: estimate for each category listed the corresponding portion of your users. [Universities, Research Institutes & Schools; Hospitals; Control & Reference analyses Laboratories; Other (specify)]

- > None
- > Some
- About half
- > Most
- ≻ All

75. Concerning the users from the profit sector: estimate for each category listed the corresponding portion of your users. [*Agronomy*; *Bioremediation*; *Chemical*; *Environmental*; *Food* & *Feed*; *Pharma* & *Medical*; *Veterinary Other* (*specify*)]

- > None
- > Some
- About half
- Most
- ≻ All

76. From which country are the users of your CC? [Same country as the CC; Other European country; Country outside Europe]

- > None
- > Some
- About half
- > Most
- ≻ All

Services offered

77. Which services regarding deposit of biological material does your CC offer? [*Public deposit; Safe deposit; Deposit for patent purposes (IDA Budapest Treaty)*]

78. In which formats can biological material be supplied by your CC?[*Dried; Frozen; Active culture; Genomic DNA; Other (specify)*]

79. In which of the following has your CC staff expertise, which is at present offered as a service by your CC staff, and which does your CC intend to implement in the future?

[Isolation of pure cultures; Microbial count; Identification; Phylogenetic studies ; Phenotypic characterization; DNA sequencing; Whole genome sequence data analysis; Gene sequence data analysis; RNA sequencing; Plasmid profile analysis of bacteria; Sequence analysis of non-characterized plasmids; DNA-DNA hybridization; Pulsed-field gel electrophoresis; RAPD; AFLP; Ribotyping; Real-time PCR; Serotyping; Fatty acid profiling (FAME-MIDI); MALDI-TOF; Polar lipids determination; Metabolite production; Enzyme production; Pathogenicity tests; Antibiotic sensitivity tests; -omics; Screening for specific properties; Other (specify)]

- > Expertise
- > Offered as service
- > Intend to implement

80. Which other services are offered by your CC? [Screening of the biological materials of the CC; Training; Consultancy; Other (specify)]

81. Which research areas are covered by your CC staff members? Indicate for each the corresponding portion of the total research effort. [*Agronomy; Bioremediation; Chemical; Environmental; Food & Feed; Pharma & Medical; Veterinary; Other (specify)*]

- > None
- > Some
- About half
- > Most
- > All

82. What is the total number of peer reviewed papers over the last five years in which one or more staff members of your CC are authors?

83. Is your CC involved in externally funded research projects? [Y; N]

84. If yes, which are the funding sources? [International non-EU; EU; National]

Annex 2: Non-ECCO Culture Collection questionnaire

MIRRI Statement on Use, Access and Protection of collected data

 Do you agree with the MIRRI Statement on Use, Access and Protection of collected data? [Y; N]

General information

2. Give the full name and address of the Unit (department, laboratory, research group, section, etc.) holding the collection. [*Full name of the Unit; Address; City/Town; ZIP/Postal Code; Country; Acronym used for the collection (if applicable)]*

3. Give the webpage of the Unit holding the collection, if applicable.

4. Give the name, email address and telephone number of the managing director/responsible person of your collection. *[Name; Email Address; Phone Number]*

5. If different from above, give the name, email address and telephone number of the person of your Unit authorized to discuss the function and the content of MIRRI and a possible collaboration between your Unit and the future MIRRI Infrastructure. *[Name; Email Address; Phone Number]*

6. Give the name of the Institution to which your Unit belongs.

7. Indicate to which category the Institution belongs. [University; Government; Hospital; Public Health Laboratory; National Reference Laboratory; Company; Other (specify)]

8. Indicate the legal authority over the biological material in the collection. [*The Institute; Do not know; Other (specify)*]

Holdings

9. For each type of biological material present in your collection specify the total number of holdings. [*Archaea; Bacteria; Cell lines_animal; Cell lines_human; Cell lines_ plants; Cyanobacteria; Filamentous fungi; Genomic DNA; Hybridomas_animal; Hybridomas_human; Lichens; Micro-algae; Phages; Plasmids; Protozoa; Viruses_animal; Viruses_human; Viruses_plants; Yeasts; Prokaryotic consortia; Eukaryotic consortia; Mixed consortia (Prokaryotic/Eukaryotic); Other (specify and give the number)]*

10. What is the highest biosafety containment level implemented to handle your collection? *[L1 (to handle biohazard group 1 organisms); L2 (to handle biohazard group 2 organisms); L3 (to handle biohazard group 3 organisms); L4 (to handle biohazard group 4 organisms); Not applicable]*

11. Is your collection specialized, e.g. in particular taxa and/or habitats? If yes, please list these specializations (e.g. Campylobacter, extremophiles, plant or soil associated microorganisms ...). [Specialized in particular taxa (specify); Specialized in particular environments (specify); Specialized in particular microbial function or applications (specify); Specialized in other aspects (specify); Not specialized/general collection; I don't know]

List specializations: [free text]

12. In your opinion, does your collection contain species/genera that are not well represented in public Culture Collections? If yes, please list them. [*N*; *Y* (*list them*)]

13. Indicate the scopes applicable for the biological material present in your collection. [Broad-scope; Agronomy; Bioremediation; Chemical; Environmental; Food & Feed; Pharma & Medical; Veterinary; Taxonomy; Other (specify)]

14. What is the rationale behind building and maintaining the collection? [free text]

Expertise

15. In which of the following subjects has your Unit strong and sustainable expertise, and which of these expertises are offered as a service to third parties? [Isolation of pure cultures; Microbial count; Identification; Phylogenetic reconstructions based on molecular data; DNA sequencing; Whole genome sequence data analysis; Gene sequence data analysis; RNA sequencing; Plasmid profile analysis of bacteria; Sequence analysis of non-characterized plasmids; DNA-DNA hybridization; Pulsed-field gel electrophoresis; RAPD; AFLP; Ribotyping; Real-time PCR; Serotyping; Fatty acid profiling (FAME-MIDI); MALDI-TOF; Polar lipids determination; Metabolite production; Enzyme production; Pathogenicity tests; Antibiotic sensitivity tests; Screening for specific properties of the biological materials of your collection; Cell wall composition; ANI (Average Nucleotide Identity Analysis); Training; Consultancy; Other specific expertise (specify)]

- > Strong expertise
- Offered to third parties

16. Indicate which research areas are covered by the staff members of your Unit. [Agronomy; Bioremediation; Chemical; Environmental; Food & Feed; Pharma & Medical; Veterinary; Taxonomy; No Research; Other (specify)]

17. How important is the collection for the future of your Unit's research? [Very important; Important; Moderately important; Of little importance; Unimportant]

Sustainability

18. Is the future of the collection in danger? If Yes, please specify why (e.g. lack of funding, retirement of the responsible scientist/director, etc.). [*N*; *Y* (*specify why*)]

19. In order to avoid loss of the biological material, would fostering the holdings (most important strains/items) in a consolidated/public collection be something that would interest you? [*Y*; *N* (specify why not)]

20. Is the collection of your Unit part of national or international networks? If yes, please specify (avoid acronyms) and, if possible, provide the link to their website. *[No; Y (specify)]*

21. Are you willing to associate with national or international networks, such as the future MIRRI, to make biological material from your collection available to third parties? [Y; N]

Biological resources - Characterization and preservation

22. Up to which level are your holdings identified? Indicate for each level the portion of your holdings identified. [At (sub)species level; Only at genus level; Only at level of higher taxonomic ranks; No taxonomic identification]

- > None
- > Some
- About half
- > Most
- ≻ All

23. Are your holdings characterized in terms of functionalities, serology, pathogenicity, molecular discrimination of strains, etc.? Indicate for each type the portion of your holdings characterized. [Functionalities (production of metabolites, enzymatic activity, degradation of substrates, etc.); Serology; Pathogenicity; Molecular typing at strain level; Other (specify)]

- > None
- Some
- About half
- > Most
- > All

24. Which methods are used to preserve the biological material in your collection? [Active culture; Freeze-drying; Liquid-drying; Freezing above -70°C; Freezing between -70 and - 140°C; Freezing in/over liquid N₂; Mineral oil; Water; Other (specify)]

Not used

- Occasionally used
- Frequently used

25. Is the same material preserved by more than one method? [Yes, for all holdings; Yes, for the vast majority of holdings; Yes, for a specific part of holdings; No]

26. Which of the next characteristics do you generally check after preservation? [*Viability; Purity; Taxonomic Identification; Original features; None*]

Biological resources - Supply of samples

27. Are the resources of the collection shared with third parties (outside the Laboratory Unit)? [*No;* Yes, upon simple request; Yes, but only in specific cases (specify)]

29. Are you aware of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (CBD)?

28. To which third parties do you provide samples from your collection? [Universities, Research Institutes & Schools; Hospitals; Control & Reference Laboratories; Industry; Other (specify)]

- > None
- > Some
- > Most

30. Will the entry into force of the CBD Nagoya Protocol on Access and Benefit Sharing change the operation of your collection? [Yes; No; This is unclear to us]

Personnel

31. Estimate the total Full Time Equivalents on average per year involved in the management and maintenance of your collection. [free text]

32. Which external training do you consider necessary for better management/maintenance of your collection? [No training needed; Quality Management; IT; Characterization of the biological resources; Preservation of the biological resources; Legal matters and international regulations; Other (specify)]

Quality Management Systems

33. Does your Unit have a Quality Management Policy? [Y; N]

34. Which Quality Management System(s) does you Unit have that apply to the material in the collection? [None; ISO 17025; ISO Guide 34; ISO 9001; ISO 14000; Other (specify)]

Informatics

35. Do you maintain an inventory/database of the biological material in your collection? [Yes, *in a database program; Yes, in an electronic file; Yes, on paper; No*]

36. Which subjects regarding the biological material are covered in the inventory/database(s) and which ones are available online? [Scientific name; Authors of the scientific name; Year of publication of scientific name; Type-strain status; Accession number(s) in public culture collection(s); Geographic origin of the biological material; Date of sampling; Substrate from which the biological material was isolated; Isolator; Date of isolation; Depositor; Date of deposit in the culture collection; History (from isolation to arrival at the culture collection); Growth conditions; Pathogenicity; Quarantine status in Europe; Dual-use status; Morphology; Photos, images, pictures; Gene sequences; Physiological and biochemical properties; Applications; Patent references; Literature References; Other (specify)]

- In the database
- > Online

Annex 3: User questionnaire

MIRRI Statement on use, access and protection of collected data

1. Do you accept the MIRRI Statement on use, access and protection of collected data? [Y; N]

2. Do you want to answer this questionnaire anonymously? [Y; N]

General Information

3. Give the full name of your Organization.

4. Give the name of the Department or Section in which your laboratory is included within the Organization, if applicable.

5. Give the full name and complete address of your Laboratory unit. [Full name; Address; City/Town; State/Province; ZIP/Postal Code; Country]

6. Give your name, function, email address and phone number. [Name; Function; Email Address; Phone Number]

7. If different from the person filling in this questionnaire, give the name, function and contact information of the appropriate person to discuss your Laboratory unit's future needs regarding microbial resources and related services. *[Name; Function; Email Address; Phone Number]*

User profile

8. To which sector does your Organization belong? [Profit sector; Non-profit sector]

9. In case your Organization belongs to the profit sector, what is the size of your enterprise? [*Micro-enterprise (less than 10 employees); Small to Medium size enterprise (between 10 and 250 employees); Large enterprise (more than 250 employees)*]

10. In case your Organization belongs to the non-profit sector, to which organization type does your Organization belong? [University; School; Hospital; Control or Reference Analyses laboratory (e.g. health, diagnostic, inspection, official controls); Research Institute; Foundation; Other (specify)]

11. To which field of activity does your Laboratory unit belong? [Research & Education; Agronomy; Bioremediation; Chemical; Environmental; Food & Feed; Pharma & Medical; Veterinary; Other (specify)]

12. Which kind of microbial/genetic resource(s) does your Laboratory unit use at present (the past five years), and/or might use in the future (the next five years)? [Archaea; Bacteria; Cell lines_animal; Cell lines_human; Cell lines_ plants; Cyanobacteria; Filamentous fungi;

Genomic DNA; Hybridomas_animal; Hybridomas_human; Lichens; Micro-algae; Phages; Plasmids; Protozoa; Viruses_animal; Viruses_human; Viruses_plants; Yeasts; Other (specify)]

- Used in the past five years
- Intend to use in the next five years

13. For which application(s) does your Laboratory unit use microbial/genetic resources at present (the past five years), and/or might use in future (the next five years)? [Fundamental research; Research & Development; Commercial applications; Diagnostics; Quality control; Teaching or Training; Other (specify)]

- Used in the past five years
- Intend to use in the next five years

14. What are the qualification levels in microbiology of the laboratory staff handling the microbial/genetic material in your Laboratory unit? [No training in microbiology; Laboratory technician; University degree; PhD degree; Other (specify)]

15. Which one of the mentioned qualification levels dominates in your Laboratory unit? [No training in microbiology; Laboratory technician; University degree; PhD degree; Other]

16. Which Quality Management System (QMS) is in place at your Laboratory unit? Is it related to activities in microbiology? [*No QMS in the laboratory; QMS not assessed by Third Party (no certification or accreditation)*; *ISO 9001; ISO 17025; ISO 14000; ISO Guide 34; Good Manufacturing Practice (GMP); Good Laboratory Practice (GLP); Other (specify)*]

- > In place
- Related to activities in microbiology

17. Which microbial analyses does your Laboratory unit outsource (to any third party, not necessarily to service Culture Collections) at present (the past five years), and/or intend to outsource in the future (the next five years)? [Isolation of pure cultures; Microbial count; Identification; Phylogenetic studies; Phenotypic characterization; DNA sequencing; Whole genome sequence data analysis; Gene sequence data analysis ; RNA sequencing; Plasmid profile analysis of bacteria; Sequence analysis of non-characterized plasmids; DNA-DNA hybridization; Pulsed-field gel electrophoresis; RAPD; AFLP; Ribotyping; Real-time PCR; Serotyping; Fatty acid profile (FAME-MIDI); MALDI-TOF; Polar lipids; Metabolite production; Enzyme production; Pathogenicity tests; Antibiotic sensitivity tests; -omics; Screening for specific properties; Consultancy; Training; Other (specify)]

> Outsourced in the past five years

> Intend to outsource in the next five years

Origin of the microbial/genetic resources used / Legal issue related to the CBD

18. Where are the microbial/genetic resources that are used within your Laboratory unit sourced from? [Isolated by your Organisation; From Research Laboratories; From Service Culture Collections; From Private Companies; Other (specify)]

- > None
- Some
- About half
- > Most
- ≻ All

19. Are you aware of the Convention on Biological Diversity (CBD)? [Y;N]

20. In case your Laboratory unit isolated microbial/genetic resources, did it ask Prior Informed Consent (PIC) from the appropriate authority in the country of origin of the sample, according to the CBD? [Always; In some cases (specify); Never (specify); Not Applicable (specify)]

21. Did your Laboratory unit experience any problems in obtaining microbial/genetic resources? [Specific conditions in the Material Transfer Agreement of the provider; Principles of Access and Benefit Sharing; Biosecurity rules; Transport regulations; Scientists reluctant to share their resources; Difficulty to find the provider of the required resources; Lack of documented properties of the resources; Other problems]

- > Never
- Occasionally
- Frequently

22. Specify for each of the subjects in which you experienced problems in obtaining microbial/genetic resources, the nature of the problem. [Specific conditions in the Material Transfer Agreement of the provider; Principles of Access and Benefit Sharing; Biosecurity rules; Transport regulations; Scientists reluctant to share their resources; Difficulty to find the provider of the required resources; Lack of documented properties of the resources; Other problems]

23. Do you have additional comments to share about the origin of microbial/genetic resources that your Laboratory unit uses and/or legal issues related to the CBD? [free text]

Use of the services that Culture Collections currently offer

24. Regarding the services currently offered by Culture Collections, please indicate which ones you ordered from Culture Collections in the past five years, and which ones you intend to order from Culture Collections in the next five years. [Public deposit of biological material; Safe deposit of biological material; Deposit of biological material for patent purposes; Supply of biological material; Supply of genomic DNA; Isolation of pure cultures; Microbial count; Identification; Phylogenetic studies; Phenotypic characterization; DNA sequencing; Whole genome sequence data analysis; Gene sequence data analysis; RNA sequencing; Plasmid profile analysis of bacteria; Sequence analysis of non-characterized plasmids; DNA-DNA hybridization; Pulsed-field gel electrophoresis; RAPD; AFLP; Ribotyping; Real-time PCR, Serotyping; Fatty acid profile (FAME-MIDI); MALDI-TOF; Polar lipids; Metabolite production; Enzyme production; Pathogenicity tests; Antibiotic sensitivity tests; -omics; Screening for specific properties; Consultancy; Training; Other (specify)]

- > Ordered in the past five years
- > Intend to order in the next five years

25. In case your Laboratory unit never ordered a particular service from Culture Collections in the past five years, please indicate the reason. [Public deposit of biological material; Safe deposit of biological material; Deposit of biological material for patent purposes; Supply of biological material; Supply of genomic DNA; Isolation of pure cultures; Microbial count; Identification; Phylogenetic studies; Phenotypic characterization; DNA sequencing; Whole genome sequence data analysis; Gene sequence data analysis; RNA sequencing; Plasmid profile analysis of bacteria; Sequence analysis of non-characterized plasmids; DNA-DNA hybridization; Pulsed-field gel electrophoresis; RAPD; AFLP; Ribotyping; Real-time PCR; Serotyping; Fatty acid profile (FAME-MIDI); MALDI-TOF; Polar lipids; Metabolite production; Enzyme production; Pathogenicity tests; Antibiotic sensitivity tests; -omics; Screening for specific properties; Consultancy; Training]

- > Not aware of
- Because of gaps (e.g. missing taxa, missing analyses)
- Because of other shortcomings (e.g. price, time frame, administrative burden)
- Is taken care of in-house
- Not needed

26. In case you have indicated 'because of gaps' for any of the services in the previous question, describe these gaps in a few words in the corresponding textbox(es). *[Biological*

material not accepted for deposit; Taxa or biological material missing in catalogues; Missing analyses; Missing data related to the resources; Other]

27. In case you have indicated 'because of other shortcomings' for any of the services, describe these shortcomings in a few words in the corresponding textbox(es). [*Price; Time frame; Administrative burden; Other*]

28. In case you would use the training service in the next five years, what kind of training program(s) would be useful for your Laboratory unit? [Data analysis; Taxonomy; Cultivation (e.g. anaerobic, fermenters, intracellular bacteria); Preservation; Molecular tools; Genotyping; Phenotyping; Culture collection management; Microbial identification and characterization; Handling of hazardous microorganisms; Risk assessment; Microbial detection and diagnostic techniques; Legal aspects related to the microbial/genetic resources; Other (specify)]

29. On which subjects do you expect to receive information from the Culture Collections, with respect to the biological material they offer? [Scientific name; Authors of the scientific name; Year of publication of the scientific name; Nomenclatural status of the strain (e.g. holotype, neotype, pathovar); Isolator; Depositor; Date of deposit in the Culture Collection; History (from isolation to arrival at the Culture Collection); Accession number(s) in other Culture Collection(s); Geographic origin; Substrate from which the biological resource was isolated; Date of sampling; Date of isolation; Growth conditions; Pathogenicity; Quarantine status in Europe; Dual-use status in Europe; Patent references; Gene sequences; Full genome sequence; Literature References; Morphology; Photos, images, pictures; Physiological and biochemical properties; Applications; Other (specify)]

- > Not required
- Yes, if available
- Yes, important
- > Yes, indispensible

30. In which format(s) do you prefer to access the information on the biological material offered by the Culture Collections? [Hardcopy; CD-DVD; Online (open access); Online (user account required)]

31. In case the Culture Collection presents information on its biological material online, which tools would you like to see implemented? [Data download to process data locally; Online data processing; Other (specify)]

32. What kind of information, linking the phenotype of the biological material to its genotype, is of relevance for your work? *[Accession numbers linking to genes or genomes in public*

sequence repositories (e.g. EMBL, GenBank); Links to protein databases (e.g. UniProt); Links to metabolic databases (e.g. KEGG); Other (comment])

33. Has your Laboratory unit already collaborated with a service Culture Collection in research projects? [*Y*; *N*]

34. What was/were the source(s) of financing of the research project(s)? [Financed only by your Organization; Co-financed by the project partners' own budgets; Financed externally (e.g. by European Commission)]

35. Was the service Culture Collection in these research projects a full partner or a subcontractor? [*Full partner; Subcontractor*]

36. Do you have additional comments to share about the services that Culture Collections offer? [free text]

Commercial use of the microbial/genetic resources supplied by service Culture Collections

37. Is your Laboratory unit using for commercial purposes microbial/genetic resource(s) that were supplied by a service Culture Collection? [*Y*; *N*]

38. Does your Laboratory unit have an agreement with the service Culture Collection on return of benefits resulting from the commercial use of these microbial/genetic resources? [Y; N]

39. Are you aware of the recommendations for fair and equitable Sharing of Benefits arising from the utilization of microbial/genetic resources, according to the Convention on Biological Diversity (CBD)? [Y; N]

40. Do these recommendations for fair and equitable Sharing of Benefits apply to the microbial/genetic resources used by your Laboratory unit for commercial purposes? [*Y*; *N*]

41. Do you have additional comments to share about the commercial use of microbial/genetic resources supplied by service Culture Collections? [free text]

Annex 4: Innovative Services questionnaire

Introduction

TARGET GROUPS

End-users of microbial resources in schools, universities, public or private institutes and bioindustry (e.g. Biotechnology, Agriculture, Food, Health, Energy & Climate, Environment)

PERIOD OF CONSULTATION

Start date: January 29th - March 31st, 2014

BACKGROUND TO THE MIRRI INITIATIVE

Microbial Resource Centres (MRCs) are the suppliers of a broad range of microbial biodiversity, providing essential, well-described and authentic raw materials for fundamental research and for applications in biotechnology, agriculture, health, food and other sectors. However, microbial resources and expertise are currently offered in a fragmented, uncoordinated and unharmonized way. Improved and centralized access to good quality microbial resources, data and services in an appropriate legal framework would bridge the gap between this important resource potential and envisaged biotechnological solutions and products, enhancing competitiveness of Europe's scientific community and bio-industry.

The 'Microbial Resource Research Infrastructure' (MIRRI) is an initiative endorsed by the European Strategy Forum on Research Infrastructures (ESFRI) and is included in their roadmap 2010. MIRRI will construct a pan-European distributed Research Infrastructure connecting MRCs with each other and with their stakeholders (researchers from private and public institutions, companies, policy makers, funding bodies, etc.) in a sustainable multipurpose platform.

The current Preparatory Phase (2012-2015) of MIRRI is financed by the European Commission with the following goals:

- to investigate the needs and expectations of all parties involved, with focus on providers and users of microbial materials
- to decide on the resources, data, and related services that should be part of the shared infrastructure
- to find the gaps in materials, data, and services offered at present
- to harmonize and implement the legal commitments derived from the Convention in Biological Diversity regulations that affect the access, distribution and use of the microbial material
- to define the function, governance and management of the infrastructure Page 64 of 82

An intensified collaboration between MRCs and their users will be of considerable benefit for European science and bio-economy. At present eighteen partners from twelve European countries work as a consortium in this Preparatory Phase.



OBJECTIVES OF THE CONSULTATION

This consultation is intended to gather input from our main stakeholders, being users of microbial resources, to shape the service output of MIRRI. We want to know the degree of your interest about innovative aspects of MIRRI in order to prioritize the actions towards the construction of the Infrastructure.

Your feedback will have an impact on the design and content of MIRRI as a new concept, with goals beyond what single MRCs can offer individually, considering that MIRRI will be a portal facilitating access to microbial material, data, expertise, and services distributed in Europe.

HOW TO SUBMIT YOUR CONTRIBUTION

The questionnaire starts on the next page and will take less than 15 minutes to complete. For clarity on what will happen with the information you provide, the first question will ask your agreement with the MIRRI Statement on Use, Access and Protection of collected data, a condition to proceed.

Your contribution can be made anonymously if preferred, but in that case please observe that MIRRI cannot contact you anymore for further dialogue on your needs and expectations.

You can exit the survey any time and resume later, provided the same computer and browser are used and session cookies are enabled and saved for the required period of time.

CONTACT

In case you need more information or want to verify, modify, or delete any of you responses, contact MIRRIsurveys@cect.org with the details of your request.

RESULTS OF THE CONSULTATION

A report with the digested and anonymized results derived from this and other consultations will be presented on the MIRRI website after the results have been presented to and accepted by the European Commission.

Privacy Statement

1. Do you agree with the MIRRI Statement on Use, Access and Protection of collected data? [Y; N]

General information

2. In which country is your Organization located? [drop-down list]

3. Is your Organization involved in any way with microbial resources for its professional activities? [Yes; No -> DISQUALIFIED, only respondents answering "Yes" are able to continue]

4. To which sector does your Organization belong? [Profit sector; Non-profit sector]

5. What is the size of the enterprise? [*Micro-enterprise* (less than 10 employees); Small to Medium size enterprise (between 10 and 250 employees); Large enterprise (more than 250 employees)]

6. In which field(s) is your Organization active? [Academic & Education; Quality Analytical Lab; Pharma & Medical; Veterinary; Agronomy; Food & Feed; Chemical; Cosmetics; Diagnostic; Bioremediation; Environmental; Other (specify)]

7. Are you a current user of the microbial resources or related services provided by public Microbial Resource Centres (MRCs)? [*Y*; *N*]

Search for mi	crobial r	resources	and	associated	data	provided	by	Microbial	Resource
Centres (MRC	s)								

SITUATION AT PRESENT	WHAT MIRRI CAN DO DIFFERENTLY	WE VALUE YOUR OPINION
To search for specific microbial resources, customers have to navigate through different catalogues and contact different MRCs.	MIRRI proposes to set up a unique search tool, covering all microbial resources offered by the participating European MRCs.	8. For my work such unique and integrated search tool for MRC catalogues [is a major improvement; is only a minor improvement; has no impact; is a drawback; is not applicable]
MRC catalogues and public databases on microorganisms generally provide non-integrated and sometimes inconsistent or incorrect data.	MIRRI will aim to integrate and curate microbial resource data that is available from participating European MRCs (e.g. growth conditions, properties) and other online sources (e.g. publications, genomic data).	9. For my work such integrated and curated database [is a major improvement; is only a minor improvement; has no impact; is a drawback; is not applicable]

10. For each of the following types of information related to microbial resources, please indicate the relevance for your work: *[taxonomy and classification; habitat and environmental information; growth conditions and requirements; physiology and metabolism; pathogenicity; genomic data, including sequences; biotechnological applications; related patents; literature references; Other information types (specify)]*

- very useful
- only of little use
- ➢ of no use
- > not applicable

11. Please list existing databases that are very useful for your work, and to which MIRRI could establish a direct link. [free text]

Quality of materia	l provided by	public Microbial	Resource Centres	(MRCs)
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SITUATION AT PRESENT	WHAT MIRRI CAN DO DIFFERENTLY	WE VALUE YOUR OPINION
Although many MRCs have a quality	MIRRI wants to set up criteria assuring a	12. For my work a standardized and high quality

13. Do the MRCs need to be formally certified or accredited in order to be a supplier of microbial material for your work? *[this is mandatory; this is preferred; this is not necessary]*

Ordering material from public Microbial Resource Centres (MRCs)

SITUATION AT PRESENT	WHAT MIRRI CAN DO DIFFERENTLY	WE VALUE YOUR OPINION
To order microbial resource samples offered by different MRCs, customers have to navigate through different websites and contact the different MRCs.	MIRRI proposes to complement the unique search tool with a unique one-stop shop, allowing customers to search and order resources from the different participating European MRCs.	14. For my work such one-stop shop for ordering microbial materials [is a major improvement; is only a minor improvement; has no impact; is a drawback; is not applicable]
MRCs have Material Transfer Agreements that can differ in several respects.	In support of the one-stop shop, MIRRI proposes to harmonize the conditions for access to, and (commercial) use of, the microbial resources offered by the participating European MRCs.	15. For my work harmonized conditions for access and use [are a major improvement; are only a minor improvement; have no impact; are a drawback; are not applicable]

16. When the order is made through the one-stop shop, the material will be shipped by the respective MRCs involved in the order. Regarding invoicing such a split order, what is required by your organization? [One compiling invoice per order will be mandatory; It is acceptable that each shipment is accompanied by a corresponding invoice]

Deposit of material at public Microbial Resource Centres (MRCs)

SITUATION AT	WHAT MIRRI CAN DO	WE VALUE YOUR OPINION
Scientists willing or obliged to deposit microbial material at public MRCs (i.e. for publication), encounter problems to identify the appropriate MRCs.	MIRRI proposes to set up a unique guidance system, directing depositors to the participating European MRCs suitable for the specific material to be deposited.	17. For my work such deposit guide [is a major improvement; is only a minor improvement; has no impact; is a drawback; is not applicable]

SITUATION AT PRESENT	WHAT MIRRI CAN DO DIFFERENTLY	WE VALUE YOUR OPINION
Supply of microbial cultures is mainly as pure cultures, individually preserved, and of unknown count.	MIRRI will gain new expertise and implement new technologies to offer microbial materials in alternative formats.	18. For my work alternative formats of supply [are a major improvement; are only a minor improvement; have no impact; are a drawback; are not applicable]

Offer of microbial materials at Microbial Resource Centres (MRCs)

19. For each of the following formats, please indicate the relevance for your work. [Single culture with known Colony Forming Units; Mixed culture with known composition; Specific purpose strain panel (e.g. in microtiter plates); Large scale inoculum; Permanent microscopy slide set; Other formats (specify)]

- > very useful
- > only of little use
- > of no use
- > not applicable

SITUATION AT PRESENT	WHAT MIRRI CAN DO DIFFERENTLY	WE VALUE YOUR OPINION
Gaps in authentic and publicly available microbial resources are often due to requirements for highly specialized cultivation and/or preservation conditions.	MIRRI will gain new expertise and implement new technologies to successfully cultivate and preserve recalcitrant/ fastidious microorganisms currently not covered by the participating European MRCs.	20. For my work this enhanced capacity of MRCs
Next to public MRCs, specialized collections of microbial resources exist, but are kept at laboratories of universities or other scientific centres, and remain unaccessible for the scientific community.	MIRRI will encourage specialized laboratories to associate with MIRRI for bringing this material into the public domain, in compliance with the MIRRI criteria.	21. For my work broadening the scope of offered material [is a major improvement; is only a minor improvement; has no impact; is a drawback; is not applicable]

22. Please list the top three of microorganism groups important for your work but at present not offered by public MRCs. [*free text*]

<u>DZ. I</u>

SITUATION AT PRESENT	WHAT MIRRI CAN DO DIFFERENTLY	WE VALUE YOUR OPINION
To search for specific microbiology related analyses offered on a service basis by MRCs, customers have to navigate through the different websites and contact the different MRCs.	MIRRI proposes to set up a unique integrated search tool, covering the services offered by the participating European MRCs.	23. For my work such integrated search tool for MRC services [is a major improvement; is only a minor improvement; has no impact; is a drawback; is not applicable]
To order specific microbiology related analyses (services), customers have to contact different MRCs.	MIRRI proposes to complement the service search tool with a unique one-stop shop, allowing customers to search and order services from MRCs in different European countries.	24. For my work such one-stop shop for MRC services [is a major improvement; is only a minor improvement; has no impact; is a drawback; is not applicable]
For comparable services, MRCs and customers conclude Service Agreements which can differ in several respects.	In support of the one-stop shop, MIRRI proposes to harmonize the service agreements concluded between the participating European MRCs and their customers.	25. For my work uniform service agreements [are a major improvement; are only a minor improvement; have no impact; are a drawback; are not applicable]
Changing needs of academics and bio- industry are not fully met by services in the portfolio of MRCs. <i>An overview of</i> <i>the main services currently</i> <i>provided by most MRCs</i> <i>can be viewed <u>here</u>.</i>	MIRRI will develop new services guided by the feedback received from academia and bio- industry.	26. For my work [the services currently offered by MRCs suffice; additional MRC services are necessary]

Services in microbiology provided by Microbial Resource Centres (MRCs)

27. For each of the following suggestions for new services, please indicate the relevance for your work. [*customized isolation of microorganisms; customized cultivation of microorganisms, including media optimization; customized preservation of microorganisms; screening for specific genes, enzymes, metabolites, or other features; data analysis and interpretation; organization of proficiency tests or ring tests; primer design for specific target sequences; supply of specific amplified genes; supply of cDNA*]

- very useful
- only of little use
- > of no use
- > not applicable

28. It is fundamental for efficient service output that MIRRI focuses on new services that are required by the user community. Please list other new services that will be very useful for your work. [free text]

SITUATION AT PRESENT	WHAT MIRRI CAN DO DIFFERENTLY	WE VALUE YOUR OPINION
In search for advice, consultancy or training on matters related to microbial materials, customers have to contact different MRCs.	MIRRI proposes to set up unique expert platforms, offering customers access to the combined expertise of specialists from within and outside European MRCs.	29. For my work facilitated access to expertise in microbiology <i>[is a major improvement; is only a minor improvement; has no impact; is a drawback; is not applicable]</i>

Expertise available from Microbial Resource Centres (MRCs)

30. For each of the following subjects for these expert platforms please indicate the relevance for your work. [microbial taxonomy and identification, including related technology; isolation and cultivation of microorganisms; preservation of microbial resources; applied microbiology, including screening technology; information technology, including data analysis; legal matters related to access, distribution, and (commercial) use of microbial resources, including Intellectual Property Rights and Benefit Sharing; biosafety and biosecurity; set-up of Level 1, Level 2 or Level 3 facilities; Other (specify)]

- > very useful
- > only of little use
- > of no use
- > not applicable

31. Regarding access to the expertise offered by the platforms, please indicate your interest in each of following formats. *[searchable database with individual experts per subject; on-line guides, documents, presentations; webinars; symposia and workshops; on-site at the relevant MRCs, on individual basis; on-site at the relevant MRCs, in group with other interested persons; on-site at your organization; collaboration in fundamental or applied research projects]*

SITUATION AT	WHAT MIRRI CAN DO	WE VALUE YO

Involvement of Microbial Resource Centre (MRC) stakeholders

SITUATION AT	WHAT MIRRI CAN DO	WE VALUE YOUR OPINION
PRESENT	DIFFERENTLY	
Dialogue between MRCs	MIRRI aims to involve its	32. Would you be interested
and their User	stakeholders in the further	to act as an expert from your
communities is limited.	development of the	sector?
	Infrastructure and its	[yes, I am interested; no, I
	envisaged output.	am not interested; I do not
		know at this moment]

33. What is your field of expertise? [free text]

Contact information

34. Give the full name of your Organization. [free text]

35. Give the full name and complete address of your Laboratory unit. [Full name; Address; City/Town; State/Province; ZIP/Postal Code; Country;

36. Give your name, function, email address and phone number. [Name; Function; Email Address; Phone Number]

37. If different from the person filling in this questionnaire, give the name, function and contact information of the appropriate person to discuss your Organization's/Laboratory's future needs regarding microbial resources and related services. *[Name; Function; Email Address; Phone Number]*

Further communication with relation to MIRRI

38. How did you learn about MIRRI? [*Present questionnaire; Previous questionnaire;* Colleagues; MRCs supplying material or services; Press; Social Media; Conference; MIRRI website; Mail; Other (specify)]

39. Would you like to be further informed about MIRRI's activities? [Y; N]

40. How do you prefer to be informed about MIRRI? [*email*; *e-newsletter*; *MIRRI website*; *Social Media*; *Workshops*; *Other* (*specify*)]

In 2013, MIRRI organized a survey to map the Users of microbial resources, being the prime stakeholder of the MIRRI initiative. In case you would be willing to complete this questionnaire (i.e. the User questionnaire, annex 3) as well, please click this <u>link</u>. Otherwise, please click Done.
Annex 5: Correlation between OECD guidelines for BRCs and questions in the MIRRI survey of ECCO CCs

OECD Guidelines 2007	Corresponding section and questions in the MIRRI survey of the ECCO CCs	Criteria Nr
General Best Practice Guidelines for all BRCs		
General information on CC holdings	Biological resources - General / Biosecurity / Biosafety	
	Q13. For each type of biological material present in your CC specify the total number of holdings. > micro-organisms > human / animal / plant-derived materials (cell lines, animal hybridomas) > other (plasmids, DNA libraries) Q62. What is the highest containment level implemented in your CC? Q57. Does your CC host microorganisms for which the use and/or distribution are governed by (inter)national regulations? > Dual-use > Quarantine > GMO Q11. Is your CC recognized by the World Intellectual Property Organization as an International Depositary Authority for patent purposes?	
General awareness and compliance to the Guidelines	Operational Guidelines	
	Q69. Is your CC aware of the existence of the OECD 'General best practice guidelines for BRCs'? Q70. If your CC is aware of the existence of the OECD BPG for BRCs, to what extent does your CC comply? > FULLY Q70. If your CC is aware of the existence of the OECD best practice guidelines for biological resource centres, to what extent does your CC comply? > PARTIALLY	
4. Organisational requirements		
1	l	

4.1. Long-term sustainability	Finances	
	Q31. Please estimate the portion of the total funding that your CC received from different funding sources to cover all operational aspects (on average over the past five years). > Gets at least some funding from Government	1
	> Gets at least some funding from Private	
	> Gets at least some funding from Host Institution	
	> Gets at least some funding from Own revenues	
	> Gets at least some funding from Research grants	
	Q32. For each funding source, what are your expectations for the coming three years?	
	> CC expects their main funding source(s) to be maintained or increased (~sustainability next three years).	3
4.2. Responsibilities of management	Personnel / Quality management / Biosecurity	
	Q34. How many Full Time Equivalents are currently allocated to your CC for the different job types? > Quality manager FTE > 0.1	
	Q39. Does your CC have a Quality Management Policy?	
	Q42. Which accreditation(s) does your CC have?	2
	Q43. Which certification(s) does your CC have?	2
	Q58. Are you aware of the Code of Conduct on Biosecurity for Biological Resource Centres (BRCs)?	
4.3. Staff - qualifications and training	Personnel	
	 Q38. Do you consider that external job-specific training is necessary for some of the staff? > Training needed in Quality management > Training needed in IT > Training needed in Characterization > Training needed in Preservation Some data from survey on education level of staff, but cannot be correlated to their specific job type or function 	
4.4 Health and safety (biosafety)		
5 Promises		
5.1 PPC operations	Proconvation and storage	
J.I. DRC operations	Close your CC maintain in a congrate building	
	 duplicates of the biological material? Yes, for <u>all</u> holdings Yes, for the <u>vast majority</u> of holdings Yes, for a <u>specific part</u> of holdings 	5

5.2. Construction and operation		
5.3 Access	Biosecurity	
	Q56. Is the physical access to the collection stocks secured (locked storage / access control / telesurveillance)?	6
5.4 Maintance and inspection		
5.5 Outside support services and supplies		
6. Equipment use, calibration,		
testing and maintenance records		
7 Documentation management		
7.1 Compliance with internal documentation		
8. Data and informatics		
8.1 Data management Each biological material record should contain a Minimum Data Set, a Recommended Data Set and/or a Full Data Set in accordance with domain specific criteria. These can be deduced from Q55 – Which subjects are covered in the database?	Informatics Q49. Which guidelines/standards regarding database structure and/or data formatting does your CC take into account? > standardized, but not following a specific guideline > OECD > CABRI > other standard (MINE, ABCD, MCL, GBIF,) Q50. Does your CC perform regular curation of the data concerning the biological resources? > data curation with SOPs > data curation considering inconsistencies with other CCs' data > other approaches	8
8.2. Data processing	Informatics	
	Q54. If the information on the biological resources is presented online, is your online catalogue integrated into other public web tools? > CABRI > CABRI > Straininfo > GBIF > WDCM > GCM > Other	

	Q48. Is there a backup procedure in place for the database(s) of the CC?	
8.3. Access to data and publication	Informatics	
	Q51. In which format(s) is the information on the biological resources presented to the CC's users? > Online	9
	Q53. If applicable, estimate the percentage of the publically available biological material that is presented in your online catalogue.	9
	Q52. If the information on the biological resources is presented online, which of the following tools do you implement? > Download from website with restricted access (user	
	account) > Download from website with open access > Other tools (FTP, Web services, …)	
9. Preparation of media and reagents		
10. Accession of deposits to the BRC		
10.1. Receipt and handling of biological material	Biosecurity	
	Q59. Does your CC conduct risk assessments of the biological material present in the collection to implement appropriate biosecurity measures? > yes, on <u>all</u> material > yes, on <u>specific</u> material	7
10.2. Accession	Informatics	
	Q21. Are conditions for deposit of biological material at your CC determined, agreed and laid down in an agreement with the depositor?	
	Q22. Does this agreement with the depositor refer to the PIC of the country of origin of the biological resource as described in the CBD?	10
	Q23. Does your CC currently accept new deposits without PIC or any other proof of permission by local authorities in the country of origin of the biological resource for collecting the material from nature?	
	Q55. Which subjects regarding the biological material are "mandatory to accept a deposit"? Scientific name Depositor Substrate Page 76 of 82	11

	Date of isolation Geographic origin Accession number(s) in other CC(s) Growth conditions Pathogenicity Quarantine status Dual-use status	
10.3. Quality checks on the biological material	Quality management	
	<pre>Q44. Which quality control checks are carried out upon receipt of the biological material at your CC? > Viability > Purity > Identification > Authenticity Q45. Which quality control checks are carried out after preservation of the biological material at your CC? > Viability > Purity > Identification > Authenticity</pre>	1
11. Preservation and maintenance		
11.1. Methodology	Preservation and storage	
	 Q19. Does your CC apply more than one preservation technique on the biological material in your CC? > on all holdings > on (at least the) vast majority of holdings > on (at least) a specific part of holdings 	4
11.2 Stock control of the preserved biological materials		
11.3 Storage of preserved biological materials		
	see 5.1 (separate building) and 11.1 (two preservation methods)	
11.4 Validation of methods and procedures		
12. Supply		
12.1. Order placement	Biosafety	
	Q64. For which biological material does your CC ask a certificate/declaration/permit from the end-user, regarding the use of the material and/or the suitability of the infrastructure for handling the material ordered? > Biohazard group 1 Page 77 of 82	

	> Biohazard group 2 > Biohazard group 3	
	> GMOs	
	> Quarantine organisms	
	> Dual-use organisms	
12.2 Availability of the biological material ordered		
12.3. Information provided with the biological material supplied	Biological resources - supply of samples	
	Q25. Are conditions for the supply of samples by your CC determined, agreed and laid down in an MTA with the recipient of the samples (MTA for supply of samples)?	
	Q26. If your CC uses an MTA for supply of samples, is this MTA complying with the ECCO core MTA?	
	Q27. In case the recipient uses the biological material, supplied by your CC, for commercial purposes, does your CC refer the recipient to the country of origin of the biological material with respect to fair and equitable Benefit Sharing?	12
12.4. Packaging		
	Q63. Indicate which of the following package regulations	
	Sour CC applies. > IATA PI 650 - ADR P 650 (L2)	
	> IATA PI 602 - ADR P 620 (L3)	
12.5 Invoicing for supply charges		
12.6 Traceability of biological materials supplied		
	Q30. Does your CC keep record of which biological material is distributed, and of the respective recipients?	13
12.7 Handling complaints and anomalies		
	Q40. Does your CC measure satisfaction levels of the users?	
	Q41. Does your CC have a documented procedure about user complaint management?	
12.8 Refunds		
12.9 Confidentiality		
13. Quality audit and quality review		

13.1 Purpose		
	see 4.2 (Quality management policy, accreditation, certification)	
13.2 Responsibility		
13.3 Implementation		
13.4 Method and procedure for quality checks		

OECD Guidelines 2007	Corresponding section and questions in the MIRRI survey of the ECCO CCs	Criteria Nr
Best Practice Guidelines on Biosecurity for BRCs		
4. Assessing biosecurity risks of biological material		
	Q60. Does your CC conduct a risk assessment to assign the biological material present in the collection to the biosecurity risk levels "high", "moderate", "low" or "negligible", according to the OECD Biosecurity guidelines?	7
5. New acquisitions/ re-assessment		
of inventory		
6. Biosecurity risk management Practices		
	see GENERAL 4.2 (awareness of the Code of Conduct on Biosecurity)	
6.1 Physical security of BRCs		
	see GENERAL 5.3 (secured access)	
6.2 Security management of personnel		
6.3 Security management of visitors		
6.4 Incident response plan		
6.5 Staff training and developing a biosecurity-conscious cultur		
	see GENERAL 4.2 (awareness of the Code of Conduct on Biosecurity)	

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6.6 Material control and accountability		
6.7 Supply of material		
6.8 Transport security		
	Q61. Does your CC have a deputy/expert/responsible person who keeps the CCs export control regimes up-to- date? See also GENERAL 12.4 (packaging)	
6.9 Security of information		
	see GENERAL 4.2 (awareness of the Code of Conduct on Biosecurity)	

OECD Guidelines 2007	Corresponding section and questions in the MIRRI survey of the ECCO CCs	Criteria Nr
Best Practice Guidelines for the micro-organism domain		
4. Specific BRC Best practice guidelines 4.1 Staff- gualifications and training		
4.2 Health and safety		
5. Premises		
5.1 Construction and operation		
5.2 Maintenance and inspection		
6. Equipment use, calibration, testing and maintenance records		
7. Informatics		
	Q55. Which subjects regarding the biological material are covered in the CC database(s)? > Scientific name > Type strain status > accession number(s) in other CC(s) > geographic origin > substrate > growth conditions > pathogenicity	

	> quarantine status in Europe	
	> dual-use status	
	> patent references	
	> date of deposit	
	> authors of scientific name	
	Year of publication scientific name	
	> isolator	
	> history (from inclution to deposit)	
	> date of sampling	
	> date of isolation	
	> gene sequences	
	> literature references	
	> morphology	
	> photos, images, pictures	
	> physiological and biochemical properties	
	> applications	
8. Preparation of media and		
reagents		
9. Accession of deposits to the BRC		
9.1 Receipt and handling of		
biological materials		
	see GENERAL 10.1. (Receipt and handling of biological	
	see GENERAL 10.2. (Accession)	
	see GENERAL 10.3. (Quality checks on the biological material)	
	matchar	
10. Preservation		
10.1 Long-term preservation		
	Q16. To what extent are the listed preservation methods	
	used by your CC to preserve the biological material	
	present in your CC (during the past five years)?	
	Freezing in liquid N2	
	Freezing between -70 and -140°C	
	Freeze-drving	
	Liquid-drving	
	Mineral oil	
	Water	
	Agar culture	
	Q78. In which formats can biological material be	
	supplied by your CC?	
10.2 Validation of methods and		
procedures		

11. Supply of material		
11.1 Order placement		
	see GENERAL 12.1 (Order placement)	
11.2 User validation		
	see GENERAL 12.1 (Order placement)	
11.3 Availability of the biological material ordered		
11.4 Packaging and Transport		
	see GENERAL 12.4. (Packaging)	
11.5 Traceability of hazardous biological material	see GENERAL 12.6 (Traceability of biological materials	
	supplied)	
12. Micro-organism Biological		
national and international law		
	see GENERAL, different headings	
12.1 Classification of micro-		
organisms according to risk-groups		
12.2 Overentine regulations		
12.2 Quarantine regulations		
12.3 Intellectual Property Rights		
(IPRs):		
	see GENERAL 10.2. (Accession)	
	see GENERAL 12.6 (Traceability of biological materials	
	see GENERAL 12.3. (Information provided with the biological	
	material supplied)	
12.4 Safety information provided to the recipient of micro-organisms		
12.5 Control of Distribution of Hazardous Micro-organisms		
	see General 12.1. (Order placement)	