

Overview of the networking development and output of EMbaRC

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Summary

Goal

- EMbaRC lays the foundation for the European node of the GBRCN
- Common approach to deliver products and services meeting user expectations

Networking Outputs from 3 work packages

- Enhance delivery of high quality biological materials and information
- Enable an evidenced based selection of appropriate protocols for handling and storage of microorganisms and associated data - Deliver the BRC standard
- Offer information resources and tools for capacity building
- Address key aspects of regulations e.g. Biosecurity to present a common harmonised and transparent operational framework
- Outreach to potential new members; encourage new users of member collections
- Encourage deposit of strains from publications or publicly funded research
- Elucidate and validate business models
- EMbaRC, ECCO and the GBRCN initiate the Microbial Resources Research Infrastructure: an opportunity to engage collections in research innovation

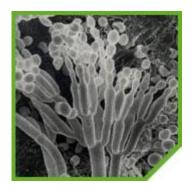






Operating environment – policies and strategies

- Authenticated and well-managed organisms are essential
 - to guarantee quality and safety in areas of application
 - to ensure controlled access to hazardous organisms
 - to ease and improve the utilisation of microorganisms
- Facilitating policy from Governments is needed
- Need a legal operational framework and strategies to
 - Encourage deposit
 - Encourage adding value
 - Encourage data and material sharing
 - Encourage development an environment of improvement
 - Encourage innovation











European Microbial Resources Consortium – EMbaRC

European platform of future GBRCN

Improved protocols, authentication, preservation

Biosecurity code

Information resource

Capacity building tools

DNA banking

Enzyme screening



INRA, FR
Institut Pasteur, FR
CABI, GB
KNAW-CBS, NL
BCCM, BE
(3 legal entities:
SPP-PS, UGent &
UCL)
DSMZ, DE
UVEG-CECT, SP
UMinho-MUM, PT





DEVELOP COMMON STANDARDS AND PROTOCOLS

- NA1.1: Harmonisation of methods and associated data
- NA1.2: Implementation of network best practice and customer delivery
- NA1.3: Preparation of a Code of Conduct for Biosecurity for European Microbial Biological Resource Collections







Self assessment to OECD Best Practice Guidelines for BRCs – evaluation of implementation in 4 sections

- Organisational requirements
- Equipment use, calibration, testing and maintenance records
- Documentation management
- Data management, processing and publication
- Preparation of media and reagents
- Accession of deposits to the BRC
- Preservation and maintenance
- Supply
- Quality audit and quality review

Best Practice Guidelines on Biosecurity for BRCs

- Assessing biosecurity risks of biological material
- New acquisitions/ re-assessment of inventory
- Biosecurity risk management practices
- Physical security of BRCs
- Security management of personnel and visitors
- Incident response plan
- Material control and accountability
- Supply and transport security

Best Practice Guidelines for the Micro-Organism Domain

- Staff-qualifications and training
- Hygiene und biosafety
- Equipment use, calibration, testing and maintenance records
-
- Preparation of samples
- Information provided with the biological material supplied

-







GBRCN audit checklist for Internal Audits

To ensure that the conformity to the specific requirements is succeeded an internal audit is performed following a matrix comprised by six columns:

- Chapter of the guide
- Requirement
- Procedure in Place
- Compliance
- Comments
- Score

Chaptero	Requiremento	Procedures in places	Compliance			Comments	Score	ľ
	·	·	Yo	No	NA _P			Jº
¶ ¶								
	BRC general criteria							ŀ
	Certified BRCs must comply with:¶		-	-				7°
	 Their national and international legislation, regulations and policies concerning acquisition, conservation, utilisation, including the fair and equitable sharing of benefits arising from utilisation of genetic resources, and distribution of biological resources and data related thereto.ff 							
	The regulations of the relevant countries when moving biological materials across national boundaries. The regulations of the relevant countries when moving biological materials across national boundaries. The regulations of the relevant countries when moving biological materials across national boundaries. The regulations of the relevant countries when moving biological materials across national boundaries.							
	 The relevant national and international agreements, regulations, policies, frameworks and recommendations. () 							
-	Certified BRCs have in place a mechanism that					п		┨╸
	updates their knowledge of the above.□				_			ı
4	1 .					l		ь
4.0	Organisational requirements							70
	The BRC should meet the OECD definition and be	0	0	0			0	١.
	compliant with appropriate national law, regulations							ı
	and policies. The application for certification must							ı
	describe and document the nature of the biological							ı
"	resources being held and for which certification is							ı
	being sought. It must define the biological domain and							ı
	therefore the domain specific criteria that apply e.g.							ı
	micro-organisms or human materials.							
4.1.0	Long-term sustainability							ŀ
4.1.1.0	The BRC should provide evidence of a strategy for its		-	-	-	0		ŀ
	long-term sustainability. Adequate and reliable							
	sources of funding vary from government support.							
	income from services and private support.							

Score:

full compliance

• Compliance with minor rework = 1

• non-compliance = 0





= 2



OECD Best Practice Guidelines for BRCs – self-evaluation

> 8 GBRCN Pilot Project Partners performed an Internal Audit according to the OECD BPG checklist:

Belgium BCCM

France CRBIP

Netherlands CBS

Spain CECT

Brazil CBMAI

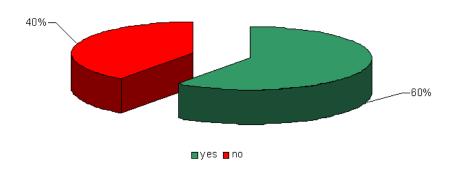
Finland VTT

UK CABI

Germany DSMZ

50% of the GBRCN partners responded to the call – 6 of the 8 EMbaRC partners

Overall compliance to OECD BPG for BRCs



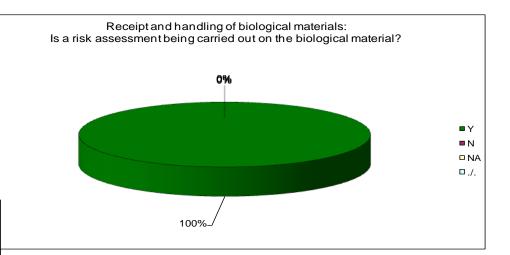






Selected results: biosafety and monitoring programme

By Courtesy Dunja Martin GBRCN Secretariat

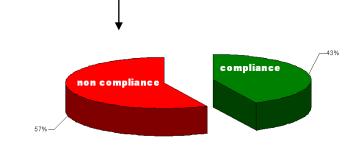


environmental monitoring of laboratory air and surfaces?

NA

Is a contamination monitoring programme in place to include

All respondents carried out risk assessments on materials held but only 47% complied with biosecurity needs









Comparison of common standards for implementing OECD best practice

General comparison on major requirements

	Type of conformity assessment	management systems compliance	technical skills and competence	product compliance	process in use compliance	specific regulatory compliance (e. g. B&B, IT, sustainability)
ISO Guide 34	Product Certification	х	xx	xxx		
ISO 17025	Process Competence Acceditation	х	xxx		xx	x
ISO 9001	Organisation Certification	XXX	х			
NF S96-900 (Fr)	Organisation Certification	XX	х	•	х	
OECD BRC PBG	Organisation and Process in Use "Certification"	XXX	XX	х	xxx	xxx

Major overlap of OECD BPG with other standards

	Type of conformity assessment	management systems compliance	technical skills and competence	product compliance	process in use compliance	specific regulatory compliance (e. g. B&B, IT, sustainability)
ISO Guide 34	Product Certification	x	XX	xxx		
ISO 17025	Process Competence Acceditation	х	XXX		xx	x
ISO 9001	Organisation Certification	XXX	х			
NF S96-900 (Fr)	Organisation Certification	XX	х		х	
OECD BRC PBG	Organisation and Process in Use "Certification"	XXX	xx	х	xxx	xxx

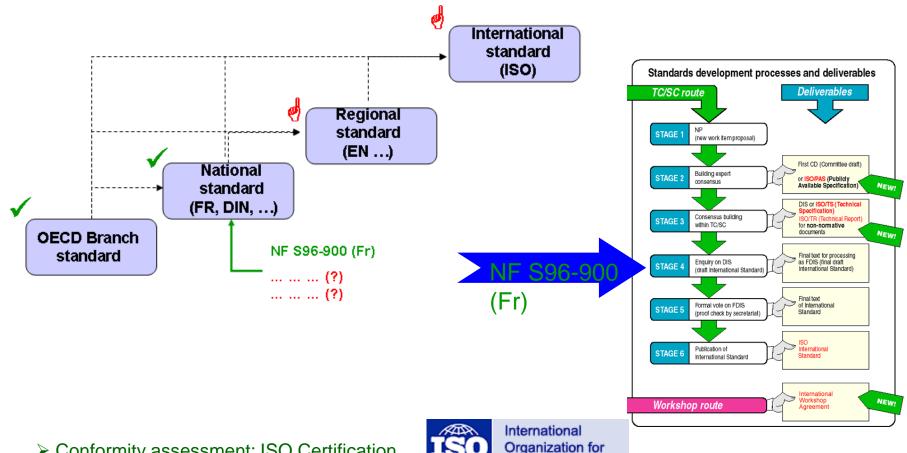






Alternatives in international recognition of the OECD BPG for BRCs

Alternative 1: Inventing a new ISO Standard



> Conformity assessment: ISO Certification

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Standardization

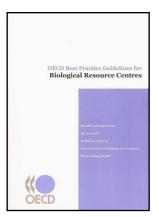


International Recognition of the OECD BRC Best Practices

Alternative 2: Keep as an International OECD Standard



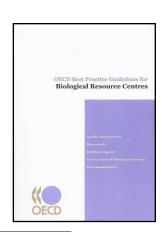
OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring



OECD Best Practice Guidelines for Biological Resource Centres

➤ Conformity assessment: Conformity Certification

<u>Alternative 3: GBRCN Certification Baseline for Excellence</u>



OECD Best

Practice

Guidelines for

Biological

Resource

Centres



Quality stamp

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Conformity assessment: Conformity Certification to excellence stage







Access to member collection data

- Test existing systems
- Utilise CABRI data management standard
- Testing the straininfo.net Microbial Common Language (MCL) for data linkage and exchange
- Gateways to subsets of a single set of data
 - Collections provide data once no extra work
 - Project consortia; Network member;











Verslyppe, B., Kottmann, R., De Smet, W., De Baets, B., De Vos, P., and Dawyndt, P. (2010). **Microbiological Common Language (MCL): a standard for electronic information exchange in the Microbial Commons.** Research in Microbiology 161(6), 439-445. <u>doi:10.1016/j.resmic.2010.02.005</u>







USER ACCESS, TRAINING AND OUTREACH

- Task NA2.1: Design and delivery of training for new users vocational training (ERASMUS); capacity building tools
- Task NA2.2: Management of the calls for access and evaluation of the access given – Presentation by Philippe Desmeth
- Task NA2.3: Dissemination and outreach to users







EMbaRC outreach

Goal

- Dissemination and outreach strategy to engage stakeholders with a view to the long term sustainability of the partnership and wider community
- An EMbaRC web portal to provide access to services
- An EMbaRC eNewsletter disseminating project results and calls for access
- Gaps in information provision will be identified i.e. services and data not provided by other BRC communities will be provided or linked to
- Communication strategy







ACTION TABLE

TARGETS	Objectives	Tools & actions	Frequency/timing	Who involved
Users- Scientists	i) Stimulate participation call for access;	e-letter and direct to mailing list - advertising in Journals, Newsletters Presentations – conferences, seminars	Continuous – open call	NA2.3 task leader and participants
	ii) Disseminate main results of JRA	Papers Conferences and symposia Websites e-letter	As generated on going	e-letter Editors Scientists involved in the result Website via Project Manager
Users -Bioindustry	Convince them to use and support BRCs	- identify - feedback on needs	Throughout project	NA3.2 task leader and participants
Funders	Convince of importance of funding BRCs	identifypersuasive argumentmeet them	Ongoing as identified	NA3.2 task leader and participants
Policy makers	Demonstrate impact of BRC output	Identify	Ongoing as identified	NA3.2 task leader and participants







ACTION TABLE

TARGETS	Objectives	Tools & actions	Frequency/timing	Who involved
Other bioresource projects	Improve the link and complementarity	Identify Collaborative plan if appropriate	Ongoing as identified	-Identify: all participants of project with feedback to Executive Committee -Collaborative plan: NA2.3 & NA3.2 task leaders together, with Executive Committee
Journals editors	Convince them to recommend deposit of key bioresources	 specific workshop dedicated to Journals editors; invite them to Workshops 	Begin M0 – deliverable by project end	NA3.2 task leader with support from task participants
Other collections or BRC	i) Stimulate participation call for access	e-letter + specific mailing; culture collection events (ECCO, etc.) specific EMbaRC workshops (Brazil; Italy)	Continuous Leading up to seminars	NA 2.3 task leader with approval of Executive Committee
	ii) diffuse results from NA and JRA	e-letter; culture collection events (ECCO, etc.) specific EMbaRC workshops (Brazil; Italy) Conferences	As generated on going	Relevant Work package and subtask leaders with approval of Executive Committee
	iii) help when endangered	Prepare strategy Identify Contact	As identified	NA2.3 task leader and Co-ordinator with Executive Committee
Press	Make use of Year of Biodiversity Identify opportunity	 press conferences invite them to the Work shops 	To publicise key deliverables e.g. Launch of web site	each NA2.3 participant to make recommendations to Executive Committee







SUSTAINABLE ACTIVITY OF BRCs

- Task 3.1 Gap Analysis and Strategic Plan to Increase Holdings of Biological Resources included in the Scientific Literature – presentation by Erko Stackebrandt
- Task 3.2 To define a sustainable strategy







BRC and **Network** sustainability

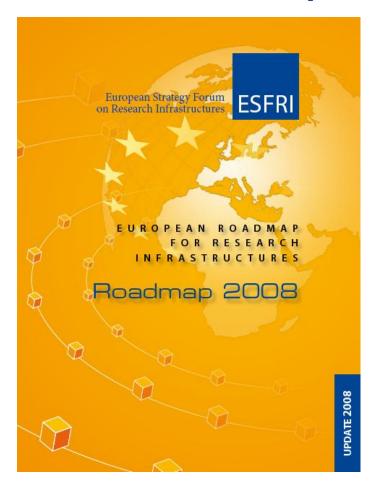
- Generic BRC business plan drafted
- Funding models report being drafted
- Securing networks for the long-term
 - Architecture; Governance
 - Funding
 - Considerable diversity of individual centres
 - Most BRCs will require some core funding from governments or host institutions
 - Other funding sources include industry, research grants, cost-recovery through feesfor-service, development of databases and tools that complement the core role of BRCs; funding from charitable sources, e.g. those associated with public health or sustainable development
 - There is not one financial model for culture collections or BRCs. A combination of governmental support, commercial lines and project portfolia offers the best chance for long-term sustainability







Securing the future: Update of the ESFRI Roadmap









Microbial Resources Research Infrastructure

- MIRRI
- Enhancement of BRCS and broadening of resources and information
 - Investment by nations in facilities and human resources
- Co-ordination and focus of activities on resource and service provision towards key issues
 - guided by policy makers, programme funders and users
- Common policy on key issues of biosafety, biosecurity and legislation compliance
 - Facilitated and guided by policy makers
- Operational framework that facilitates exchange of materials and information
- Partners 66 European BRCS addition 400 globally
 - Policy makers, funders, International Organisations, Scientific communities, sector representatives







BRCs underpin the life sciences



Need to work together to address the challenges

Thank you



Visit: www.embarc.eu for further information





