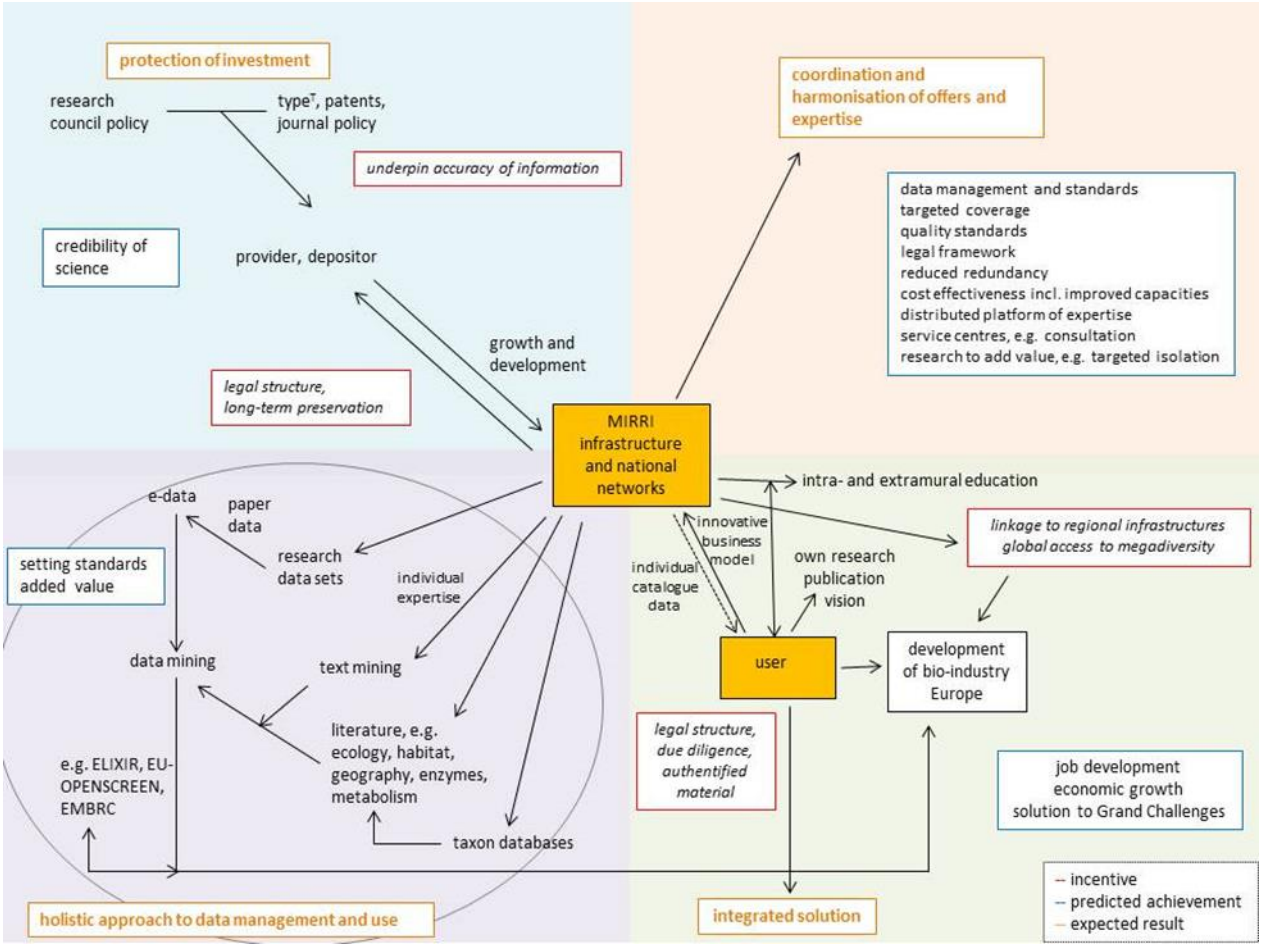
Annex WP1-1 The four major MIRRI domains: incentives, predicted achievements and expected results



Annex WP2-1 Overview of the targets and expected outputs of the WP2-surveys conducted during the period M1 – M18

MIRRI stakeholder group	**Microbial Resource HOLDERS/PROVIDERS**		**Microbial Resource USERS**	
Survey Name	**a. ECCO-CC survey**	**b. non-ECCO-CC survey**	**c. USER survey**	**d. INNOVATIVE SERVICES survey**
Target	Public MRCs/CCs that are member of the European Culture Collections' Organization (ECCO)	Non-public collections within laboratories of European research institutes, public health centres, universities, national reference laboratories and hospitals	Current and potential users of microbial resources and services	Current users of microbial resources and services Potential users from industry (Bio-, Food & Health industry)
Distribution of questionnaires	• to ECCO collection managers	• to compiled list of contacts provided by MIRRI partners and collaborating parties (1st period) • to updated contact lists per country (2nd period)	• to customers of MIRRI collections[1] • to members of scientific microbiology associations in Europe • via European Federation of Biotechnology (email to members + link on EFB website) • via MIRRI website and social media	• to customers of MIRRI collections[1] • to (bio-)industry contacts identified by MIRRI partners and collaborating parties • via European Enterprise Network (EEN) • via MIRRI website and social media
Output to WP2	• Profiles of public MRCs/CCs in Europe (WP2.1) • Inventory of the microbial resources and services offered (WP2.1) • Assessment of compliance to general BRC standards and regulations (WP2.2) • Identified networks (WP2.5)	• Inventory of microbial resources preserved in European laboratory collections (WP2.1) • Assessment of access to these resources and willingness to cooperate with MIRRI (WP2.1) • Assessment of compliance to standards and regulations (WP2.2) • Identified networks (WP2.5)	• Profiles of users of microbial resources (WP2.1, 2.4) • Identified user needs (WP2.4)	• Interest in innovative aspects of MIRRI (WP2.4) • Contribution of the user community to the MIRRI platform (WP2.4)
Output to other WPs	• Assessment of compliance to CBD and biosecurity regulations (WP9) • Assessment of quality and accessibility of collection data (WP8) • Assessment of need for training (WP7.3) • Assessment of quality management (WP3)	• External experts in taxonomy (WP6.2) and R&D (WP5.2) • Opportunities for filling gaps in microbial resources and services (WP6.1, 6.3)	• Identified gaps in resources and services offered by public MRCs/CCs (WP6.1, 6.3) • Identified gaps in available expertise (WP6.2) • Assessment of need for training (WP7.3)	• Identified gaps in resources and services offered by public MRCs/CCs (WP6.1, 6.3) • External experts in taxonomy (WP6.2) and R&D (WP5.2)
1st period	April 9th - May 21st, 2013	Sept 26th - Nov 4th, 2013	April 9th - May 21st, 2013	Jan 29th, 2014 - ongoing
WP2 reporting to MIRRI consortium	MIRRI meeting, Athens, June 2013	2nd General MIRRI meeting, Schiphol, Nov 2013	MIRRI meeting, Athens, June 2013	-
2nd period	June 20th - July 1st, 2013	Nov 27th, 2013 - March 3rd, 2014	Jan 29th, 2014 - ongoing	-

[1]Public MRCs/CCs that are a full partner or collaborating party in the MIRRI preparatory phase.

Annex WP2-2 Overview of feedback received in WP2-surveys conducted during the period M1 – M18

Survey	a. ECCO-CC survey	b. non-ECCO-CC survey	c. USER survey	d. INNOVATIVE SERVICES survey
Number of contacts reached	75	Approx. 500	Unknown (overlapping distribution channels)	Unknown (overlapping distribution channels)
Number of respondents	60 (July 1st, 2013)	158 (March 3rd, 2014)	1146 (May 21st, 2013) ongoing	865 (March 20th, 2014) ongoing
Response rate	80%	Approx. 30%	unknown	unknown
Main categories of respondents	MIRRI collection (34) Other ECCO collection (26)	Government (60) University (57) National Reference Laboratory (13) Hospital (6) Public Health Laboratory (5) Company (3) Other (14)	non-profit (875) profit (271)	non-profit (572) profit (293)
Geographical coverage *Respondents outside Europe in italic*	France (8) Belgium (7) UK (6) Italy (4) Russian Federation (4) Czech Republic (3) Germany (3) Greece (3) Portugal (3) Denmark (2) Finland (2) Poland (2) Spain (2) Bulgaria (1) Estonia (1) Hungary (1) Latvia (1) Sweden (1) Switzerland (1) Slovakia (1) Slovenia (1) The Netherlands (1) Turkey (1)	Spain (43) Italy (27) Belgium (14) France (11) Czech Republic (9) Germany (9) Finland (8) Portugal (8) Greece (7) Russian Federation (4) United Kingdom (4) Latvia (3) the Netherlands (3) Slovak Republic (2) Sweden (2) Georgia (1) Hungary (1) Norway (1) 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 (17) Russian Federation (17) Austria (14) Ireland (10) Finland (8) Hungary (7) Turkey (7) Norway (6) Poland (6) Greece (5) Other[1] (19) *Asia (98)* *North-America (75)* *South-America (16)* *Africa (14)* *Australia & Oceania (11)*	Spain (278) Germany (108) Italy (57) the Netherlands (30) Portugal (30) Belgium (27) Switzerland (27) France (31) United Kingdom (20) Denmark (17) Czech Republic (13) Greece (13) Sweden (13) Austria (11) Finland (9) Poland (9) Hungary (8) Bulgaria (7) Turkey (7) Ireland (6) Other[1] (36) *Asia (57)* *North-America (29)* *South-America (22)* *Africa (11)* *Australia & Oceania (7)*

[1]Other European countries with less than five respondents in the survey.

Annex WP2-3 Specializations of public MRCs/CCs participating in the ECCO-CC survey

Country	Acronym	Specializations of the collection (particular taxa, habitats, …)
Belgium	BCCM-DCG	*Bacillariophyceae*
Belgium	BCCM-IHEM	Dermatophytes, *Cryptococcus, Scedosporium/Pseudallescheria, Candida*
Belgium	BCCM-ITM	*Mycobacterium* species
Belgium	BCCM-LMBP	Tools for functional genome analysis in the biomedical sciences, including expression vectors for overexpression of specific genes as well as expression vectors for downregulation of specific genes.
Belgium	BCCM-LMG	Acetic Acid Bacteria, Lactic Acid bacteria, Plant pathogens including Quarantine bacteria, Plant associated bacteria, Marine bacteria, *Burkholderiaceae*
Belgium	BCCM-MUCL	Arbuscular mycorrhizal fungi
Belgium	BCCM-ULC	Polar habitats (Antarctic and Arctic)
Czech Republic	CCM	*Staphylococcus, enterococcus, Aeromonas, Lactobacillus*
Denmark	IBT	Filamentous fungal genera: *Penicillium, Aspergillus, Fusarium, Trichoderma, Alternaria, Ulocladium, Cladosporium* and related
Estonia	HUMB	Lactobacilli
Finland	HAMBI	Genus *Rhizobium* s.l., Cyanobacteria from fresh and brackish waters, wood rotting fungi from boreal forests
Finland	VTTCC	Enzyme producers, brewing yeast strains, GMOs constructed in-house as part of research projects
France	BRC-Leish	*Leishmania*
France	CIRM-BP	Pathogenic bacteria of veterinary and medical interest
France	CIRM-CF	Polyporales
France	CIRM-CFBP	Plant-associated bacteria, including quarantine and dual-use organisms.
France	CIRM-Levures	French fermentation such as wine making, cheese making, cider making
France	CRB-Oenologie	Vine, wine, fermented beverages
Germany	CCAC	Microalgae
Germany	DSMZ	Actinobacteria, firmicutes, myxobacteria, anaerobic phototrophs, extremophiles, archea, anaerobs, immortalised cell lines, plant virus
Germany	SAG	Microscopic algae and cyanobacteria from freshwater or terrestrial habitats, marine algae; broad taxonomic range with algae and cyanobacteria originating from diverse geographical and ecological niches
Greece	ATHUM	Macromycetes, airborne fungi, mycophilic fungi
Greece	UOA-HCPF	Human and animal primary and opportunistic pathogenic yeasts and fungi from clinical specimens, food, feed, drinks, building and building materials, recreational fresh, sea water and terrestrial environment, archaelogical and ecclesiastical specimens.
Italy	DBVPG	*Saccharomyces cerevisiae* and related species - yeasts isolated from extreme environments (tropic forests and glacial habitats) - microalgae of the genus *Prototheca*
Italy	MUT	Marine fungi, fungi from polluted sites and wastewaters, macromycetes, air- and foodborne fungi, mycorrhizal fungi and lichenized fungi.
Poland	CCIM-IAFB	Bacteria, yeasts, filamentous fungi
Portugal	MUM	*Aspergillus* and *Penicillium,* the major substrata are food commodities (grapes, wine, almonds, etc)

Portugal	PYCC	Yeasts
Russian Federation	IEGM	Non-pathogenic Actinobacteria able to oxidize natural and anthropogenic hydrocarbons
Slovakia	CCY	Isolation of yeasts and yeast-like species from natural sources such as soil, water and plant material
Slovenia	EX-F	Extremophilic fungi from salterns and other hypersaline environments, from Arctic glaciers and other water-based Arctic environments, Contaminants of domestic appliances, and objects of cultural value such as historical textile, paintings and frescoes
Spain	CECT	Halophilic archaea and bacteria, Lactic acid bacteria, *Rizhobium* and related, Marine habitat
UK	CABI	Agriculture, environmental, broad coverage from 147 countries
UK	CCAP	Algae, including marine, freshwater and terrestrial microalgae, seaweeds, cyanobacteria and protozoa
UK	NCYC	Yeasts

Annex WP2-4 Examples of non-public CCs' specializations per category (non-ECCO-CC survey)

Specialized in particular environments
• food and environmental niches
• air borne fungi
• micro-organisms associated with production animals (pigs, poultry, cattle), fish and seafood
• freshwater benthic diatoms (european, tropical rivers and lakes)
• lake Cyanobacteria
• extremophiles (halophiles)
• wood inhabiting fungi
• plant associated microorganisms
• metal contaminated environments
• soil anthropized, industrial areas (waste), heavy metal, organic xenobiotics, space environments
• endophytic fungi
• dairy products
• human gastrointestinal tract
• yeast of vineyard, must and wine
• intracellular symbiotic bacteria and algae
• rhizospheric bacteria, plant-associated bacteria
• harmful marine microalgae
Specialized in particular taxa
• *Phytophthora, Pythium*
• *Bordetella* spp., *Burkholderia* spp., *Legionella* spp.
• *Pseudomonas, Salmonella, Campylobacter*, STEC-E. coli, *Listeria*
• *Clavicipitaceae*
• measles virus
• *Clostridium difficile, Staphylococcus aureus*
• *Aspergillus, Candida, Zygomycetes,* Actinobacteria
• *Sinorhizobium meliloti, Medicago sativa, Medicago truncatula* symbiont
• *Zygnematophyceae* (syn. *Conjugatophyceae*)
• *Borrelia burgdorferi*, relapsing fever borreliae
• *Venturia* sp. (mainly *V. inaequalis, V. pirina, V. asperata*)
Specialized in particular microbial function or applications
• microbial ecology, functional food and feed, medical microbial ecology, risk assessment, biomaterials and nanotechnology, water treatment, aquaculture, bio-energy, soils and sediments.
• entomopathogens; Microbiological control
• plant pathogen agents and biocontrol agents (BCAs)
• Screening and research on natural products and secondary metabolites, Infection biology and mechanisms of pathogenicity
• wine making, dairy processing, meat processing and nutraceuticals
• IAA producing, lytic enzyme producing
• populations of root endophytic fungi of economic interest for fruit tree and arable crops
Specialized in other aspects
• highly pathogenic bacteria (BSL3)
• fungi on grain (production mycotoxine)
• measles virus
• food contaminants harboring antibiotic resistance genes

Annex WP2-5 Expertise in service offer in microbial analyses in ECCO-CCs (a) and non-public CCs (b)

Figure 2. In which of the following has your CC staff expertise and which are at present offered as a service by your CC staff? (ECCO CCs)

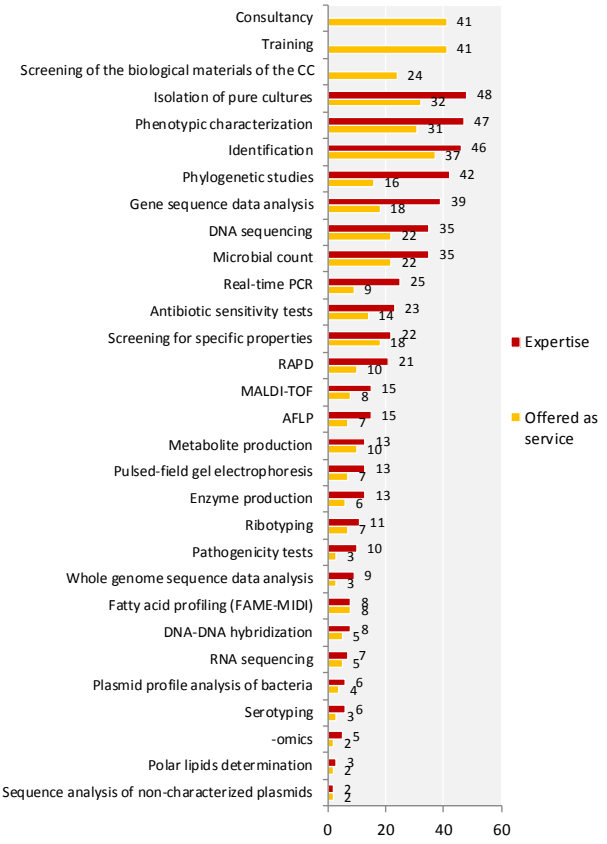
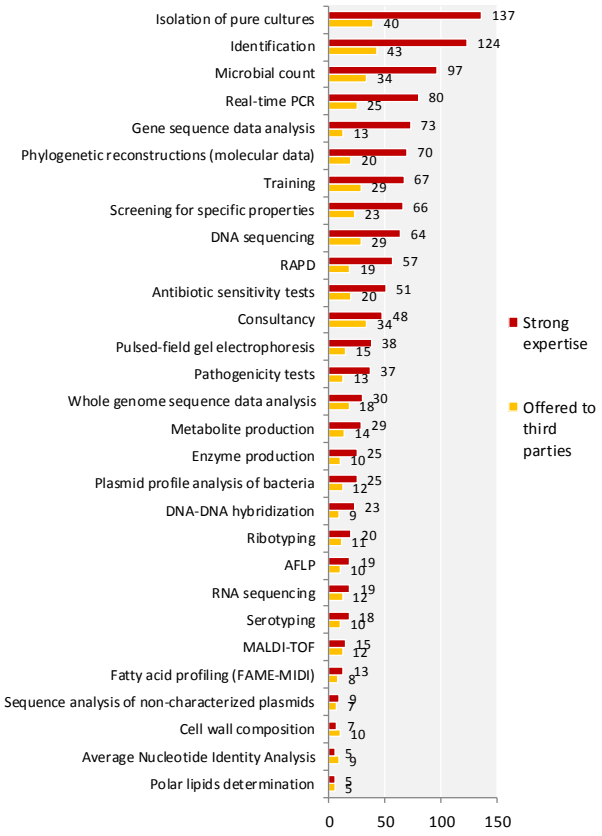


Figure 3. In which of the following subjects has your Unit strong and sustainable expertise, and which of these expertises are offered as a service to third parties? (Non-ECCO CCs)



Annex WP2-6 Expertise in service offer in microbial analyses in ECCO-CCs (a) and non-public CCs (b)

Figure 2. In which of the following has your CC staff expertise and which are at present offered as a service by your CC staff?
(ECCO CCs)

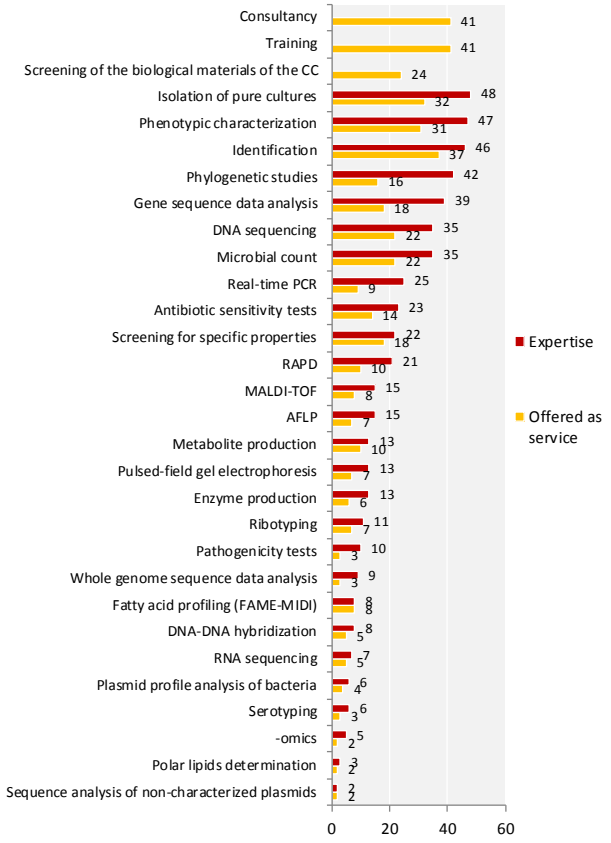
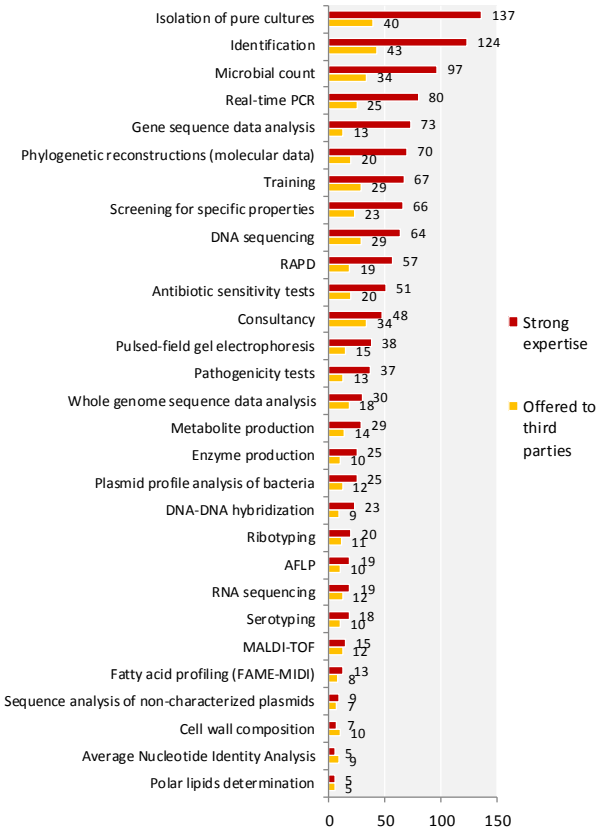


Figure 3. In which of the following subjects has your Unit strong and sustainable expertise, and which of these expertises are offered as a service to third parties?
(Non-ECCO CCs)



Annex WP3-1 Main characteristics of legal forms

Legal forms	Comparison				
	Partnership	**Liability of stakeholders**	**Access policy**	***Advantages***	***Disadvantages***
Legal forms under national law					
Company - Unlimited liability	Public, private, large number of European and non-European countries, large flexibility for newcomers to join as contracting party or as scientific associates	Unlimited liability for debts in proportion to shares	Access according to scientific excellence (peer review) for scientists from contracting parties or associate countries Free for non-proprietary research Access fees for proprietary research	· Clear management, governance and accountability · Clear accounting rules · Adapted to industrial use · Flexible policy staff (limited by national labour rules) · Avoid high cost intergovernmental institute	Unlimited liability
Company - Limited liability	Public, private, large number of European and non-European countries, large flexibility for newcomers to join as contracting party or as scientific associates	Limited by shares	Access according to scientific excellence (peer review) for scientists from contracting parties or associate countries Free for non-proprietary research Access fees for proprietary research	· Clear management, governance and accountability · Clear accounting rules · Adapted to industrial use · Flexible policy staff (limited by national labour rules) · Avoid high cost intergovernmental institute · Can attract additional external investment/funding (in return for shares) · Limited liability	· Some organisations are not able to hold shares · Some national laws are more formal than others: Director General nationality, minority voting rights, salary scale, procurement rules · When shareholders are public organisations : less commercial freedom, uncertain accountabilities state aid rules may apply
Foundation	Private, public bodies with a pre-existing legal entity (may vary from one country to another) (examples: Belgian AISBL or Dutch ANBI, French Association, German Gemeinwohlkonforme Allzweckstiftung etc)	Usually shared equally between members but depends from countries to countries	Custom-fit access rules User fees possible	· Clear management, governance and accountability · Clear accounting rules · Adapted to industrial use · Flexible policy staff (limited by national labour rules) · Avoid high cost intergovernmental institute	· Some country laws other than The Netherlands or Germany are restrictive for foundations

	Partnership	**Liability of stakeholders**	**Access policy**	***Advantages***	***Disadvantages***
Legal forms under community law					
Article 171 joint undertaking	European community, European bodies, - public and private including third countries and investment banks-procedure for new members	Unlimited liability of members	Access to contracting parties only Proprietary of IP	· Clear management and governance · Sound and effective financial rules · Flexible policy staff (limited by national labour rules) · Adapted to industrial use	· Difficulty for non European countries to join · Unlimited liability for debts/joint liability of members
Article 169 European Economic Interest Grouping	European private, public bodies (two members from different member States)	Unlimited liability of all members and associates (except European community) for the RI debts	Custom-fit access rules – User fees possible Proprietary of IP arising from joint initiatives	· Clear management and governance · Sound and effective financial rules (defined in the EEIG convention) · Flexible policy staff (limited by national labour rules and by EEIG convention) · Adapted to industrial use	· Difficulty for non European countries to join · Unlimited liability/joint liability of members · Upper limit of number of employees
ERIC Council Regulation 723/2009	· EU Member states, associated countries, third countries, intergovernmental organisations represented by public or private entities	· Limited to respective contributions to the ERIC	· Flexible, set up in statutes	· Easy for non-European countries to join · Well defined set up process with technical support and advices from the EC ERIC office · Limited liability · Adapted to distributed infrastructure	· Bottom up process to build the infrastructure and obtain support from national authorities · Differs from countries to countries

	Partnership	**Liability of stakeholders**	**Access policy**	***Advantages***	***Disadvantages***
Legal forms under international law					
International Organisation	Any country as member states of an intergovernmental treaty or convention – member states are from Europe (CERN) or from the world (ITER) Other statuses (CERN) for any other country in the world : Associated states, Observers or other partnerships based on cooperation agreement" European Commission is an observer for CERN and a full member for ITER ·	Liability of the member states according to the convention or intergovernmental Treaty	Free worldwide access to results. Full free access for scientists from Member States (ITER,CERN) and from non-Member States according to respective co-operation agreements (CERN) IP rules according to treaty or convention	· Sound and complete convention or treaty (mission, function and structure) · Clear management and governance Attractive privileges and immunities for staff · Attractive staff salaries · Flexible staff policy	· Heavy and lengthy negotiation procedures for reaching a formal agreement between member states
Open-ended international co-ordination body	Any country in the world or relevant international organisation (non-binding Memorandum of Understanding). Two kinds of membership: Voting Participants (making a financial contribution) and Associate Participants (no direct financial contribution)	No binding commitment from members—is based on a non-binding Memorandum of Understanding	Free worldwide access to data provided by participant members. Users must respect conditions for data use set by the providers. IP rules stipulated in data-provider and data-user agreements	· Non-binding nature of MOU facilitates rapidity of agreement between a large number of countries · Attractive privileges and immunities for staff · Attractive staff salaries (tax exemption) · Very flexible staff policy · Independence from interference of the Host Country – financially, politically.	· Memorandum of understanding : 5 years commitment only · Budget not assured as is based on voluntary contributions · Critical phase when transferring from one MOU to the next

Annex WP3-2 National contact points

Country	First Name	Family Name	Email
Austria	Dr. Daniel	WESELKA	daniel. weselka@bmwf.gv.at
Belgium	Dr. Jean	MOULIN	jean.Moulin@stis.belspo.be
Croatia	Ms. Ebonita	CURKOVIC	ebonita.curkovic@hit.hr
Cyprus	Mr. Telemachos	TELEMACHOU	ttelemachou@planning.gov.cy
Denmark	Mr. Anders	ØDEGAARD	aod@fi.dk
	Mr. Troels	RASMUSSEN	trra@fi.dk
Estonia	Mr. Priit	TAMM	priit.tamm@archimedes.ee
Finland	Ms. Eeva	IKONEN	eeva.ikonen@aka.fi
	Mr. Petteri	KAUPPINEN	petteri.kauppinen@minedu.fi
France	Mr. Bertrand	BOUCHET	bertrand.bouchet@recherche.gouv.fr
Germany	Mr. Stefan	KERN	stefan.kern@ bmbf.bund.de
	Mrs. Andrea	OEPEN	Andrea.Oepen@dlr.de
Ireland	Ms. Sarah	DUNNE	fp7infrastructure@hea.ie
Italy	Mr. Giorgio	ROSSI	rossi@tasc.infm.it
	Ms. Caterina	PETRILLO	Caterina.Petrillo@pg.infn.it
Latvia	Mrs. Irina	ARHIPOVA	irina.arhipova@izm.gov.lv
	Ms. Liene	GRINVALDE	liene.grinvalde@mfa.gov.lv
Lithuania	Dr. Gintaras	VALINCIUS	gintaras.valincius@bchi.vu.lt
Luxembourg	Mr. Robert	KERGER	robert.kerger@mesr.etat.lu
Malta	Dr. Joseph	MICALLEF	jjmica@eng.um.edu.mt
Netherlands	Dr. Jeannette	RIDDER-NUMAN	j.w.a.ridder@minocw.nl
	Mr. Richard	DERKSEN	r.h.derksen@minocw.nl
Norway	Mr. Odd Ivar	ERIKSEN	oie@rcn.no
Poland	Mr. Jacek	GIERLINSKI	jacek.gierlinski@nauka.gov.pl
Romania	Mr. Ionel	ANDREI	aionel@mct.ro
Serbia	Dr. Darko	DJUKIC	darko.djukic@nauka.gov.rs
Slovenia	Mr. Sergej	MOZINA	sergej.mozina@gov.si
Spain	Mr Juan Miguel	GONZÁLEZ ARANDA	juanmiguel.gonzalez@mineco.es
Sweden	Mr. Lars	BÖRJESSON	lars.borjesson@vr.se
Switzerland	Dr. Andrea	AEBERHARD	andrea.aeberhard@sbf.admin.ch
United Kingdom	Dr. Peter	FLETCHER	peter.fletcher@stfc.ac.uk

Annex WP5-1 Draft list for potential experts (to be revised)

Full name	**Institution**	**Country**	**Gender**	**Sector (pick one option)**	**Activity (pick one option)**	**Field of expertise (pick one)**	**Additional comments to take into consideration (about expertise or any other reason)**
Spyridon Agathos	Catholic University of Louvain	Belgium	Male	Waste Technology	Academic & Education	Mycology	international expert in Biotechnology and evaluator of EU projects
Nico Boon	Ghent University	Belgium	male	Climate and Environment			Environmental
Nico Callewaert	Ghent University	Belgium	male		Pharma & Medical	Bacteriology and Mycology	Biomedical
Peter Van Damme	Ghent University	Belgium	male			Bacteriology	
Wim Soetaert	Ghent University	Belgium	male		Chemical		Applied microbiology
Stephan De Clercq	Université Catholique de Louvain	Belgium	male	Agriculture and Rural Development		Mycology	Agro-industry
Rudi Beyaert	VIB	Belgium	male		Pharma & Medical	Bacteriology	Biomedical, molecular
Luc De Vuyst	Vrije Unievrsiteit Brussel	Belgium	male	Nutrition and Consumers		Bacteriology and Mycology	Food, fermentation
Carlos Augusto Rosa	Universidade Federal de Minas Gerais	Brasil	Male	Nutrition and Consumers	Food & Feed	Mycology	Yeasts; Industrial Microbiology; Patents
Erna Storgards	VTT Culture Collection	Finland	Female	Nutrition and Consumers	Food & Feed	Mycology	Industrial microbiology and biotechnology; industrial production yeast strains
Benoit Cournoyer	CNRS	France	Male	Climate and Environment	Environmental	Bacteriology	

David Prangishvili	Institut Pasteur	France	Male	Climate and Environment	Environmental	Virology	Additional Alternative Field of activity: Academic and Education; Sector: Education and Culture/ Climate and Environment
Dea García-Hermoso	Institut Pasteur	France	Female	Health Care	Pharma & Medical	Mycology	
Olivier Chesneau	Institut Pasteur	France	Male	Health Care	Pharma & Medical	Bacteriology	Gram-positive bacteria, antibioresistance
Chantal Bizet	CRBIP	France	Female	Nutrition and Consumers	Food & Feed	Bacteriology	**Steering Committee**
Emilie Esnault	National Agency for Food Safety, Work and Environment (ANSES)	France	Female	Health Care	Food & Feed	Bacteriology	Yersinia enterocolitica
Christophe Sola	Université Paris Sud	France	Male	Health Care	Pharma & Medical	Bacteriology	Mycobacteriology
Vincent Cattoir	University Hospital of Caen	France	Male	Health Care	Pharma & Medical	Bacteriology	Antibiotic resistance
Fabien Garnier	University Hospital of Limoges	France	Male	Health Care	Pharma & Medical	Virology	As well as bacteriology
Manuela Schuengel	DSMZ	Germany	Female				**WP5 Leader**
Peter Schumann	DSMZ	Germany	Male	Education and Culture	Academic & Education	Bacteriology	MALDI, Ribo,typing, taxonomy prokaryotes
Erko Stackebrandt	DSMZ	Germany	Male	Education and Culture	Academic & Education	Bacteriology	**Steering Committee**
Rudi Amann	Max-Planck, marine Microbiology Bremen	Germany	Male	Climate and Environment	Environmental	Bacteriology	Ecology, -omics, diversity

Garabed Antranikian	Technische Universität Hamburg	Germany	Male	Energy	Chemical	Bacteriology	Additional Alternative Field of activity: Bioremediation/ Academic and Education; Sector: Waste Technology/ Education and Culture/ Climate and Environment
Peter Kaempfer	University Giessen	Germany	Male	Education and Culture	Academic & Education	Bacteriology	Diversity, systematics prokaryotes
Francois Buscot	University Halle	Germany	Male	Education and Culture	Academic & Education	Mycology	Diversity, soil organisms and mycorrhizas
Effie Tsakalidou	Agricultural University of Athens	Greece	Female	Food Science and Technology	Academic & Education	Bacteriology	Expertise in lactic acid bacteria as functional starters in food and health
Ilaria Nardello	National University of Ireland Galway	Ireland	Female	Climate and Environment	Academic & Education	Algology	After ten years of active research in bio-optical oceanography and marine primary production, I am now in charge of the coordination of the marine biotech research area for NUI Galway and partner institutes.
Magro Francesco	Sipcam Italia S.p.A	Italy	male	Agriculture and Rural Development	Agronomy	Mycology	I'm working in Sipcam Italia R&D, with a special interest in biofertilizers and biostimulants of microbial origin (bacterial and micological mainly)
Paola Battilani	Università Cattolica	Italy	Female	Agriculture and	Academic &	Mycology	Agronomy Mycology

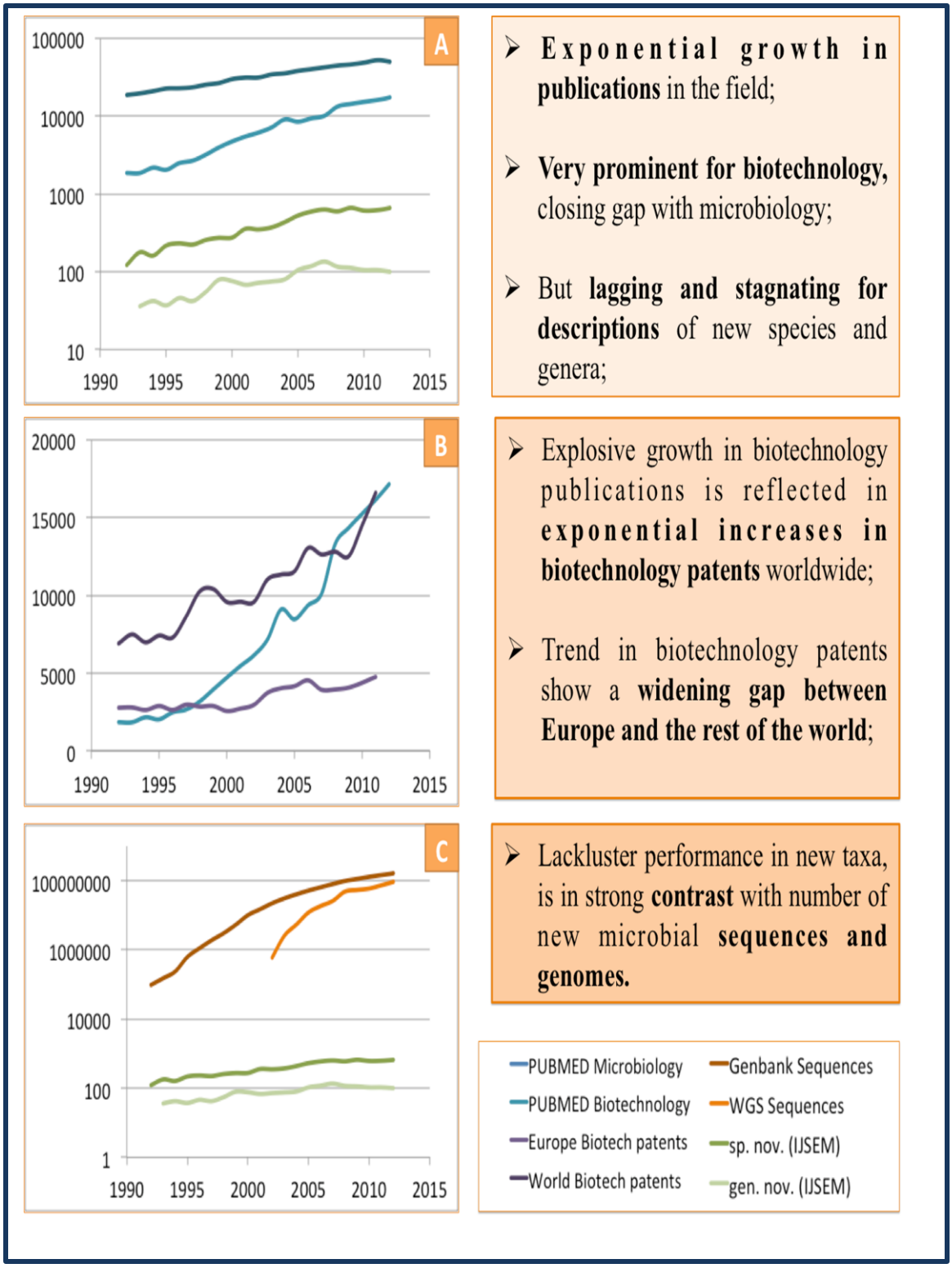
	del Sacro Cuore			Rural Development	Education		
Pietro Buzzini	University of Perugia	Italy	male	Yeast biodiversity & biotecnology	Academic & Education	Mycology	Study of yeast biodiversity from extreme environments (e.g. Antarctica, tropical habitats); Collaboration with SMEs and companies for screening programmes amied at selecting new yeast strains for biofuels, new enzymes and molecoles; IDA center: conservation of patented yeast strains
Cristina Varese	University of Turin	Italy	Female	Waste Technology	Academic & Education	Mycology	Since many years I'm working in collaboration with private companies and in international projects in the exploitation of fungi in the bioremediation of polluted soils and wastewaters. More recently my team has set up a process for the use of oxidative enzyme in wastewater treatments and in the set up of new teechnologies to couple fungal and bacterial treatments.
Anne van Diepeningen	CBS-KNAW, Utrecht	Netherlands	Female	Science	Academic & Education	Medical Mycology	in principle available

Gerard Verkley	CBS-KNAW, Utrecht	Netherlands	Male	Science	Academic & Education	Fungal taxonomy	Access & Benefit Sharing;in principle available
Ronald de Vries	CBS-KNAW, Utrecht	Netherlands	Male	Science	Academic & Education	Fungal physiology	Ronald has experience in collaborating with green biotech companies; in principle available
Piotr Heczko	Jagiellonian University of Cracow	Poland	male	microbiology	Academic & Education	bacteriology	
Jacek Bielecki	University of Warsaw	Poland	male	Microbiology	Academic & Education	Bacteriology	
Małgorzata Gniewosz	Warsaw University of Life Science	Poland	female	microbiology	academic & Education	biotechnology	
Anna Przondo-Mordarska	Wroclaw Medical University	Poland	female	microbiology	Academic & Education	bacteriology	
Cristina L. M. Silva	Catholic University of Portugal	Portugal	Female				Member of the EU Bioeconomy Panel (E02859)
Lilia Santos	Universidade de Coimbra	Portugal	Female	Maritime Affairs and Fisheries	Academic & Education	Algology	Additional Alternative Field of activity: Environmental; Sector: Education and Culture/ Climate and Environment
Carmen Socaciu	Universitatea de Stiinte Agricole si Medicina Veterinara din Cluj-Napoca	Romania	Female	Agriculture and Rural Development	Agronomy		Member of the EU Bioeconomy Panel (E02859)
Natalia Prisyazhnaya	IBPM, VKM	Russia	Female	Education and Culture	Academic & Education	Bacteriology	Maldi-tof mass spectrometry for systematics
Natalia	IBPM, VKM	Russia	Female	Education and	Academic &	Mycology	The main interest -

Ivanushkina				Culture	Education		Biocorrosion
Oleg Stupar	IBPM, VKM	Russia	Male	Agriculture and Rural Development	Bioremediation	Bacteriology	The main interest - Frankia - actinorhizal symbiosis
Carmen Torres	Centro de Investigación Biomedica de La Rioja	Spain	female	Nutrition and Consumers	Veterinary	Bacteriology	Antiobiotic resistance
Antonio Ventosa	Univeridad de Sevilla	Spain	Male	Maritime Affairs and Fisheries	Environmental	Bacteriology	Additional Alternative Field of activity: Academic and Education; Sector: Education and Culture/ Climate and Environment
David Ruiz Arahal	University of Valencia	Spain	Male	Education and Culture	Academic & Education	Bacteriology	**Task 5.2 leader**
Elisabeth Inganäs	CCUG, Sahlgrenska University Hospital	Sweden	Female	Health Care	Pharma & Medical	Bacteriology	Clinical Microbiology. Oversees institutional biosafety and certifications actions, expertise in bacterial identification and diagnostics
Saara Kotila	Nestlé Research Center	Switzerland	Female	Nutrition and Consumers	Food & Feed	Bacteriology	Indutrial Microbiology
Kevin Newsham	BAS (British Antarctic Survey)	UK	Male	Climate and Environment	Academic & Education	Mycology (Fungal ecology and mycorrhizae)	
Mark Bailey	Director, Centre for Ecology & Hydrology	UK	Male	Climate and Environment	Academic & Education	Microbial ecology	

Mel Austin	PML (Plymouth Marine laboratory)	UK	Male	Maritime Affairs and Fisheries	Academic & Education	Marine microbiology	
Haroun N. Shah	Public Health England	UK	Male	Health Care	Pharma & Medical	Bacteriology	
Paul Cannon	Royal Botanical Gardens	UK	Male	Agriculture and Rural Development	Academic & Education	Mycology	If another mycologist is needed
Naresh Magan	Univ Cranfield	UK	Male	Climate and Environment	Academic & Education	Mycology	
Grace Alderson	University of Bradford	UK	Female	Pharma & Medical	Academic & Education	Medical microbiology	
Liz Wellington	University of Warwick	UK	Female	Climate and Environment	Academic & Education	Meta genomics	
David Smith	CABI	UK	Male	Climate and Environment	Agronomy	Mycology	**Steering Committee**

Annex WP5-2 Trends in number of publications, sequences, new species and genera, and patents associated with microbiology. Data collected from Pubmed (publications), Genbank (sequences), International Journal of Systematic and Evolutionary Microbiology (new species and genera), World Intellectual Property Organization (patents).



- **Exponential growth in publications** in the field;
- **Very prominent for biotechnology,** closing gap with microbiology;
- But **lagging and stagnating for descriptions** of new species and genera;

- Explosive growth in biotechnology publications is reflected in **exponential increases in biotechnology patents** worldwide;
- Trend in biotechnology patents show a **widening gap between Europe and the rest of the world**;

- Lackluster performance in new taxa, is in strong **contrast** with number of new microbial **sequences and genomes.**

Annex WP5-3 a Full list of measurable indicators

	Category	Sub-Category	Measurables
Science and Technology	User Services	Services and opportunities for users	
		User proposals	
		Access and maintenance time	
		Users by country, field, and sector	
		Monetary value of offered access time	
	Scientific Outcome	Publications (all types)	
		New scientific methods, experimental techniques, and software applications	
		New standards and procedures	
		Developed metadata (and integration?)	
	Innovation Outcome	Intellectual property rights (IPR)	
		Instruments and products	
	Networking and Collaboration	Strategy for networking and collaboration	
		Attracted research contracts and project funds	
		Guest scientists	
		Organised scientific events and participants	
		Major scientific networks	
		Major networks with industries	
		Regional R&D network	
	Impact on suppliers (Industry)	Relevant industrial sectors and markets	
		Joint development with suppliers	
		High-tech contracts, utilities, and other benefits	
		Low-tech contracts and other benefits	
	More impacts on firms and costumers	Scientific and analytical services	
		Customers and contracts	
		Industrial use	
		Revenues	
		Joint R&D projects with industry	

		Scientific papers cited in industrial patents	
		Benefits from improved general services and infrastructures	
Jobs: Work & Population	**Category**	**Sub-Category**	**Measurables**
	Generated economic activity	Generated economic effect	
	Directly created working places	HR by occupation category and gender	
		HR by level of formal qualification	
		Recruitment markets by occupation category	
		Sectors of recruitment by occupation category	
		Type of contract by gender and nationality	
		Expected staff development (trend)	
		Spending on HR by type of cost (€, % of budget)	
		Attractiveness of working places and compensation	
	Training of students	Theses completed at the RI	
		Nationality of trained students	
		Scholarships for research training	
		Resources for research training (staff, spending)	
		Students participating in user experiments	
		Events for students	
		Teaching in Universities (and others?)	
	Training of scientists and technicians	Strategy for scientific and technical skill development	
		Scientific and technical skill development activities	
		Participants in scientific and technical skill development activities	
		Expected impacts of scientific and technical skill development activities	
	General staff training	General training programmes	
		General staff training intensity (hours, persons)	
		Annual spending on general staff training	
		Expected impact of general staff training	
	Labour Market	Impact on career possibilities	
		Long-term impact on jobs and employment	
		Long-term impact on the quality of jobs	

		Long-term impact on salaries	
	Population	Long-term impact on age distribution, educational/social structure, wealth	

Annex WP5.3 b Extended short-list of measurable indicators

Impact Overview

	Areas		Sub-topics
1	Science & Technology	1.1	Publications
		1.2	IP (Patents) and spin-off companies
		1.3	New equipment, techniques, software
2	Networking, Communication, and Collaboration (Interactions: BRC-BRC; Business-BRC; Society-BRC)	2.1	Guests/users
		2.2	Research contracts and project funds
		2.3	Events and participants (e.g. conferences)
		2.4	Networks and Forums
		2.5	Online presence (e.g. website and social media)
3	Organization & Methods	3.1	Unified standards & SOPs
		3.2	Adoption, Implementation, and creation of standards
4	H.R., Education & Training	4.1	Training (external/internal)
		4.2	Access (external/internal)
5	Services	5.1	Service quality
		5.2	Service added-value
		5.3	New services and/or expansion
6	Reputation & Label	6.1	Awards, Invitations, Press
7	Other/ General	7.1	General Benefits of Microbiology (Feed, Cure, Fuel)

		7.2	Better benefit distribution to place of origin
		7.3	Brain drain, cohesion, dissemination

1. Science & Technology

	Sub-topics	**Measurables**
1.1	Publications	Number of MIRRI publications
		Impact factor of MIRRI publications
		Number of MIRRI partners per publication
		Use of MIRRI strains (strains cited in papers)
		Number of citations
1.2	IP (Patents) and spin-off companies	Number of MIRRI patents
		Number of MIRRI spin-off companies
		Number of MIRRI partners per patent
		Number of co-patents (MIRRI-industry) [?]
		Use of MIRRI strains (strains cited in patents)
		Commercial value of patents [feasible?]
		Commercial value of spin-off companies [feasible?]
1.3	New equipment, techniques, software	Number of new equipment, techniques, software
		Extra sales or gains from these innovations

2. Networking, Communication, and Collaboration
(Interactions: BRC-BRC; Business-BRC; Society-BRC)

	Sub-topics	**Measurables**
2.1	Guests/users	Number of guests/users of MIRRI (totals and by type: e.g. MIRRI, industry)
		Hours of use (totals and by type)
		Income of use (totals and by type)
		Nationalities of users
2.2	Research contracts and project funds	Number of contracts (totals and by type: e.g. MIRRI, MIRRI-industry, others)

		Value of contract funding (totals and by type)
		Source of funding (e.g. public, private)
		Number of MIRRI partners per contract
		Number of nationalities [?]
2.3	Events and participants (e.g. conferences)	Number of participants (totals and by types)
		Type of participants (e.g. Academia, MIRRI, Industry, society)
		Type of meetings
		Number of nationalities
2.4	Networks and Forums	Number of networks created (total and by type)
		Number of new participants in created networks
		Number of networks joined (total and by type)
2.5	Online presence (e.g. website and social media)	Number of Hits
		Number of Page views
		Number of individual Users
		Other statistics

3. Organization & Methods

	Sub-topics	**Measurables**
3.1	Unified standards & SOPs	Number of unified standards/SOPs and effects
3.2	Adoption, Implementation, and creation of standards	Number of adopters
		Number of standards/SOPs created

4. H.R., Education, and Training

	Sub-topics	**Measurables**
4.1	Training (external/internal)	Number of courses
		Type of courses
		Duration of courses
		Number of trainees (total and by type)

		Nationalities of trainees
4.2	Access (external/internal)	Type of access
		Duration of access
		Nationalities

5. Services

	Sub-topics	**Measurables**
5.1	New services and/or expansion	Number of MIRRI assets/holdings (strains/biological material)
		Number of services available
		Number of new services created
		Users of services (total and by type)
		Income from services (total and by type)
		Coverage of total biodiversity [?]
5.2	Service added-value	New data created
		Access to new data
5.3	Service Quality and Satisfaction	Customer satisfaction level

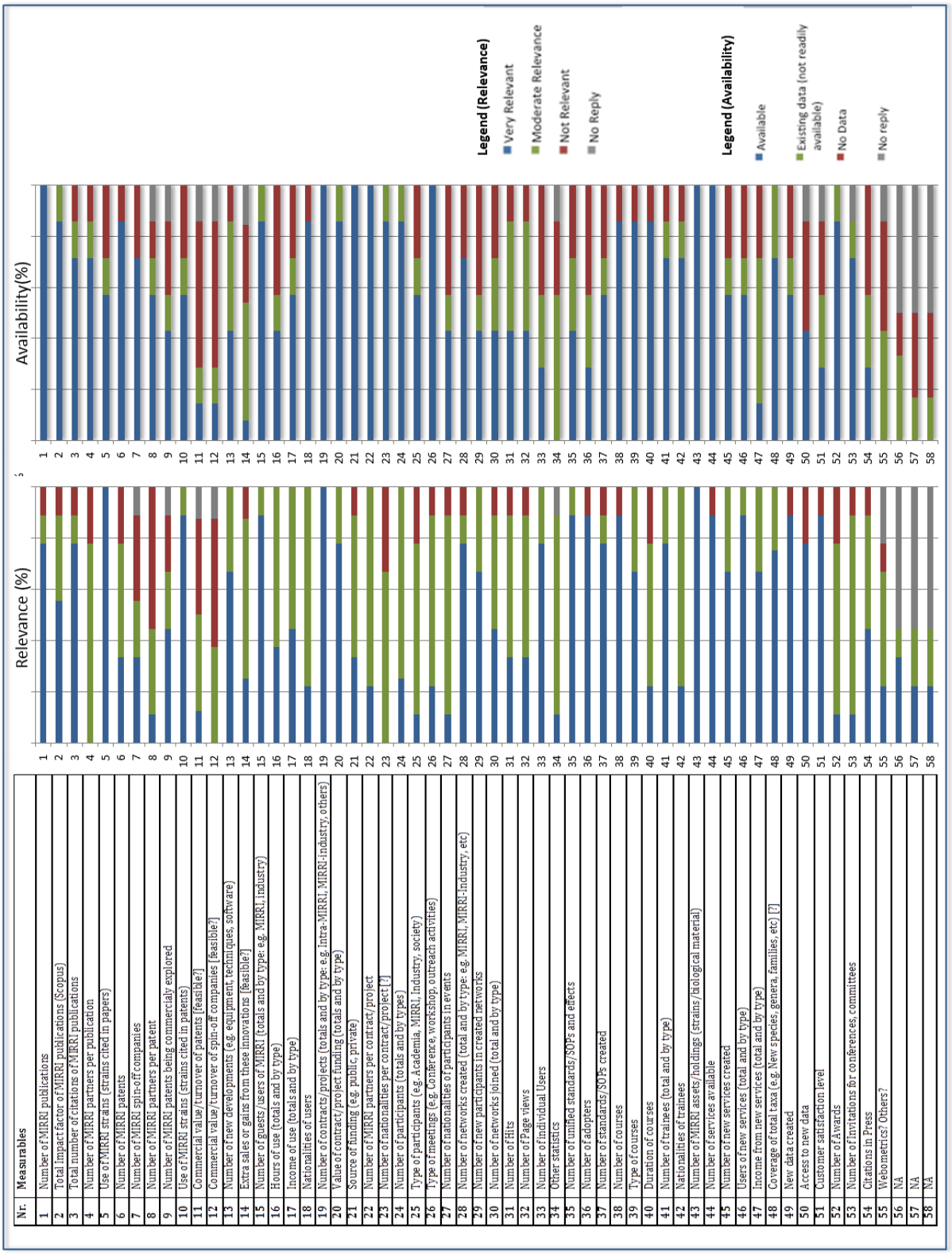
6. Reputation & Label

	Sub-topics	**Measurables**
6.1	Awards, Invitations, Press	Number of Awards
		Number of Invitations for conferences, committees
		Citation in Press
		Webometrics?

7. Other/General

No measurables expected. Overview and brief discussion of benefits of microbiology for society and MIRRI's potential influence.

Annex WP5-4 Compilation and optimization of a list of relevant measurable indicators of MIRRI's impact



Nr.	Measurables
1	Number of MIRRI publications
2	Total Impact factor of MIRRI publications (Scopus)
3	Total number of citations of MIRRI publications
4	Number of MIRRI partners per publication
5	Use of MIRRI strains (strains cited in papers)
6	Number of MIRRI patents
7	Number of MIRRI spin-off companies
8	Number of MIRRI partners per patent
9	Number of MIRRI patents being commercialy explored
10	Use of MIRRI strains (strains cited in patents)
11	Commercial value/turnover of patents [feasible?]
12	Commercial value/turnover of spin-off companies [feasible?]
13	Number of new developments (e.g. equipment, techniques, software)
14	Extra sales or gains from these innovations [feasible?]
15	Number of guests/users of MIRRI (totals and by type: e.g. MIRRI, industry)
16	Hours of use (totals and by type)
17	Income of use (totals and by type)
18	Nationalities of users
19	Number of contracts/projects (totals and by type: e.g. intra-MIRRI, MIRRI-industry, others)
20	Value of contract/project funding (totals and by type)
21	Source of funding (e.g. public, private)
22	Number of MIRRI partners per contract/project
23	Number of nationalities per contract/project [?]
24	Number of participants (totals and by types)
25	Type of participants (e.g. Academia, MIRRI, industry, society)
26	Type of meetings (e.g. Conference, workshop, outreach activities)
27	Number of nationalities of participants in events
28	Number of networks created (total and by type: e.g. MIRRI, MIRRI-industry, etc)
29	Number of new participants in created networks
30	Number of networks joined (total and by type)
31	Number of Hits
32	Number of Page views
33	Number of individual Users
34	Other statistics
35	Number of unified standards/SOPs and effects
36	Number of adopters
37	Number of standards/SOPs created
38	Number of courses
39	Type of courses
40	Duration of courses
41	Number of trainees (total and by type)
42	Nationalities of trainees
43	Number of MIRRI assets/holdings (strains/biological material)
44	Number of services available
45	Number of new services created
46	Users of new services (total and by type)
47	Income from new services (total and by type)
48	Coverage of total taxa (e.g. New species, genera, families, etc) [?]
49	New data created
50	Access to new data
51	Customer satisfaction level
52	Number of Awards
53	Number of invitations for conferences, committees
54	Citations in Press
55	Webometrics? Others?
56	NA
57	NA
58	NA

Annex WP5-5 Key contacts for national authorities (as reported by the MIRRI participants)

MIRRI partner, responsible person	**Task WP2.4 –** Define the stakeholder community	**Task WP3.2 –** Analyse the most appropriate legal status for MIRRI	**Task WP4.3 –** Engage funding bodies	Entry onto **National Roadmap**	**Task WP9.1 –** Define a MIRRI policy on IPR and ABS
CABI David Smith	Research Councils – BBSRC; NERC etc.	???ESFRI representative Prof John WOMERSLEY Director of Science Programme Office Science and Technology Facilities Council, Polaris House North Star Avenue Swindon SN2 1SZ Tel: +44 (0) 1793 442199 Fax: +44 (0) 1793 442036 E-mail: john.womersley@stfc.ac.uk	Research Councils – BBSRC; NERC etc	Research Councils – BBSRC; NERC etc. – Could be the same as for Task WP4.3	DEFRA: Julian Jackson and/or Huw Joynson International Biodiversity Policy Unit, Biodiversity Programme Zone 1/15, Temple Quay House, 2 The Square, Temple Quay, Bristol BS1 6EB. Tel +44 777 5544716 Fax + 44 117 372 3632 E-mail: huw.joynson@defra.gsi.gov.uk
DSMZ Erko Stackebrandt	BMBF, DFG industry: European Enterprise Network (EEN)	Dr. Henk van Liempt BMBF, Referat 617/Bioökonomie henkvanliempt@bmbf.bund.de Stephanie Schneider BMBF, Referat 611 stephanie.schneider@bmbf.bund.de	BMBF, DFG industry: European Enterprise Network (EEN)	*to be identified*	Ute Feit Bundesamt für Naturschutz, FG II 5.1 ute.feit@bfn-vilm.de Nicola Breier Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit, Referat N I 4 nicola.breier@bmu.bund.de
MUT Cristina Varese	For industrial stakeholders EEN (European Enterprise Network) and Assobiotech. Academia will be contacted via congresses and personal communications. We are trying to identify the right Ministry to contact: MIUR	The new ESFRI Rapresentative is Prof Cristina MESSA Rector of the University of Bicocca-Milan and Vice Director of CNR. Tel: +39 02 64488265 Email: cristina.messa@unimib.it The former ESFRI Rapresentative Prof. Maria Luisa Lavitrano Email: marialuisa.lavitrano@unimib.it	different ministries: MIUR, MIPAAF, etc	different ministries: MIUR, MIPAAF, etc	The NFP for Italy is: Mr Sergio Salandri Ministry of Environment, Land and Sea via Capitan Bavastro 174 00154 Rome Tel: +39 06 5722 8234 E mail: salandri.sergio@minambiente.it
CECT Rosa Aznar			Luis Eduardo Ruiz López de la Torre Ayllón , Deputy Director General for International Relations and European Affairs luis.ruiz@mineco.es;		

			Juan Miguel González Aranda, Head of Area for International Relations and European Affairs, juanmiguel.gonzalez@mineco.es		
CRBIP Chantal BIZET	**Institut Pasteur** **AVIESAN and ALLENVI - WGs on Research Infrastructures** **Ministry of Higher Education and Research (MESR/DGRI)** Jean-Michel HEARD Département de Neuroscience, Institut Pasteur 25-28 rue du Dr. Roux 75724 Paris Cedex 15 FRANCE Tel: +33(0) 1 45 68 82 46 jean-michel.heard@pasteur.fr	**Institut Pasteur lawyer** Marie GLOMET Direction Juridique, Institut Pasteur 25-28 rue du Dr. Roux 75724 Paris Cedex 15 FRANCE Tel: +33(0) 1 45 68 81 82 marie.glomet@pasteur.fr **Directorate General for Research and Innovation (DGRI)** Jean-Pierre CAMINADE Direction Générale pour la Recherche et l'Innovation, Ministère de l'Enseignement Supérieur et de la Recherche 1 rue Descartes F-75231 Paris cedex 05 +33(0) 1 55 55 80 39 +33(0) 6 76 87 03 84 jean-pierre.caminade@recherche.gouv.fr Jean-Michel HEARD Département de Neuroscience, Institut Pasteur 25-28 rue du Dr. Roux 75724 Paris Cedex 15 FRANCE Tel: +33(0) 1 45 68 82 46 jean-michel.heard@pasteur.fr	**Ministry of Higher Education and Research (MESR)** with the advice of the **Steering Committee of Very Large Research Infrastructures (CD-TGIR)** **Funding partners** (Institut Pasteur, CNRS, Others)	Decision of the **Directorate General for Research and Innovation (DGRI)** Roger GENET Direction Générale pour la Recherche et l'Innovation, Ministère de l'Enseignement Supérieur et de la Recherche 1 rue Descartes F-75231 Paris cedex 05 Roger.genet@recherche.gouv.fr on the advice of the **Steering Committee of Very Large Research Infrastructures (CD-TGIR)**	Elen LEMAITRE-CURRI Head of global public goods and the future French executive on ABS. Bureau des Biens publics globaux, Ministère de l'Ecologie, du Développement durable et de l'Energie Tour Voltaire 92055 La Défense Cedex Tel: +33(0) 1 40 81 84 62 Fax: +33(0) 1 40 81 71 73 elen.lemaitre-curri@developpement-durable.gouv.fr
CBS-KNAW Gerard Verkley	NWO PO Box 93138, NL-2509 AC, The Hague Tel: +31 70 344 06 40	Mr. Drs. E. (Eli) van der Heide, Senior beleidsmedewerker Ministery of Education, Culture and Sciences Directie OWB Tel + 31 70 412 33 07 E-mail: e.vanderheide@minocw.nl	See WP2.4	See WP3.2	Dr Ir Bert Visser, National Focal Point for Access and Benefit Sharing Centre for Genetic Resources, P.O. Box 16, 6700 AA Wageningen, The Netherlands. E-mail: bert.visser@wur.nl

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IAFB-CCIM Anna Misiewicz	Ministry of Science and Higher Education, Ministry of Agriculture, ?Ministry of Health?	Ministry of Science and Higher Education, ESFRI Representative Dr Jacek Gierliński, tel. + 48 22 5292676, Jacek.Gierlinski@nauka.gov.pl Warszawa, Wspólna1/3, Poland	Ministry of Higher of Science and Education, ?Ministry of the Environment, ?Ministry of Economy?	Ministry of Science and Higher Education, Dr Jacek Gierliński Jacek.Gierlinski@nauka.gov.pl, tel. + 48 22 5292676, Michał Rybiński michal.rybinski@nauka.gov.pl, 22 52 92 225 Warszawa, Wspólna1/3, Poland	*To be identified*
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UGOT Ed Moore					
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Annex WP5-6 Number and type of engagement in the MIRRI social media presence.
*MIRRI-related = involved person is participant of the project

	no. and type of engagement	therefrom MIRRI-related*
Facebook	143 page likes	8 page likes
Twitter	105 followers	3 follower
LinkedIn	25 group members	12 group members
Google+	in the circle of 16 persons	2 persons

Annex WP5-7 Overview on MIRRI outreach activities within the first 18 months

Type of activities	Main Leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
Web	DSMZ	Start signal for MIRRI – first European research infrastructure for microbial resources	23.11.2012	www.dsmz.de	Scientific community, Policy makers, Industry, Media, Civil society	> 10,000	International
Other	DSMZ	Kick-Off Meeting MIRRI	27.-30.11.2012	Braunschweig, Germany	Scientific community, Policy makers	51-100	European
Web	DSMZ	www.mirri.org	27.11.2012	www www.mirri.org	Scientific community, Policy makers, Industry, Media, Civil society	> 10,000	International
Other	DSMZ	Kick-Off Meeting MIRRI, Conference Booklet	27.-30.11.2012	Braunschweig, Germany	Scientific community, Policy makers	51-100	European
Flyer	DSMZ	Flyer	27.11.2012	Braunschweig, Germany	Scientific community, Policy makers, Industry, Media	> 100	International
Other	DSMZ	1st Advisory Board Meeting	28.11.2012	Braunschweig, Germany	Scientific community	0-5	International
Presentation	Verkley	NBRC 10th Anniversary Symposiuim	06.12.2012	Tokyo, Japan	Scientific community, Policy makers, Industry	> 100	International
Publication	Portuguese Society for Microbiology Magazine	Notification	27.12.2012	www http://www.spmicrobiologia.pt/	Scientific community	> 10,000	International
Publication	CECT	Novedades de la CECT desde su traslado al Parque Cientifico de la Universidad de Valencia en 2011 [SEM@FORO no. 54]	Dec. 2012	SEM@FORO	Scientific community, Policy makers, Industry, Media	> 10,000	Spain
Other	DSMZ	1st Steering Committee Meeting	11.01.2013	Paris, France	Scientific community	0-5	European
Article published in the popular press	DSMZ	Article	01.02.2013	BIOSpektrum, 19. Jahrgang, 01.13, S. 6	Scientific community, Policy makers, Industry	> 1,000	Germany
Press release	CABI	Article	01.02.2013	CABI, Knowlegde for Life	Scientific community	> 100	National
Other	WP2	1st WP2 Work Package Meeting	18.-19.02.2013	Valencia, Spain	MIRRI	6-15	International
Other	DSMZ	1st Steering Committee - Work Package Leader Meeting	28.02.2013	Ghent, Belguim	MIRRI	6-15	European
Web	DSMZ	Facebook, Twitter, LinkedIn, Google+	March 2013	www	Scientific community, Policy makers, Industry, Media, Civil society	> 10,000	International
Presentation	Smith, Glöckner, Stackebrandt	MIRRI-Symposium, Annual Conference of the Association for General and Applied Microbiology (VAAM)	12.03.2013	Bremen, Germany	Scientific community, Policy makers, Industry, Media	> 1,000	European
Poster	DSMZ	DSMZ assessment by WGL + experts	18.03.2013	Braunschweig, Germany	Scientific community, Policy makers	16-50	National
Presentation	Stackebrandt	LifeWatch Meeting	18.03.2013	Brussles, Belgium	Scientific community, Policy makers	16-50	European
Presentation	Varese	Reserach Day, Universita degli Studi di Modena e Reggio Emilia	22.03.2013	Modena, Italy	Scientific community	51-100	Italy
Presentation	Varese	BioGenRes, Network Italiano delle Risorse Genetiche	09.04.2013	Roma, Italy	Scientific community, Policy makers	> 100	Italy
Web	Smith	link to MIRRI website on the EFB website	18.04.2013	www.	Scientific community, Policy makers, Industry, Media, Civil society	> 1,000	International
Presentation	Lima	UFAM	19.04.2013	Manaus, Brasil	Scientific community	16-50	National
Article published in the popular press	Stackebrandt/ Oumard	MIRRI - Großes Netz für kleine Organismen	01.04.2013	GIT Verlag (Germany), 04/2013, p.210	Scientific community, Policy makers, Industry, Media	> 1,000	National
Publication	CECT	MIRRI. Microbial Resource Research Infrastructure	01.04.2013	Online-Journal of the Spanish Society for Microbiology, NoticiaSEM No. 63	Scientific community, Policy makers, Industry, Media	> 1,000	Spain
Press release	DSMZ	MIRRI newsletter @ EFB	Mai 13	email	Scientific community, Policy makers, Industry, Media, Civil society	> 1,000	International
Presentation	Stackebrandt	TRUST, Mosaic Workshop	21.05.2013	Shanghai, China	Scientific community, Policy makers	6-15	International
Poster	Romano, Klindworth, Smith, Vasilenko, Glöckner	BITS 2013 (9th Annula Meeting of the Bioinformatics Italian Society	21.-23.05.2013	Udine, Italy	Scientific community, Policy makers, Industry	> 100	Italy
Exhibition	Schüngel	Open house presentation DSMZ	25.05.2013	Braunschweig, Germany	Scientific community, Policy makers, Industry, Media, Civil society	> 1,000	Germany
Poster	Bizet, Hurtado	Departemental day of Microbial Department Institut Pasteur	27.-29.05.2013	Vichy, France	Scientific community, Policy makers	51-100	France
Workshop	Schüngel	EMBRC meets other RIs	28.-30.05.2013	Heraklion, Crete	Scientific community	16-50	European
Article published in the popular press	Stackebrandt, Fritze, Oumard	MIRRI - Large Network for Mico-organisms	June 2013	G.I.T. Laboratory Journal 5-6/2013, p. 8ff	Scientific community, Policy makers, Industry, Media	> 1,000	European

Publication	Aznar	Una gran red de microorganismos	June 2013	SEM@FORO	Scientific community, Policy makers, Industry, Media	> 1,000	Spain
Article published in the popular press	DSMZ	Think big - think microbe: MIRRI	June 2013	"Zellstoff", corporate publishing DSMZ	Scientific community	> 100	Germany
Other	Bizet, Hurtado, Clermon	MIRRI Presentation - Meeting with Representatives of Research Ministry	03.06.2013	Paris, France	Scientific community, Policy makers	0-5	France
Other	DSMZ	2nd Steering Committee Meeting	11.06.2013	Athens, Greece	Scientific community	0-5	European
Other	DSMZ	2nd Steering Committee - Work Package Leader Meeting	11.-12.06.2013	Athens, Greece	MIRRI	16-50	European
Presentation	Stackebrandt	ECCO	14.06.2013	Athens, Greece	Scientific community, Policy makers, Industry, Media	51-100	International
Workshop	Stackebrandt	Infect-ERA meeting	27.06.2013	Lisbon, Portugal	Scientific community, Policy makers	16-50	European
Workshop	Stackebrandt	BMS Group Meeting	02.07.0213	London, UK	MIRRI, ESFRI	6-15	European
Other	Lima	EuroRIsNet+ Workshop	05.07.2013	Lisbon, Portugal	Scientific community, Policy makers	16-50	European
Other	Bizet, Hurtado, Clermon	MIRRI Presentation - Meeting with Representatives of Research Ministry	08.07.2013	Paris, France	Scientific community, Policy makers	0-5	France
Other	Bizet, Hurtado	ESFRI-BMS RI Workshop	09.07.2013	Brussels, Belgium	Scientific community, Policy makers	16-50	European
Press release	DSMZ	press release concerning MIRRI representation on the FEMS	09.07.2013	www	Scientific community, Policy makers, Industry, Media, Civil society		Germany
Presentation	Aznar	XXIV Congreso de Microbiologia. SEM 2013	10.-13.07.2013	Barcelona, Spain	Scientific community, Policy makers	> 100	Spain
Poster	Romano, Klindworth, Smith, Vasilenko, Glöckner	ISMB/ECCB 2013	21.-23.07.2013	Berlin, Germany	Scientific community, Policy makers	> 1,000	International
Press release	DSMZ	FEMS 2013	10.07.2013	www.	Scientific community, Policy makers, Industry, Media, Civil society	> 10,000	International
Exhibition	Schüngel	company booth on FEMS, 5th Congress of European Microbiologists	21.-25.07.2013	Leipzig, Germany	Scientific community, Policy makers, Industry, Media	> 1,000	International
Presentation	E. Stackebrandt, C. Varese, D. Smith	FEMS 2013	21.-25.07.2013	Leipzig, Germany	Scientific community, Policy makers, Industry, Media	> 1,000	International
Publication	Rohde	FOCUS 15, July 2013 (FEMS Newsletter)	.07.2013		Scientific community, Policy makers, Industry, Media, Civil society	> 1,000	International
Presentation	Rohde	European Forum Alpbach	19.08.2013	Alpbach, Germany	Scientific community, Policy makers	> 100	International
Publication	Schüngel, Stackebrandt, Bizet, Smith	EMB.net Journal	21.08.2013	www	Scientific community, Policy makers, Industry, Media, Civil society	> 1,000	International
Article published in the popular press	Romano (CABRI)	CABRI newsletter	26.08.2013	email	Scientific community, Policy makers, Industry	16-50	International
Conference	Glöckner	Biodiversity Informatics Horizons 2013	03.-06.09.2013	Rome, Italy	Scientific community, Policy makers, Industry, Media	> 100	International
Conference	Schüngel	65. Jahrestagung der DGHM e.V., Jahrestagung der DGI e.V.	22.-25.09.2013	Rostock, Germany	Scientific community, Policy makers, Industry, Media	> 1,000	
Presentation	Stackebrandt Smith	WFCC (ICCC13) Plenary Lecture Session	23.-27.09.2013	Beijing, China	Scientific community, Policy makers, Industry, Media	> 1,000	International
Workshop	Hurtado	ISBE-Synergies Workshop	23.09.2013	London, UK	Scientific community, Policy makers	16-50	European
Poster	Misiewicz	4th Polish Congress of Genetics	10.-13.09.2013	Poznan, Poland	Scientific community, Policy makers, Industry	> 100	Poland
Conference	Stackebrandt	IV Simpósio de Coleções de Cultura, Congresso Brasileiro de Microbiologia	29.09.-03.10.2013	Natal, Brasil	Scientific community, Policy makers, Industry	> 1,000	International
Conference	Schüngel	EFIB 2013 (The European Forum for Industrial Biotechnology & the biobased Economy	02.10.2013	Brussels, Belgium	Scientific community, Policy makers, Industry, Media	> 1,000	International
Poster	Bizet, Hurtado, Clermont	10th International Meeting on Microbial Epidemiological Markers (IMMEM-10)	02.-05.10.2013	Paris, France	Scientific community, Policy makers, Industry, Media	> 1,000	International
Poster	Stackebrandt, Schüngel	The Society for Low Temperature Biology Conference 2013	06.-09.10.2013	Hanover, Germany	Scientific community, Policy makers	51-100	International
Other	Schüngel	Biotechnica 2013	08.10.2013	Hanover, Germany	Scientific community, Policy makers, Industry, Media	16-50	European
Workshop	Bizet, Hurtado, Clermont	CARNOT Meetings	09.-10.10.2013	Lyon, France	Scientific community, Policy makers, Industry, Media	> 1,000	France
Workshop	Smith	Fall 2013 Meeting of the US Culture Collection Network	09.-10.10.2013	Maine, USA	Scientific community	16-50	International
Exhibition	Schüngel	Biotechnica 2013; presence at the DSMZ booth	10.10.2013	Hanover, Germany	Scientific community, Policy makers, Industry, Media	> 1,000	International

Flyer	Bizet, Hurtado	Annual Conference of the DIM Malinf	16.10.2013	Paris, France	Scientific community, Policy makers, Industry	> 100	European
Workshop	Schüngel	Workshop on expanded cooperation between ESFRI, JPI and pertinent ERAnets in the fiels of BMS	17.-18.10.2013	Brussels, Belgium	MIRRI, ESFRI, other EU projects	16-50	European
Presentation	Varese	EEN Biotech and Bioeconomy Partnering Event - IFIB 2013	21.-22.10.2013	Naples, Italy	Scientific community, Policy makers, Industry	51-100	European
Presentation	Varese	2nd International Conference on Microbial Diversity	23.-25-10.2013	Torino, Italy	Scientific community, Policy makers, Industry, Media	> 1,000	International
Poster	Rohde	Medical Biodefense Conference 2013	22.-25.10.2013	Munich, Germany	Scientific community, Policy makers, Industry	> 100	International
Presentation	Klenk (DSMZ)	DAAD-HEC International Summer School on 'Food Security in Times of Climate Change: bringing translational research from banch to field'	02.-04.11.2013	Islamabad, Pakistan	Scientific community, Policy makers	16-50	International
Presentation	Smith	Seminar in Santiago at the Department of Intellectual Property and Patents Seminar at University of Concepcion	11.-14.11.2013	Chile	Scientific community	> 100	International
Workshop	Smith	Workshop with representatives from PROCISUR	11.-14.11.2013	Chile	Scientific community, Policy makers	16-50	International
Presentation	Schüngel	5th Project and 3rd Stakeholder Meeting, EU-OPENSCREEN	19.11.2013	Oslo, Norway	Scientific community, Policy makers, Industry	16-50	European
Other	DSMZ	3rd Steering Committee - Work Package Leader Meeting	19.11.2013	Schiphol, Netherlands	Scientific community	6-15	European
Other	DSMZ	3rd Steering Committee Meeting	19.11.2013	Schiphol, Netherlands	Scientific community	0-5	European
Other	WP3	WP3 Work Package Meeting	19.11.2013	Schiphol, Netherlands	Scientific community	6-15	European
Other	MIRRI	2nd General Meeting	19.-22.11.2013	Schiphol, Netherlands	MIRRI	16-50	International
Other	WP2	2nd WP2 Work Package Meeting	20.11.2013	Schiphol, Netherlands	Scientific community	6-15	European
Other	DSMZ	2nd Advisory Board Meeting	21.11.2013	Schiphol, Netherlands	Scientific community	6-15	International
Other	WP8	1st WP8 Work Package Meeting	23.11.2013	Schiphol, Netherlands	Scientific community	6-15	European
Other	BCCM	30 years BCCM: Microbial diversity for science and industry	26.-27.11.2013	Brussels, Belgium	Scientific community, Policy makers, Industry	> 100	Belgium
Workshop	Smith	Ministry of Industry and Primary Resources National Symposium on Managing Microbial Diversity to Underpin a Bio-Economy for Brunei-Darussalam	28.11.2013	Brunei	Scientific community, Policy makers, Industry	> 100	International
Conference	Rohde	2. Wiesbaden Conference	03.-04.12.2013	Wiesbaden, Germany	Scientific community, Policy makers	51-100	International
Conference	Smith	Portuguese Congress of Microbiology and Biotechnology, Micro Biotech 2013	06.-08.12.2013	Aveiro, Portugal	Scientific community, Policy makers, Industry, Media	> 1,000	European
Exhibition	Hurtado	Genetics and Nosocomial Resistance Colloquium, French Society of Microbiology	04.12.2013	Institut Pasteur, Paris, France	Scientific community	51-100	France
Workshop	Stackebrandt	BMS Group Meeting	13.-14.12.2013	HInxton, UK	Scientific community, Policy makers	16-50	European
Presentation	Stackebrandt	IBiSA panal (Coordination of Infrastructures for Life Sciences and Agronomy of the French Ministry of Science	16.01.2014	Paris, France	Scientific community, Policy makers	6-15	National
Workshop	Stackebrandt	ppEMBRC Workshop on Horizon2020 Calls	23.01.2014	Naples, Italy	Scientific community	16-50	European
Workshop	Stackebrandt	BMS Coordinator Meeting - cluster projects	11.02.2014	Amsterdam, Netherlands	Scientific community	16-50	European
Press release	CECT	Portal europeo para el soporte de I+D+i en microbiologia	13.02.2014	Spain	Scientific community, Policy makers, Industry, Media, Civil society	> 10,000	Spain
Workshop	MIRRI MRC Heads	Microbial Resource Centres Heads Meeting: 1st MRCs Heads Meeting	17.02.2014	Hanover, Germany	Scientific community	6-15	European
Other	WP8	2nd WP8 Work Package Meeting	25.-26.02.2014,	Rome, Italy	Scientific community	6-15	European
Poster	Romano	BITS 2014 (11th Annual Meeting of the Bioinformatics Italian Society	26.-28.02.2014	Rome, Italy	Scientific community, Policy makers, Industry	> 100	Italy
Conference	Smith	Second BioMedBridges Annual General Meeting	10.-12.03.2014	Florence, Italy	Scientific community, Policy makers	16-50	European
Poster	Hurtado	10th National Congress of the French Society of Microbiology	31.03.-01.04.2014	Paris, France	Scientific community, Policy makers, Industry	> 100	France
Conference	Hurtado	2nd International Conference on Research Infrastructures (ICRI2014)	02.-04.04.2014	Athens, Greece	MIRRI, ESFRI, other EU projects		International

Workshop	Stackebrandt	Coordinator meeting ESFRI ENV - cluster calls	07.-08.04.2014	Amsterdam, Netherlands	MIRRI, ESFRI, other EU projects	16-50	European
Workshop	Stackebrandtd	Extraordinary ESFRI BMS RI meeting to define H2020 BMS RI Cluster project(s)	28.04.2014	Amsterdam, Netherlands	MIRRI, ESFRI, other EU projects	16-50	European
Other	Stackebrandt, Smith	Steering Committee Meeting	06.-07.05.2014	Braunschweig, Germany	Scientific community	0-5	European
Workshop	Schüngel	EMBRC meeting to prepare the I2EMBR proposal under H2020 INFRADEV-4	07.-08.05.2014	Lisbon, Portugal	Scientific community	6-15	European
Presentation	Stackebrandt	Genetic Resources Repository for Plant Metabolic Engineering and Synthetic Biology (PlantEngine COST Action FA1006)	08.-09.05.2014	Helsinki, Finland	Scientific community, Policy makers	16-50	European
Exhibition	Schüngel	Open house day Federal Council of Germany	17.05.2014	Berlin, Germany	Scientific community, Policy makers, Industry, Media, Civil society	> 10,000	Germany
Poster	CRBIP	Molecular Biology of Archea 2014	19.-22.05.2014	Paris, France	Scientific community, Policy makers, Industry	> 100	European
Presentation	Smith	USCCN Workshop: NSF supported Research Coordination for a community of ex situ microbrial germplams repositories	19.-21.05.2014	State College, Pennsylvania, USA	Scientific community, Policy makers, Industry	> 100	International

Annex WP5-8 List of scientific (peer reviewed) publications

Title	Main Author	Title of the periodical or the series	Number, date or frequency	Publisher	Place of publication	Year of publication	Relevant pages	Permanent identifiers (if available)	Is open access provided to this publication?
On the fitness of microbial taxonomy	J. Tamames, R. Rosello-Mora	Trends in Microbiology	Vol. 20, No. 11	Elsevier Ltd.	The Netherlands	2012	514-516	http://www.sciencedirect.com/science/article/pii/S0966842X12001576	yes
Investment into the future of microbial resources: Culture Collection funding models and BRC business plans for Biological Resource Centres	D. Smith K. McCluskey E. Stackebrandt	SpringerPlus	Vol. 3	Springer Science+Business Media	Luxemburg	2014	online publication	http://www.springerplus.com/content/3/1/81	yes
Deposit of microbial strains in public service collections as part of the publication process to underpin good practice in science	E. Stackebrandt D. Smith S. Casaregola G.C. Varese G. Verkleij N. Lima P. Bridge	SpringerPlus	Vol. 3	Springer Science+Business Media	Luxemburg	2014	online publication	http://www.springerplus.com/content/3/1/208	yes

Annex WP6-1 Holdings (type and non-type strains) of genera per phylum of four major MIRRI partner MRCs. Taxa and number in red indicate individual collection strength. Total number of validly named species are included for comparison.

Phyla	**Validly described genera**	Genera represented in			
		DSMZ	CIP	LMG	CECT
Archaea					
Crenarchaeota	**26**	**24**	-	-	-
Euryarchaeota	**65**	**58**	-	-	**12**
Bacteria					
Aquificae	**12**	**12**	1	-	-
Thermotogae	**6**	**5**	2	-	-
Thermodesulfobacteria	**4**	**4**	1	1	-
Deinococcus/Thermus	**6**	**6**	2	3	1
Chrysiogenetes	**1**	**1**	-	-	-
Chlorobia	**3**	**3**	3	-	-
Chloroflexi	**13**	**9**	-	-	-
Thermomicrobia	**1**	**1**	-	-	-
Nitrospirae	**3**	**2**	1	-	-
Deferribacteres	**6**	**4**	2	-	-
Synergistetes	**5**	2	1	-	-
Planctomycetes	**9**	**6**	-	-	-
Fusobacteria	**9**	**5**	4	1	-
Chlamydiae	**5**	1	-	-	-
Spirochaetes	**14**	7	4	-	-
Fibrobacteres	**1**	-	-	-	-
Acidobacteria	**6**	**5**	-	-	-
Verrucomicrobia	**13**	5	3	-	-
Dyctioglomi	**1**	**1**	-	-	-
Gemmatimonadetes	**1**	**1**	-	-	-
Lentisphaera		-	-	-	-
Bacteroidetes	**181**	**105**	**107**	**76**	**13**
Firmicutes	**306**	**264**	**146**	**76**	**42**
Actinobacteria	**238**	**226**	**147**	**79**	**46**
Proteobacteria	**746**	**572**	**367**	**277**	**126**

Annex WP6-2 Specialized Bacteria collections maintained in European laboratories/institutes (data collected from MIRRI-WP2 survey for laboratory collections).

Country	Bacterial Holdings	Specializations / holdings not well represented in public MRCs
Belgium	> 10,000	*Salmonella enterica* subsp. *enterica*, *Yersinia*, highly pathogenic bacteria (BSL3)
Belgium	10000	foodborne pathogens, isolates from foodborne outbreaks
Belgium	> 5,000	Bacilli, food and environmental niches, Archaea
France	4000	dairy environments (cheese, milk, atmosphere,..), *Psychrobacter* sp., *Arthrobacter* sp., *Leucobacter* sp.
Germany	>10000	*Clostridium difficile, Staphylococcus aureus*
Greece	3000	genus *Streptomyces*, extreme environments like volcano, isolated islands, rhizosphere of indigenous plants, sea habitats
Italy	10000	*Bifidobacteriaceae*
Italy	3000	human pathogens, Risk group 3 and 4 agents, MDR bacteria, *Mycobacterium tuberculosis,* clinical isolates
Italy	2000	Animal origin, mastitis pathogens
Portugal	30000	staphylococci, streptococci, enterococci, *Bacillus subtilis*
Spain	2600	All genera related to plants
The Netherlands	6500	Different plant pathogenic bacteria, agricultural environments, water environments, *Dickeya* spp., *Pectobacterium* spp., *Clavibacter* spp., *Xanthomonas* sp., *Pseudomonas* sp., *Erwinia* sp.
United Kingdom	11000	Plant pathogens. Especially *Pseudomonas* and *Xanthomonas* from different plants (*Prunus*, peas, beans) and geographical origins

Annex WP6-3 Specialized Fungi (F) and Yeast (Y) collections maintained in European laboratories/institutes (data collected from MIRRI-WP2 survey for laboratory collections).

Country	Fungi & Yeast Holdings	Specializations / unique holdings of the collection
Czech Republic	1449 (F)	*Clavicipitaceae*
Finland	2000 (F)	*Armillaria* spp., *Heterobasidion* spp., *Phlebia* spp., *Lophodermium* spp. All fungi of this collection are isolated from trees
France	4500 (F)	*Venturia* sp. (mainly *V. inaequalis, V. pirina, V. asperata*)
Germany	15000 (F)	Specialized taxa: *Aspergillus, Candida, Zygomycetes*
Italy	2000 (F)	Plant pathogen agents and biocontrol agents (BCAs)
Italy	1509 (Y)	Grape and wine microorganisms
Portugal	650 (Y)	Indigenous yeasts of the Demarcated Douro Region
Spain	1224 (Y)	Yeasts from apple juice and cider from Asturias (Spain)
Spain	1060 (F)	*Phycomyces blakesleeanus, Blakeslea trispora, Phycomyces nitens, Mucor circinelloides*
The Netherlands	3700 (F)	Obligatory fungi as mildews, smuts and rusts, plant pathogenic fungi (quarantine organisms and their close relatives): *Phytophthora* spp., *Phoma* spp., *Fusarium* spp., *Synchytrium endobioticum, Guignardia* spp. / *Phyllosticta* spp., *Diaporthe* spp. / *Phomopsis* spp., *Synchytrium endobioticum*,
United Kingdom	500 (F)	Anaerobic fungi, whiterot fungi, dark septate endophytes, *Moniliophthora perniciosa*

Annex WP6-4 Holdings (number of strains) of specialized laboratory collections (data collected from MIRRI-WP2 survey for laboratory culture collections).

Country	Cyano-bacteria	Micro-algae	micro-algae viruses	Proto-zoa	plant viruses	phyto-plasma	viroids	human viruses	con-sortia
Czech Republic		236							
France	124	372							
France	415	2000	160						
Germany		502							
Greece	100	100							
Russian Federation		400		2000	200				300
Belgium				80				150	
Belgium					250	22	25		
the Netherlands					100		10		
Italy					758	27			
Belgium									100
Finland									4000

Annex WP7-1 Survey on training, current tools and contents (used and produced) by MIRRI partners- Aug 2013

	Question	Reply options	X	Remarks
1	Do members of your collection receive training?	Yes		Go to 1.1
		No		Skip to 2
1.1	Source of training received	Internal		
		External		
		Both		
2	Does your collection provide training?	Yes		
		No		Skip to End
3	Who is responsible for training provided by your collection?	Culture Collection		
		University		
		Both		
		Other (Specify below)		
4	Type of training provided?	Exclusively Theoretical		
		Exclusively Practical		
		Theoretical and Practical		
5	Training format	Face-to-face Learning		
		Distance Learning		
		Blended or Hybrid Learning (mix of face-to-face and distance learning)		
6	Do you produce digital content for training? Which types?	None		Please add further details on content at the end of survey
		Text (e.g. Powerpoint)		
		Video		
		Audio		
		Virtual Labs		
		Interactive		
		Other (Specify Below)		
7	Do you make use of digital content for training? Which types?	None		
		Text (e.g. Powerpoint)		
		Video		
		Audio		
		Virtual Labs		
		Interactive		
		Other (Specify Below)		
8	Do you use e-learning authoring tools?	None		Skip to 9
		Powerpoint Plugin		

	(Tools for development or addition of interactivity)	Authoring Tools (PPAT)		
		Desktop Authoring Tools (DAT)		
		Sever-based Tools (SBT)		
8.1	Software tools used	Articulate (PPAT)		
		Adobe Captivate (DAT)		
		Lectora (DAT)		
		Coursebuilder (SBT)		
		Mohive (SBT)		
		Other (Specify below)		
9	Do you use Virtual Learning Environments/ Course Management Systems?	None		Skip to End
		Blackboard		
		Moodle		
		Sakai		
		Other (Specify below)		

-End-

If you produce contents for training, please provide us with additional details in this box (please include links or attach examples of produced contents in your e-mail reply):

Additional Comments:

Annex WP7-2a Overview of different Learning Experience Dimensions (L.E.D.) and synchronicity: examples of face-to-face alternatives and enhancements.

L.E.D.	Synchronicity	Face-to-Face Alternative	Face-to-Face Enhancement
Expository	**Synchronous**	Live, one-way webcast of online lecture course with limited learner control (e.g., students proceed through materials in set sequence)	Viewing webcasts to supplement in-class learning activities
	Asynchronous	Course taught through online video lectures that students can access on their own schedule	Online lectures on advanced topics made available as a resource for students in a conventional class
Active	**Synchronous**	Learning how to troubleshoot a new type of system by consulting experts through live chat	Chatting with experts as the culminating activity for a curriculum unit
	Asynchronous	Course taught entirely through Web quests that explore specific issues	Web quest options offered as an enrichment activity for students completing their regular assignments early
Interactive	**Synchronous**	Course taught entirely through an online, collaborative simulation that multiple students interact with at the same time	Supplementing a lecture-based course through a session spent with a collaborative online simulation used by small groups of students
	Asynchronous	Professional development through "threaded" discussions and message boards on topics identified by participants	Supplemental, threaded discussions for participants in a face-to-face course

Annex WP7-2b Types of Authoring Tools: Overview and Examples

	Powerpoint Plugin Authoring Tools	Desktop Authoring Tools	Server-Based Tools
Overview	Powerpoint-based Very easy to use	More complex, but more control over style and interactions	Server-hosted Better suited for frequent updates and file management Suited for large, dispersed teams working together
Examples	Articulate	Adobe Captivate Lectora Articulate Storyline	Coursebuilder Mohive Atlantic Link

Annex WP7-3 French stakeholders targeted by the training provider survey

Structure	**Number**	**Persons contacted**
University Institutes of Technology (deliver Licence degree)	39	91
Private organisms delivering Advanced Technician Certificate (equivalent to Licence degree)	47	47
Public organisms delivering Advanced Technician Certificate (equivalent to Licence degree)	98	98
University departments delivering microbiology specialised Master degrees	22	36
Graduate schools for engineers (Master degree)	8	29
Private foundations for research / training and private entities	19	51

Background information

***1. In which country are you located?**

***2. What is the type of structure that you represent?**

- ◯ Graduate school for engineers / technicians in microbiology
- ◯ Foundation for research/training
- ◯ Private entity selling life-long training courses
- ◯ Research institute
- ◯ University (please specify city and school/teaching department)

Please specify the full name + acronym

Organisation of the training

3. Who is the target audience for your training offer?

- ◯ Technicians (or future technicians)
- ◯ Engineers (or future engineers)
- ◯ Research scientists / university lecturers
- ◯ Students/PhD students
- ◯ Other (please specify)

4. What is the mean duration of the course in hours?

5. How many participants (mean number) are admitted?

6. (If applicable) how much does training cost?

7. Which language is used for the course?

- ☐ Language of your country
- ☐ English

8. How is the training performed?

- ◯ Face-to-face teaching
- ◯ E-learning

9. How is the participant's evaluation made?

- [ ] Self-assessment
- [ ] No evaluation: certificate of attendance provided
- [ ] Assessment questionnaire
- [ ] Oral exam
- [ ] Theoretical written exam
- [ ] Practical exam
- [ ] Other (please specify)

10. What kind of course material is provided?

- [ ] Written form, prepared using electronic resources
- [ ] Written form, prepared using classical bibliographic resources (books, articles…)
- [ ] Multimedia support (CD-Rom, audio & video)
- [ ] No course material
- [ ] Other (please specify)

11. Is the training associated to:

- ◯ ECTS (European Credits Transfer System) ?
- ◯ Certificate of attendance?
- ◯ Diploma?

12. Is there an evaluation of the training?

- ◯ Yes
- ◯ No

13. Is customized training offered?

- ◯ Yes
- ◯ No

Content of the training

14. What do the courses consist of?

- [ ] Theoretical courses
- [ ] Practical courses
- [ ] Demonstration workshops
- [ ] Discussion sessions
- [ ] Other (please specify)

15. What are the main topics of the theoretical courses?

- [ ] Cellular biology, metabolism, molecular genetics
- [ ] Biodiversity and taxonomy
- [ ] Evolutionary biology, phylogeny
- [ ] Population biology
- [ ] Ecology, environmental role
- [ ] Human/animal health
- [ ] Phytopathology
- [ ] Industrial applications, biotechnology
- [ ] No theoretical course
- [ ] Other (please specify)

16. On which area is the training centred?

- [ ] Specific microbial ecosystem
- [ ] Specific taxonomic group
- [ ] Specific research area
- [ ] Specific technique
- [ ] Other (please specify)

17. What type of micro-organisms, sorted by taxon, is the training centred on?

- [ ] Eubacteria
- [ ] Archaea bacteria
- [ ] Cyanobacteria
- [ ] Filamentous fungi
- [ ] Lichens
- [ ] Micro-algae
- [ ] Protozoa
- [ ] Viruses
- [ ] Yeasts
- [ ] Other (please specify)

18. What are the technical skills acquired during the practical courses?

- [ ] Preservation and storage of microbial material
- [ ] Identification / characterisation, on a molecular basis
- [ ] Identification / characterisation, on a phenotypic basis
- [ ] Risk analysis related to hazardous organisms
- [ ] Bioinformatics
- [ ] Database management
- [ ] No practical course
- [ ] Other (please specify)

19. Concerning the trends in similar training courses; from your point of view, could you identify topics/skills that are no longer relevant?

- ◯ Yes
- ◯ No

Content of the training

20. Please specify which topics/skills are no longer relevant:

- [ ] Characterisation based on optical microscopy
- [ ] Characterisation based on phenotypic basis (biochemical tests,…)
- [ ] Taxonomy
- [ ] Other (please specify)

***21. Have you planned to provide new courses in the near future?**

- ◯ Yes
- ◯ No

Content of the training

22. Please specify the course you are planning to provide:

In which field of study/topic?

Who is the target audience?

23. What kind of difficulties do you face when preparing new courses?

- ☐ Lack of classical bibliographic resources (books,…)
- ☐ Lack of electronic resources
- ☐ Lack of information concerning the level of your audience and the main features of the current offer
- ☐ Lack of information about the exact needs of your audience in microbiology
- ☐ Other (please specify)

Organisation of the teaching

24. What is the number of hours per course you provide in microbiology, per year and academic degree?

Bachelor:

Master (1st year):

Master (2nd year), post-master:

Life-long training:

Other (please specify):

25. What kind of course material do you offer?

- ☐ Written form, prepared using numeric resources
- ☐ Written form, prepared using classical bibliographic resources (books,…)
- ☐ Multimedia support (audio&video)
- ☐ No course material
- ☐ Other (please specify)

Content of the courses

26. What do the courses in microbiology consist of?

- [ ] Theoretical courses (face-to-face)
- [ ] Practical courses
- [ ] Tutorial exercises (face-to-face)
- [ ] E-learning
- [ ] Other (please specify)

27. What are the main topics of the theoretical courses?

- [ ] Cellular biology, metabolism, molecular genetics
- [ ] Biodiversity and taxonomy
- [ ] Evolutionary biology, phylogeny
- [ ] Population biology
- [ ] Ecology, environmental role
- [ ] Human/animal health
- [ ] Phytopathology
- [ ] Industrial applications, biotechnology
- [ ] No theoretical course
- [ ] Other (please specify)

28. On which area is the training centred?

- [ ] Specific microbial ecosystem
- [ ] Sspecific taxonomic group
- [ ] Specific research area
- [ ] Specific technique
- [ ] Other (please specify)

29. What type of micro-organisms, sorted by taxon, is the training centred on?

- [ ] Eubacteria
- [ ] Archaea bacteria
- [ ] Cyanobacteria
- [ ] Filamentous fungi
- [ ] Lichens
- [ ] Micro-algae
- [ ] Protozoa
- [ ] Viruses
- [ ] Yeasts
- [ ] Other (please specify)

30. What are the technical skills acquired during the practical courses?

- [ ] Preservation and storage of microbial material
- [ ] Identification / Characterisation, on a molecular basis
- [ ] Identification / Characterisation, on a phenotypic basis
- [ ] Risk analysis related to hazardous organisms
- [ ] Bioinformatics
- [ ] Database management
- [ ] No practical course
- [ ] Other (please specify)

31. Concerning the trends in similar training courses; from your point of view, could you identify topics/skills that are no longer relevant?

- ◯ Yes
- ◯ No

Content of the courses

32. Please specify which topics/skills are no longer relevant:

- [ ] Characterisation based on optical microscopy
- [ ] Characterisation based on phenotypic basis (biochemical tests,…)
- [ ] Taxonomy
- [ ] Other (please specify)

***33. Have you planned to provide new courses in the near future?**

- ◯ Yes
- ◯ No

Content of the courses

34. Please specify the course you are planning to provide:

In which field of study/topic?

Who is the target audience?

35. What kind of difficulties do you face when preparing new courses?

- ☐ Lack of classical bibliographic resources (books,…)
- ☐ Lack of electronic resources
- ☐ Lack of information concerning the level of your audience and the main features of the current offer
- ☐ Lack of information about the exact needs of your audience in microbiology
- ☐ Other (please specify)

General

1. What is the name of your Microbial resources centres (MRC)?

Full Name:

Acronym:

*2. In which country are you located?

*3. Have you planned to provide Microbiology-related training in the near future?

- ◯ Yes
- ◯ No

General

4. Please specify the course you are planning to provide:

In which field of study/topic?

Who is the target audience?

5. What kind of difficulties do you face in the preparation of this new offer?

- ☐ Lack of classical bibliographic resources (books,…)
- ☐ Lack of electronic resources
- ☐ Lack of information concerning the level of your audience and the main features of the current offer
- ☐ Lack of information about the exact needs of your audience in microbiology
- ☐ Other (please specify)

*6. Does your MRC currently offer Microbiology-related training?

- ◯ Yes
- ◯ No

Thank you for your time! Unfortunately, you do not meet our criteria to take the survey at this time. Please exit the browser.

Thank you for your time! Unfortunately, you do not meet our criteria to take the survey at this time. Please exit the browser.

Organisation of the training

7. How is the training offer proposed?

- ◯ Training course
- ◯ Workshop
- ◯ Seminar
- ◯ Other (please specify)

8. What do the courses consist of?

- ☐ Theoretical courses
- ☐ Practical courses
- ☐ Demonstration workshops
- ☐ Discussion sessions
- ☐ Other (please specify)

9. Who is the target audience for your training offer?

- ◯ Technicians (or future technicians)
- ◯ Engineers (or future engineers)
- ◯ Research scientists / University lecturers
- ◯ Students/PhD students
- ◯ Other (please specify)

10. Which criterion(a) is (are) used to select the participants?

- ◯ Curriculum vitae
- ◯ Motivation letter
- ◯ Recommendation letter
- ◯ Grade
- ◯ None
- ◯ Other (please specify)

11. How many participants (mean number) are admitted?

12. What is the mean duration of the course?

13. (If applicable) how much does training cost? (If the training offer includes several courses, please give a range.)

14. Which language is used for the course?

- [ ] Language of the MRC
- [ ] English

15. How is the training performed?

- ◯ Face-to-face teaching
- ◯ E-learning

16. How is the participant's evaluation made?

- [ ] Self-assessment
- [ ] No evaluation: certificate of attendance provided
- [ ] Assessment questionnaire
- [ ] Oral exam
- [ ] Theoretical written exam
- [ ] Practical exam
- [ ] Other (please specify)

17. What kind of course material is provided?

- [ ] Written form, prepared using electronic resources
- [ ] Written form, prepared using classical bibliographic resources (books, articles …)
- [ ] Multimedia support (CD-Rom, audio & video)
- [ ] No course material
- [ ] Other (please specify)

18. Is the training associated to:

- ◯ ECTS (European Credits Transfer System) ?
- ◯ Certificate of attendance?
- ◯ Diploma?

19. Is there an evaluation of the training, i.e. do attendants evaluate the training offered?

- ◯ Yes
- ◯ No

20. Is customized training offered?

- ◯ Yes
- ◯ No

Content of the training

21. If applicable, what are the main topics of the theoretical courses?

- ☐ Cellular biology, metabolism, molecular genetics
- ☐ Biodiversity and taxonomy
- ☐ Evolutionary biology, phylogeny
- ☐ Population biology
- ☐ Ecology, environmental role
- ☐ Human/animal health
- ☐ Phytopathology
- ☐ Industrial applications, biotechnology
- ☐ No theoretical course
- ☐ Other (please specify)

22. On which area is the training centred?

- ☐ Specific microbial ecosystem
- ☐ Specific taxonomic group
- ☐ Specific research area
- ☐ Specific technique
- ☐ Other (please specify)

23. What type of micro-organisms, sorted by taxon, is the training centred on?

- [ ] Eubacteria
- [ ] Archaea bacteria
- [ ] Cyanobacteria
- [ ] Filamentous fungi
- [ ] Lichens
- [ ] Micro-algae
- [ ] Protozoa
- [ ] Viruses
- [ ] Yeasts
- [ ] Other (please specify)

24. If applicable, what are the technical skills acquired during the practical courses?

- [ ] Preservation and storage of microbial material
- [ ] Identification / Characterisation, on a molecular basis
- [ ] Identification / Characterisation, on a phenotypic basis
- [ ] Risk analysis related to hazardous organisms
- [ ] Bioinformatics
- [ ] Database management
- [ ] No practical course
- [ ] Other (please specify)

***25. Concerning the trends in similar training courses; from your point of view, could you identify topics/skills that are no longer relevant?**

- ◯ Yes
- ◯ No

Content of the training

26. From your point of view, which topics/skills are no longer relevant?

- [ ] Characterisation based on optical microscopy
- [ ] Characterisation based on phenotypic basis (biochemical tests,…)
- [ ] Taxonomy
- [ ] Other (please specify)

Please fill in separately for each course / workshop / seminar

MRC: Full name + Acronym

Address

City/Town

State/Province

ZIP/Postal code

Country

Webpage

Type and title of the training

- ◯ Course
- ◯ Workshop
- ◯ Seminar

Title of the training:

Name of the responsible person for the training

E-mail address

Phone Number

Frequency of the course

Total hours of training

Language

Course fee in €

Does the fee include course material or not?

- ◯ Yes
- ◯ No

Maximum number of participants

Participant selection is based on

- ☐ Academic degree
- ☐ Experience
- ☐ Scientific excellence
- ☐ Application letter
- ☐ Other (please specify)

Number of staff involved

Percentage of theoretical content

Percentage of practical content

Target audience

Objective of the Training

General contents

Type of evaluation

Is the training part of a Master program. If yes, please specify the European Credits Transfer System (ECTS) number?

- ◯ Yes
- ◯ No

ECTS number:

If the training is not included in a Master program, do the participants receive another type of diploma or certificate?

- ◯ not applicable
- ◯ diploma
- ◯ certificate of attendance
- ◯ certificate of successful completion
- ◯ Other (please specify)

Could this training be integrated in a MIRRI training program?

- ◯ Yes
- ◯ No

How should people apply to attend the training?

- ◯ Paper application form
- ◯ Electronic application
- ◯ Application letter
- ◯ Other (please specify)

ANNEX WP8-1

DATA MANAGEMENT IN CULTURE COLLECTIONS

MIRRI WP8 18 month

Vincent Robert, David Smith, Paolo Romano, Alexander Vasilenko, Anna Klindworth, Frank Oliver Glöckner

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20.03.2014

1. INTRODUCTION

Culture collections are dealing with an increasing number of objectives and duties. Clients want more information about the strains, improved quality services for identification, the choice of a large panel of strains, order strains online and rapid delivery, etc. At the same time, funding bodies are increasing their expectations requiring more scientific publications of high impact factor, increased security, tracking of the origin of the strains, while maintaining or improving the overall quality of the collection. Of course, all these objectives should be achieved, with reduced staff and money. As if these problems are not sufficient, our (taxonomic) science is in a deep mutation phase with the introduction of new technologies that are producing large amounts of data. More and more, culture collection staff has to handle increasing amounts and diversity of data quickly with limited resources. While for decades, culture collections or museums were considered as core facilities to access type or reference material, there is a current trend to consider them as less important since data acquisition on newly sampled material is becoming cheaper and easier when using new methodologies such as next generation sequencing (for example). Therefore, strains or specimens that are poorly annotated or lacking useful metadata can be considered by some as useless.

This paper intends to list and discuss informatics infrastructure needs for culture collections, their curators, associated technicians, researchers and clients or end-users. In order to find the best model or system to handle culture collection's operations the expected features demanded by curators and their clients are listed first and then the possible technical options that could be implemented for the curation, the publication and the use of culture collection's data are discussed.

To create a modern and advanced tool for the management, the analysis, the publication and the interoperability of data, there are a number of important prerequisites that need to be present:

1. Well curated and maintained database
2. Well-structured database
3. Data must be consistently and properly coded and stored
4. Database must be as complete as possible and missing data should be limited

These points form the foundation of everything discussed in this paper. Without them, the whole system would be built on a weak and unstable base.

A series of topics are presented with the advantages and disadvantages of the different possible solutions. Some of the answers are partial and slightly subjective but are needed to stimulate the development of the future MIRRI information system and its outreach globally.

The document is divided into four major sections:

1. Management systems to assist collection curators
2. Publication of data for third parties
3. Interoperability

The second and third section is somehow related but deserves separate treatments.

2. DESIRED FUNCTIONS

Culture collections data management systems (CCMS) must include functionalities that will be useful to curators, technicians, researchers from the collection, clients buying the strains and end-users of the website wishing to get data for their studies.

One should clearly distinguish features needed by curators, researchers or technicians managing or working on CC's databases and the features needed or wanted by the CC's clients or end-users.

Clients of a CC are usually looking for strains that have a number of properties and want to order them quickly via an order form available from printed or, more likely now, web based catalogues. They usually want to know how much strains will cost and when they will be delivered. Previously, CC's catalogues were the only way to list all the strains and provide additional data to clients. Nowadays such printed catalogues are abandoned and most CCs have websites that contain the list of available strains with some additional features. Many CCs still do not provide more data than those previously disclosed in printed catalogues. However, there is certainly a trend to increase the amount of data associated with each strain since it gives serious added value to the strains. Most CCs allow searching for basic strain data such as strain number, species name, country of origin, substrate or equivalent CC numbers in other collections. Few collections allow clients to query their databases by multiple criteria, e.g. morphology, physiological, chemistry, molecular, ecology, geo-localization, bibliography data or other properties.

"Researchers" interested in using CC's data might not be clients (yet) and might use CC's websites and associated databases to retrieve specific information, to perform correlation analyses or identify their unknown strains against one or several reference databases. CCs that have created websites that are more than just online catalogues are more likely to attract more traffic and therefore clients than the ones just posting basic strain data without any additional tools or features recurrently attracting "Researchers". Good examples of such websites are the CBS-KNAW or MycoBank websites offering online pairwise DNA sequence alignments against reference, curated databases. MycoBank attracts between 1200 and 2000 unique users per day by offering a number of (free) tools that allow researchers to find

some solutions to their problems. Other websites such as BOLD or GenBank attract even more users by providing extremely useful functionalities.

To be helpful for the previously cited categories of users, six major lines of tools must be present and integrated in a CCMS. A non-exhaustive list of the major desired features for the curation of collections follows:

1. Data retrieval
    a. A laboratory information management system (LIMS) module to manage and track DNA sequencing projects including revival of strains from collection stocks, DNA preparation, PCR, gels, viewing, aligning and editing DNA sequences, and depositing consensus DNA sequences into the database and online catalogue
    b. DNA gel analysis
    c. Cell size determination
2. Data importation and exportation
    a. Ability to import and export data as text, images, DNA trace files, microplate reader data, MS-Excel, HTML, XML, FASTA, NCBI and more
    b. Reporting functions allow export of data in many formats including tab delimited, text, MS-word, PDF, MS-excel, HTML, FASTA, NCBI, etc.
    c. Import, manage, analyse and export spectral data such as MALDI TOF or other systems
3. Data storage and management
    a. Advanced security and access management
    b. Tracking of database modifications by each user
    c. Strains stock management
    d. Customer information management
    e. Orders and invoices management
    f. Ability to create custom layouts such as invoices, catalogues, sample labels
    g. Scripting tools to automate routine tasks and extend functionalities of the software
    h. Integration of scripts within existing menus of the software
    i. Storage, editing and analysis of DNA and protein sequence data, including pairwise and multiple alignments, BLAST alignment of public or custom databases for identification and classification
    j. Storage of data of many formats including text, dates, calculations, literature references, DNA sequence trace files, electrophoresis gel photos, GPS coordinates, microplate reader data (96 or 384 wells), and photos. Data types

can thus include morphological, physiological, molecular, chemical, ecological, geographic, and literature reference data

4. Data analysis

a. Polyphasic identification and classification, to identify and classify strains based on a custom weighted combination of DNA sequence, physiological, morphological and other
b. Species determinations
c. Cluster analysis using various algorithms such as UPGMA, WPGMA, Single and Complete Linkage, Ward's Minimum Variance, and Neighbour Joining
d. Dendrogram generation
e. Pairwise DNA sequence alignment.
f. Multiple DNA sequence alignment
g. Generation of dynamic geographic distribution maps using Google Maps or similar tools

5. Data publication

a. Direct access to published data. This means that changing data from the management software can easily and quickly be made available to the website
b. Easy release of new strains and associated data
c. Restrict data access to Internet users/clients if needed
d. Easy adaption of webpages and website content. Information additions, deletions and updates should be fast and easy
e. Websites should be seen as a way to communicate with clients and end-users. This could be done by:
f. simple webpages
g. forums
h. news systems
i. Change the look and some functionalities of the website on the fly without the intervention of website developers
j. Allow deposit forms to be filled by depositors of strains without having to re-type all data manually. However, they still want to control deposited data and be able to correct them if needed
k. Allow clients to be registered on their website and know all the information needed to contact them and send cultures with their invoices
l. Allow clients to easily select strains to be ordered via a Cart system
m. Know pending orders, payments and data associated with any client
n. Allow end-users searching their databases according to the specificities of their collection

    o. Allow third parties to take advantage of their CC's data to increase traffic to their websites. This can be done via friendly URLs, simple or advanced web services (REST, SOAP, etc.).

6. Data exchange/interoperability
7. Linking or exportation of data to other websites such as GBIF, StrainInfo, NCBI, etc

Some of the features desirable for the "researchers" or clients of the CC and website:

Easy searching system on as many features as possible, separately or at the same time (Google like queries)

1. Advanced query system allowing to combine queries in complex ones using AND, OR and NOT operators (including brackets to group conditions)
2. Simple Cart system allowing selection of strains to be ordered online
3. Not having to retype all personal or institutional information each time they order strains
4. Fast and easy communication with curators or sales departments of the CC
5. Frequently asked question (FAQ) section answering most of their questions
6. Easy copy-pasting of data
7. Easy exportation of selected data, manually or via software (web services)
8. Pairwise DNA or protein sequences alignments against reference databases
9. Polyphasic identifications and/or classifications against reference databases
10. MLST (or similar methods) allowing identifications or typing of strains
11. Forum to discuss questions related to the community of users
12. Online support

There are many more features that could be listed above and this list is certainly non-exhaustive and will grow over the years.

3. DATA MANAGEMENT SYSTEMS

To create an efficient and advanced data storage, analysis and publication system for culture collections, a number of different technological options are possible but some present more advantages than others. These are discussed here. This section is critically important if one wants to create a data system that will be used by third parties in an efficient way. Before thinking of creating high level applications and interoperability scenarios, each participating culture collection must have a well-structured data management system. Without the right foundation (structure, data, software tools and IT infrastructure), it is impossible to create advanced functionalities that will position CCs adequately in a modern scientific and interoperable landscape.

3.1. MANAGEMENT OF COLLECTION'S DATA USING DESKTOP APPLICATIONS

Desktop applications (DA) constitute the majority of software that is available at the moment. Software such as Word, Excel, and Access from Microsoft are typical DA. Most of the collections are currently using DA to manage their collections with Excel being the tool of choice for the smaller Culture Collection, as it is easy to use and understand. It contains a lot of functionalities that might be useful for a large number of operations. Collections that need more advanced systems might use Access or FileMaker Pro. Unlike Excel, the latter systems are multi-users and relatively easy to use without programing skills.

Table 1: Advantages and disadvantages of desktop applications

Advantages	**Disadvantages**
Rich software interface	Installation can be problematic (different Operating System (OS) versions, missing Dynamic-link library, etc.)
Easy to use	DA are usually made for one OS (Windows, Mac or Linux) but won't work with others
Fast response to user's commands	When installed on different computers, updates and upgrades of the software must be re-installed everywhere making bug fixing or new version less easy to fix or install
Memory demanding or interface rich operations can easily be performed (to the technical limits of the OS, computer, etc., of course)	DA are usually not accessible from a remote computer or device
Relatively easy to develop (for basic functionalities at least)	For software working with limited installation options (fixed number of licenses), DA might become expensive and/or difficult to update/upgrade
Interactions with other software can be easy to establish. Pipelines can be created and import-export functionalities easy to implement or to use	Can be heavy to manage for IT departments
Data access security can easily be ensured	

DAs remain the dominant systems to access and manage collection's data. They are easy to use and fast but installations and software maintenance can be challenging, especially in collections with multiple curators or users (technicians, researchers, etc.) using different OS. Also, in such a multi-user environment, which is the majority of the cases, connections to the central database must be relatively fast in order to avoid slow responses or disconnections and consequent data losses.

All of the above mentioned disadvantages can be alleviated by using application servers and remote desktop access (RDA) software such as RDP from Microsoft or Citrix XenApp or

XenDesktop that are even more efficient in terms of memory usage, speed and display quality (other RDA systems are also available). Currently, using Citrix to publish DA is certainly the best possible combination and allows access to a rich and fast interface on any OS with any version and on any device (Desktop, laptop, tablet, smart phone, etc.) from anywhere. Installation is central and updates or upgrades are easily installed centrally.

3.2. MANAGEMENT OF COLLECTION'S DATA USING WEB BASED APPLICATIONS

Web based applications (WA) constitute a good alternative to DA. They are typically accessible using a browser that can be found on any device using any OS.

Table 2: Advantages and disadvantages of Web based applications

Advantages	**Disadvantages**
Accessibility to databases from anywhere	Development costs are usually higher
Accessibility to databases from multiple platforms	Developments can be significantly more complex to support all browsers and their versions
Possibly easy to use for basic editing of data	Some functionalities are more difficult or impossible to program
Maintenance is easy for IT departments since the software is centrally installed and maintained	Rich interfaces or memory demanding operation might be impossible
No need for installation on curator's, researcher's or technician's devices (Desktop, laptop, tablet, smart phone, etc.) since access is via browsers	Interface can be much slower than DA
The same software might be used for the management and the publication of data	Interactions with other software might be more difficult or impossible
	Maintenance of software might be more intensive to allow new versions of browsers to still function properly
	Security issues are more complex to handle with WA than with DA since the application is potentially accessible from any device by anyone
	Stable Internet connections are needed

While the advantages listed above seem attractive, currently, WA remains too slow and limited in their functionalities and capacities to handle some specific data. Technological advances (.NET, Java, Silverlight, HTML 5, etc.) might resolve some of the issues mentioned above. As an example, Microsoft office is now partly available in a web based form and many desktop features are also available in the web based version.

Some culture collections have moved from DA to WA but the majority of them are still using DA for the management/curation of their databases. So for the management and curator's operations, it seems that DA remains the best choice for the moment but this might change in the future.

3.3. CREATE BESPOKE MANAGEMENT SOFTWARE USING IN-HOUSE RESOURCES

A number of large culture collections have developed their own systems to manage their data. This is certainly a possible solution when good and stable programing skills are easily accessible.

Table 3: Advantages and disadvantages of in-house software developments

Advantages	**Disadvantages**
Tailor made application fitting perfectly with the needs of the curators (at design time at least)	Curators or researchers are rarely good software designers or programmers making the resulting solution uneasy to use, maintain and further develop
Fast response to implement new features and bug solving	Real developers are rarely available in culture collections (CC) because they are expensive
This solution can be quite cheap if the software remains simple	Good developers tend to leave the CC to find better paid positions leaving the software unmaintained and hardly usable by newly recruited developers
	This option can be extremely expensive when the wanted functionalities are complex and large
	Most in-house solutions are not (easily at least) scalable (add/modify/remove more tables, fields, operations, etc.) and redesign or complete; rewriting of software is often needed. This leads to interfacial instability for the users which is a key issue
	Developments take a long time before being usable and stable especially for single or small developer's teams
	Many software were abandoned after a few months because they were too slow, difficult to use, user-unfriendly, buggy or unstable. This is a common situation in a CC

While for a very small CC with one or two users (curator/researcher, technician), this can be seen as a viable solution provided that the system to be developed remains simple, it is certainly not an advisable solution for most CC particularly when serious teams of developers are lacking. Note that human IT resources have to be distinguished from developers. They

have quite different skills, though overlapping a little. It is a common mistake to confuse IT people with developers and this often leads to disappointment when IT staff are forced to program data management or (even worse) analysis software.

3.4. USE OF EXISTING OPEN-SOURCE OR FREE SOFTWARE

Using open-source or free software is really common among CCs due to the lack of financial resources to buy commercial solutions. Many tools have been developed to manage, analyse and publish data. Some are easy to use and propose very interesting functionalities. A typical example is the BLAST software family that allows aligning sequences very efficiently which is one of the many operations that curators are doing on a regular basis. Many other excellent open-source or free software can be listed that can perform basic or even advanced functionalities requested by curators in their daily operations. They include BLASTN, BLASTP, BLASTX, Geneious (entry version free), Mantis, Mega, RasMol, Scratchpads, SeqView, Serial Cloner, Specify, World Data Centre for Microorganisms (WDCM) workbench, etc. (a far from exhaustive list)

While some of the solutions are extremely efficient in their field, there is no open-source or free solution that can handle all the operations that are needed by curators. However, some solutions are quite interesting such as ScratchPads (SP) and the newly developed WDCM workbench (WB) created by the Chinese Academy of Sciences (CAS).

SP were created by a researcher of the Natural History Museum in London; their website states “Scratchpads are an online virtual research environment for biodiversity, allowing anyone to share their data and create their own research networks. Sites are hosted at the Natural History Museum London, and offered freely to any scientist that completes an online registration form. Sites can focus on specific taxonomic groups, or the biodiversity of a biogeographic region, or indeed any aspect of natural history. Scratchpads are also suitable for societies or for managing and presenting projects. Key features of Scratchpads (see also Scratchpads feature list) include: tools to manage biological classifications, bibliography management, media (images, video and audio), rich taxon pages (with structured descriptions, specimen records, and distribution data), and character matrices. Scratchpads support various ways of communicating with site members and visitors such as blogs, forums, newsletters and a commenting system.”

SP are more oriented towards the management of museum data and are therefore lacking a number of features that are absolutely needed for the CC, such as stock management, orders management, and other advanced tools that are used on a daily basis by curators for example tools that support electrophoresis, microplate management, MALDI-tof, DNA & Protein sequences management tools.

Since SP are free, support is quite limited and additional tailor-made developments are not possible from the developers.

The WB is an interesting initiative from CAS and intends to propose a ready to use system for the management and the publication of CC data. The system is hosted at the CAS and a few small to medium collections are using it although the system is still in its early stages of development. The system is fixed by nature (not dynamic) which means that fields and tables cannot be added by the curators of the collections in order to correspond to their own needs. This is certainly a major issue since each collection is specific and hosts different types of organisms and therefore data requiring significant differences in fields and tables. WB can however be an interesting solution for a small collection with limited resources particularly if the data sets defined in the OECD Best Practice Guidelines for BRCs (OECD 2007) or the CABRI guidelines (www.cabri.org) are used i.e. the Minimum Data Set (MDS), Recommended Data Set (RDS) or Full Data Set (FDS) relevant for each group of microorganism.

Open-source software can be of interest for collections having serious teams of developers but as a general rule, using the code of third parties is often a real challenge, especially for large software. Even experienced developers can struggle to understand the code written by others even if the code is well documented which is not always the case. The major advantage of Open-source software remains the ability to add missing functionalities to already existing and almost perfect software. Unfortunately (to our knowledge) there is no such complete (open-source) solution that could be used for the management of a CC.

Free software (non-open source) can be of interest of course but here again there is no free solution that would fit all needs. Using a large number of different software complementing each other can be a solution but this option is often less efficient than a completely integrated system fulfilling all or almost all the needs of curators. Some pipeline software (integrating different software) such as Taverna (there are probably many others) can be used to better integrate several individual software by joining the inputs and outputs. This is certainly a solution for some scenarios but not a viable solution for a complete CC management system.

3.5. USE EXISTING COMMERCIAL SOFTWARE

There are a few commercial software options that could be used to manage all the operations associated within a CC. Again, a non-exhaustive list is presented: BioloMICS, Bionumerics, FileMaker Pro, Geneious, KE Emu, LabCollector LIMS, MS-Access, MuseumPlus, Oracle, Etc.

There are many commercial software options that were specifically created for the management of museums operations and two of them are cited above (KE EMu and

MuseumPlus) since they seem to be among the most popular ones. Those solutions are used by major players in the museum arena but culture collections needs are slightly different and certainly more extensive since most CCs are dealing with data such as morphology, physiology, chemistry, ecology, molecular and many more that are usually not handled by museum targeted software.

Other software such as FileMaker Pro, MS-Access or Oracle are based on databases and can be completely or partly programmed to fit the needs of curators of CCs. Here again, programmers are needed to create a complete and functional package and once again, many of the needed functionalities are not present as such in those software.

Laboratory Information Management Software (LIMS) belong to another family of solutions that can in some cases provide an accurate but partial and often very expensive solution. LIMS are made to track samples, experiments, etc. and provide advanced reporting solutions. Some collections such as the BCCM have followed this route to handle some of their operations and are implementing a LIMS solution provided by Siemens. Such systems are extremely expensive (buying and maintenance costs) and require a lot of investment in terms of adaptations to the needs and specificities of the different CC. LIMS alone do not provide all the functionalities needed by a CC.

Some software like BioloMICS, Bionumerics or Geneious propose advanced solutions that can fit with some or all (depending on the complexity) the management needs of a CC.

Geneious is a relatively new player and is a “DNA, RNA and protein sequence alignment, assembly and analysis software platform, integrating bioinformatics and molecular biology tools into a simple interface”. It offers a wide-ranging functionality:

- Access essential molecular biology analysis tools and plugins, and search public and private databases, all from one location
- Organized Data, step into the future with simple drag and drop import of a vast range of formats. Arrange and browse your data library how you like
- Superior Visualization, switch to a clear and bold graphical interface. Eliminate the need for command-line operations and stop battling with poorly designed software.

A LIMS module is also available for the management of 1st generation sequences. Another one can handle NGS data. This system allows importing data from a number of databases but is not genuinely accessing database records directly. In fact, Geneious is a great tool integrating a number of analysis modules but cannot be considered as data management software that can be used for all basic CC operations.

Bionumerics software features a very large number of analytical modules capable of analysing a very number of data types. From this point of view it is probably one of the most complete since morphological, chemical, physiological, electrophoresis, spectroscopic or molecular data can be used to identify or classify strains or species records. Bionumerics is used by a very large number of laboratories, including culture collections. This software is mainly used for its analytical features. However it can import and handle data from many database sources. It also offers a scripting tool using its own language. Bionumerics developers can also write scripts in Python for their customers at an hourly rate. This is a major and important feature allowing the customization of the software but the language used is non-conventional and cannot offer all the advantages of modern programming languages such as Visual Basic, C#, C++ or Java. Bionumerics imports records from existing databases in order to analyse them but no queries can be performed which makes it impossible to use for most of the common operations of a CC.

BioloMICS was first created almost 25 years ago to manage yeast collections and perform batch morphological and physiological identifications. This software went through a large number of iterations and the current version is 10. “BioloMICS is the most complete software solution for storage, management, analysis and publication of biological data and is of choice for any research or industrial laboratories, museums, culture collections and many more.” Any data type can be stored and handled in BioloMICS, from morphology, physiology, biochemistry, chemistry, chromatography, electrophoresis, molecular to bibliography, taxonomy, geography, ecology or administrative. The data structure is fully flexible. One can very easily create tables and fields (24 different field types can be used to manage all possible types of data) of interest on the fly and handling data of any kind. The system keeps track of all the changes ever made in the database. The system currently uses MySQL for the underlying database but a new version under preparation will allow using MSSQL, PostgreSQL or MongoDB for very large datasets. Data cannot only be managed but also analysed in a similar way to Genieous and Bionumerics. It offers a large number of tools to analyse morphological, physiological and sequence data. Polyphasic or multi-locus identifications are possible as well as clustering tools that can produce hierarchical trees or three dimensional structures.

The BioloMICS software provides LIMS for the complete management and analysis of 1st generation sequencing data. The software allows writing scripts but unlike Bionumerics it uses Visual Basic or C#. Scripts can be integrated in the existing interface allowing the extension of the functionalities of software to fit with the needs of the end-users. Recently a debugger and a form designer have also been integrated that makes this software the most complete of its kind.

This software has been created for culture collections and is now sold as a commercial product to a number of CCs world-wide such as CBS-KNAW, CABI, Pasteur Institute, CDC, University of California, almost all Australian microbial culture collections and many more. It is certainly the most complete software for a CC for the moment since it also includes a web publication interface that is used by a number of large international initiatives such as MycoBank, Q-bank or the European Barcoding Database Mirror. Support is also efficient and developers can write tailor-made programs at an hourly rate.

Commercial software are usually more expensive by definition since they are not free. On the other hand they are ready to use and there is no lag phase between the buying stage and the moment where curators can have a functional system. Our experience shows that CC that have developed their own projects often abandon them due to the lack of ability to achieve their primary goals or the inability of their software to cope with new types of data or operations. It is finally often cheaper to buy commercial software and pay for the updates rather than supporting expensive developers within a CC. Curators are neither software developers nor software designers and cannot properly manage or guide teams of developers. Therefore, software developed within a CC can be badly designed and take a long time before being usable.

Table 4: Advantages and disadvantages of commercial software solutions

Advantages	**Disadvantages**
Ready to use	Some solutions can be expensive and sometimes extremely expensive
Known solution with known limits and advantages from the beginning	All commercial solutions are not of equal quality and not all are suitable for a CC
Software are usually well-written and maintained by professional developers	When access to the databases is not possible via scripting or via database direct access, specific developments can be impossible and this is a major issue for possible future extensions and needs
Can be much cheaper in the long term than paying software developers internally	Dependency on the software and the company producing and maintaining it
Take advantage of solutions developed by others	
Professional support	

3.6. CHOICE OF DATABASES

Different types of databases or supporting tools are used, some of these are listed below in increasing order of complexity or capacity: Catalogues on paper (not a database sensu stricto but still used); Word processing software (not a database but used by a number of collections); Excel (not really a database but still used by a large number of CCs; inexpensive); MS-Access (basic relational database; inexpensive); FileMaker Pro (basic relational database; not free and associated with the management software); MySQL (simple relational database; free); PostgreSQL (relational database; free); MSSQL (relational database; not free, not cheap); Oracle (relational database; not free and expensive); MongoDB (document oriented database; free); Vertica (grid-based column oriented database; expensive); Etc.

While a few CCs are still managed by paper cards systems or by paper like catalogues, some are using word processors to keep track of the information associated with their strains. Such systems are of course outdated and should certainly be replaced by more efficient tools that can be used to efficiently manage a CC data and publish them on dedicated websites. The number of collections operating with such outdated systems is certainly not negligible but probably limited to small or non-professional CCs.

While Excel cannot be considered as a real database it can certainly deliver a number of advantages and interesting features to a very small CC. It is certainly not the system of choice to manage medium to large CCs with more than one curator/technician.

MS-Access can be considered as a relational multi-user database. “Microsoft Access stores data in its own format based on the Access Jet Database Engine. It can also import or link directly to data stored in other applications and databases. Software developers and data architects can use Microsoft Access to develop application software, and "power users" can use it to build software applications. Like other Office applications, Access is supported by Visual Basic for Applications, an object-oriented programming language that can reference a variety of objects including DAO (Data Access Objects), ActiveX Data Objects, and many other ActiveX components.” (source Wikipedia). It offers a number of advantages over Excel but the system is moderately supporting simultaneous updates and therefore, it should not be recommended for medium to large CCs.

“FileMaker Pro is a cross-platform relational database application from FileMaker Inc., formerly Claris, a subsidiary of Apple Inc. It integrates a database engine with a GUI-based interface, allowing users to modify the database by dragging new elements into layouts, screens, or forms. Current versions are: FileMaker Pro 12, FileMaker Pro Advanced 12, FileMaker Server 12, FileMaker Server Advanced 12, and FileMaker Go 12 for iPhone and

iPad. FileMaker evolved from a DOS application, but was then developed primarily for the Apple Macintosh. Since 1992 it has been available for Microsoft Windows as well as Mac OS/OS X, and can be used in a cross-platform environment. FileMaker server briefly ran on Linux, but Linux support was abandoned with FileMaker 7, and the server currently runs only on Windows or OS X servers. It is available in desktop, server, iOS and web-delivery configurations. FileMaker, since version 9, includes the ability to connect to a number of SQL databases without resorting to using SQL, including MySQL, SQL Server, and Oracle. This requires installation of the SQL database ODBC driver to connect to a SQL database. SQL databases can be used as data sources in FileMaker's relationship graph, thus allowing the developer to create new layouts based on the SQL database; create, edit, and delete SQL records via FileMaker layouts and functions; and reference SQL fields in FileMaker calculations and script steps. It is a cross platform relational database application." (source Wikipedia). FileMaker Pro has been used by a number of CCs thanks to its ease of use and flexibility.

MySQL, PostgreSQL, MSSQL and Oracle belong to the same family of relational databases that are used by most of the medium to large size collections. Such databases offer a wide range of possibilities and they all present advantages and disadvantages. MySQL is certainly one of the most used since it is free, easy to use and fast. However, MySQL does not offer all the tuning tools and programming interfaces that PostgreSQL, MSSQL and Oracle can offer. All these databases can handle most of the datasets that medium to large CCs have to deal with. They are probably the solution to 90% of the datasets management issues.

"MongoDB (from "humongous") is an open source document-oriented database system developed and supported by 10gen. It is part of the NoSQL family of database systems. Instead of storing data in tables as is done in a "classical" relational database, MongoDB stores structured data as JSON-like documents with dynamic schemas (MongoDB calls the format BSON), making the integration of data in certain types of applications easier and faster." (source Wikipedia). MongoDB could be a good solution for very large and distributed datasets. Very few software mentioned above are able to use or connect to such a database. This will probably change in the near future due to the need to handle very large datasets produced by high-throughput systems (NGS for example).

There are many other database types. One of them is Vertica that is a grid-based, column-oriented database. "Vertica Analytic Database is designed to manage large, fast-growing volumes of data and provide very fast query performance when used for data warehouses and other query-intensive applications." (source Wikipedia). Scenarios where such databases could be used remain marginal in the CC world but the so-called "Tsunami of data" problem might push some CCs to adopt such extreme (today) technical solutions.

Data standards are not discussed here since they should be considered as more or less independent from the databases in which they are stored. The way data are stored in databases is usually depending on the software managing and using them. There is certainly no strong reason to enforce some specific formats at this stage (see the Interoperability section for more on standards).

3.7. BACKUP OF DATABASES

The system chosen must include a systematic automated backup procedure because humans tend to forget to do them or do so at irregular intervals. Most database systems integrate automated backup procedures. Backups should not be stored on the same computer or server as the running database. Ideally, some backups should be stored on one or several remote computers or servers in order to prevent problems related to computer failure, power problems, fires, etc.

A good practice is to backup databases once or twice a day and keep all the versions for one week; keeping copies on a weekly and monthly basis.

Some databases can be stored on several database servers in order to propose a highly available system (redundancy). Other databases can also do *Sharding* which is the process of storing data records across multiple servers, some records being stored on some machines while others will be stored on others. The management of such systems is usually done by the database engine. MongoDB (and many others) makes use of such very interesting options.

Depending on the chosen system/software, some files might not be included in the database as blobs but are stored in the file systems. In such a case a database backup is not sufficient and one must also backup all the files associated with the records in the database.

3.8. INSTALLATION OF SOFTWARE, VERSIONING INFORMATION AND TECHNOLOGY (IT) RESOURCES NEEDS

Different CCs are working with different software systems and different operation systems. However, the vast majority of computers are still working under Microsoft Windows (XP, 7 or 8 and equivalent versions for the servers). Some are using Mac OS while a very limited number of CCs might use Linux. The following statistics obtained from Netmarketshare website (sources http://www.netmarketshare.com/operating-system-market-share.aspx?qprid=10&qpcustomd=0) allow to objectivate the assumption above: 90.7% of the computers and therefore software are running under Windows, 7.7% with Apple IOS and 1.6% with Linux. Therefore, the system recommended for the management of a CC should be able to work properly (at least) under a Microsoft Windows OS. Creating or selecting desktop software that can work on all existing OS is an unnecessary challenge or burden.

Therefore it is strongly recommended that the chosen software is capable of running on Microsoft Windows.

However, if the software can be installed on an application server and served to the end-users using Citrix XenApp or XenDesktop, RDP or any similar system, then the operating system of the end-user is not a limiting factor anymore. In such a case, an Apple based OS software could be used under Microsoft OS and vice-versa. In such a scenario any device can be used by the end-user, including thin-clients. This being said, creating an application server requires hardware resources as well as IT skills and support that are above the normal level of IT support. This cannot easily be achieved for small to medium size collections.

When software is installed as a client server solution (Software on the PC of the end-user and the database on a central server), updates and upgrades of the software can be challenging and may require quite some time for IT personnel. When updates are frequent it becomes important to choose software that can be updated or upgraded automatically. Most software can now do it but this should certainly be a requirement in a client server solution.

In the application server scenario mentioned above, this is less of an issue since the software is installed centrally and update once on the central/application server. For medium to large CCs, this option is certainly the best one.

While for a small CC, dedicated IT staff might not be needed but for medium to large CCs, it is important to be able to rely on skilled and effective IT staff. They usually take care of backups, software installations and maintenance. In the case where many servers need to be used and maintained a number of specialized software will have to be acquired in order to monitor and manage the whole system. Software such as VMWare, Citrix XenApp/XenDesktop, HyperV and many others that are expensive tools must be used to have a professional system with a high level of availability and security. Such a system is expensive to establish and to maintain. Most often small CCs are hosted in research institutions or Universities that have their own IT support.

3.9. HOSTED SOLUTIONS

When IT staff and hardware resources are lacking or when financial resources are limited, hosted solutions are certainly interesting and should be favoured. The hosting company usually takes care of everything for their end-users including: installation of CC management software (possibly of the publication software as well); updates and upgrades of the software; installation of database(s) and file system needed to store associated documents; Backups of databases; make applications available via an application server for desktop applications; make a website available to third parties/publication of CC data; high availability of the

system; hosting is almost always done from professional data centres with high security standards (redundant power supply, protection against fire and theft, firewalls, etc.).

Table 5: Advantages and disadvantages of hosted solutions

Advantages	**Disadvantages**
Easy to use	Require recurrent payments (monthly or annually) which means that these costs must be part of the annual budget of the CC
End-users can directly have access to a complete and efficient system with lag period	Access to a database engine might not be possible (only backups of databases are provided from time to time)
No need to buy hardware (server, SAN, firewalls, etc.)	Dependency on the hosting company
No need to buy and maintain expensive and sophisticated software for the management and the monitoring of the system (VMWare vSphere, for example)	Need Internet connection to work
No need to hire IT staff	Extremely slow or erratic Internet connections might unable to use such a system
Continuous monitoring and support	
Given the number of services provided, hosted solutions are often much cheaper than running a complete infrastructure in house	
Access to database and software from anywhere at any time on any device	
Management of CC software and associated database can directly be connected to the website used for publication of CC data	

Few companies offer complete solutions but two can be mentioned that not only offer the software that can be used to manage a CC but also publish CC data and propose a hosted system:

- ScratchPads (no desktop application to manage data but web based), no real support since it's a free service (see discussions above about the limits of this system). Hosted at London Natural History Museum.
- BioloMICS. Hosted in professional data centre. Desktop and web portal are both included. Remote access to management of the CC application via Citrix XenApp/XenDesktop.

4. PUBLICATION OF DATA FOR THIRD PARTIES AND INTEROPERABILITY

Common data management standards including adopting common ontologies are essential for interoperability between collections and outside to other types of data. The collection community has standards for data management; the EMbaRC and GBRCN project consortia partners, the predecessors of MIRRI, decided that the CABRI guidelines could be amended and adopted by MRCs. However, in MIRRI the focus is on what the user needs are and how this impacts on the stored data and thus on the ways of presenting them. Lists of fields and types of fields have been addressed, the OECD best practice guidelines for Biological Resource Centres (BRC) published in June 2007 brings together previous work and makes appropriate recommendations (http://www.oecd.org/health/biotech/oecdbestpracticeguidelinesforbiologicalresourcecentres.htm.). Controlled vocabularies/ontologies need to be addressed in some way. MIRRI needs to find an appropriate way to address the complexity of fungal names for example. The mycological community should continue to find an appropriate solution (see section 4.3 below) whilst MIRRI should focus on an approach that reduces confusion for the users. This issue as well many other issues that arise when linking to other data types, it very much depends on the questions being addressed, these not only come from the CCs but more importantly from the user. MIRRI therefore needs to know what its users' priorities are.

MIRRI needs a strategy on what data is needed to help facilitate the uptake and use of microbial diversity in research and development. Analysis is needed of what data is out there, how MIRRI data is linked to it and what needs to be done to make it interoperable. This would include a combination of literature databases, chemistry, habitat and ecosystem information, taxonomic hierarchy and relationships, etc; some of the databases to provide this exist whereas in other areas such as environmental or ecosystem data may not be so accessible. Utilising data mining tools can be used to predict new uses of strains. MIRRI also needs to know what additional data that its users need and how this is made available to them. MIRRI needs partners in this process and needs to work closely with ELIXIR and other research infrastructures such as EU-OPENSCREEN; other players such as STRAININFO.NET, WDCM - their Global strain database have created tools that MIRRI can harness. Above all MIRRI needs to work with the user to see how best this information can be delivered. The MIRRI strategy is essential - all the rest is detail that can be prioritized appropriately and dealt with once the concept of what the MIRRI system will look like is defined.

In order to link CCs data to other systems it is imperative to follow the necessary standards to allow third parties to use our data with confidence and include them in their analyses. In order to do so, software systems used by CCs need to be able to easily export or expose

data and ideally automatically using a number of formats that are usually XML based and that should probably be independent from the format of the original database where data are maintained. There are many initiatives trying to establish biological data standards as well as standards that are used by biologists such as geographic, climatic or ecological data, for example. It seems that reinventing such standards is certainly not a good idea since our community does not have the ability or capcity to contribute to this. What we should certainly do is to identify a number of standards that are relevant to the type of data that CCs are likely to use and produce and ensure that the software used by CCs are able to utilise such standards. A number of websites, documents or working groups are certainly of major interest with respect to data standards:

1. BioSharing (http://biosharing.org/)
2. Biodiversity Information Standards (TDWG; http://www.tdwg.org/)
3. Genomic Standards Consortium (GSC; http://en.wikipedia.org/wiki/Genomic_Standards_Consortium)
4. More are available

4.1 StrainInfo

The StrainInfo (SI) portal has been gathering data at the strain level between participating CCs for several years. Originally SI was screening websites of collections but this system seemed to be inefficient and their initiators decided to create the Microbiological Common Language (MCL) which is an XML based format allowing culture collection's microbial data to be exchanged between CCs and SI. "In short, MCL defines terms which can be used to reference and describe microorganisms. It is designed to form a simple and generic framework leveraging the electronic exchange of information about microorganisms. MCL is loosely coupled from its actual representation technologies and is currently used to structure XML and RDF files" (from http://www.straininfo.net/projects/mcl).

SI is a useful portal since data from many CCs are centralized and compared and discrepancies between identical strains present in different CCs are highlighted for curation purposes. SI also associates molecular and bibliographic data from NCBI and PubMed to basic strain data. SI also provides links to websites and databases where the strains are originated from.

SI is quite comprehensive and software managing CC's data should have the ability to export data in MCL format that can be used by SI and therefore ensure better visibility of participating CCs. Currently, MCL does not include all data held by microbial resource collections but it could easily be extended to cover all data elements MIRRI would need.

4.2 World Data Centre for Microorganisms

The World Data Centre for Microorganisms (WDCM) is based in Beijing, China and managed by the Chinese Academy of Sciences. WDCM maintains a catalogue of the largest CCs in the world. It was created "to enable broader and easier access to the reference strains listed by the ISO TC 34 SC 9 Joint Working Group 5 and by the Working Party on Culture Media of the International Committee on Food Microbiology and Hygiene (ICFMH-WPCM) in their publication Handbook of Culture Media for Food and Water Microbiology. It fulfils a need expressed by these bodies for a unique system of identifiers for strains recommended for use in quality assurance." (from http://refs.wdcm.org/home.htm). WDCM is requesting data to be submitted using a tab delimited format. WDCM is proposing services that are very similar to the ones proposed by SI.

4.3 TAXONOMIC DATABASES

One of the most fundamental problems of managing a collection of microorganisms is keeping pace with the taxonomy and resultant name changes being introduced for species. This is highlighted when databases are brought together; a specific case in point being the tremendous amount of time taken up during the integration of MINE – Microbial Information Network Europe data. This was again highlighted during the CABRI – Common Access to Biological Resources and Information project www.cabri.org. In producing a MIRRI – Microbial Resources Research Infrastructure information system this issue raises its head once again. Some attempts have been made but the problem is still encountered by databases such as the WDCM when it lists the numbers of species (names) held by its registered collections and demonstrated by species lists and strain number linkages shown when Straininfo.net (www.straininfo.net) is searched. There are very few tools that can cope with this centrally and to get every name right for the 2 million plus strains in the WDCM database would be a tremendous task; several attempts have been made to do this over the years. What MIRRI can achieve centrally is to indicate where possible problems are in its database content and offer tools to enable all possible strains linked to the name that is searched for are found.

A number of taxonomic or nomenclatural databases are available to link CCs strains data to currently recognized scientific names. For Fungi, MycoBank (MB; http://www.mycobank.org; nomenclature and taxonomy) and Index Fungorum (IF; http://www.indexfungorum.org; nomenclature) are the main players. For bacteria, DSMZ culture collection (http://www.dsmz.de/; nomenclature and taxonomy) publishes monthly updates of bacterial nomenclature and taxonomy. The latter is not searchable online but can be downloaded. Another interesting website is certainly the List of Prokaryote Names with Standing in Nomenclature available at http://www.bacterio.net/. The system is rich in terms of data but has serious limitations in terms of interoperability since data are not stored in a database but

in html pages and there are no real web services allowing to easily link and retrieve data. Therefore, for the MIRRI project, a Bacterial names search engine with associated web services has been created, working exactly like MycoBank (http://www.mycobank.org/bacteria).

The Catalogue of Life (CoL; http://www.catalogueoflife.org) initiative is another solution to get access to taxonomic information that is not just specialized for Fungi or Bacteria but integrates higher organisms as well.

The Encyclopedia of Life project (EOL; http://eol.org) is yet another database with a nice website offering species descriptions and associated metadata on the many life-forms on Earth - of animals, plants, fungi, protists and bacteria. Like CoL, EOL is an aggregator of data obtained from other databases such as MB or IF, for example.

For the management of names, CCs should not maintain their own nomenclature and taxonomic databases since this task is far too complex and would require important dedicated resources that are, most of the time, not available. MycoBank is an example that is delivering a number of web services that can be used to link CC's strains to a central and curated system (http://www.mycobank.org), that should be followed.

4.4 Global Biodiversity Information Facility

The Global Biodiversity Information Facility (GBIF) is an integrator system that centralizes data from a diversity of resources including major CCs. Data from different museums, collections, nomenclators and others are combined into their system and linked on the basis of their geographical or ecological origins. Data can be queried and links to the original websites are provided to get more information on the interesting records.

GBIF aggregates more than 400 million data records and is therefore a serious source of information for people working with biodiversity related matters.

Exports to GBIF are usually done using a Darwin Core archive format (DwC). The information system that will be chosen by CCs should therefore offer the ability to export to DwC.

4.5 Molecular and associated data resources

Most molecular data produced by researchers worldwide are deposited in one of the three International Nucleotide Sequence Database Collaboration (INSDC):

- NCBI-GenBank in the USA (www.ncbi.nlm.nih.gov)
- EMBL in the UK (www.ebi.ac.uk/ena)
- DDBJ in Japan (www.ddbj.nig.ac.jp)

Most sequences (DNA or Proteins and associated metadata) are regularly synchronized between the three databases and the main part, that is available from the first database, is available from the others as well.

INSDC databases are major sources of genomic and metagenomic information and links to and from them are of key importance to any CCs. Exportation to and importations from INSDC database tools must be available in the software system managing CC's data.

The Barcoding of Life Database (BOLD; www.barcodinglife.com) is a major international initiative that was started a few years ago and that has gained a lot of popularity in recent years. BOLD is focused on DNA barcoding and most of the available data are related to higher organisms. Very few microbes are represented in their databases but the intention is certainly to include more of them. This is likely to evolve in the future since a number of fungal institutions such as CBS-KNAW are dedicated to produce large numbers of fungal ITS sequences in the near future and the latter will be submitted to BOLD and GenBank.

CBS-KNAW will soon launch the European mirror of the BOLD system but unlike the latter will include much more fungal ITS sequences that could be used for identification. The BioloMICS software used by CBS-KNAW for this mirror and for MycoBank allows CCs using this software to create a portal that can be accessed remotely and used to perform pairwise sequence alignments against CCs that would like to share their DNA sequence databases. This system attracts visitors to the CCs and can potentially increase visibility and initiate business opportunities.

Q-bank (http://www.q-bank.eu) is another international initiative related to the barcoding of quarantine related organisms that links, among other types of organisms, microbial data to DNA barcodes and quarantine related data. This initiative can also attract traffic to culture collections.

ELIXIR is a major EU funded project that "unites Europe's leading life science organizations in managing and safeguarding the massive amounts of data being generated every day by publicly funded research. It is a pan-European research infrastructure for biological information. ELIXIR will provide the facilities necessary for life science researchers - from bench biologists to cheminformaticians - to make the most of our rapidly growing store of information about living systems, which is the foundation on which our understanding of life is built. The purpose of ELIXIR is to construct and operate a sustainable infrastructure for biological information in Europe to support life science research and its translation to medicine and the environment, the bio-industries and society. The collection, curation, storage, archiving, integration and deployment of biomolecular data is an immense challenge that cannot be handled by a single organization or by one country alone, but requires

international coordination. ELIXIR will provide the facilities necessary for Europe's life science researchers to make the most of our rapidly growing store of information about living systems, which is the foundation on which our understanding of life is built. In order to achieve its mission, ELIXIR will construct, operate and enhance a distributed research infrastructure in accordance with the requirements of the scientific community and under the direction of the ELIXIR Board. The ELIXIR Hub will be connected to ELIXIR Nodes to provide infrastructure for data, compute, tools and standards and training as well as support for the ESFRI biological and medical science infrastructures." (from http://www.elixir-europe.org/). As far as we are aware, the ELIXIR system will be a distributed system of resources that will be usable for specific purposes. Specialized consortia will produce software or combine new or existing ones to allow answering specific questions such as for example: screening organisms for solutions or products for the market; e.g. ways to accelerate the discovery of new antimicrobials where one may have uncharacterised organisms or even microbial diversity in the soil where nobody has any idea of their potential.

Annex WP8-2

MIRRI WP8 strategy paper about data resource management

18 MONTH REPORT

Status of data management and interoperability in CCs and BRCs

At present, most Biological Research Centers (BRCs) and Culture Collections (CCs) are acting as proprietary entities with respect to data acquisition, data quality management, data exchange and interoperability. Despite the fact that 'OECD Best Practice Guidelines for Biological Resource Centers and CABRI guidelines for minimal datasets exists, standardized protocols for submission of strain specific associated data (metadata) to BRCs/CCs collections have not been commonly implemented. CABRI established a European online catalogue bringing together 8 partner collections covering 28 catalogues (more than 100,000 items) demanding the implementation of quality control of both microbial materials and data. However, despite the CABRI guidelines (www.cabri.org) (1) being adopted internationally, few European collections beyond the initial partners have adopted them. Heterogeneous and incomplete datasets in BRCs/CCs are the consequence. Furthermore, the lack of commonly agreed exchange formats as well as heterogeneous and often insufficient IT-competences hamper data exchange and interoperability between BRCs/CCs as well as third party databases. Straininfo.net (2), in combination with the exchange language MCL (5), have exemplified that data integration across BRCs/CCs is appreciated by the users, but so far only 20 out of 220 European BRC/CCs culture collections participate in this service. As a consequence, the usage of the accumulated knowledge stored in BRCs/CCs is hampered for stakeholders in academia and industry and an improved access to biological materials and its metadata is clearly needed. Gaps must be closed and important services must be covered.

Vision

The vision of the MIRRI Information System (MIRRI-IS) is to establish and deploy an integrated, high-quality, manually annotated, non-redundant micro-biological resource database which provides all relevant data and associated contextual data (metadata) about a particular biological resource. It will link this data to other relevant data sets to facilitate the generation of knowledge from data. It will provide high quality well curated strain data to enable discovery of new products and properties and drive innovation in microbiology. Innovative links to ecological (substrate and habitat), genomic and chemical properties and metabolic pathways to taxonomic and environmental relationships will facilitate the user finding microbial resources to enhance their studies and find new leads and products.

MIRRI-IS will distinguish itself by:

i) high data quality and intensive data curation,

ii) interoperability and data integration across BRCs/CCs,

iii) providing an open platform for innovative downstream data analysis and product development.

iv) establishing complementarity with ontologies used in other disciplines, applying appropriate data structure and standards interrogation of the information landscape at many levels; currently only possible through direct links via strain numbers and organism names.

MIRRI-IS will integrate services and resources, bridging the gap between the BRCs/CCs and the stakeholders. MIRRI-IS will focus on smaller datasets, but very well curated, which are expected to be highly appreciated by the community, and will serve as a reference for academia and industry stakeholders. MIRRI-IS will be designed as the central entry point for users, curators and developers that need access to the integrated knowledge of BRCs/CCs and selected third party databases (Figure 1).

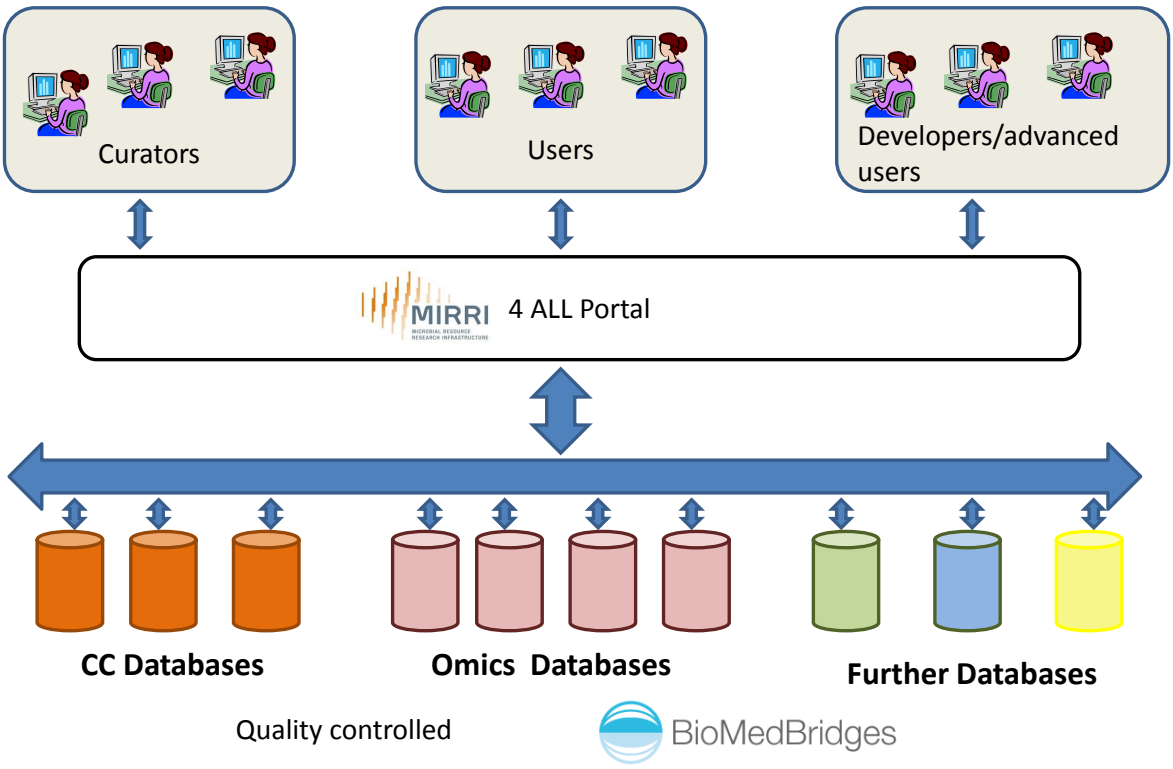

Figure 1: The MIRRI Information System (MIRRI-IS) providing access to integrated, quality controlled information and associated contextual data (metadata) about a particular biological resource.

Provision of innovative services

MIRRI-IS will mobilize and gather comprehensive information about functional genes, marker genes, genomes, taxonomy and metadata (e.g. chemical and environmental parameter) for each entry across participating BRCs/CCs. Up-to-date high data quality will be achieved via regular manual annotation by specialists which includes combined information extracted from scientific literature and biocurator-evaluated computational analysis. Furthermore, a wide variety of different customer services will be available. This includes custom tailored data packages, identification service with respect to taxonomy and support with species circumscription, deposition of strains, sequence data and metadata.

MIRRI will establish an IT coordination unit and competence center to deliver solutions more swiftly and efficiently. This will address IT problems faced by BRCs/CCs and provide custom tailored solutions for curators and users. Training of BRCs/CCs as well as an IT task force for on-site help will be established to balance the heterogeneity in IT capacities. Furthermore, a helpdesk will serve as the primary contact point for MIRRI partners, stakeholder and users as demands vary a lot and cannot be serviced by one collection alone; hence a coordinated response to user needs is required. All BRCs/CCs will be represented by a single MIRRI web portal offering an easy to use entry point for all stakeholders while assuring that each BRC/CC keeps its own visibility.

Implementation

A careful evaluated and detailed position paper on the IT status and needs of the European BRCs/CCs is currently being prepared. Based on this knowledge, MIRRI WP8 will further specify the MIRRI-IS including the MIRRI Minimum Data Set (MIRRI MDS) and a common exchange format.

The next step is to identify the data sets MIRRI needs to connect to in order to facilitate the generation of knowledge. The data sets identified and the disciplines' ontologies will influence the data sets collections need to maintain, the formats used to store the data and the standards implemented in data acquisition and management. These third party data sets include sequence data, ecology, geography, climate, literature etc. MIRRI will need to collaborate with BioMedBridges project, ELIXIR and Biological and Medical Sciences Research Infrastructure partners to achieve this successfully.

The specification of MIRRI MDS is an essential prerequisite for MIRRI-IS. It addresses the need for a minimal common data set for BRCs/CCs. Preliminary, the core set of descriptors will include 1) Primary Strain Number, 2) Secondary Strain Number, 3) Name, 4) Organism Type, 5) Restrictions, 6) Status, 7) History of Deposit, 8) Growth conditions, 9) Form of supply, 10) Geographic Origin and 11) accession number(s) to link the data to INSDC (under debate). To achieve high quality data, the semantic content and type of field will be exactly specified. Besides this core set of mandatory fields,

specific “packages” and additional subfields can be added to enrich the MDS. MIRRI MDS will follow the concept of MIxS (Minimum Information about any (x) Sequence) standard (3) were specific packages with a mandatory and recommended fields are available. An obvious extension to the MDS would be the "Environmental packages" describing the habitat of isolation. Additional subfields will further enrich the quality of the data. For example, the core field "Geographic Origin" may be expanded by subfields like "Country", "Longitude", "Latitude" or "Altitude".

Both the core set of fields and the extensions will be based on existing recommendations – mainly ‘OECD Best Practice Guidelines for Biological Resource Centres’ and CABRI (1). MIRRI MDS should become a standard under the umbrella of GSC (http://gensc.org/ (4)) including a publication on, e.g., a Minimum Information about Biological Resources (MIaBRe) standard and checklist. The standard and checklist is also intended to serve as a benchmark for data curation and interoperability between BRCs/CCs.

Interoperability between databases will be granted by an extension of the Microbiological Common Language (MCL) (5) introduced by StrainInfo (2). This will guarantee that the 20 BRCs/CCs that already use MCL to exchange data can be easily integrated into MIRRI-IS.

Timeline

Implementation of MIRRI-IS will follow a time line (Figure 2). The initial MIRRI MDS (defined above) serves as an entry point which needs to be fulfilled by the BRCs/CCs to join MIRRI-IS. This will be extended towards a recommended and finally full data set (RDS/FDS) within 3 years. This takes into account the common integration of microbial strain data with the third party discipline data sets identified above. The initial MIRRI-IT coordination and competence unit will evolve into a MIRRI-IT infrastructure center over time to fully support internal and external (user) needs. Improved IT competences will enhance interoperability between BRCs/CCs and external resources. MIRRI will foster cooperation with BioMedBridges and ELIXIR to further enhance interoperability in the biological domain (see Figure 3 for possible interactions). Finally, MIRRI-IS will support downstream analysis and product development (applications) in every step of its development. When MIRRI-IS is running in “full-featured” mode it will be a trusted platform not only for high quality biological material but also for data and information. With the establishment of MIRRI-IS and the associated European network of different expertise, the project aims to establish a trademark for high quality which enhances the reputation of participating BRCs/CCs.

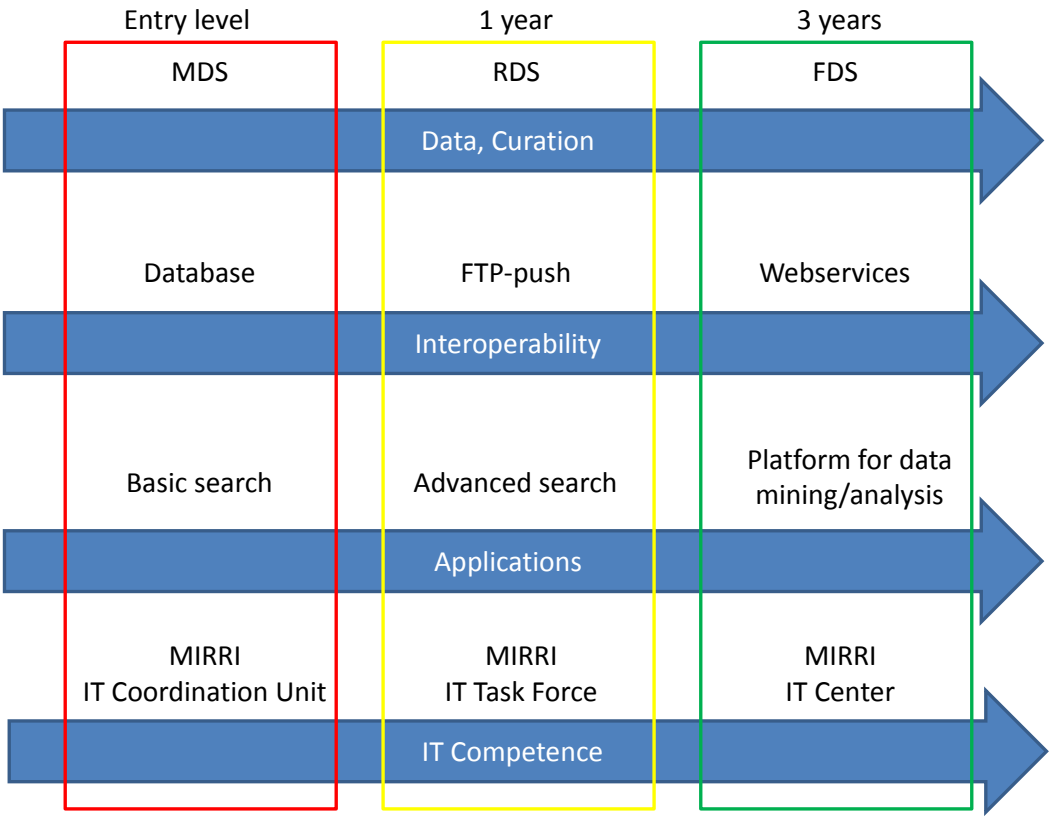

Figure 2: Schematic overview of MIRRI-IS implementation steps

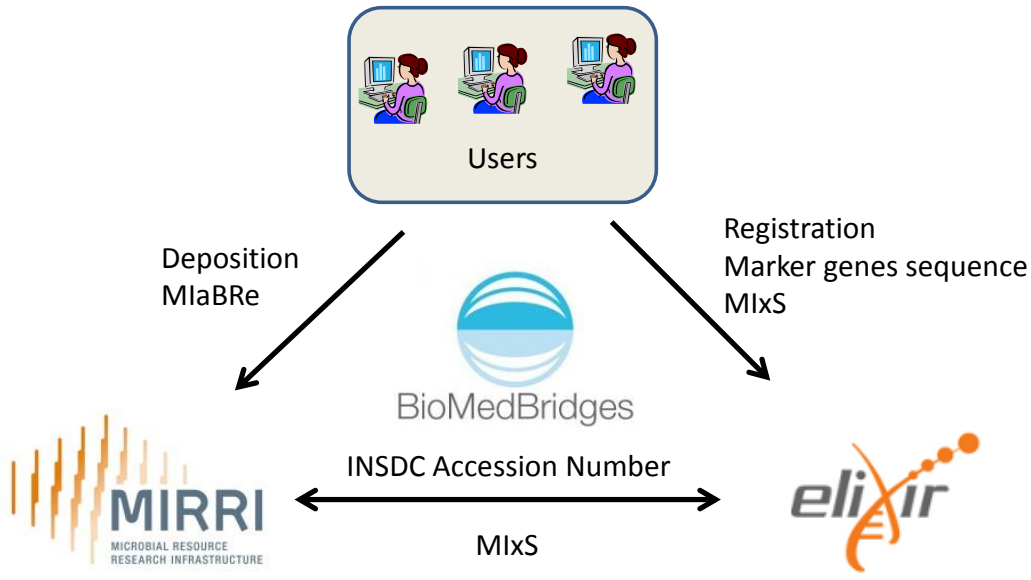

Figure 3: Schematic overview of the MIRRI IS interactions and splitting of workload between MIRRI and ELIXIR with respect to culture and sequence deposition.

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01.02.2014

Annex WP9-1

Response of MIRRI to

the

"Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union"

The Microbial Resources Reseach Infrastructure (MIRRI) is an initiative within the European Strategy Forum on Research Infrastructure (ESFRI), including 16 European public microbial culture collections and resource centres, supported by 17 European and several non-European partners. It has received FP7 funding for a 3-year Preparatory Phase since November 2012. MIRRI aims to facilitate access to high quality microbial Genetic Resources (GR), related data and services, to connect users and providers, and to establish a platform of expertise. One of the focal points is the legal operational framework for culture collections. The „Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union" has been thoroughly studied, and the opportunity to provide a response to it is gratefully accepted. The decision of the European Commission to design a regulation that will introduce measures for user compliance based on due diligence obligations for all users throughout the Union is strongly supported.

The system of "**Union Trusted Collections**" proposed in Art. 5 of the Regulations is welcomed by MIRRI because it creates the potential to aptly support scientists within the Union to comply with the Nagoya Protocol and these Regulations. The scientific community is in need of a broad system of trusted sources that will **offer a full spectrum of high-quality microbial GR**. The ex-situ conservation of microbial GR requires specific expertise that is distributed over specialized culture collections across Europe. Scientists residing in developing countries often have to rely on these collections for preserving the GR because the expertise and capacity is still wanting in those countries. There is a big variation in size and scope of the Collections within the EU and, although many collections will be able to demonstrate that

their procedures meet (most of) the criteria for a trusted source as set out in Art 5, par. 3 of the draft proposal, it is unlikely that they all will be able to handle the extra structural administrative work related to the checking and/or collecting of all relevant documentation, without additional funding to hire more staff. The system should not favor only a select group of (larger) culture collections that are able to find the needed resources. **The Member States should therefore take measures to support collections under their jurisdiction that meet the criteria of trusted collections but lack sufficient resources to fulfill the tasks of a Union Trusted Collection.** Thus, additional financial support for maintaining the system of Union Trusted Collections will be required, be it at national or Union level, for example through support of a research infrastructure like partners envisage for the future of MIRRI. Without such support the collections will be facing significant budgetary implications for their active research programs, with negative consequences for these institutions and their partners in developing countries that currently benefit from collaboration programs. If in time a global multilateral benefit sharing mechanism is to become operational, it should also provide financial support to collections that are recognized as trusted sources.

The criteria for Union Trusted Collections laid down in Art. 5, par. 2 are rather broadly formulated and we suggest to improve the text by more specifically formulating the minimum administrative duties. It is clear from the present draft that collections need to keep documents providing evidence that microbial GR were legally accessed and also keep record of supply of GR to third persons. Collections are not able to monitor third person compliance as users of the same microbial GR, or that of subsequent users further down the value chain. Moreover, under the standard Material Transfer Agreement of most European collections such further transfers of GR are not allowed. **Although it is our current understanding that the collections do not have to monitor the use by those receiving GR, and are not legally qualified / authorized to do so, this has to be clearly stated in Art. 5 of the Regulations**. These amendments would enable collections to better estimate the workload and ensure (long-term) compliance.

Public culture collections are the only gateway for scientists to bring microbial GR accessed *in situ* into the public domain so they can be exchanged and shared in a transparent way and used by other scientists for further research and development. Microorganisms often need to be studied in the laboratory for many years before scientists can publish the results. For example, in order to fulfill the requirements for valid publication of new prokaryote species, a type culture has to be deposited in public culture collections in two different countries. It is our great concern that after the Nagoya Protocol (NP) enters into force, the numbers of microbial GR that are deposited in the public collections

will severely decrease. One reason for this can be that scientists may experience great difficulties in obtaining Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT). Parties to the NP are committed to have the required legal instruments and Competent National Authorities in place when the Protocol enters into force, but experiences from the past are reason to expect that not all Parties will meet the deadline. Incompletely documented GR could not be accepted by the collections under the currently proposed Regulation for the Union. In order to avoid the risks of severe impairment of the current practice of shared microbial GR in public collections, **the EU regulations should provide the option for collections to accept material in cases that the depositor can reasonably explain why the documentation is not (yet) complete**. The collections' curators need to exercise due diligence by at least trying to clarify with depositors any issues regarding the legality and the available documentation, before they can decide on acceptance of the GR for deposit in the collection. Also, **curators should not accept any GR without at least information on the country of origin**, a practice most European collections have already exercised since the CBD entered into force and has met with general acceptance by scientists as a necessary measure to seek compliance.

Most culture collections supply microbial GR to users on a global scale and exchange microbial GR with culture collections in other regions. At the Symposium "Impact of the Nagoya Protocol on management of Biological Resource Centers", organized by the NITE-NBRC collection for its 10th Anniversary, Dec. 6, 2012, in Tokyo, the idea of a system of Union Trusted Collections met with great interest from the stakeholders in Asia and delegates from other regions. It is of great importance that the Commission continues to discuss the proposed system of trusted sources with authorities in other regions with the aim to establish a global solution or at least reach a level of compatibility between the systems for trusted sources that will stimulate and not discourage international cooperation and development, and does not set back the competitive position of researchers in Europe relative to researchers in other regions or in countries that did not ratify the NP.

MIRRI is in favor of building a general term into Art. 5 of the proposed regulation, that states that GR designated as **ex-type strains and strains accepted as reference strains for International Standard Norms should not be subject to these regulations**. Type strains are the reference material for taxonomy and systematics which are basic tools to research in the life sciences, such as on ecosystem functioning and effects of climate change, which contribute to conserving the planets microbial diversity. The status of these strains can be verified through scientific and technical publications. Users of these microbial GR normally have no intent of commercial use and always make their results publicly available providing non-monetary benefits to society. By excluding these kinds of resources from the scope of the

Regulation, the Union would justly underline the importance of **simplified, yet effectively conveyed access for non-commercial research**.

MIRRI trusts that the above-mentioned concerns and suggestions for improvement will be taken into consideration. We hope that these Regulations in their finally adopted version will provide sufficient legal certainty for both the users of the microbial GR as the collections that have the conservation of these resources as their primary mission.

Braunschweig, Utrecht, 14 March 2013

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Annex WP9-2

Utrecht, 22 May, 2013

Dear Mrs Bélier and Mr Acquarone,

Thank you again for your time and willingness to listen on May 15th, to the response from the MIRRI community. As promised, I am providing you with a list of key-issues we would like to bring forward, as a response to the latest amendments you made for the regulations.

Amendment 21

We discussed what the meaning of 'new utilization' is, and you clarified :

Utilisation that is different from that which has been agreed in PIC or MAT prior to this use. For genetic resources (GR) without such documents, the terms should first be negotiated with the relevant party (is competent authority in country of origin) before starting the use.

Most of the GR preserved in public microbial resource collections were accessioned prior to the CBD, and generally without PIC and/or MAT. In most cases, the country is known and according to the suggested amendment, prior to dispatch PIC and MAT have to be settled between the user and provider country. It is our fear that most researchers cannot or will not oblige because of administrative problems, unacceptable delays etc. and that they will therefore no longer make use of GR in the public collections. This could lead to a shift from use of GR in public collections to GR outside the public domain, counter to the objective of improving monitoring of use of GR in the Union. This would also have severe consequences for the operation of collections, and (micro)biodiversity research in general. Many collections depend financially on revenues from distribution of GR to users, and a sudden and strong decrease in numbers of cultures distributed will have severe budgetary consequences for the operation of these collections. Remember that member states and also the EU (by providing framework program grants) have invested lots of money into these public service collections.

Amendment 28 (Proposal art. 3)

The proposed definition of 'research and development' is very general, and would also include any routine DNA extraction for the sole purpose of identifying a microorganism. Almost any microorganism has to be DNA-sequenced in order to determine its identity. If a user is only interested in identifying a GR from a culture collection dating from before 1994 (to update previous identification, for example), and only produce a publication about this, a PIC and MAT still have to be negotiated first, while the activity itself is directly to benefit of the GR-provider country and to society in general. Specialists will no longer be interested in contributing in this way, as they have to invest extra time without the prospect of getting compensated.

Amendment 36 (Proposal art. 4)

We discussed the problem of discriminating between non-commercial and commercial research. Indeed, it is often difficult to determine this, but there are a number of occasions (moments in a period of time a user works with the

GR), where it can become very clear if benefits should be shared. You have justly proposed these occasions (a-d) in amendment 47.

Amendment 47

We suggest to add to your amendment of art. 7 of the regulation a text referring to occasion ' (a) *establishing prior informed consent and mutually agreed terms*' for GR obtained by a user from a Union Trusted Collection, as follows:

A user seeking to obtain GR from a union trusted collection and for which PIC and MAT are lacking the time of user's request, will be allowed to receive such GR under a Material Transfer Agreement between the Collection and the user that allows the user to do basic taxonomic research, including DNA-based or other types of identification, and comparative taxonomic studies (organism characterisation) aiming to improve the knowledge of biodiversity. If the user wants to utilize the GR for any other kind of research activities or for any type of commercial utilisation, the users should in advance of such utilisation actively seek contact with the country of origin of the GR to establish PIC and MAT for that new type of utilisation.

[consequently, any user that fails to comply would have a problem when entering occasions (b)-(d), where he has to provide proof of PIC and MAT].

Amendment 71

MIRRI welcomes the idea of creating a Union benefit sharing fund, and would like to bring to your attention that *ex situ* collections could use additional resources from this fund to increase their capacity to act as trusted collections, and supporting expert centres for collections in developing countries. The European collections must be able to continue their (taxonomic and biodiversity) research, especially since implementation of the Nagoya Protocol and EU regulations will put pressure on available budgets due to extra administrative work. Many biodiversity rich third countries have at this time no or few collection facilities in place. Under guidance of organisations such as the European Culture Collection Organisation (ECCO) or the MIRRI network, resources from this fund could also be used for training staff from such countries in collection management and other supporting activities.

Thank you in advance for considering the above. I will be available for any questions.

With highest regards,

Gerard Verkley

MIRRI WP 9 Leader

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MIRRI
MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE

Mr. H-M. Schally,
Head of Unit
Directorate E – Global and Regional Challenges, LIFE
ENV.E.2 – Global Sustainability, Trade & Multilateral Agreements
European Commission
Directorate General Environment

Your ref.: ENV.E.2 VK/rf ARES(2013)

Utrecht, July 19, 2013

Dear Mr Schally,

Thank you for your invitation to provide information on developments in the work area of microbial culture collections regarding model contractual clauses, best practices etc. in view of the entry into force of the Nagoya Protocol.

Since the entry into force of the CBD, our community of Microbial Resource Centres (MRCs) has worked to reach compliance and harmonise practices. Several initiatives emerged, often leading to EU-funded projects aiming to develop model contractual clauses and best practices. Some projects are now completed, others are currently underway using output of earlier projects that will be updated and supplemented with new elements for best practices. A summary of the work done is presented below. Footnotes and Appendices provide further detailed information.

A first voluntary Code of Conduct

The project **MOSAICC**[1], which was financially supported by European Commission DG Research, aimed to develop a voluntary **Code of Conduct** that provides a set of **model clauses for PIC and MAT** for providers and recipients of microbial genetic resources (MGRs), and for **Material Transfer Agreements** (MTA) for the deposit in public collections (also referred to as Material Accession Agreements) and supply of MGRs by these collections to users. Key elements identified for MTA included (i) description of the MGRs, (ii) specifications of terms of use (commercial or non-commercial) and, (iii) terms of benefit sharing (monetary or non-monetary). MOSAICC was completed in 1999, became listed on the CBD website in the Nagoya Protocol webpage and also appears on the WIPO list of sources of model contractual clauses in the context of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore. MOSAICC also influenced the drafting process for the CBD Bonn

Guidelines. Appendix 1 provides the MOSAICC document in a version of 2011. The follow-up project **MOSAICS**[2], also funded by the EU, aimed at the development of an Integrated Conveyance System, offering (i) tools to evaluate the economic value of MGR, (ii) standard provisions to enable uncomplicated tracking of MGR, and (iii) a way of balanced benefit sharing for those that are entitled to be rewarded for the services and products they provide to society.

The practice of sharing MGRs and related information by scientists world-wide for research purposes, known as **Microbial Commons**[3, 4, 5] has been key to the development of microbiology over more than a century. Collections have been involved in several recent studies and meetings on the subject of microbial commons, which aimed at analysing current practices of sharing MGRs and information by collections, researchers and their networks, and how this practice could be placed on a more solid scientific, and legally sound, institutional basis. The complicated issues of ownership was also addressed and a "**bundle of rights**" [6] attached to MGRs was proposed, which should be regulated by law and managed through agreements and contracts between stakeholders.

Best practice and the ECCO-Core MTA

Even years after the publication of the Bonn Guidelines in October 2001, many Parties to the CBD still failed to set in place authorities with competence for processing requests for PIC and MAT. Meanwhile, the collections continued their efforts to find ways to enhance compliance under these quite difficult circumstances.

After considerably discussion in various meetings, most public collections adopted a best practice for deposit and supply of MGRs. The main elements for this best practice are:

- Accession forms to be completed by the depositor of the MGR where information on the PIC and MAT should be provided, if applicable
- No acceptance of MGRs without information about the country of origin
- Supply by the collection of MGRs to users under MTA settling the most important conditions for supply and terms of use

Collections recognised that a highly harmonised MTA for supply by all European collections would contribute to improving legal certainty and transparency to both users and suppliers of MGRs. Therefore, the European Culture Collection's Organisation [7, 8] (**ECCO**) developed the **"ECCO-Core MTA"** [9] (full text in Appendix 2), taking recommendations of MOSAICC into account. The Core MTA answered to the need of collections to have a harmonised MTA that settles terms for use of supplied MGRs, and also effectively raises awareness with the users of MGRs about their obligations under the CBD, especially with regard to benefit sharing. The Core MTA was agreed upon by the ECCO members in 2009, and subsequently implemented in many European collections.

Next steps to prepare for the entry into force of the Nagoya Protocol

Member collections of ECCO and other participants in the Global Biological Resource Centre Network (**GBRCN**) Demonstration Project[10], joined in an endeavour to establish a new Research Infrastructure (RI) for microbial collections, the Microbial Resource Research Infrastructure[11] (**MIRRI**). In its EC funded three-year Preparatory Phase (2012-2015), MIRRI is focussing on **the preparation of a legal operational framework** for the RI. In the **MIRRI Response**[12] to the EC proposal for a Regulation for ABS in the Union, partners have expressed their support but also several concerns regarding important articles of the proposed text. MIRRI will take the output of previous projects and initiatives into the next process of formulating minimal requirements for compliance and use these to develop a new common policy for ABS and IPR for MGRs. Alongside, partners of the MOSAICC project have started recently to review its

set of model clauses and recommendations with the help of other experts to make it fully compliant with the Nagoya Protocol.

Beyond the borders of the Union

European MRCs are currently also involved in discussions about the consequences of the NP with collection institutions outside Europe. During international meetings[13] addressing these issues where curators of European as well as non-European collections and representatives of various governments were also present, considerable interest and positive responses were seen to the system of **Union Trusted Collections**, as proposed by the EC in the draft Regulations. On the basis of growing consensus among MRCs world-wide on how to achieve compliance, the "**TRUST**" initiative was coined by the World Federation of Culture Collections (**WFCC**). The acronym stands for "TRransparent User-friendly System of Transfer for Science & Technology". TRUST aims to create an effective global system of trusted sources for microbiology, which could be supported by further development of its pioneering database system which is maintained by the World Data Centre for Micro-organisms[14] (**WDCM**). In the WDCM CCInfo-database, collections can register through a unique acronym and numerical identifier in its official list of MGRs. Today, 644 culture collections are registered in CCInfo, holding over 2 300 000 cultures of microorganisms. The WDCM system will use the recent technology of electronic markers called "Globally Unique Identifiers (GUIDs)" that could be used to set up a robust system to organise transfers of (micro) biological items, tracking the flow of resources and related information.

Conclusions

Our community of microbial collections in Europe has been very active and continues to be so. We are following the negotiations in the European Union regarding the Regulation on ABS with great interest, as the final result will largely determine next steps to be taken towards the development of best practises suited for the new situation. We highly appreciate the interest shown by the EC for what is being done by the collections to reach improved harmonisation and compliance to the expected ABS regime for the Union. Based on our long-standing cooperation in ECCO, WFCC and during several projects that became possible through funding by the EU, we are fully prepared to go forward and contribute to a successful implementation of the NP. It is our hope that it will bring more legal certainty and also justice to the goals of the CBD.

We will be happy to provide more information or answer any questions you might have.

With highest regards,

Gerard Verkleij

Leader MIRRI Workpackage 9 (Legal Operational Framework)

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[1] MOSAICC stands for Microorganism Sustainable use and Access regulation International Code of Conduct (http://bccm.belspo.be/projects/mosaicc/). MOSAICC recommendations facilitate access to MGRs and help partners to make appropriate agreements when transferring MGRs, in the framework of the CBD and other applicable rules of international and national laws. A version that was updated in 2011 is provided as Appendix 1.

[2] MOSAICS stands for "Microorganisms Sustainable use and Access management Integrated Conveyance System". It was funded by Directorate General Research of the European Commission under the Sixth Framework Program. The consortium of the MOSAICS project is made of partners from developed and developing countries, including culture collections, international organisations, branch federations and specialised research institutes. Already in 1999, the MOSAICC project had identified three necessary features for a system to implement coherently the CBD provisions on ABS. MOSAICS central objective is the development of such an integrated conveyance system that:

- has reliable tools to evaluate the economic value of microbiological resources;
- disposes of validated model documents with standard provisions to enable tracking via an uncomplicated procedure, widely applied by microbiologists;
- combines valuation and tracking in one system for trading of microbiological resources, with balanced benefit sharing for those that are entitled to be rewarded for the services and products they provide to society.

[3] Dijkshoorn L, de Vos P, Dedeurwaerdere T (2010). Understanding patterns of use and scientific opportunities in the emerging global microbial commons. Research in Microbiology 161: 407-413.

[4] Dedeurwaerdere, T (2010). Global microbial commons: institutional challenges for the global exchange and distribution of microorganisms in the life sciences. Research in Microbiology 161: 414-421.

[5] Dedeurwaerdere, T (2010). Self-governance and international regulation of the global microbial commons: introduction to the special issue on the microbial commons. International Journal of the Commons 4: 390-403. URN:NBN:NL:UI:10-1-100217.

[6] The innovative concept of "bundle of rights" is a dynamic model of ownership management moving away from the static concept of ownership towards a flexible allotment of rights. Ownership constitutes a "bundle" of use and decision rights that are attributed to a number of stakeholders / economic agents. It is a set of operational and collective choice rights defining respectively who decides upon the use that one can make of a resource, and who decides upon the future exercise of the rights on the resource. Such scheme allows multi-ownership of a gradual level of use and decision rights. These rights can begin with basic access rights, encompassing research delivering outputs to the public domain, distribution on to third parties, exploitation rights to develop intellectual property and its ownership which may include reach through rights. Furthermore, the application of the "bundle of rights" makes possible the enforcement of the "sovereign rights of States over their natural resources" without prejudice to private rights. Unambiguous allotment of rights in advance will facilitate rightful benefit sharing "at the end of the pipe". See also Dedeurwaerdere, T : Understanding ownership in the knowledge economy: the concept of the bundle of rights. BCCM News Edition 18 - Autumn 2005.

[7] The European Culture Collections' Organisation (ECCO, http://www.eccosite.org/) was established in 1981. ECCO comprises 61 members from 22 European countries, holding over 350.000 strains of yeasts, filamentous fungi, bacteria and archaea, phages, plasmids, animal cells including human and hybridoma cell lines, viruses, plant cells, algae and protozoa. The aim of the ECCO is to promote collaboration and exchange of ideas and information about all aspects of culture collection activity. ECCO meetings are held annually and are a valuable forum for discussion and innovation on the future development of member collection activities.

[8] Fritze D (2010) A common basis for facilitated legitimate exchange of biological materials, proposed by the European Culture Collections' Organisation (ECCO). International Journal of the Commons 4: 507-527. URN:NBN:NL:UI:10-1-100222.

[9] Janssens D, Tindal B, Green P, Garay E, Fritze D, Stalpers J, Smith D, Bimet F, Desmeth P (2009). The ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection. Article 7 of this standard MTA is cited here: "If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSE(S), it is the responsibility of the RECIPIENT, in advance of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the MATERIAL, as

indicated by the COLLECTION's documentation." Full text is provided in Appendix 2 (also downloadable from http://www.eccosite.org/)

[10] Global Biological Resource Centre Network Demonstration (GBRCN) Project was supported by the German Federal Ministry of Research and Education (BMBF) following work in the OECD to improve access to high quality biological resources and information to support research and biotechnology as a platform for a knowledge-based bioeconomy. Partners included collections from 15 countries, with representatives of the WFCC, a global network and regional networks, ECCO and the Asian Consortium for Microorganisms (ACM). The final report of the project which was completed in 2012 can be downloaded at http://www.gbrcn.org/.

[11] Microbial Resource Research Infrastructure (MIRRI) is an EU funded project that aims to build one pan-European infrastructure for microbial collections that will more effectively facilitate access to high-quality microorganisms, their derivatives and associated data and services, for research, development and applications. After its acceptance on the European Strategy Forum on Research Infrastructures road-map, MIRRI obtained funding from the European Commission and on Nov 1st, 2012 it entered a three-year Preparatory Phase, in which partners will focus on governance and structure, and technical, legal, and financial issues to build the network. This will establish the links across the distributed RI and between the RI microbiological resource centre (MRC) community, its users, policy makers and potential funders. www.mirri.org

[12] Response of MIRRI to the "Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union" E. Stackebrandt & G. Verkleij, March 14, 2013. [this document was sent to your office by email 12/04/2013]

[13] For example: NITE-NBRC 10th Anniversary Symposium "Impact of Nagoya Protocol on management of Biological Resource Centers", Tokyo, Japan, Dec. 6, 2012.

[14] The World Federation for Culture Collections (WFCC) has developed a pioneering database system by registering its members through a unique acronym and numerical identifier in its official list and urging them to catalogue their microbiological resources. This system is maintained and improved by the World Data Centre for Micro-organisms (WDCM). Combining the WDCM system and the use "Globally Unique Identifiers (GUIDs)" set up a robust system to organise transfers of (micro) biological items, tracking the flow of resources and related information. This system also facilitates the application of ABS since it can potentially retrieve all kinds of information about microbiological resources, including information related to the location and movements of the resource. The WDCM portal acts as an information broker between all online catalogue entries of the culture collections. See http://www.wdcm.org and http://bccm.belspo.be/projects/mosaics/reports/files/ics_report.pdf7.

Appendices

Appendix 1

MOSAICC text (version 2011)

Appendix 2

ECCO Core MTA

MOSAICC

MICRO-ORGANISMS SUSTAINABLE USE AND ACCESS REGULATION INTERNATIONAL CODE OF CONDUCT

Updated June 2011

Louis Pasteur: "The role of the infinitely small is infinitely large"

BCCM

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INTRODUCTION

The World Federation for Culture Collections (WFCC)[1] describes micro-organisms as follows:

"Micro-organisms" comprise viruses, all prokaryotes (archaea and bacteria), some eukaryotic organisms fungi, including yeasts, algae, protists, their replicable parts and other derived materials e.g. genomes, plasmids, cDNA. They are considered ubiquitous and found everywhere not recognising country boundaries although many do have various physiological requirements or are obligate pathogens or symbionts and don't grow everywhere. However, it is becoming more apparent that the environment in which a particular species is found has impact on its chemistry and properties.

Fifty percent of the living biomass on the planet is said to be microbial and micro-organisms have the potential to provide solutions to many problems in agriculture, industry, plant, animal and human health and several other biotechnological applications. The vast majority (95%) of microbial diversity is yet to be discovered. They are involved in nutrient recycling (e.g. breaking down complex plant and animal remains), beneficial mutualistic relationships (e.g. nitrogen fixation, animal digestion, mycorrhiza), and production of atmospheric oxygen; some are pathogens causing disease of man, plants or animals.

Micro-organisms have been used as tools for the production of products for millennia. Their various properties can be harnessed by man for many uses which include the biological control of pests and diseases in agriculture and horticulture; production of natural products (e.g. valuable drugs, enzymes, and metabolites) for pharmaceutical, food and other applications, composting, bioremediation and detoxification of wastes. They play a major role in soil fertility and plant and animal health and are employed in diagnostics, efficacy testing of drugs, biocides, vaccine production and disinfectants or as reference strains. They are multifunctional and consequently have multi-use. The unravelling of the structure of DNA (deoxyribonucleic acid), various species of ribonucleic acid (RNA), and the various processes whereby the manufacture of protein from the nucleic acid templates occurs was pivotal in advancing the use of micro-organisms in biotechnology.

With the passing of time, the realized and potential benefits of micro-organisms and the implementation of strict standards of microbe sustainable use provides increasingly for economic and social benefit at global scale.

On the other hand, many micro-organisms are pathogenic for human, animal, plants or other micro-organisms and must be monitored, studied, controlled and quarantined, to avoid health hazard, depleting food and feed stock or economic loss.

Containment of hazardous micro-organisms or sustainable use of beneficial micro-organisms is possible provided that facilitated, save and sound access as required in CDB article 15 is ensured. That is the purpose of MOSAICC: contributing to facilitate access and transfer of microbiological material.

MOSAICC is a voluntary Code of Conduct. It is developed to facilitate access to microbial genetic resources (MGRs)[2] and to help partners to make appropriate agreements when transferring MGRs, in the framework of the Convention on Biological Diversity (CBD)[3] and other applicable rules of international[4] and national[5] laws. MOSAICC is a tool to support the implementation of the CBD at the microbial level; it can also serve as a model when dealing with genetic resources other than MGRs.

MOSAICC is the result of the European Commission DG Research funded project called "Elaboration and diffusion of a code of conduct for the access to and sustainable use of microbial resources within

the framework of the convention on biological diversity"[6]. MOSAICC was first issued in spring '99, two years before the Bonn Guidelines[7], as result of five successive drafts improved through dialogue between MOSAICC partners and a network of experts of more than 15 different nationalities. The present version is an update that takes over the innovative ideas developed the last decades by life sciences and social sciences researchers to meet the evolving socio-economic environment.

Access to MGRs is a prerequisite for the advancement of microbiology and world-wide sustainable development. Furthermore, monitoring the transfer of MGRs is necessary to identify the individuals or groups that are entitled to be scientifically or financially rewarded for their contribution to the conservation and sustainable use of the MGRs. Therefore, MOSAICC combines the need for easy transfer of MGRs and the need to monitor the transfer of MGRs. It proposes a system that works through two operating principles:

1. The *in situ* origin of the MGRs is identified via initial **Prior Informed Consent** (**PIC**) procedure providing authorisation for sampling. The *in situ* origin of the MGRs is always mentioned when transfer occurs.
2. The transfer of MGRs is monitored and occurs under **Material Transfer Agreement** (**MTA**) which terms are defined by both recipient and provider**.** MTA is a generic term that covers very short shipment document, simple standard delivery notice, standard invoice containing minimal standard requirements, or more detailed specific contract including tailor-made mutually agreed terms. According to the use and intended distribution of the MGRs, mutually agreed terms can be short or very detailed.

MOSAICC aims to assist microbiologists:
- to obtain Prior Informed Consent-PIC (CBD art.15.5) ;
- to establish Material Transfer Agreement (MTA) for access to and transfer of MGRs, access to and transfer of technology, fair and equitable sharing of benefits as well as for technical and scientific co-operation (CBD art.15.4, 15.6, 15.7, 16, 18 & 19).

MOSAICC aims to assist authorities of countries providing MGRs by suggesting procedures:
- to issue PIC for access to MGRs;
- to organise facilitated access to MGRs (CBD art.15.2)
- to monitor the transfer of such MGRs, to enable fair and equitable sharing of the possible benefits arising from their utilisation.

MOSAICC includes recommendations to microbiologists. These recommendations should be considered as guidelines for an optimal implementation of the CBD. National and international legal requirements developed in or outside the framework of the CBD remain compulsory (CBD art.22). As the implementation of the CBD is ruled at national level, some suggestions to authorities are also included as well as some model forms in section II of this document.

As it is not the purpose of MOSAICC to analyse thoroughly the terms and principles of the CBD, readers are advised to check the bibliography and consult other documents for more information about the CBD. In addition, MOSAICC recommends the "OECD Best Practice Guidelines for Biological resource Centre" published in 2007 by the Organization for Economic Co-operation and Development[8] and the "WFCC Guidelines for the Establishment and operation of culture collections"[9]. These documents provide guidance and propose best practices for depositories of biological material. They contain lists of rules and regulation as well as useful references.

[1] Smith, D. & Desmeth, P. (2007). Access and benefit sharing, a main preoccupation of the World Federation of Culture Collections. In: UNEP/CBD/WG-ABS/6/INF/3 13 December 2007

[2] Short definition of microbial genetic resources (MGRs) derived from the CBD definition of genetic resources: *any microbial genetic material of actual or potential value* (article 2).

[3] The Convention on Biological Diversity (CBD, Rio de Janeiro, 5 June 1992) has three objectives " *the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources* "(art.1). To achieve these goals, the CBD lays down new principles governing, among others, access to genetic resources (art.15), access to technology (art. 16, 18 & 19) and fair and equitable sharing of benefits (art. 15 & 19). Since microbiologists must deal with MGRs from all over the world, there is a need for a Code of Conduct dealing with these matters in a practical way. MOSAICC is the result of a consensus obtained between a balanced group of representatives from North and South, including representatives from the public (government, culture collections, academics, NGOs) and the private sector (pharmaceutical, chemical and food industry), from the not-for-profit-sector as from the commercial sector.

[4] Among others the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (28 April 1977, amended on 26 September 1980 and Regulations) and the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS Agreement, Marrakech, 15 April 1994). See also CBD article 22.

[5] Individual countries may retain their own special interests and goals, even if this involves rules that go beyond those laid down by the CBD. However, a uniform set of guidelines could be more economic and effective to implement the principles of the CBD. The success of countries in co-operating with each other and exploiting in a sustainable way their microbial biological diversity will depend on the feasibility of the national regulations and procedures that these countries impose.

[6] Concerted action n° BIO4-CT97-2206 (DGXII - SSMI). The MOSAICC project involved twelve partners. For more details, see webpage http://bccm.belspo.be/projects/mosaicc/

[7] Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (see Convention on Biological Diversity – Conference of Parties 6 Decision VI/24. http://www.cbd.int/decision/cop/?id=7198)

[8] OECD Best Practice Guidelines for Biological resource Centre, 2007, OECD, Paris. See also document "Biological Resource Centres Underpinning the future of Life Sciences and Biotechnology". OECD Science & Information Technology, May 2001, vol. 2001, no.7, pp.1-68 (69 pages) OECD.

[9] See http://www.wfcc.info/index.php/guidelines/

SECTION I. TERMS OF ACCESS to MGRs

I.1. Prior Informed Consent: definition and contents[9]

In the system proposed by MOSAICC, the "prior *informed consent*" (PIC) is a document / a record that officially identify the *in situ* origin of MGRs and authorise the access to *in situ* MGRs. It is the result of a procedure put in place to monitor the access to and the transfer of MGRs.

The PIC must be: - obtained prior to accessing the MGRs;

- based on legally correct and trustworthy information provided by the applicant;
- granted by a competent authority of the country where the MGRs is provided from and according to the national legislation and procedures. (For the purpose of MOSAICC, the competent authorities that are entitled to provide the authorisation for access to MGRs will be called "PIC-providers[10]").

MOSAICC recommends that, in all cases, the PIC-document or the PIC record should contain[11] (see section II for model PIC):

- the names and addresses of the PIC-applicant and the « PIC-provider »;
- a confirmation of the authority exercised by the « PIC-provider »;
- a confirmation of the precise scope of the PIC (cf. annexed PIC-application, area of sampling, when possible description of MGRs to be accessed);
- a reference to the national legislation concerning the PIC, whether this national legislation is related to regulations or recommendations expressed in an international convention (such as the CBD) or not;
- a reference to a Material Transfer Agreement, if any[12];
- and in annex, if relevant, the permission of right holder (such as landowner and/or usufructuary).

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9 MOSAICC refers to the principles laid down in CBD article 15, in particular:
- the « *sovereign rights of States over their natural resources* " in the sense that " *the authority to determine access to genetic resources rests with the national governments and is subject to national legislation* » (CBD art. 15.1);
- « *Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention* » (CBD art. 15.2);
- « *Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article* » (CBD art. 15.4)
- « *access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources unless otherwise determined by that Party* » (CBD art. 15.5).

10 There are different kinds of PIC-providers. PIC-providers that have received a mandate from their government to issue PIC within the framework of the CBD and PIC-providers that have received a mandate within national legislation that does not refer to the CBD. Some of these PIC-providers have a limited mandate, for instance the authority to issue PIC for access to certain geographical area(s) like a Department of Forestry or an administration supervising a National Park. Some PIC-providers have a broader competence related to the access to genetic resources (e.g. department of Environmental Affairs). In practice a country may organise itself in different ways. In this regard countries could take two useful steps to facilitate the implementation of the PIC principle: first, designate one or more PIC-providers, secondly, regularly publish updated list of names and addresses of their competent PIC-providers. The lists should include specifications on the scope of the respective mandates of those PIC-providers (kind of genetic resources covered, geographical areas of competence etc.). Countries which have designated PIC-providers, could use standardised PIC-certificates such as the MOSAICC model forms (see section II).

11 Some conditions could be added according to the country's national legislation and/or the specific rules applied by a PIC-provider but too restrictive rules might run counter the attainment of the general objectives of the Convention on Biological Diversity (CBD articles 1 and 15.2).

12 The transfer without MTA of *in-situ* MGRs to *ex-situ* conservation facilities is possible when the present depository has itself isolated the MGRs directly from *in-situ* conditions and stored them at its facilities. In any other cases transfer of MGRs without MTA is inadvisable. Note that when receiving strains of micro-organisms to conserve, culture collections ask the depositor to fill in an "accession form" where basic information is recorded. The accession form is usually one of the first official documents recording the trail of movements of a micro-organism, alongside any scientific paper describing the micro-organisms and its properties.

I.2. Procedure for access to *in situ* MGRs[13]

Prior Informed Consent

MOSAICC recommends that microbiologists, wishing to access *in situ* MGRs, endeavour in all cases to apply for a **Prior Informed Consent** (PIC) both in countries that have or have not yet designated a competent « PIC-provider » within the framework of the CBD[14].

Because "PIC-providers" are not always identifiable where access to *in situ* MGRs is required, MOSAICC recommends that microbiologists:

- always make best efforts to identify the competent « PIC-provider » and to acquire a PIC before accessing MGRs;
- keep proof of their efforts and steps made to acquire PIC;
- when wishing to access *in situ* MGRs[15], always attempt to acquire written permission from identifiable right holders, such as the landowner and/or the usufructuary of the land or water area before accessing this area and its genetic resources;
- use the MOSAICC model PIC-application form as model (see Section II model documents);
- in absence of official forms, ask "PIC-providers" to use the MOSAICC model PIC-document (see Section II model documents).

The PIC gives access to *in situ* MGRs; it authorises sampling of MGRs under certain conditions. Subsequently, for each MGR isolated during the specific field survey / sampling campaign it covers, the PIC proves that the MGR has been isolated in a legitimate way and it identifies officially the *in situ* origin of the MGR. At this point, the issuance of a **Global Unique Identifier** (GUID)[16] attached to the "item" can make the conveyance of MGRs transfer feasible. Another moment when the issuance of a GUID is recommended is the deposit in an *ex situ* long term conservation facility, a culture collection. The World Federation for Culture Collections (WFCC) pioneered the development of an international database on culture resources worldwide: the World Data Centre for Micro-organisms (WDCM)[17]. WDCM has inaugurated a system of tagging strains of micro-organisms in a consistent manner that allows finding back the trail of exchanges of the micro-organisms samples through the culture collections network.

A **fast-track procedure** should be available in cases of emergency such as epidemic or for MGRs needed for biocontrol of non-indigenous pests/flora/fauna originating from the same habitat/ecosystem as the MGRs. In case of such procedure, the use of GUIDs renders the backward procedure possible: instead of getting the PIC before access, here access is granted first and the GUID acts as an electronic tag helping retrieve the item and following the trail of its movements in a backward process. The fast-track procedure is coupled to a regularising procedure (see page 9).

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[13] Given the provisions included in CBD article 15, and the use of terms for the purposes of the CBD (article 2), which state:
- "*country of origin of genetic resources means the country which possesses those genetic resources in in situ conditions* "
- "*in situ conditions means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties* ",
MOSAICC defines *in situ* MGRs as micro-organisms or material of microbial origin containing functional units of heredity, as existing within ecosystems and natural habitats, and, in the case of domesticated or cultivated species in the surroundings where they have developed their distinctive properties. Note: This definition excludes MGRs having acquired their distinctive properties in ***in vitro*** conditions, outside their ecosystems and natural habitats (laboratory conditions).

[14] The last phrase of article 15.5: "*unless otherwise determined by that Party*" means also that imposing the requirement of prior informed consent is an option rather than an obligation and this has the consequence that a user is only required to submit to prior informed consent, if the providing Party has taken steps to establish the necessary procedure in its legal system (Hendrickx/Koester/Prip, The Convention on Biological Diversity – Access to Genetic Resources: A legal Analyses, 23 Environmental Law and Policy 250 (1993)).

[15] The country where the *in situ* MGRs were accessed is the country of origin.

[16] More information related to GUIDs is available at http://bccm.belspo.be/projects/mosaics/reports/files/ics_report.pdf and at https://www.cbd.int/doc/programmes/abs/studies/study-regime-05-en.pdf "Studies on Monitoring and Tracking genetic Resources. Garrity G.M. et al, 2009.

[17] Work of Professor Skerman, University of Queensland, Australia, and his colleagues in the 1960's. See www.wfcc.info

Given the flexibility of the CBD[18] concerning the PIC requirement and the need for appropriate procedure for special cases, countries could put in place such fast-track procedure with shortest possible administrative delay according to the level of urgency, giving access to *in situ* MGRs on basis of minimum information about the purpose of the purchase. This procedure should still enable the monitoring of the distribution and utilisation of the MGRs. In the system proposed in this Code of Conduct, fast-track procedure will match with the contents of Material Transfer Agreement excluding further distribution of MGRs and use-category I (see types and contents of Material Transfer Agreement on page 10 and following).

Having in mind that access to MGRs is the necessary prerequisite to enable basic, upstream research, and the non-monetary benefits it generates[19], a State, exercising its sovereign rights over the natural resources under its jurisdiction (CBD article 15.1), could consider organising a simplified system that will facilitate non-commercial research without jeopardizing potential commercial benefits.[20] Such simplified system can make use of the different tools in development such as GUIDs, bio-molecular markers, fingerprinting, most produced initially by basic life-science non-commercial research.

I.3. Procedure for access to *ex situ* MGRs[21]

Prior Informed Consent

MOSAICC recommends that microbiologists wishing to access *ex situ* MGRs:

- to endeavour in all cases to get, at least, the country of origin or a reference such as a GUIDs that leads to the initial Prior Informed Consent issued when access to *in situ* MGRs was authorised or to an equivalent document delivered when the MGRs were originally deposited in *ex situ* collections[22] (see also recommendation for regularising procedure). When the origin of an *ex situ* MGRs is not known, the source (institution or individual who deposited the MGRs in an *ex situ* conservation facility) must be documented.
- to keep files of correspondence when dealing with *ex situ* resource centres, including possible Material Transfer Agreement (see definition of MTA, page 10).

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18 As already mentioned in footnote 14 , the phrase, "*unless otherwise determined by that Party*" gives the countries some flexibility to deal with the principle of PIC requirement and to provide for possible special procedures. For instance in case of emergency, when a dramatic outbreak of parasitic disease (whether human, animal or plant disease) could cause health or environmental damages, access to the pathogenic MGRs should be possible without delay and restriction for *bona fide* researchers. Indeed, in such case, it is irresponsible for a country to deny or delay access to MGRs and so impeding international aid, and it counters the provisions of CBD article 14 (e) stating « *(Each Contracting Party, ..., shall) Promote national arrangements for emergency responses to activities or events, whether caused naturally or otherwise, which present a grave and imminent danger to biological diversity and encourage international co-operation to supplement such national efforts and, where appropriate and agreed by the States or regional economic integration organizations concerned, to establish joint contingency plans*».

19 As described in appendix II of the Bonn Guidelines and in COP Decision VI/24 Annex II. These benefits include, but are not limited to: human and institutional capacity building, education and training; technology transfer, new research approaches and access to facilities; access to data, information and knowledge that contributes to policy- and decision-making on all levels; and participation in collaborative, multidisciplinary research activities and networks.

20 Schindel et al. Workshop report on access and benefit sharing in non-commercial biodiversity research. Bonn, Germany, 17-19 November 2008. Document accessible at http://barcoding.si.edu/ABSworkshop.html

21 Given the provisions included in CBD article 15, and the use of terms for the purposes of the CBD (CBD art. 2), which state:
-"*country providing genetic resources means the country supplying genetic resources collected from in situ resources, including populations of both wild and domesticated species, or taken from ex situ sources, which may or may not have originated from that country* ",
-"*ex situ conservation means the conservation of components of biological diversity outside their natural habitat* "
MOSAICC defines *ex situ* MGRs as material of microbial origin containing functional units of heredity that is kept outside its natural habitat (such as *in vitro* or laboratory conditions).

22 *Ex situ* MGRs are originally isolated from *in-situ* conditions and subsequently kept *in vitro*. According to the CBD provisions, these MGRs isolated from *in-situ* conditions should have been accessed through a PIC identifying their origin and making reference to the terms of the access.

– to check that the ***necessary minimal information*** regarding the MGRs is attached or retrievable via GUIDs.

– to always mention provider, strain reference number and country of origin in their scientific papers/publication.

MOSAICC recommends that the provider of the MGRs transfer them with the ***necessary minimal information*** about their *in situ* origin**:**

– a reference to the original PIC or to an equivalent document delivered when the MGRs were originally deposited in *ex situ* collections;

– the name of the country where the MGRs were accessed;

– a strain reference number or GUIDs;

– if available, the species name identifying the strain (see comments in footnote 24);

– the place and date of isolation as well as the name of the individual that has isolated the strain from *in situ* conditions or, for lack of individual's name, the name of the institution (legal entity) that employed the individual at the time of the isolation of the strain;

– previous Material Transfer Agreement, if any.

One key procedure at the point of junction between *in situ* and *ex situ* life conditions of micro-organisms is the deposit of a strain in an *ex situ* long term conservation facility. When accepting strains, culture collections require basic information from the depositor which is similar to the necessary minimal information as listed here above. This information is recorded on what is usually called an "**accession form**". The "accession form" is the very first document attached to strains entering a collection. Appropriate use of this form will facilitate management of the micro-organisms throughout its *ex situ* lifespan.

Complementary to the recording of basic information at key point of the micro-organisms life, the use of Global Unique identifiers (GUIDs) will help retrieve the necessary minimal information and more[13].

Many *ex situ* MGRs are not yet covered by a PIC because individuals as well as institutions, including *ex situ* resource centres, have sometimes acquired in the past, and in particular cases are still acquiring MGRs without a PIC.

MOSAICC recommends that a **regularising procedure** will be followed for these *ex situ* MGRs that have been acquired / isolated from *in situ* conditions without a PIC. This regularising procedure consists of the applicant providing the competent authority with an inventory of indexed strains in pure culture, whether identified or not, kept at its facilities. This correcting measure will fulfil the need to identify the *in situ* origin of the strains by recording and transferring the adequate information. This measure must remain exceptional. It is intended to get back into the regular circuit MGRs that have for any reasons bypassed the standard procedure. The regularising procedure applies also in the context of fast-track procedure (see page 7).

Amongst the strains kept *ex situ*, those used in standards for assays and proficiency tests are called reference strains, and the strains that underpin taxonomy and nomenclature are defined as Type strains. The availability of these strains is of central importance in a comparative science, it is essential that access and exchange of these reference strains and Type strains is not impeded to facilitate microbiological systematic research. The emergence of individuals and organisations attempting to restrict use, access or protect intellectual property threatens this access[23], and runs contrary to CBD

[23] Tindall, B.J. & Garrity, G.M. (2008). Proposals to clarify how type strains are deposited and made available to the scientific community for the purpose of systematic research. International Journal of Systematic and Evolutionary Microbiology 58, 1987–1990.

Article 15.2. MOSAICC recommend that the States exercise their sovereign rights upon their natural resources to request *ex situ* MGRs providers such as culture collections in which such strains are deposited to make these available without restriction, a reasonable costs fee, to facilitate future research and enable proper identification.

I.4. Settlement of Material Transfer Agreement

MOSAICC recommends that all transfers of MGRs (*in situ* MGRs to *ex situ* conditions and transfers of *ex situ* MGRs) occur under **Material Transfer Agreement** (**MTA**) the terms of which are mutually agreed[24] upon between the provider and the recipient.

Material Transfer Agreement (**MTA**) is a generic term that includes very short shipment document, simple standard delivery notice, standard invoice containing minimal standard requirements, or more detailed specific contract including tailor-made mutually agreed terms. All these documents can be designated as MTA as long as they contain at least:

- information about the *in situ* origin or the source (see PIC);
- information about provider and recipient ;
- mutually agreed terms for the access to and the transfer of MGRs, the access to and the transfer of technology, the fair and equitable sharing of the benefits as well as for technical and scientific co-operation.

According to the use and intended distribution of the MGRs, mutually agreed terms can be either very short or very detailed.

Model MTA and Standard MTA

For usual transfers, such as delivery of test strains and exchanges between scientists, etc., partners are advised to use widely accepted **model MTA**. The European Culture Collections Organisation (ECCO) is striving towards such a model MTA with a standard core completed with facultative provisions. Such regional model MTA can foster the exchanges of microbial material in a uniform legal system. Designing a model MTA for the members of the World Federation for Culture Collections (WFCC) would be a significant sector based ABS approach for the culture collections community across the world, facilitating exchanges although its members operate in different legal system.

It is also advisable to strive towards the development of sector-based **Standard MTA** (sMTA) such as the one designed for the International Treaty for Plant Genetic resources for Food and Agriculture (ITPGR)[25]. sMTA adapted to the bilateral framework of the CBD can be inspired by the ITPGR sMTA although the latter is used in a multilateral system.

Common rules of access to MGRs and related data can be part of a process to reconstruct "commons" in microbial data, information and material. That is to establish "**microbial commons**" for the exchange of (micro) biological material which would provide basic common use principles for access to both material and information. This development will be complementary to the national regulations on ABS and to existing IPR laws, as it will constitute a demarcated space where material and information are relatively freely accessible provided that the outputs is injected back in this open space, to be shared again[26]. Inside this space access and benefit-sharing are "commonly shared".

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[24] "*Access, where granted, shall be on **mutually agreed terms** and subject to the provisions of this Article*" (CBD art. 15.4).

[25] See www.planttreaty.org

[26] See Reichman, J.H., Dedeurwaerdere, T., Uhlir, P.F. (2008). Designing a Microbial Research Semicommons: Integrated Access to Scientific Materials, Literature and Data in a Highly Protectionist Legal Environment. Paper presented to the conference on the Microbial Commons. Ghent, Belgium, 12-13 June 2008

Outside this demarcated space, access and benefit-sharing will be ruled through ordinary national and international laws, including IPR and specific CBD inspired regulations.

The WFCC supports similar views on such "microbial commons"[27]. Considering that fair and equitable benefit sharing depends upon the usage and activities undertaken with the resource, the benefits for most research and education activities should extend to depositing in collections, publication of associated data including experimental results, and making both material and associated information widely and easily available to stakeholders including the (source) country of origin. If the MGRs are made available with the purpose of commercial exploitation then other ways of sharing could apply such as access, milestone and royalty/license payments, or mechanisms such as IPR related patent and royalties could be activated.

MOSAICC recommends also, as suggested by WFCC, to refer to the concept of "**bundle of rights**"[28] as a dynamic adaptive way to allot rights to stakeholders over microbial material and related information, resulting in effective benefit sharing.

Ownership can constitute a "bundle" of use and decision rights that are attributed to a number of stakeholders / economic agents.

The "bundle of rights" is a scheme allowing multi-ownership structured in gradual levels of use and decision rights. Several rights-owners determine use and access to resources. These rights can begin with basic access rights, up to encompassing research delivering outputs to the public domain, distribution to third parties under the terms agreed and described in a MTA, exploitation rights to develop intellectual property and its ownership which may include reach through rights.

Furthermore, the application of the "bundle of rights" makes possible the enforcement of the "sovereign rights of States over their natural resources" without prejudice to private rights. Unambiguous allotment of rights in advance will facilitate rightful benefit sharing "at the end of the pipe".

Tailored MTA

When sMTA and model MTA do not meet the requirements of the stakeholders and that a more custom-made agreement is needed, partners are advised to use the MTA check list[29] to avoid

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[27] Smith, D. & Desmeth, P. (2007). Access and benefit sharing, a main preoccupation of the World Federation of Culture Collections. In: UNEP/CBD/WG-ABS/6/INF/3 13 December 2007 Compilation of submissions provided by parties, governments, indigenous and local communities and stakeholders on concrete options on substantive items on the agenda of the fifth and sixth meetings of the ad hoc open ended working group on access and benefit sharing. Canada: UNEP/CBD. p 68-70

[28] Dedeurwaerdere, T. (2005) Understanding ownership in the knowledge economy: the concept of the bundle of rights. BCCM News Edition 18.
Dedeurwaerdere, T. (2006). The institutional economics of sharing biological information. Int Soc Sci J 58, 351–368.

[29] **Material Transfer Agreement contents :**

- Accompanying terms
  Mention of the country of origin, reference to the original PIC; previous MTA-terms if any.
- Basic terms
  - Description of MGRs (country of origin, place and date of isolation, strain reference number, identification data, name of the individual that has isolated the strain from *in situ* conditions or, if individual's name is not available, the name of the institution (legal entity) that employed the individual at the time of the isolation of the strain) ;
  - *Bona fide* and sustainable use, following the CBD principles ;
  - Clause governing the payment of the costs of handling ;
  - Type of transfer**:** transfer where distribution to 3rd parties is **either** excluded (by default option) or possible. The choice between these two options is subordinate to the kind of recipients.
  - Information about provider and recipient: names, addresses.
- Use-specific terms
  Category 1: Use for test, reference, bioassay, control, training, and research purposes. No commercial use. No IPR on MGRs, derived technology and information. The recipient has to follow the protocols of standard test and reference procedures.
  Category 2 : Commercial use. Need for more precise MTA provisions on IPR, information feedback, patent application and benefit-sharing (see additional terms).

overlooking important terms when negotiating. Partners are free to draw up these custom-made terms according to their needs, provided that these terms are lawful and in accordance with the principles of the CBD.

The contents of the MTA are defined by two main criteria:

1. the kinds of use of the MGRs.
2. the possibility to distribute the MGRs to third parties, or not ;

1. MOSAICC divides the possible uses of MGRs into two categories:

- Category I: Use for test, reference, bioassay, control, training and research purposes.
- Category II: Commercial use

These categories of use will determine use-related terms to include in each MTA. Potential use and intentions may shift accordingly to results of R&D programmes and subsequent perspectives of new applications (actually, all micro-organisms have the potential to be of commercial interest). In this context all agreements to be signed between the different parties should clearly indicate the need that changes of categories must be negotiated and agreed with the rightful owner or provider. In order to help the partners make the appropriate choice between the categories of use, non-ambiguous definitions and clear descriptions of the uses are needed, especially the definition of "commercial use" with regard to the need for more precise terms for sharing of financial benefits. **"Commercial use"** of MGRs includes but is not limited to the following activities: sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence, product development and seeking pre-market approval.

2. MOSAICC recommends distinguishing between two types of material transfer.

- I. By default, transfer where further distribution is excluded (MTA excluding distribution to 3rd parties)
- II. Exceptionally, transfer where further distribution is allowed (MTA allowing distribution to 3rd parties)

The choice between these two types of transfer will be determined by the capacity of the users as well as of the suppliers for keeping records of the individuals or institutions from where or where to they transfer MGRs[30]. MOSAICC recommends that the MTA by default prohibit further down-the-line transfers.

• Additional terms
- IPR related to MGRs and derived technology,
- Terms on training, technical and scientific co-operation, access to and transfer of technology, exchange of information and publication policy. Terms providing possibilities for capacity building in, among others, taxonomy and general microbiology for the provider of microbial genetic resources should be emphasised and prioritised to compensations such as financial arrangements.
- Conservation of MGRs.
- Partnerships involving other stakeholders than provider and recipient of MGRs, including indigenous and local communities
- Monetary terms: Initial, up-front payment; milestones payment and royalties payment.

[30] **I.** MTA **excluding distribution to 3rd parties** is recommended in the following cases :
- Deposition of *in situ* MGRs in a culture collection, when the depositor imposes restriction of distribution (e.g.: patent deposit, some safe deposits). Take care that this does not run counter the principles of CBD art.15.2. *"facilitated access to MGRs"*.
- Deposition of *in situ* MGRs in a laboratory other than a culture collection, in a laboratory that is not used to record information about the transfers it does.
- Transfer of *ex situ* MGRs from an individual or an institution that is not a culture collection to a culture collection, when the depositor imposes restriction of distribution (e.g.: patent deposit, some safe deposits).
- Transfer of *ex situ* MGRs from a culture collection to individuals or institutions that are not used to record information about the transfers they do.
- Transfer of *ex situ* MGRs between individuals or institutions that are not used to record information about the transfers they do.
- Fast-track procedure (see page 7).

II. MTA **allowing distribution to 3rd parties** can be used exceptionally in two cases :
- Deposition of *in situ* MGRs in a culture collection (CBD art.9 (a) « *preferably in the country of origin* »)
- Legitimate exchanges defined as follows:

I. When they choose a MTA **excluding distribution to 3rd parties**, provider and recipient agree that the recipient cannot distribute the MGRs to anybody outside his/her institution. A MTA excluding distribution to 3rd parties stops the further distribution of the MGRs along a chain of contacts. From the provider's side, the monitoring of the distribution of the MGRs is limited to the registration of one recipient. In cases where scientists other than the original recipient would like to acquire a strain of the same MGRs, they can apply to the original provider. Provisioning of strains from the original source also guarantees the quality of the MGRs. This option must be chosen for transfers between individuals or institutions whose primary mission is not the *ex situ* conservation and valorisation of MGRs**19.I**. The MTA excluding distribution to 3rd parties will also be used in case of fast-track procedure (see page 7).

II. MTA **allowing distribution to 3rd parties** should be used exceptionally, in case of a MGRs collected *in situ* and deposited into a culture collection to allow further distribution, and in case of "**legitimate exchanges**".

"**Legitimate exchange**" is defined as "The transfer of the MGRs between named culture collections / Biological Resources Centres (BRC)[31] for accession purposes, provided that further distribution by the receiving culture collections / biological resources centre is under MTA provisions compatible and equivalent as those in place at the supplying collection." In other words, transfer is accepted when MGRs are transferred to a recipient that is a culture collection or when both recipient and provider are culture collections**19.II**. The terms of the transfer will be consistent with the best practices of culture collections and set in the framework of collaborative agreements, when such agreements exist.

Legitimate exchange also includes the transfer of MGRs within a "research group". A "research group" is defined as "Entitled scientists working in a same laboratory, or contractually bound to work on the same research topic."

This system limits the distribution in cascade/in series. It facilitates tracking of the MGRs by shortening the chain of distribution. It also ensures that MGRs keep their original quality and characteristics. Microbiologists wanting to get MGRs should ask for the MGRs preferably to a culture collection and avoid asking fellow microbiologists to provide them with the microbial resources. Note that the kind of MTA covering a particular transfer depends on the terms of a previous MTA when it exists. It also depends on the terms of the PIC because national legislation takes precedence over any specific terms that runs counter the law.

I.5. Monitoring the distribution and utilisation of MGRs

There is a need for a simple administrative system that enables easy circulation of MGRs. Such a system must also monitor the distribution and the utilisation of MGRs, to identify the individuals or groups that are entitled to share «*in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources* » (CBD art.15.7) because they have contributed to the conservation and sustainable use of the MGRs.

MOSAICC proposes a system that meets both these needs and:

1. allows easy circulation of MGRs at the first level of distribution and

- Transfers of *ex situ* MGRs between culture collection, between microbial genetic resource centre who's primary mission is the *ex situ* conservation and valorisation of MGRs; with terms according to specific collaborative agreements between these institutions
- Transfers between entitled scientists working in a same laboratory, or contractually bound to work on the same research topic. This concept is called a "research group."

[31] For more information related to the concept of BRC see http://www.oecd.org/dataoecd/55/48/2487422.pdf

2. limits the further distribution to third parties, in order to shorten the chain of distribution along which the monitoring of the transfer of MGRs may be lost.

The system works through the adequate choice of MTA terms governing the conditions of transfer (see pages 10 and following), these terms being mutually agreed upon between the provider and the recipient. The expectations of provider and recipient, the available trustworthy information, the legal context (national and international laws) and the contractual context (terms of possible previous agreements) will determinate the contents of the MTA.

More specifically, a balanced use of the options governing -allowing or excluding- the further distribution of the MGRs will help to arrange the flows of MGRs. To make the appropriate choice, to use the adequate option governing the further distribution of the MGRs, provider and recipient will check the following options when they want to transfer MGRs (see figure 1):

A. The MGRs are *in situ* **or** *ex situ*

B. A Prior Informed Consent (PIC) is available **or** not

C. There is a previous Material Transfer Agreement (MTA) **or** not

D. If there is a previous MTA, it may be

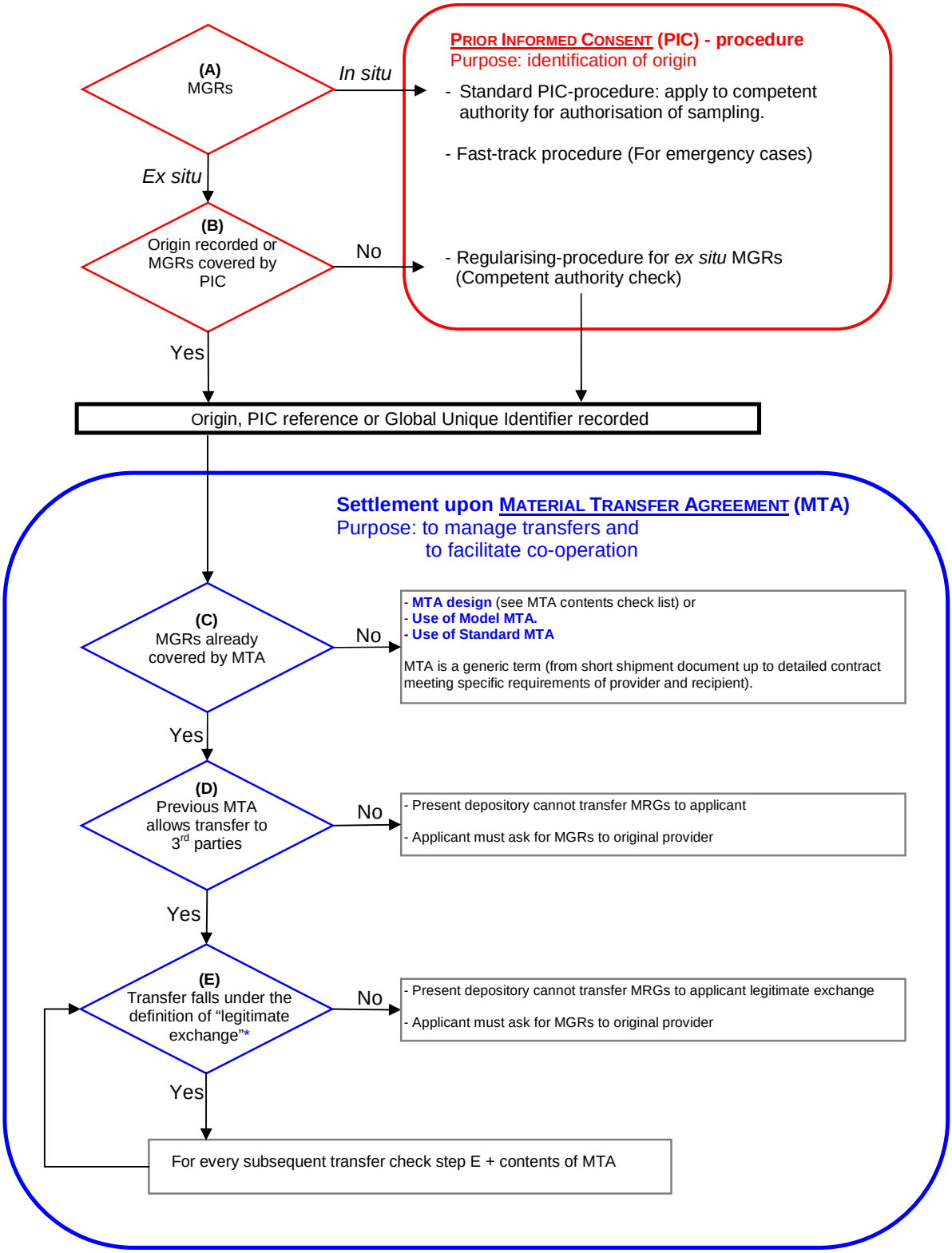
either a MTA excluding distribution to 3rd parties, **-It is the option by default-.**

or a MTA allowing distribution to 3rd parties.

E. A transfer under MTA allowing distribution to 3rd parties is possible in case of "legitimate exchanges", when the MGRs are transferred to a recipient that is a culture collection or when both recipient and provider are culture collection, or when the MGRs is transferred between people working in the same research group. When the MGRs is transferred to a recipient that is not a culture collection, then the transfer of MGRs will be covered by a MTA excluding distribution to 3rd parties.

The use of Global Unique Identifiers as electronic tools to help tracking MGRs and retrieving related information is also recommended.

Figure 1. : Procedure of transfer of Microbial Genetic Resources (MGRs)



*LEGITIMATE EXCHANGE is defined as follows: The transfer of MGRs within the RESEARCH GROUP. LEGITIMATE EXCHANGE also includes the transfer of MGRs between named culture collections/biological resources centres for accession purposes, provided that further distribution by the receiving culture collections/biological resources centre is under MTA provisions compatible and equivalent as those in place at the supplying collection.
RESEARCH GROUP is defined as follows: Entitled scientists working in a same laboratory, or contractually bound to work on the same research topic.

I.6 Definition of terms

Unambiguous definition of terms decreases the level of uncertainty and the risk of dispute between providers and recipients, stakeholders in general. Consistency between definitions existing in various MTA is also necessary to ease dialogue in a uniform textual environment[32], especially for compatibility between several model MTAs and standard MTAs.

Considering the many kinds of MTA, the CBD ABS expert groups' recommendations and culture collections experience, the following key terms should be defined in simple terms:

- **PROVIDER:** whoever provides MATERIAL to RECIPIENT.
- **RECIPIENT**: legal entity or individual who purchases and/or uses the MATERIAL.
- **DEPOSITOR**: legal entity or individual who deposits ORIGINAL MATERIAL in the custody of the PROVIDER.
- **RESEARCH GROUP**: Entitled scientists working in a same laboratory, or contractually bound to work on the same research topic.
- **MATERIAL**: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include MODIFICATIONS. The description of the MATERIAL being transferred is on delivery note and invoice.
- **ORIGINAL MATERIAL**: that which was supplied to the PROVIDER by the DEPOSITOR.
- **PROGENY**: Unmodified descendant from the ORIGINAL MATERIAL, such as cell from cell, or organism from organism.
- **UNMODIFIED DERIVATIVES**: Substances created by the RECIPIENT which constitute an unmodified functional subunit of the MATERIAL.
- **MODIFICATIONS**: Substances created by the RECIPIENT using the MATERIAL, which are not ORIGINAL MATERIAL, PROGENY or UNMODIFIED DERIVATIVES, and which have new properties.
- **LEGITIMATE EXCHANGE**: The transfer of the MATERIAL within the Research Group. LEGITIMATE EXCHANGE also includes the transfer of MATERIAL between named culture collections/biological resources centres for accession purposes, provided that further distribution by the receiving culture collections/biological resources centre is under MTA provisions compatible and equivalent as those in place at the supplying collection.
- **COMMERCIAL USE**: the use of the MATERIAL for the purpose of profit. COMMERCIAL USE shall include the sale, leasing, exchange, license, or other transfer of MATERIAL for profit purposes. COMMERCIAL USE shall also include uses of MATERIAL to establish service business activities, to manufacture products, to perform contract research, or to conduct research activities for profit purposes.

All nouns used in MTA provisions must be defined. Each additional noun adds to the complexity of the contractual engagement that constitutes the MTA. Short definitions with a minimum of words to define subsequently themselves are to be preferred.

[32] MOSAICC wish to point the specific challenges of nomenclature and classification confronted to the concept of species, especially for the prokaryotes. This is an important factor related to the consistent identification of MGRs, what is important for tracking of MGRs. For more information read Krichevsky, M.I., *Taxonomic Nomenclature: A Useful Tool, Not Truth*. SIM NEWS January / February 2007

I.7. Terms of agreement on benefit sharing, access to and transfer of technology, scientific and technical co-operation as well as technology transfer.

MOSAICC recommends the partners signatory of a MTA to include additional clauses, if applicable, in order to facilitate benefit sharing as foreseen by the CBD[33], especially scientific and technical co-operation as well as access to and transfer of information and technology.

CBD art. 15.7 terms "*... sharing in a fair and equitable way...*" imply that the return for each partner should correspond fairly with the time, money, intellectual input and inventive effort invested by that partner (including for the maintenance of the MGRs), and also reflect the respective specific values that will be added during the execution of the additional terms-package agreement.

When agreeing upon the terms of the MTA, the partners can decide either to wait until benefit arises from some commercial use and other utilisation of MGRs and to specify that complementary terms dealing with these topics will be discussed when the time had come. Or they can decide to agree upon the terms on benefit sharing preliminary to the start of the collaboration, not waiting till the necessity makes law. MOSAICC recommends the partners signatory of a MTA to come to a preliminary agreement about financial benefit sharing.

Partners should prefer terms providing possibilities for capacity building in, among others, taxonomy and general microbiology for the provider of microbial genetic resources.

In accordance with the principles and recommendations of the CBD it is recommended that the partners come to an agreement, as far as wished for, and as far as possible, about the following topics:

- **IPR related to MGRs and derived technology[34]**

  Terms of agreements on IPR related to MGRs and derived technology are recommended use-specific terms when commercial use is involved. MOSAICC recommends partners:

  – to agree on the IPR of the MGRs and/or derived technology before investing in research and development that could lead to the commercial use of the MGRs or derived technology;

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[33] Article 15.7 : " *... the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources* "

Apart from the basic terms and the use-specific terms included in the Material Transfer Agreement standard model, MOSAICC foresees the possibility to have complementary mutually agreed terms dealing specifically with benefit sharing, transfer of technology, scientific and technical co-operation and technology transfer (technology including biotechnology). The existence of such additional terms, as well as their precise composition, will depend on each particular case (e.g. countries and organisations involved; nature and value of the MGRs involved; commercial or non-commercial uses, etc.).

In the case where additional terms are used, the success of the negotiation will depend on the goodwill of the respective partners to come to an overall win-win situation and the mutual understanding of each others' interests and the added value of their respective contributions. Such additional terms can, apart from the recipient and the provider of the MGRs, also involve local microbiologists, local competent authorities as well as representatives of local and/or indigenous communities.

[34] MOSAICC refers to CBD articles :

- 1 which mentions as ways to serve the purposes of the CBD "*by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies* ".
- 15.1 "*Recognizing the sovereign rights of States over their natural resources* " in the sense that "*the authority to determine access to genetic resources rests with national governments and is subject to national legislation* ". The latter does not imply, however, that the CBD does grant the state a property right over such genetic resources (Glowka et al. 1994).
- 16.2 stating that "*In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights* ", as well as CBD-article 16.5 stating that "*The contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives* ".

While IPR laws often differ from country to country, some general principles and rules laid down in international legislation must be shared by those countries that are party to these international arrangements (e.g. Budapest Treaty, TRIPS, Paris Convention). A growing number of countries permit the patenting of micro-organisms, as well as of derived products, technology and processes, and this as far as the criteria of invention, novelty and utility are met. Patent law does not in general consider 'experimental use' for non-commercial purposes as an infringement of the rights of a patent owner.

Partners could make different agreements for different categories of MGRs and derived technology, and this depending on a gliding scale of value added during the acquirement of MGRs (isolation, purification), the characterisation of MGRs (identification of the MGRs; detection of possible uses) and the further development of those MGRs and derived technology. Agreements could range from single to shared IPR-ownership.

- to allocate the IPR to the inventing partner(s); and this while not necessarily excluding that other partners can, in the exceptional case of a successful commercial use of the MGR and/or derived technology, profit from forms of monetary compensation (royalties or other) and/or of a license on concessive or preferential terms (cf. CBD art. 16.2);
- to timely apply for a patent (e.g. before one publishes, if one goes for a patent in a country that does not provide for a so-called grace period).

- **Training, technical and scientific co-operation, technology transfer, exchange of information and publication policy**[35]

  - MOSAICC recommends partners to look for co-operative research programmes since as in most cases, the best training can be provided through technical and scientific co-operation.

  - As also recommended by IUMS, all scientific papers should mention provider, country of origin, date and place of isolation and identification data[36].

- **Place and ways of conservation of MGRs**[37]

  International co-operation can lead to the establishment of conservation facilities in the country of origin or to the development of agreements between on the one hand countries of origin having no conservation facilities yet and on the other hand foreign microbial genetic resource centre.

  In addition, to avoid loss of interesting *ex situ* MGRs in cases where individuals or institutions stop their activities, there should be an arrangement with culture collections that could take over the conservation of those *ex situ* MGRs that have no known duplicates elsewhere.

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[35] **Research and training** : CBD art.12(a) « *establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for the specific needs of developing countries* »;
Access to and transfer of technology : CBD art.16 « *Access to and transfer of technology,..., to developing countries shall be provided and/or facilitated under fair and most favourable terms* »;
Exchange of information : CBD art.17: « *such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such in combination with the technologies referred to in article 16* »;
Technical and scientific co-operation :
CBD art.15.6: « *endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties* »;
CBD art.18.1: « *cooperation in the field of conservation and sustainable use of biological diversity,...*»;
CBD art.18.2: « *..., the development and strengthening of national capabilities, by means of human resources development and institution building* »;
CBD art.18.4: « *encourage and develop methods of cooperation for the development and use of technologies* »;
CBD art.18.5: « *the establishment of joint research programmes and joint ventures for the development of technologies...* »;
CBD art.19: « *the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties* ».

[36] Dr. Cletus P. Kurtzman - US Nat'l Committee for the IUMS and Ms Robin Schoen - US Nat'l Academy of Sciences / National Research Council

[37] CBD art.9: *"Each contracting Parties shall as far as possible and as appropriate,... (a) adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components;..., (e) cooperate in providing financial and other support for ex-situ conservation,..., and in the establishment and maintenance of ex-situ conservation facilities in developing countries"*.

- **Partnerships involving stakeholders other than provider and recipient of MGRs, including indigenous and local communities**[38]

  MOSAICC recommends that partners include indigenous or local communities as parties of an agreement in so far as the community is:

  - owner or usufructuary of the area where the *in situ* MGRs were accessed;
  - well represented by officially recognised representative(s) in their country, and
  - willing to preserve and maintain knowledge, innovations and practices relevant for the conservation and sustainable use of MGRs (CBD art. 8 (j)).

- **Monetary terms**[39]

  MOSAICC recommends that monetary compensations to those that provide or enable access to MGRs should be dedicated to technical and scientific co-operation programmes.

  - Initial, up-front payments[40]

  Initial payments can be made before or after accessing the MGRs, but this does not always take into account the possible, successful commercial use of the MGRs.

  MOSAICC recommends to calculate the importance of the initial payments in terms of the actual involvement of the provider in the delivery of the MGRs (e.g. local community participating or not to field survey; costs of maintenance of *ex situ* MGRs, etc.)

  - **Milestones payments**

  Milestones payments are dependent on the progress of the R&D process leading to a commercialization of a product derived from MGRs. At specific stages of the R&D process, set beforehand by both parties
  The users pays a fixed amount to the provider, as a kind of acknowledgement that the MGRs has some particular feature with possible industrial application.

  - Royalty payments

  Royalty payments are fully dependent on the successful commercial use of the MGRs concerned.

  MOSAICC recommends that public not-for-profit *ex situ* resource centres should not pay any royalties for MGRs they have acquired, and this foreseen that these *ex situ* MGRs, according to their public mission, will be made publicly available for a costs-covering fee.

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38 Apart from suggesting that recipients of MGRs cooperate with , among others, governmental institutions and the private sector of the country providing the MGRs (CBD art. 16.4) and/or the appropriate international and national institutions (CBD art. 18.1), the CBD also makes reference to indigenous and local communities (CBD art. 8 j). However, the CBD does not provide its users with a definition of these communities or guidelines on how to deal with them.

39 Monetary terms can be broadly split into, on the one hand, terms concerning initial payments (e.g. up-front payments) that are made independently of, as well as before, any possible successful commercial use of the MGRs concerned; and on the other hand, royalty payments that are only made in the exceptional cases of successful commercial use of MGRs.

40 In this category, we can consider the normal fees applied by most *ex-situ* resource centres and payable by the recipients of the MGRs after the delivery of the requested MGRs. In case of access to *in-situ* MGRs, up-front payments could be linked to programmes for training, technical and scientific co-operation.

SECTION II. MODEL DOCUMENTS

List of documents that should « cover » the MGRs to guarantee a transfer consistent with the principles of the CBD.

ACCESS TO *IN SITU* MGRS

- **Prior Informed Consent - PIC** obtained from a competent authority
- Optional: permission of the landowner and/or usufructuary
- **Material Transfer Agreement - MTA**

ACCESS TO *EX SITU* MGRS

- **Material Transfer Agreement - MTA**
- **One or more of these options: use of GUIDs, reference to the origin, reference of the PIC, reference of the "accession form"** or equivalent document delivered when the MGRs were originally isolated from *in situ* conditions and deposited in *ex situ* collections (See pages 8 and 9)

MOSAICC recommends that each document (PIC-application, PIC, MTA, accession form):

- fully identifies the parties involved, as well as their representative(s);
- is dated;
- contains a clear indication about duration of its terms;
- in the case of PIC-application and PIC-certificate, is signed by the sender;
- in the case of MTA, is signed by all parties involved, or seen as approved on basis of the purchase order or the notice of receipt of the MGRs. Both options are legally valid. The choice depends on the Provider's policy. Furthermore, considering that electronic ordering via internet is becoming a preferred way to purchase a MGRs from a culture collection/ biological resource centre, the buyer's consent via "click and wrap" or similar procedure like "shrink wrap" at delivery will become the option by default. It has the advantage of facilitating electronic recording and conveyance of the transfers, eventually by using GUIDs.

MOSAICC proposes:

- a model of Material Transfer Agreement;
- a PIC-application model form for access to *in situ* MGRs;
- a model of PIC for access to *in situ* MGRs.

DEFINITIONS

- **PROVIDER:** whoever provides MATERIAL to RECIPIENT.
- **RECIPIENT**: legal entity or individual who purchases and/or uses the MATERIAL.
- **DEPOSITOR**: legal entity or individual who deposits ORIGINAL MATERIAL in the custody of the PROVIDER.
- **RESEARCH GROUP**: Entitled scientists working in a same laboratory, or contractually bound to work on the same research topic.
- **MATERIAL**: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include MODIFICATIONS. The description of the MATERIAL being transferred is on delivery note and invoice.
- **ORIGINAL MATERIAL**: that which was supplied to the PROVIDER by the DEPOSITOR.
- **PROGENY**: Unmodified descendant from the ORIGINAL MATERIAL, such as cell from cell, or organism from organism.
- **UNMODIFIED DERIVATIVES**: Substances created by the RECIPIENT which constitute an unmodified functional subunit of the MATERIAL.
- **MODIFICATIONS**: Substances created by the RECIPIENT using the MATERIAL, which are not ORIGINAL MATERIAL, PROGENY or UNMODIFIED DERIVATIVES, and which have new properties.
- **LEGITIMATE EXCHANGE**: The transfer of the MATERIAL within the Research Group. LEGITIMATE EXCHANGE also includes the transfer of MATERIAL between named culture collections/biological resources centres for accession purposes, provided that further distribution by the receiving culture collections/biological resources centre is under MTA provisions compatible and equivalent as those in place at the supplying collection.
- **COMMERCIAL USE**: the use of the MATERIAL for the purpose of profit. COMMERCIAL USE shall include the sale, leasing, exchange, license, or other transfer of MATERIAL for profit purposes. COMMERCIAL USE shall also include uses of MATERIAL to establish service business activities, to manufacture products, to perform contract research, or to conduct research activities for profit purposes.

[33]The RECIPIENT will respect, if applicable, the accompanying PIC-terms and the terms laid down in the previous Material Transfer Agreement (see annexes).

[34]The RECIPIENT will use the MGRs described and listed in annex, in a sustainable way, for *bona fide* purposes and in full respect of the principles of the Convention on Biological Diversity and other applicable rules of international and national laws.

[35]The RECIPIENT will not distribute the MGRs delivered.
The RECIPIENT may distribute the MGRs in case of legitimate exchanges, provided that the following conditions are observed:

The RECIPIENT will keep records of the full co-ordinates of all downstream recipients of the MGRs concerned. This information will be available on request (= monitoring the transfers).

The RECIPIENT will transmit to the PROVIDER, as far as applicable, information (e.g. intentions for commercial use,) provided by the downstream recipient(s) of the MGRs concerned (= information feedback);

[36]The RECIPIENT and the PROVIDER distinguish the following categories of use of MGRs:

Category 1: Use for test, reference, bioassay, and control (covering only their use within the framework of the corresponding official (inter)national test-, bioassay and control protocols); use for training and research purposes;

Category 2: Commercial use. Commercial use of MGRs includes but is not limited to the following activities: sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence, product development and seeking pre-market approval.

For category 1 uses:

The RECIPIENT will not claim ownership over the MGRs received, nor seek intellectual property rights over them or related information. If the RECIPIENT wishes to utilise or exploit such organisms commercially he will first inform the PROVIDER; when applicable, suitable and adequate recompense to those entitled to be rewarded, and the country of origin will be discussed in the spirit of the Convention on Biological Diversity.

THE RECIPIENT will ensure that any individual or institution, to which the RECIPIENT makes samples of the MGRs available, is bound by the same provision.

For category 2 uses,

In order to ensure adequate benefit sharing with the country of origin and « *names of those entitled to be rewarded* », according to the principles of the Convention on Biological Diversity,

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[33] Accompanying terms: Reference of PIC, mention of the country of origin; previous MTA-terms if any

[34] Basic terms : Description of MGRs (country of origin, place and date of isolation, strain reference number, identification data, name of the individual that has isolated the strain from *in situ* conditions or, if individual's name is not available, the name of the institution (legal entity) that employed the individual at the time of the isolation of the strain.) ;
Bona fide and sustainable use, following the CBD-principles ;
Clause governing the payment of the costs of handling.
Information about provider and recipient: names, addresses
Scientific feedback: publication will mention provider, strain reference number and country of origin. .

[35] Key-terms that differentiate MTA excluding or allowing distribution to 3rd parties

[36] Use-specific terms
Category 1: Use for test, reference, bioassay, control, training and research purposes.
- No commercial use ;
- No IPR on MGRs, derived technology and information ;

Category 2 : Commercial use
- Terms on IPR, information feedback about patent application; need precise terms for benefit-sharing (see additional terms).

the RECIPIENT will immediately inform the PROVIDER and the country where the MGRs were originally accessed, of the intended commercial use(s) of the MGRs and/or derived technology and/or related information. The terms upon which benefit sharing with the stakeholders takes effect are laid down in annex.

For all categories of uses,

The RECIPIENT will mention the PROVIDER, the strain reference number and the country of origin in publication presenting scientific results and related information resulting from the use of the MGRs.

MTA ADDITIONAL TERMS CHECK LIST

- **IPR related to MGRs and derived technology**

  Different regimes[37] of IPR-ownership could be related to different values added by the respective partners during the acquirement (isolation, purification) and/or the characterisation of MGRs (identification of the MGR, detection of possible use(s), etc.).

  Check the following categories: IPR-ownership of the MGRs
  IPR-ownership of the derived technology

- **Terms on training, technical and scientific co-operation, technology transfer, exchange of information and publication policy[38]**

  Terms providing possibilities for capacity building in, among others, taxonomy and general microbiology for the provider of microbial genetic resources should be emphasised and considered as important as financial arrangements. MOSAICC recommends partners to look for co-operative research programmes since as in most cases, the best training can be provided through technical and scientific co-operation.

- **Place and ways of conservation of MGRs**

  International co-operation can lead to the establishment of conservation facilities in the country of origin or to the development of agreements between on the one hand countries of origin having no conservation facilities yet and on the other hand foreign microbial genetic resources centres[39].

- **Partnerships involving other stakeholders than provider and recipient of MGRs, including indigenous and local communities**

  MOSAICC recommends that partners include indigenous or local communities as parties of an agreement in so far the community is:
  - owner or usufructuary of the area where the *in situ* MGRs where accessed;
  - represented by officially recognised representative(s) and
  - willing to preserve and maintain her knowledge, innovations and practices relevant for the conservation and sustainable use of MGRs (cf. CBD-article 8 (j)).

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[37] For instance : - single ownership or co-ownership of the IPR;
- a single or different regimes of IPR-ownership, and the latter depending on the category of MGRs.

[38] As the publication of results of the joint programme might prohibit a successful patent application, no publication should be made without the written agreement of the concerned partner. It is to remember that scientific publications should always mention provider, strain reference number and country of origin.

[39] In this case, a country could transfer *ex-situ* MGRs to (an) *ex-situ* resource centre(s) in (an)other country(ies). This transfer should be covered by an extended MTA including provisions for access and benefit-sharing modalities. Detailed terms may be desired by the respective partners, for example by distinguishing type strains from non-type strains, or by making ad hoc agreements for herbarium material (in case of fungal material) etc.

- **Warranties and liability**

  Stipulate what the warranties offered by the providers of MGRs are. Set who is liable for damage to third parties.

- **Monetary terms**

  MOSAICC recommends that monetary compensations to those that provide or enable access to MGRs should be partly dedicated to technical and scientific co-operation programmes.

  - Initial, up-front payment

    Initial payments can be made before or after accessing the MGRs, but this always independently of the possible, successful commercial use of the MGRs. MOSAICC recommends calculating the importance of the initial payments in terms of the actual involvement of the provider in the delivery of the MGRs[40].

  - Milestones payments

    Payments related to the progress made in the development of a product or process that could be commercialised in fine.

  - Royalty payments

    Royalty payments are fully dependent on the successful commercial use of the MGRs concerned. Agreements should always make reference to net royalties[41].

- **Applicable laws and competent authorities**

  Usually, the applicable laws are these of the country where the culture collection is vested. Unfortunately, there is no agreement on this matter at international level. Specify the applicable laws to avoid uncertainty.

  Competent courts are those of the judicial district of the culture collection establishment.

[40] For example: local community participating or not to field survey, costs of maintenance of *ex-situ* MGRs, etc.

[41] Net royalties mean the gross amount of royalties, license fees, profits or any other payments which result from the use of a MGR and derived technology, less: - the costs incurred by the royalty paying partner to develop a patentable application making use of the MGRs;
- the costs incurred by the royalty paying partner for patenting derived technology;
- the costs of marketing the application.

Examples of Prior Informed Consent (PIC) documents

Considering the minimal information necessary for an authority to assess the purposes and the lawfulness of a demand, a PIC application form must include a minimum of data: information about the applicant, the time frame, the area where the material is accessed, the kind of biological resource, and reference to a Material Transfer Agreement if any. The way it is put in form is secondary; the models hereunder are examples. In cases where the authorisation of a third party (right holders like usufructuary or landowner) is required, a copy should be annexed.

PIC application form for access to *in situ* MGRs

(*Date*)

(*Name and address of the PIC-provider*)

Dear (.....),

According to article 15 of the Convention on Biological Diversity (CBD) stating that «*the authority to determine access to genetic resources rests with the national governments and is subject to national legislation* » and that «*Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention* », as well that «*access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources* »;

and, as ratified by (*Name of the Country where one wants to access MGRs*),

I would like to get access to (*Name of the field survey area*), as well as to its genetic resources, more specifically samples or isolates from (*name or description of group of plant, animal or microbial resources*), with your prior informed consent (PIC), during the period and under the conditions specified in annex *(copy of MTA if any; copy of authorisation of third party if any)*.

(*Name, address and signature of the PIC-applicant*)

In return, the PIC certificate should confirm the ranges / limits of time, of geographic area and of kind of biological resources it is valid for. Complementary information concerning relevant legislation is recommended.

PIC certificate for access to *in situ* MGRs.

(*Date*)

(*Name and address of the PIC applicant*)

Dear (*Name of the PIC-applicant*),

In reply to your PIC-application of (*date of written demand*) as annexed, we have the pleasure to provide you with the present PIC, in conformity with the CBD provisions, and national regulations referred to in annex.

As competent authority for controlling *in situ* access to the genetic resources of (*Name of the field of competence or geographical area of competence*), we confirm that the present PIC is valid for access to *in situ* MGRs from (*Name of the field survey area*). It grants access to this area from (*date*) to (*date*). This PIC is not transferable from one organisation to another without written agreement of the undersigned authority.

(*Place and date of issue, official administrative seals, name, address, and signature of the CBD PIC-provider*.)

* When applicable

ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection

Scope of agreement

This Agreement applies to the use, handling, distribution and any disposition of the MATERIAL supplied by the COLLECTION, and addresses the identified key points

- Traceability
- Fair and Equitable Benefit Sharing
- Intellectual Property Rights
- Quality
- Safety and Security

Definitions

a. **The COLLECTION – acronym and address of the Collection/BRC supplying the material.**

b. **AGREEMENT**: This document.

c. **RECIPIENT**: The party to whom the COLLECTION sends the MATERIAL. In case this is not the END-USER but an INTERMEDIARY, this INTERMEDIARY agrees (i) to forward to the END-USER the present MTA and the MATERIAL in unchanged form and quantity as received from the COLLECTION, and (ii) to use for this further shipping the proper packaging, a trained shipper, and an authorized carrier, according to the applicable laws and regulations.

d. **END-USER**: Scientist working with the supplied MATERIAL.

e. **INTERMEDIARY**: Third party, different and independant from the END-USER, that makes an order on behalf of the END-USER, and to which the COLLECTION addresses the MATERIAL. These can be whole-salers, importers, or other type of intermediary agents, unrelated to the END-USER's institution.

f. **DEPOSITOR**: Person(s) or entity that provided the COLLECTION with the ORIGINAL MATERIAL.

g. **MATERIAL**: ORIGINAL MATERIAL, PROGENY and UNMODIFIED DERIVATIVES. The MATERIAL shall not include MODIFICATIONS.

h. **ORIGINAL MATERIAL**: That which was originally supplied to the COLLECTION by the DEPOSITOR.

i. **PROGENY**: Unmodified descendant (e.g. sub-culture or replicate) from the ORIGINAL MATERIAL.

j. **UNMODIFIED DERIVATIVES**: Replicates or substances which constitute an unmodified functional subunit or product expressed by the MATERIAL, such as, but not limited to, purified or fractionated subsets of the MATERIAL, including expressed proteins or extracted or amplified DNA/RNA.

k. **MODIFICATIONS**: Substances produced by the RECIPIENT by using the MATERIAL, which are not the ORIGINAL MATERIAL, PROGENY, or UNMODIFIED DERIVATIVES, and which have new properties. MODIFICATIONS include, but are not limited to, recombinant DNA clones.

l. **COMMERCIAL PURPOSES**: The use of the MATERIAL for the purpose of profit.

m. **LEGITIMATE EXCHANGE**: The transfer of the MATERIAL between scientists working in the same Laboratory, or between partners in different Institutions collaborating on a defined joint project, for non-commercial purposes. This also includes the transfer of MATERIAL between public service culture collections/BRCs for accession purposes, provided the further distribution by the receiving collection/BRC is under MTA conditions equivalent and compatible to those in place at the supplying collection.

THE **COLLECTION** WILL TRANSFER THE MATERIAL UNDER THE TERMS AND CONDITIONS SPECIFIED IN THIS MATERIAL TRANSFER AGREEMENT.
THE **RECIPIENT** – BEING END-USER, INTERMEDIARY OR CULTURE COLLECTION / BRC – ACCEPTS THE TERMS AND CONDITIONS OF THIS MATERIAL TRANSFER AGREEMENT BY PLACING AN ORDER WITH THE COLLECTION.

Following AGREEMENT is between the COLLECTION and the RECIPIENT of the MATERIAL:

1. RECIPIENT agrees that all information provided to the COLLECTION in connection with any order for MATERIAL is accurate and complete, and otherwise complying with applicable laws and regulations.
2. RECIPIENT agrees that MATERIAL designated Risk Group 2 or above (as defined by the national regulations of the country where the Collection is located) may cause human disease, and that MODIFICATIONS, or other MATERIAL, not so designated, may cause human disease under certain conditions.
3. RECIPIENT agrees that any handling or other activity undertaken in their laboratory with the MATERIAL will be conducted under their responsibility and in compliance with all applicable laws and regulations.
4. RECIPIENT therefore assures that within their laboratory (i) access to the MATERIAL will be restricted to personnel capable and qualified to safely handle said MATERIAL and (ii) RECIPIENT shall exercise the necessary care, taking into account the specific characteristics of the MATERIAL, to maintain and use it with appropriate precautions to minimize any risk of harm to persons, property, and the environment, and to safeguard it from theft or misuse.
5. Unless agreed in writing with the COLLECTION, RECIPIENT shall not sell, distribute or propagate for distribution, lend, or otherwise transfer the MATERIAL to any others, except those RECIPIENT that acts as INTERMEDIARY and those RECIPIENT involved in LEGITIMATE EXCHANGES as defined above.
6. Subject to the terms and conditions of this AGREEMENT and any statutory, regulatory or other restriction imposed by law or any third party interest, RECIPIENT may use the MATERIAL in any lawful manner for non-commercial purposes.
7. If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSE(S), it is the responsibility of the RECIPIENT, in advance of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the MATERIAL, as indicated by the COLLECTION's documentation.
8. Nothing in this AGREEMENT grants RECIPIENT any rights under any patents, propriety, intellectual property, or other rights with respect to the MATERIAL.
9. RECIPIENT agrees to acknowledge the COLLECTION as the source of the MATERIAL in any and all publications that reference the MATERIAL.
10. Warranty: The COLLECTION hereby assures within the scope of its quality system and as far as can be determined through the COLLECTION's test regimes, that the MATERIAL shall be viable and pure upon shipment from the COLLECTION. Any claim against the warranty will have to be communicated to the COLLECTION within a period of *XX (XX)* days from the COLLECTION's shipment, and will have to be justified to the COLLECTION's satisfaction. The primary remedy for breach of this warranty is replacement by the COLLECTION of the MATERIAL free of charge.
11. Disclaimer of warranties. Except as expressly provided in this AGREEMENT and within the limits of the scope of the COLLECTION's quality system, there are no representations or warranties by the COLLECTION with respect to the MATERIAL, express or implied, including without limitation, any implied warranty of authenticity, typicality, safety, fitness for a particular purpose, or of the accuracy or completedness of the data.

Annex WP9-4

MIRRI WP 9 Guiding document 1 – *July 19, 2013*

Guidance for collections wanting to contact the National Focal Point on ABS and/or Competent National Authority/ies in their country

Introduction

As negotiations for a final EU Regulation on ABS [(1)] are continuing , collections need to become involved as much as possible with the processes at national level towards implementing the Nagoya Protocol (NP) [(2)]. Although at this time it is unclear what the result of EU negotiations will be, it is important that microbial collections make known to their domestic authorities what their concerns are and to begin clarifying which possible roles they can and cannot play in effective implementation at national level.

The information on the national focal points can be found at the CBD website:
http://www.cbd.int/doc/lists/nfp-abs-icnp.pdf

Recommendations

A coordinated approach by all biological collections in the same country (microbial, plants, animals etc.) towards their authorities may be the way to go forward. It is therefore recommended to check first if any other biological collections in your country have already had contact. At the same time, however, it is also important that microbial collections unified in MIRRI take a coordinated approach, so that authorities in the different EU member states hear the same basic message and can work towards developing harmonized legal instruments.

MIRRI WP 9 cannot provide a generalized statement at this time on what its partner collection should accept or not accept as duties under the new ABS regime and national laws (to be designed). Your national authorities may wish to find out through dialogue what role your collection and collections holding other types of biological resources could realistically play, or they may already have strong ideas about that. The laws that will be designed in your country may differ from those in other states. You may want to keep a few points in mind:

- Monitoring of the utilization of genetic resources down the user chain is not the responsibility of the providing collections. Reporting on use at (future) check-points is the responsibility of the user, not the provider of GR. The governmental authorities have to provide the resources and instruments required to make monitoring possible
- Try to agree on a common strategy with other domestic GR collections
- Do not agree to taking up tasks if you lack human or financial resources to manage them
- Stress the special nature of living microbial genetic resources[(3)] (incomparable to many other types of biological specimens)
- If a network of microbial collections is present in your country, have it involved
- Information about progress will be highly appreciated but please respect confidentiality as appropriate about what is being discussed with your authorities

It would also be very useful that the collection send the MIRRI position document (Appendix 1, scan of signed document available with Gerard Verkley) to the National Focal Point and Competent National Authority in their country (check this link for contacts: http://www.cbd.int/doc/lists/nfp-abs-icnp.pdf). In the Netherlands, for example, we first contacted the National Focal Point to discuss the issues for culture collections, and the ministerial authorities have recently started a dialogue with the collections holding GR because they realize that the collections need be involved to reach to a workable solution and design appropriate legislation. So MIRRI input can be provided there too. As reported in Athens, several MIRRI partners have contacted the authorities already and more information can be provided if necessary.

Suggested topics for a discussion with the authorities
Below is a list of issues formulated as pertinent questions that can be used to start the discussions. They are not listed by any priority and should merely be seen as suggestions for these discussions. MIRRI partners having additional issues are requested to share them with other partners.

1. Temporal scope
(1a) How to deal with material isolated from nature and deposited post-CBD but before entry into force of the NP?
Most collections have accessioned GR lacking PIC and/or MAT in this period (because 'not available'or not applicable'), but normally only if the country of origin was known.
(1b) How to deal with benefit sharing concerning genetic resources deposited before the entry into force of the CBD [(4)] (Dec 1993) and lacking any agreements at present that would define the type of utilization allowed by the depositor or by any other rightful party?
This question is particularly relevant if the retrospective nature of the latest amendments [(5)] by the Rapporteur to EP (Sandrine Bélier) with regard to 'new utilisation' (Compromise Amendments, Am 2, to Proposal for a regulation Art 2, paragraph 1), would be accepted in the final Regulation.

Explain the approach taken by ECCO[(6)], namely to treat all GR in a similar way with reference to benefit sharing: the recipient of GR must contact the Country of Origin in advance of commercial use to negotiate benefit sharing - ECCO Core MTA [(7)].
Prior to the CBD, the Netherlands (and some other EU member states) have adhered to a policy of "national discretion" with regard to benefit sharing particularly of plant genetic resources for food and agriculture, which are often used for commercial purposes. A voluntary sharing of benefits arising from "new utilisation" of GR that were deposited in collections prior to the CBD, is favoured over a scenario of enforcement by law, which may turn out to be disastrous for collections and non-commercial research because many researchers will no longer use material that is preserved in the public domain. The ECCO Core MTA is in line with this (although benefit sharing is still in practice impossible to enforce or control by the collections).

2. Union Trusted Collections (UTC) (Art 5, EU draft Regulations on ABS [(1)])
According to this article the collections would be required (among other matters) to:

- "Supply GR and related information to third persons only with documentation providing evidence that they were legally accessed and, where relevant, with MAT"
  Collections will have very limited means to verify the correctness of information provided to them by the depositors, and will have to rely on info provided by the National Focal Point in the country of origin, or the global ABS Clearing House database . Moreover, even if the internationally recognized certificate of compliance has been issued (for the source material), the microbial strains isolated from it may not or not yet be listed as subject matter under the said certificate at the time of deposit, and the material would then have to be accepted in good faith (or refused).

(2a.) Can the authority provide assurance to the collection that, in case the documentation provided with GR at the time of deposit, later proved false or incorrect, the collection will not

be held responsible for the consequences of having distributed these GR and said documentation?

[An additional concern is reputational damage for the collection that may occur!]

- "Keep record of all GR and related info supplied to third persons"

(2 b) Can the confidentiality of the recipients of GR be guaranteed?

The collection can be expected by the authorities to provide them with information on deliveries to third parties for the purpose of control, but such information *should not become public* (confidential information is protected under Art 14, par 2 and Art 17, par 1 (a-iii), and Art 17 par 4 of the NP).

[Again, reputational damage for the collection may occur!]

(2 c) What additional criteria not mentioned in Art 5 (EU draft Regulations on ABS [(1)]) will be used by the competent national authority/ies to assess the collections that apply for recognition as UTCs?

(**2 d) What administrative duties will be done by collections and authorities?**

(2 e) Is it possible to have support from the authorities in case the administrative duties would become too much to handle for the collections?

This is very likely to be the case for all collections (both recognized UTCs and other collections); clarifying the exact duties of collections to support the monitoring of user compliance, and traceability of GR provided by the collections will have to be settled during the discussions. This may also depend on the outcome of the negotiations for the EU Regulation on ABS. Some requirements are already clear and a <u>preliminary cost estimate</u> for implementing these in the collection could be very useful as input to the discussions.

3. **Monitoring user compliance**

Specific checkpoints need to be installed for this (Art. 17 of NP [(2)]).

(3a) What is expected from the collections as regards monitoring user compliance? Will anything more than keeping register of information on the recipients and GR distributed to these recipients be required from collections?

Collections can contribute to traceability, but it is the responsibility of the authorities to enforce the regulations and take appropriate measures for monitoring user compliance.

4. **Third party transfer**

(4a) How exactly is third party transfer defined?

Collection having adopted the ECCO Core MTA need to consider their current practice, because the so-called "Legitimate Exchange" as defined in this MTA not only includes exchange between collections, but also the transfer of GR by the primary recipient to scientists within the same company or Institution or Research Group, including partners <u>in different institutes</u> collaborating on a defined joint project. However, the latter is regarded third party transfer under the NP and probably the authorities would agree. It is recommended to check this.

5. **Special considerations in the Nagoya Protocol [(2)]**

(5.a) What measures at national level are foreseen to answer to Art 8 of the NP, regarding:

- **encouraging and promoting of research, including simplified access to GR for non-commercial research** (*NP Art 8.a*);

  Parties to the NP are committed to have the required legal instruments and Competent National Authorities in place when the Protocol enters into force, but experiences from the past are reason to expect that not all Parties will meet the deadline (= entry into force). Incompletely documented GR could not be accepted by the collections under the currently proposed Regulation for the Union. In order to avoid the risks of severe impairment of the current practice of shared microbial GR in public collections, MIRRI has proposed that the EU regulations should provide the option for collections to accept material in cases that the depositor can reasonably explain why the documentation is not (yet) complete (see the MIRRI Response document) and provides the country of origin.

  This could however also pose a <u>risk for collections</u> when they would distribute such material.
- **emergency situations in human, animal and plant health** (*NP Art 8b)*;
- **GR for food and agriculture and food security** (*NP Art 8c)*.

Provisions at EU level (or at CBD level through acceptance by COP) would be most effective, but it is at this time uncertain if and how they will be implemented – the special considerations may become key items for proposed best practice.

6. Model contractual clauses and best practice.

An overview is provided in the attached document "Best practices in the microbial domain". The text is part of the MIRRI response to an invitation to provide such information to the EC office.

References

(1) Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union - (COM(2012)0576 – C7-0322/2012 – 2012/0278(COD)). http://www.ipex.eu/IPEXL-WEB/dossier/document/COM20120576.do

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(3) Fritze D (2010) A common basis for facilitated legitimate exchange of biological materials, proposed by the European Culture Collections' Organisation (ECCO). International Journal of the Commons 4: 507-527. URN:NBN:NL:UI:10-1-100222.

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(6) The European Culture Collections' Organisation (ECCO, http://www.eccosite.org/) was established in 1981. ECCO comprises 61 members from 22 European countries, holding over 350.000 strains of yeasts, filamentous fungi, bacteria and archaea, phages, plasmids, animal cells including human and hybridoma cell lines, viruses, plant cells, algae and protozoa. The aim of the ECCO is to promote collaboration and exchange of ideas and information about all aspects of culture collection activity. ECCO meetings are held annually and are a valuable forum for discussion and innovation on the future development of member collection activities.

(7) Janssens D, Tindal B, Green P, Garay E, Fritze D, Stalpers J, Smith D, Bimet F, Desmeth P (2009). The ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection. Download at http://www.eccosite.org/
Article 7 of this standard MTA is cited here: "If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSE(S), it is the responsibility of the RECIPIENT, in advance of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the MATERIAL, as indicated by the COLLECTION's documentation."

Appendix 1

Response of MIRRI to
the
"Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union"

The Microbial Resources Reseach Infrastructure (MIRRI) is an initiative within the European Strategy Forum on Research Infrastructure (ESFRI), including 16 European public microbial culture collections and resource centres, supported by 17 European and several non-European partners. It has received FP7 funding for a 3-year Preparatory Phase since November 2012. MIRRI aims to facilitate access to high quality microbial Genetic Resources (GR), related data and services, to connect users and providers, and to establish a platform of expertise. One of the focal points is the legal operational framework for culture collections. The „Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union" has been thoroughly studied, and the opportunity to provide a response to it is gratefully accepted. The decision of the European Commission to design a regulation that will introduce measures for user compliance based on due diligence obligations for all users throughout the Union is strongly supported.

The system of "**Union Trusted Collections**" proposed in Art. 5 of the Regulations is welcomed by MIRRI because it creates the potential to aptly support scientists within the Union to comply with the Nagoya Protocol and these Regulations. The scientific community is in need of a broad system of trusted sources that will **offer a full spectrum of high-quality microbial GR**. The ex-situ conservation of microbial GR requires specific expertise that is distributed over specialized culture collections across Europe. Scientists residing in developing countries often have to rely on these collections for preserving the GR because the expertise and capacity is still wanting in those countries. There is a big variation in size and scope of the Collections within the EU and, although many collections will be able to demonstrate that their procedures meet (most of) the criteria for a trusted source as set out in Art 5, par. 3 of the draft proposal, it is unlikely that they all will all be able to handle the extra structural administrative work related to the checking and/or collecting of all relevant documentation, without additional funding to hire more staff. The system should not favor only a select group of (larger) culture collections that are able to find the needed resources. **The Member**

States should therefore take measures to support collections under their jurisdiction that meet the criteria of trusted collections but lack sufficient resources to fulfill the tasks of a Union Trusted Collection. Thus, additional financial support for maintaining the system of Union Trusted Collections will be required, be it at national or Union level, for example through support of a research infrastructure like partners envisage for the future of MIRRI. Without such support the collections will be facing significant budgetary implications for their active research programs, with negative consequences for these institutions and their partners in developing countries that currently benefit from collaboration programs. If in time a global multilateral benefit sharing mechanism is to become operational, it should also provide financial support to collections that are recognized as trusted sources.

The criteria for Union Trusted Collections laid down in Art. 5, par. 2 are rather broadly formulated and we suggest to improve the text by more specifically formulating the minimum administrative duties. It is clear from the present draft that collections need to keep documents providing evidence that microbial GR were legally accessed and also keep record of supply of GR to third persons. Collections are not able to monitor third person compliance as users of the same microbial GR, or that of subsequent users further down the value chain. Moreover, under the standard Material Transfer Agreement of most European collections such further transfers of GR are not allowed. **Although it is our current understanding that the collections do not have to monitor the use by those receiving GR, and are not legally qualified / authorized to do so, this has to be clearly stated in Art. 5 of the Regulations**. These amendments would enable collections to better estimate the workload and ensure (long-term) compliance.

Public culture collections are the only gateway for scientists to bring microbial GR accessed *in situ* into the public domain so they can be exchanged and shared in a transparent way and used by other scientists for further research and development. Microorganisms often need to be studied in the laboratory for many years before scientists can publish the results. For example, in order to fulfill the requirements for valid publication of new prokaryote species, a type culture has to be deposited in public culture collections in two different countries. It is our great concern that after the Nagoya Protocol (NP) enters into force, the numbers of microbial GR that are deposited in the public collections will severely decrease. One reason for this can be that scientists may experience great difficulties in obtaining Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT). Parties to the NP are committed to have the required legal instruments and Competent National Authorities in place when the Protocol enters into force, but experiences from the past are reason to expect that not all Parties will meet the deadline. Incompletely documented GR could not be accepted by the collections under the currently proposed Regulation for the Union. In order to avoid the risks of severe impairment of the current practice of shared microbial GR in public collections, **the EU**

regulations should provide the option for collections to accept material in cases that the depositor can reasonably explain why the documentation is not (yet) complete. The collections' curators need to exercise due diligence by at least trying to clarify with depositors any issues regarding the legality and the available documentation, before they can decide on acceptance of the GR for deposit in the collection. Also, **curators should not accept any GR without at least information on the country of origin**, a practice most European collections have already exercised since the CBD entered into force and has met with general acceptance by scientists as a necessary measure to seek compliance.

Most culture collections supply microbial GR to users on a global scale and exchange microbial GR with culture collections in other regions. At the Symposium "Impact of the Nagoya Protocol on management of Biological Resource Centers", organized by the NITE-NBRC collection for its 10th Anniversary, Dec. 6, 2012, in Tokyo, the idea of a system of Union Trusted Collections met with great interest from the stakeholders in Asia and delegates from other regions. It is of great importance that the Commission continues to discuss the proposed system of trusted sources with authorities in other regions with the aim to establish a global solution or at least reach a level of compatibility between the systems for trusted sources that will stimulate and not discourage international cooperation and development, and does not set back the competitive position of researchers in Europe relative to researchers in other regions or in countries that did not ratify the NP.

MIRRI is in favor of building a general term into Art. 5 of the proposed regulation, that states that GR designated as **ex-type strains and strains accepted as reference strains for International Standard Norms should not be subject to these regulations**. Type strains are the reference material for taxonomy and systematics which are basic tools to research in the life sciences, such as on ecosystem functioning and effects of climate change, which contribute to conserving the planets microbial diversity. The status of these strains can be verified through scientific and technical publications. Users of these microbial GR normally have no intent of commercial use and always make their results publicly available providing non-monetary benefits to society. By excluding these kinds of resources from the scope of the Regulation, the Union would justly underline the importance of **simplified, yet effectively conveyed access for non-commercial research**.

MIRRI trusts that the above-mentioned concerns and suggestions for improvement will be taken into consideration. We hope that these Regulations in their finally adopted version will provide sufficient legal certainty for both the users of the microbial GR as the collections that have the conservation of these resources as their primary mission.

Braunschweig, Utrecht, 14 March 2013

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Annex WP9-5

Technical Report on the Workshop

'The role to be played by biological collections under the Nagoya Protocol as part of the Project under the 6th EU/Brazil Sectorial Dialogue Support Facility'

Brasilia
June 18-20th 2013

SUMMARY

IDENTIFICATION

Report of the workshop 'The role to be played by biological collections under the Nagoya Protocol' as part of the Project under the 6th EU/Brazil Sectorial Dialogue Support Facility

Project: Implementation of the Nagoya Protocol about the Access and Benefit Sharing - MMAA0002

Dialogue: Environmental Dimension of Sustainable Development
Brazilian Institution responsible for the project: Ministry of Environment - MMA

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OBJECTIVES

- **Main objective of the workshop**
  - Promote dialogue and create opportunities for cooperation over the medium and long term to facilitate the exchange of biological material between scientific collections and access to genetic resources (GR) from *ex situ* collections, in the context of the Nagoya Protocol and national and regional ABS legislation, as well as stimulate capacity building and awareness of ABS rules and practices.

- **Specific Objectives**
  - Enable communication between Brazilian and European holders of biological collections regarding the Nagoya Protocol and national and regional ABS legislation;
  - Discuss simplified procedures for the exchange of biological material between collections (both in Europe and Brazil) for research purposes under the Nagoya Protocol;
  - Share information on access to genetic resources from *ex situ* collections, in the context of the Nagoya Protocol.

ACTIVITIES

Pre-workshop

The list of participants and institutions is provided in Annex 2. Brazilian participants for the international workshop also participated in the first project (Brazilian) workshop (see report in Annex 3); European participants were chosen to represent sectorial associations, collections with major Brazilian specimen holdings and institutions with experience of ABS best practices.

Before the workshop, the document *'Ex situ collections and the Nagoya Protocol: A briefing on the exchange of specimens between European and Brazilian ex situ collections, and the state of the art of relevant ABS practice'* was written to provide participants with information on context and current practices. The complete document is presented in the Annex 4. The document '*Brazil's Legislation on Access and Benefit Sharing*' provided information on current Brazilian ABS legislation (see Annex 5).

The provisional agenda, setting out general goals and suggested issues for discussion, is presented in Annex 6.

Workshop structure

Day 1 - 18 June 2013

Presentations (as listed below) were delivered on Brazilian and European legislation/regulation on access to genetic resources and the Nagoya Protocol, to provide participants with information on the current and developing regulatory environments in both regions, and on the results and recommendations of the Brazilian workshop, to enrich the international discussion.

- ***Ex situ* conservation under the Nagoya Protocol and under the Brazilian ABS legislation -** Larissa Costa, Brazilian Ministry of Foreign Affairs

- **Brazilian trusted depository institutions -** Ana Yamaguishi, Ministry of the Environment

- **The E.U. Commission's legislative proposal on implementing the Nagoya Protocol -** Kate Davis, Senior Project Consultant (delivered on behalf of the E.U. Commission)

- **Report on the Brazilian workshop "O papel das coleções biológicas no cenário do Protocolo de Nagoia" -** Luciane Marinoni, Senior Project Consultant

After the presentations, a roundtable was established to discuss the subjects

related to *Research Needs and Barriers Related to ABS Legislation Suggested issues*.

Dr. Bert Visser and Dr. Arthur Mariante were invited by the organizers of the workshop to be the mediators.

Before the discussions began, Kate Davis introduced the background paper, emphasizing the history of flux in levels of control over resources and research freedom, the diversity of collections communities, the importance of networks for developing and disseminating ABS practices, the need to evaluate such practices post-Nagoya, and new key issues to address, including tracking and change of intent.

Afterwards the following topics were presented for roundtable discussion.

• Needs and barriers for research, including exchange and transfer of biological material, in the face of current national/regional legislation, guidelines, and rules of procedure; what will change under the new scenario of the Nagoya Protocol;

• Challenges and opportunities for facilitation of research collaboration, traceability of genetic resources, monitoring of utilization, changes of intent (where access for non-commercial purposes leads to interest in use for commercial purposes);

• Issues raised by the proposed European and Brazilian ABS regulations/legislation on the role played by *ex situ* collections on access to genetic resources;

• Innovative roles that biological collections can play in the implementation of the Nagoya Protocol to promote access to genetic resources and the conservation and sustainable use of biological diversity.

Day 2 - 19 June 2013

The second day's presentations (as listed below) provided further background for the discussions, focusing on practical initiatives:

- **Collecting, use and supply of plants at Kew -** Natasha Ali – Royal Botanic Gardens, Kew

- **Activities of science, technology and innovation for the systematization of knowledge and information on biodiversity -** David Oren – Ministry of Science and Technology

- **Exchange of genetic resources under the ITPGRFA -** Filipe Teixeira, Brazilian Agricultural Research Corporation – Embrapa Cenargen

Following the presentations, four small break-out groups were established, each containing EU and Brazilian representatives from different collections sectors, to discuss issues and to identify commonalities and key differences between different sectors/institutions, briefly explain these, and develop recommendations. Each group received a topic and questions intended to give direction to the discussion; a rapporteur was identified for each group to record the group's considerations.

Following the discussions in small groups, the roundtable re-assembled and the rapporteurs presented their results. All the participants were invited to contribute and to give suggestions.

The following topics and guiding questions were provided to the small groups:

Group A: Tracking/tracing + open access

What level of tracking/tracing is desired by Brazilian/EU authorities, what level is necessary for NP implementation, and what level is actually possible for collections? What do collections need (infrastructure, staff) to be able to track, or trace, material and information? What are the commonalities across collections sectors? What are some best practices? What are the vital differences that may require different approaches? Is it possible to enable open access AND to track specimens/data and their use?

Group B: Transfer to third parties + charge of intent + open access

What are the different practices currently? What are the commonalities between sectors, what are the alternatives? Do we need to transfer to 3rd parties? Would 'commons' approaches be acceptable to authorities and providers? What is the cost/benefit balance of restricting information/material flow for provider countries? How can we address possible changes in intent? What are the minimum requirements for a functional system?

Group C: Brazilian Model MTAs + alternatives

How is the Brazilian MTA system working for international exchanges, and how could it be improved? What are the 'sticking points' for international exchange? Are there differences between sectors in the MTA system's effectiveness? What are the alternatives? Is it possible to develop a standard MTA that could be used by ALL collections, or do we need different standards for different sectors? Would a model MTA – with different options for different sectors/situations – be more appropriate? Could such a standard/model be developed by an extension of this project?

Group D: Cooperation

How is the cooperation between Brazilian and European collections currently working? What are the current barriers and impediments to better cooperation? How can collections help to create new opportunities and models for cooperation?

Day 3 - 20 June 2013

On the final day the small group discussions resumed but with an exchange of topics. The rapporteurs for the previous day's topics remained with their topics while the other group members changed (although staying together); the previous day's report for each topic was circulated to the new group and introduced by the rapporteur, and participants were able to provide fresh suggestions for a second topic. Again the rapporteur was invited to present the results.

Following the reports of the rapporteurs, participants were invited to contribute any more general recommendations or observations from the meeting, and then the meeting was closed.

RESULTS

Day 1 - 18 June 2013: Presentations and roundtable discussion

The following issues and ideas emerged from the general roundtable discussion on the subjects suggested in the workshop agenda.

It was noted that, among the participants of the meeting, there is a difference in the understanding of the same terms used in the Brazilian legislation, the draft European Regulation and the Nagoya Protocol (NP). This partly stems from the use of the terms in the above-mentioned texts. For example, 'access' is not defined in the NP. The Brazilian and European definitions of 'access' are fundamentally different, while the Brazilian term 'access', the NP term 'utilization' and the draft EU Regulation the term 'use' cover very similar concepts. In addition the Brazilian concept of **Trusted Depository Collections** differs in meaning and intention from the EU concept of **Union Trusted collections** (under the proposed draft EU Regulation on ABS); the former focuses on a facility for users to deposit their germplasm as reference material in a safe way, the latter would guarantee to users that genetic resources (GR) have been acquired in harmony with the legal requirements.

Trackability and traceability were also mentioned as two different approaches to monitoring the use of GR. Tracking starts from the user end: when users receive material, they also receive documentation that allows them to track back to the source of the material/data. Tracing starts at the provider end, and necessitates a system that allows information to flow back to providers over use and user chains.

It was noted that the draft EU Regulation builds on three major pillars, i.e. due diligence, best practices and Union Trusted Collections. Due diligence means to show that the user took certain actions to ensure that "genetic resources and traditional knowledge associated with genetic resources used were accessed in accordance with applicable legal requirements and that, where relevant, benefits are fairly and equitably shared upon mutually agreed terms"). Best practices and Union Trusted Collections might take away some of the administrative burden stemming from the due diligence obligation.

The results stemming from the previous Brazilian meeting were recognized as addressing major issues to be resolved in international and national contexts and include:

- Facilitating the exchange of biological material between collections for the purpose of scientific non-commercial research;

- Addressing access to genetic resources in ex situ collections for commercial purposes;
- Facilitating cooperation and the sharing of benefits between Brazilian and European collection holders;
- Monitoring the utilization of genetic resources;
- Promoting the recognition of ex situ collections for their role to provide access under the Nagoya Protocol;
- Accrediting (national) trustee institutions.

Given the large number and variety of collection holders, the limited capacity amongst collection holders and some common types of use, developing standards and models is highly recommended, recognizing that different user sectors might need different models and standards. Jointly developing standards and models would also contribute to building trust between Contracting Parties and institutions.

Collection holders and prospective users would benefit greatly from the development of a process chart to 'translate' any legal procedure or set of procedures to comply with ABS regulations, and to identify the correct regulatory actions and forms to accompany the processes. Such a chart was for example provided in the MOSAICC project developed for microorganisms (BCCM, Belgium).

Fundamental, non-commercial research might be facilitated by transfer of GR under an MTA that provides free access to the GR involved for the purpose of that research, but that obliges the user who signs the MTA to negotiate PIC and MAT with the initial provider/country of origin, if commercial utilization is intended at a later stage. Such a provision would avoid overcautious interpretations of 'fundamental research' in an MTA that does not include such obligation for renewed negotiations at a change of intended use. The ECCO "Core MTA" was mentioned as an example of such an MTA.

Barriers to international collaboration could be removed if participation was on an equal footing, including capacity building and performing research at both ends. It would change the discourse from exportation of plant material into exchange of plant material. International collaboration for mutual gain can be regarded as an effective example of non-monetary benefit-sharing.

It was noted that GR and traditional knowledge associated with GRs within the scope of the Convention are protected under the NP. However, there are no provisions to cover the use of specific data associated with GR, e.g. phenotypic data or genomic information. Reference was made to the option of data protection by a data use agreement. Some participants mentioned that this might be in contradiction to current

open-access to e.g., sequence or genomic data emanating from research results from GR, whereas others were of the opinion that public availability would not have to be identical to unconditional use, claiming that data use agreements should not be considered as limiting public availability of the GR concerned.

On the question as to what we expect from the implementation of the NP, some participants stressed the relevance of legal certainty for users but also for collection holders. Others stressed the need and opportunities to promote increasing knowledge about the collections.

Days 2 and 3: Recommendations

The results of the small group discussions are reported. Small groups were asked to make recommendations for the wider group, with supporting arguments and further details. The recommendations below were mainly formulated by the rapporteurs and were therefore not finally agreed upon at the meeting by all participants, but reflect the results of the discussions in the small break-out groups and the round-table. The sequence of the following recommendations does not imply any weighting.

A: Tracking and tracing

Recommendation 1: Consider developing a structured unique identifier (UID) standard as an efficient way to encode minimum set of standard data fields into a single UID that can travel with a sample and derived data, and reduce the need for other forms of documentation.

> Examples of a 'lightweight' structured UID include the IPEN number: a multi-part ID separated by hyphens, containing coded information on the country of origin, restrictions (sharing rules), institute first acquiring the material, and that institution's accession number. It is thus far used for tracking but can equally facilitate tracing. The World Data Centre for Micro-organisms' (WFCC WDCM) databases system is based on assignment of Globally Unique Identifiers (GUIDs) specific to microbial items (using unique acronyms for each collection), and the Global Catalogue of Micro-organisms (GCM) provides information on the holdings of contributing collections. The ITPGRFA will implement a UID system for agricultural collections.
>
> UIDs can also be used at the transaction level (for loans/transfers), and can also be linked to the UIDs for internationally-recognised certificates of compliance of the Nagoya Protocol (which will contain information on PIC and MAT).

A standard would ideally be developed by a consensus body. Conflicting standards (e.g. from scientific community versus policymakers) should be avoided.

Recommendation 2: Consider developing standard lists of the codes for such structured UIDs and make these accessible to all from a single place on the internet.

Recommendation 3: The creation of new UID systems in fields with already working systems should be avoided, but current UID systems should be examined, considering possible synergies.

A large number of UID systems are in use, and the systems used by GBIF and SiBBr should be considered.

Recommendation 4: Any UID should preferably travel with derived data (e.g. sequence data), and this requirement should be written into MTAs.

Use of the UID in global databases would enable global searches to find where the UID is in scientific literature.

Enforcement of this requirement could be difficult; engagement from professional standards bodies, journals and societies will be required.

Recommendation 5: Consider developing a core standard, with flexibility for different sectors.

The role of the collection should meet minimum data standards (e.g. country of origin, PIC, country institute) but should not necessarily provide a service. Depending on the sector, some information may need to be kept confidential (e.g. for commercial use of agricultural germplasm and microbial collections, or to protect highly threatened species), with information provided to regulatory bodies but not made publicly available.

Recommendation 6: Unfunded mandates should be avoided. Requirements should be paired with implementation: the government that requires traceability should provide the required infrastructure (clearing house, regulating body) and funding for collections and information flow.

Recommendation 7: The degree of effort and resource expended on tracing should be proportional to the risk of mis-use.

Policy standards should be flexible to recognise differences in risk, and should be arrived at by consensus between national regulatory bodies and academics. However, some standards must be set, even if there is a range of different sectorial standards.

Recommendation 8: A tracking system must be practical, cost-effective and scalable to work for different collection holders, large and small, with different staff and infrastructure capacity.

Recommendation 9: There should be no requirement to assign UIDs retroactively to whole collections: any UIDs should be used for new acquisitions and/or transactions.

Recommendation 10: MTAs should follow samples in a chain of distribution and should require reporting back to a clearing house.

> This process could be made more efficient within 'trusted networks' such as IPEN that are treated as a **single entity for tracking/tracing of each transfer within the network** so long as the original intent (academic or commercial) is maintained. Such networks must have strong internal guidelines for membership and binding rules for use to make this a secure option.

Group B: Transfer to third parties and change of intent

Recommendation 11: Consider developing a glossary of terms, to harmonise understanding and usage of terms and concepts such as 'access', 'use' and 'utilisation', 'trusted collections', 'third party transfer' and 'MTA'.

> For example, the Brazilian legislation definition of 'access', the Nagoya Protocol definition of 'utilisation' and the current draft European ABS regulation of 'use' are very similar, while the Brazilian definition of access differs markedly from the European understanding of that term. A glossary of what is meant exactly by which term in which context is key to building understanding and reducing individual and legal confusion.

Recommendation 12: Consider the inclusion of a glossary of terms in each MTA, including a clear definition of 'third party' appropriate to the situation and sector.

> There is considerable difference of opinion between and within sectors as to what constitutes a 'third party.' For example in the case of Brazilian microbial collections, anyone outside the collection is considered a third party, even within the same institution. This is also the case for IPEN gardens attached to universities (researchers are third parties), but within IPEN itself, other gardens are not considered third parties and transfer does not require an MTA. At the Royal Botanic Gardens - Kew and at Embrapa, a third party is an entity outside the institution, but not other collections within the institution.

Recommendation 13: At the point of material exchange, information should be disseminated on the range of different practices for transfers, depending on the type of material.

The development of standards and models can facilitate compliance with Brazilian legislation and build trust between contracting parties and institutions, e.g. for sending seed to institutes outside Brazil. For European collections, standards and models can legitimise exchange between collections and sharing of material of regular users with collaborating scientists.

There is general consensus that it is beneficial to send material to other institutions, particularly when there is not sufficient in-house expertise. Duplicate herbarium specimens are commonly exchanged.

Recommendation 14: The modalities should be considered for a system that could remove, but with safeguards, the requirement to gain Brazilian approval for third party transfer.

If material was to be deposited externally, the requirement to gain Brazilian approval for third party transfer was believed (by at least some) to be unworkable and a barrier to research and cooperation, and should be removed, with safeguards – there must be a mechanism to ensure that permission is sought/obtained for any subsequent move to commercial benefit (see, e.g., recommendation 4 and 10).

Recommendation 15: Agreements (such as MTAs) should be made at the institutional level rather than at the individual level.

This recommendation may pose problems for associates. Institutional procedures and policies may provide solutions.

Recommendation 16: The Brazilian model procedure for benefit-sharing, which contains a useful approach for identifying change of intent, should be translated and the translations should be made publicly available.

There is debate as to when change of intent from non-commercial to commercial research begins. The Brazilian approach is that the provider must be informed if there is a commercial research venture. The MTA is the preferred method for formalizing a change of intent.

Brazilian legislation defines “non-commercial” research in Resolution 21 (Annex 7). Research that is not covered in the definition is considered to have commercial potential. In the MTA used when shipping genetic heritage samples for non-commercial research purposes, change of intent is considered thus: *“In cases of any subsequent wish to make use of the samples of the genetic*

heritage components transferred under this MTA for the purposes of bioprospection, technological development, or the request of a patent, the Receiving Institution shall undertake to so inform the Sending Institution, which shall in turn inform the Genetic Heritage Management Council or an institution accredited under the terms of Article 11(IV)(e) of Provisional Act No. 2,186, dated August 23, 2001."

Recommendation 17: The minimum requirements for a functional system to enable transfer to third parties that could be considered are *inter alia*:

- A series of standard functional MTAs for different circumstances containing appropriate information about terms of use;
- Benefit-sharing models in a range of languages;
- Legal and policy support and advice;
- Databases to record/provide information for purposes of tracking and tracing, taking into account confidentiality of certain data if appropriate;
- Sufficient budget and staff resources: more standardisation lowers the costs.

Group C: The Brazilian MTA and alternatives

Recommendation 18: Consider developing a single MTA with the possibility of invoking different additional clauses, linked to a decision tree, to provide operational clarity and to ensure that appropriate legislation is followed. If it is not possible to have a single MTA, there should be a clear decision tree to determine which MTA is appropriate to use for particular situations.

Four types of MTA are being used in Brazil for biological material, derived from different instructions/ resolutions, and with officially approved text. The first three are ranked by degree of likely commercial activity, and have increasingly detailed requirements to match this; the first three cover both loans and permanent deposit in a collection (including outside the country); the fourth is exclusively for loans (and was not used by any of the group participants).There was clarity that loans should be fully returned, including any aliquots or parts if sequencing or other destructive sampling had been undertaken.

The development of a single MTA could also support user compliance, because users would become familiar with the MTA format and requirements.

Recommendation 19: There should be a means to clearly indicate relevant regulatory requirements, ideally in both Portuguese and major user languages.

There is currently no clarity in MTAs as to which Brazilian Resolutions are relevant (e.g. Resolution 21 is implicit in reference to non-commercial research

and explains what activities are possible, but is not referenced in the MTAs). Links to the relevant texts would be very helpful for foreign institutions seeking legal surety.

Recommendation 20: A web portal could be developed (on CGEN) as a tool to help institutions to develop the appropriate MTA, using such a single MTA model with options.

This tool could be comparable to those available on the SISBIO and CNPq that provide structured information on how to obtain authorisation for collecting, for Brazilians and for foreigners.

Recommendation 21: Prepare and make available a list or register of Brazilian institutions that are empowered to sign MTAs.

The current lack of such a list presents a risk to non-Brazilian collections.

Recommendation 22: Consider the practicalities and requirements of a system to track delivery of non-commercial benefits (such as publications, as set out in MTA conditions).

Such a system would assist institutions in Brazil to demonstrate their international profile and for all to manage and demonstrate the delivery of non-commercial benefits. There is also a need to 'mainstream' agreed benefits across institutions so that institutional level agreements are known and understood.

Recommendation 23: Consider a data use agreement for publication of sequence data within the International Nucleotide Sequence Database Collaboration (INSD; involving GenBank, EMBL and DDBJ), and this recommendation should be considered across the EU countries.

There is potentially a system already in place at INSD record level to assert rights and restrictions on the data but more information from these databases is needed to find out to what extent that can be implemented.

Group D: Cooperation

General observations:

Cooperation between Brazilian and European collections works quite well on an individual basis or for specific research projects, including e.g. the exchange of PhD

students. There are some minor problems and delays related to transferring material within research projects.

Recommendation 24: Disseminate information (in Portuguese and English) about relevant legislation and procedures in Brazil and EU countries that is relevant to scientific collaboration and the exchange of material covered under the NP for non-commercial research. Institutional collaboration decreased over the last decade chiefly due to European concerns related to Brazil's ABS legislation, including some rare but worrying cases in which specimens were not returned to European collections. In general European institutions are not aware that the legislation has changed recently and that it is easier to collaborate now.

Recommendation 25: Import and export requirements for the exchange of material should be streamlined and simplified so as not to unnecessarily hamper exchange.

> A significant impediment to collaboration is that it is sometimes problematic to exchange material due to quarantine restrictions, based on a lack of trust between authorities at both ends.

Recommendation 25: National authorities in Brazil should develop standardized forms and procedures to facilitate exchange of material.

Recommendation 26: Consider developing a permanent online platform to provide and explain information on specimen exchange (ABS legislation and processes related to shipment and quarantine), using user-friendly, easy-to-understand simple schema and decision trees.

> This platform could initially focus on Brazilian and European rules, but link to other initiatives as results emerge from similar discussions being conducted at other levels.

Recommendation 27: The needs of collections institutions in Brazil and in Europe that bear the costs of maintaining collections and providing services for basic research, conservation and commercial use should be recognised and supported.

> Possible options for cost recovery include receiving a percentage of monetary benefits in case of commercialization of a product derived from GR, or charging a general handling fee. This discussion is underway in Brazil, and the results could potentially serve as a model for Europe and beyond.

Recommendation 28: The establishment of national nodes to deal with benefit-sharing should be considered.

The Brazilian National authority for Genetic Resources (CGEN) is mentioned as an example of good practice in this respect.

Recommendation 29: Institutions should be encouraged to document and make their collections information available online to stimulate new collaborations and enable meta-analyses.

The current REFLORA digitisation project is seen as exemplary.

Recommendation 30: Collections should be encouraged to share information on ABS best practices with each other, between as well as within sectors.

ANNEX 1. Abbreviations and acronyms

ABS	Access to genetic resources and benefit-sharing
CENARGEN	National Research Center for Genetic Resources and Biotechnology
CGEN	Genetic Heritage Management Council
CNPq	National Council for Scientific and Technological Development
DDBJ	DNA DataBank of Japan
ECCO	European Culture Collections' Organisation
EMBL	European Molecular Biology Laboratory
Embrapa	Brazilian Agricultural Research Corporation
EU	European Union
GBIF	Global Biodiversity Information Facility
GCM	Catalogue of Micro-organisms
GUID	Global Unique Identifier
GR	Genetic Resources
INSD	International Nucleotide Sequence Database Collaboration
IPEN	International Plant Exchange Network
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
MOSAICC	Micro-organisms Sustainable Use and Access Regulations International Code of Conduct
NP	Nagoya Protocol
PIC	Prior Informed Consent
SIBBR	Information System on Brazilian Biodiversity
UID	Unique Identifier
WDCM	World Data Centre for Microorganisms
WFCC	World Federation for Culture Collections

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Christopher Lyal	Natural History Museum
Francisco Pando	Real Jardín Botánico de Madrid
Justin Paschall	European Bioinformatics Institute
Ole Seeberg	Copenhagen Botanic Garden
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Bert van den Wollenberg	International Plant Exchange Network/ Botanic Garden, Technical University of Delft
Gerard Verkley	Microbial Resource Research Infrastructure/WFCC/ CBS-KNAW Fungal Biodiversity Centre
Bert Visser	Netherlands Centre for Genetic Resources

Annex 3. Report on the First Brazilian Workshop 'The role to be played by biological collections under the Nagoya Protocol" – Brasilia, May 9 - 10th 2013

RESULTS

Following are the results of the workshop in priority order as established by the participants within the six topics proposed for discussion. Some suggestions are repeated in different themes, where they were responses to more than one question.

1. **Make the exchange of biological material between collections easier for scientific research, where there is no economic interest.**

a. CGEN Resolution No. 21 of August 31st, 2006 is useful and functional and should be used as a permanent instrument. This resolution provides for research and scientific activities that do not fall under the concept of access to genetic resources for purposes of Provisional Measure No. 2,186-16 of August 23rd, 2001. The Resolution 21 is attached to this report (Annex VI).

b. Loan forms of the collections belonging to various institutions should be similar between them with clear aims and with the same items. A model to be used by the collections could be presented by the Genetic Heritage Management Council (CGEN) or by the Technical Chamber of Biological Collections (CTCB) of the National Biodiversity Commission (Conabio).

c. To improve organization and transparency, the Biological Collections should be responsible for deploying in their institutions: a) a policy for scientific collections, b) a policy of availability of and access to scientific data and information and c) a manual of standards and collections procedures. Of course, the success of these best practices depends on the qualification and training of personnel and dissemination via the institutional web sites of its rules and the forms required for loan and material transfer.

d. The Material Transfer Agreement (MTA) - has been used by all Biological Collections and has been shown effective for our purposes. In the case of formalized cooperation with overseas institutions and development projects, there should be no need to sign the MTA. Registration for transportation must be done in the case of research with economic purpose.

e. Although the MTA, as mentioned above, meets the needs of the Biological Collections in general, there is uncertainty about the transfer of samples of seeds germplasm and, similarly, the sending of material abroad, for required services, for example for sequencing and flow cytometry. Thus there is a need to include these practices in the current model of MTA or develop a new

document that addresses them.

f. In the case of microorganisms, when a new species is described, a series of type specimens must be deposited in an international collection. This material has to be considered available as a reference. Currently the rules are not explained in relation to the rights of the institutions regarding the deposited material. Thus, the rules should be clarified and a new agreement / contract should be prepared in order to guarantee the sharing of benefits with the depositor. This applies to the ex-situ material.

g. The participation of local communities providing information to inventories of organisms should not be treated the same as those cases in which there are benefit sharing requirements arising from the use of Associated Traditional Knowledge (CTA). This type of survey does not generate any kind of information of commercial nature. In this case, procedures that involve filling out questionnaires with members of the community should be very clear.

h. Ethnobotanical Collections are a form of testimony of local knowledge of plant species and should follow the standards laid down in the Convention on Biological Diversity (CBD) and MP 2.186-16/01, as well as codes of ethics of the scientific society (Declaration of Belém 1988; De Bot Soc. Economica, 1999; Internat Soc. Ethnobiology De, 1988). The collection should be digitised and follow the Policy of Data Access and Scientific Information and may not be exchanged or transferred.

i. It is necessary and urgent to unify a system that facilitates the process of license and transport involving all agencies and institutions (ANVISA, FEDERAL POLICE, IBAMA, MAPA and POST). For this purpose it is proposed that a single portal should be created for registration of biological collections for exchange of scientific material, which can be accessed by the agencies listed above at the time of the transit.

j. To support the previous proposal, a physical barcode system should be installed to identify to the above authorities material that is not intended for commercial use or for access (in the sense of the Brazilian legislation - under current law defined as "*activity performed on the genetic heritage with the aim of isolating, identifying or using information from genetic or molecules and substances in the metabolism of living beings and extracts of these organisms, for purposes of scientific research, technological development and bioprospecting, aiming their industrial application or otherwise".*) Such a code would be recognized by the system and the registration of the collections in this system would be the

responsibility of the institutions that exchange material but do not access it, for example, the license for collection issued by SISBIO (http://www.icmbio.gov.br / SISBIO /).

k. Besides the unification of the process of material control by the agencies mentioned above, the training of inspectors and inspection agents is essential, regardless of the control system.

2. Discuss and address the access to genetic resources in *ex situ* collections for trade procedures.

a. The collections should standardize the procedures and documents required for the shipment of material - as described in items 1b and 1c.

b. The collections should be considered as sources of material for commercial purposes: they hold the information about the origin of the material, its geographic distribution, its taxonomic classification, and are the only bodies with the capacity to ensure reliability and to give such information. As the collection is responsible for the conservation of this material and bears the great costs of keeping it, it is essential that the collection be considered as a provider, as well as the depositor of the material. We suggest that 10% of the amount of the transaction should go to the provider collection.

c. Add to MTA an item obliging the recipient to sign a Prior Informed Consent Form (PIC) and to establish Mutually Agreed Terms (MAT) if there is a change of intent for bioprospecting, technological development and an application for a patent.

d. Adopt a standard model agreement for various types of material giving legal certainty to these exchanges, similar to the multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

e. Develop a national platform for data banks of genomics and proteomics, among others, of the Brazilian biological material that has clear rules for free access, use and benefit sharing.

f. Develop a plan for dissemination and training on Nagoya Protocol for all those sectors involved in the conservation of collections of genetic resources.

g. Facilitating cooperation and the sharing of benefits between Brazilian and European collections.

h. Consider what is described in item 1 d (MTAs) and 1f (deposit requirements) – focusing on cooperation with the countries of the European Community (EC).
i. Consider what is described in item 1 f - mainly because the deposit of the type material of microorganisms is done in European collections.
j. Elaborate calls for joint projects with the European Community (EC) involving Brazilian biological collections.
k. Periodically review the cooperation agreement with the EC, within the scope of Nagoya Protocol.
l. Develop a plan for ongoing training of Brazilian and European technicians who work in the collections, to ensure their knowledge of the Nagoya Protocol and associated regulations.

3. Monitor the utilization of genetic resources.

a. Establish a database of national collections that provides for tracking of the material from its origin. Such a database would provide transparency on the use of material, and also information on the status of the research. The database could be integrated into the Information System on Biodiversity (Brazilian SiBBr), converging to single platform that generates a Biological Registration Code.

b. Increase the term of maintenance of genetic heritage in the collection, beyond the end of scientific research project. The term should be defined, as well as the indication of the trustee collection at the end of scientific research.

c. Consider what is described in the item 2 g.

4. Promote recognition of *ex-situ* collections taking into account the role they play for access to genetic resources, primarily under the Nagoya Protocol.

a. Consider what is described in paragraphs 1 b and 1c.

b. Promote recognition of the collections within the institutions that maintain them, considering the three levels: local, state and federal.

c. Ensure that collections are maintained in functional units, formally recognized within their institutions, with rules and policies , staff and own budget.

d. Ensure that the collection that provides access to materials is included in contracts for benefit sharing, even if it is not a trustee collection, regardless of the original provider and the date of obtaining the material for the collection.

e. Ensure that the government assists with financial resources those collections considered trustee collections of CGEN, as well as those who can afford to be

Biological Resource Centers (CRBs).

f. National calls for project submissions by CNPq and other agencies should allocate a percentage of the financial resources to the maintenance of the collections for projects that involve access to biological resources.

g. Review the representation of the institutions in CGEN, including a chair for representatives of ex situ collections.

h. The recognition of the collection institution could be made based on certain minimum criteria such as: having a curator and deputy curator; being computerized at least in part, to ensure the traceability of biological material; possessing infrastructure and human resources to ensure the maintenance of the collection, including the activities of deposit, loan, donation, sale and exchange; capacity for quality identification of material by trained personnel.

i. The collections that meet the requirements listed above should be recognized institutionally by an ordinance that should include the names of the curator, deputy and contact.

j. Among the criteria for the recognition of the institution and its collection(s), compliance with legal requirements regarding Access and Benefit Sharing must be considered. The collection shall use the MTA (Res. 15, 20, 25 and IN 160) for the transportation of the biological material and ensure the traceability relating to the deposit of the biological material.

k. Develop workshops about the collections and the Nagoya Protocol in collaboration with other institutions.

l. Include in the institutional project a plan for application of resources.

m. Train personnel linked to the biological collections and to legal advice about the regulations and legislations of genetic heritage (MP 2.186-16/01).

n. Include in the curriculum of universities (undergraduate and graduate) subject on Access Legislation for courses related to the theme.

5. Accreditation of the trustee institutions

a. Considering item 5 h. CGEN must have a list of minimum attributes for a collection that can be accredited. In this case, the issues of computerization and traceability must have greater weight.

b. Define a flow for this institutional accreditation, using the existing Center for Technological Innovation (NIT), or similar. The responsible body would have to evaluate the function of accreditation applications, check the documentation and

forward for accreditation.

c. The group agrees that this accreditation should be unlimited but restricted to public institutions.

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ANNEX 4. Document *"Ex situ collections and the Nagoya Protocol: A briefing on the exchange of specimens between European and Brazilian ex situ collections, and the state of the art of relevant ABS practices"*. Authors: Kate Davis and Luciane Marinoni

1. Introduction

This paper seeks to lay the ground for discussions towards more effective cooperation between *ex situ* collections in Brazil and the European Union, by exploring the history of collection in Brazil, interactions between Brazilian and European collections, and the distribution of collections and important networks in Brazil and Europe. Having provided those contexts, it will focus on access and benefit-sharing practices that were developed in response to the Convention on Biological Diversity, and how such practices may be suitable or adaptable to the new realities of the Nagoya Protocol and related national legislation, with a view towards enabling discussion on viable solutions for facilitating research and cooperation.

The diversity of types of *ex situ* collections is considerable: plant, animal and microbial resources, maintained in preserved or living form, utilised for non-commercial or commercial purposes, by public or private bodies. This paper will focus predominantly on publicly-held scientific collections and non-agricultural collections and their relation to the Protocol, with the understanding that the International Treaty on Plant Genetic Resources for Food and Agriculture provides sector-appropriate measures for many exchanges via the Multilateral System. Information from private and corporate collections and informal university in-house collections is more difficult to collect, and it is hoped that the results of the discussion between public collections will be made widely available and serve to inform other collections.

2. Brief history of European collections in Brazil

2.1 Origins of European *ex situ* collections

During the Age of Discovery and European expansion, explorers brought back novel objects and creatures that were eagerly received by and exchanged between princes and grandees. The trend for accumulating 'cabinets of curiosities' gradually spread to scholars, doctors and other members of the bourgeoisie. Herbaria and botanical gardens were both first developed in the early 16th century in Italy, and then proliferated across Europe. The Muséum national d'Histoire naturelle (MNHN) arose from the 'King's Drugs Cabinet' in 1633, which gave rise to the Jardin royal des plantes médicinales, while the origins of the Natural History Museum (NHM), London lie in Sir Hans Sloane's cabinet of curiosities, which included dried plants and animal and human skeletons, acquired through his interest in natural history and travels as a doctor and scholar.

With the Scientific Revolution and the rise of taxonomy as pioneered and expanded by Linnaeus and Buffon, interest shifted towards natural history and the investigation of natural forms and variations of plants and animals, rather than curious deformities, which were often popular in earlier collections. Specimens were typically obtained from four main sources: travelling scholars, expeditions, diplomatic exchanges (especially for exotic animals), and merchants[1].

[1] Baratay, E. & Hardouin-Fugier, E. (2002) Zoo: a History of Zoological Gardens in the West. Reaktion Books, London, UK

2.2 Early colonial-era collection in Brazil

Brazilian biodiversity attracted intense European interest from the very start of the colonial era and has continued to do so through centuries of geopolitical change. Soon after the Portuguese claimed Brazil in 1500, samples of flora and fauna of potential commercial interest were shipped back to Portugal, including trunks of pau-brasil, or brazilwood (*Caesalpinia echinata*, the species that gave Brazil its name). The French sought footholds for brazilwood exploitation, but were expelled in 1567, from which time Portugal held a long monopoly on brazilwood supply. The Dutch invaded north-eastern Brazil in 1630 and in 1637 sent out two scholars, Wilhelm Piso and Georg Marcgraf, to conducted the first scientific study of Brazilian zoology and botany, published as *Historia Naturalis Brasiliae* in Leiden in 1648. The Dutch were expelled in 1654 and direct scientific research was paused for over a century[2].

Portugal conducted little exploration of Brazil and its vast biodiversity until the early nineteenth century, focusing instead on establishing sugarcane plantations, cattle grazing, and then mining the major gold and diamond deposits that were discovered at the end of the 17th century and early 18th century. To guard these valuable resources, foreign contacts were kept to a minimum; fewer than ten accounts of Brazil and its natural wonders were written during the 16th and 17th centuries[3]. However with the flowering of science in northern Europe, European scientists (and governments and companies) were increasingly eager to gain access to new specimens from unknown territories.

A few foreign explorers and naturalists did succeed in penetrating the barrier, without permission from Portuguese authorities. Charles-Marie de la Condamine entered Brazil via the Amazon River in 1743, on his way home to France after ten years on an expedition to Quito, and published an account of his Amazonian voyage[4]. The French naturalist Philibert Commerson visited briefly during a supply stop in 1767 for Louis Antoine de Bougainville's voyage of circumnavigation, and managed to collect specimens on the lands of local gentry to whom he offered his services as a physician, despite tense relations between Bougainville and the local Viceroy (due to conflicting French and Portuguese colonial maritime interests)[5]. In 1768, the *Endeavour* stopped to resupply in Rio de Janeiro on its voyage to the South Pacific; the local Viceroy forbade anyone but Captain Cook to set foot ashore for the twenty-four days of the stop, but the English naturalist Banks and fellow expedition members made illicit forays to the shore to collect specimens[6]. In 1803-04, when the expedition led by Adam Johann von

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[2] Barman, R.J. (1971) The forgotten journey: Georg Heinrich Langsdorff and the Russian Imperial Scientific Expedition to Brazil, 1821-1829. Terrae Incognitae 3 pp.67-96.

[3] *Ibid.*

[4] de la Condamine, C.M. (1751) Journal du Voyage fait par l'ordre du Roi à l'equateur, servant l'introduction historique à la Mesure des trois premiers degrés du Méridien. Paris. (Google ebook; p. 193)

[5] Including the species he named *Bougainvillea spectabilis*. Allorge, L. (2003) La fabuleuse odyssée des plantes: Les botanistes voyageurs, les Jardins de Plantes, les Herbiers. J.C. Lattès, Paris, France.

[6] See Joseph Bank's journal entry for 26 November 1768, http://gutenberg.net.au/ebooks05/0501141h.html#nov1768

Kruzenstern dropped anchor off the coast of Santa Catarina (where the orders to exclude foreigners were less well-observed), the botanist Georg Langsdorff was able to spend two months in the area[7].

In the late 18th century the Portuguese government recognised the potential benefits of scientific study of its colony, and authorised a scientific expedition to Brazil, led by Brazilian-born Alexandre Rodrigues Ferreira. The ten year expedition (1783-1792) explored the Amazon basin and Mato Grosso; specimens and Ferreira's writings were taken back to the Museum of the Palácio Nacional da Ajuda in Lisbon[8].

2.3. 19th century collection in Brazil

Napoleon Bonaparte's invasion of Portugal in 1808 impelled the Portuguese royal family to flee to Rio de Janeiro, where they lived for thirteen years and changed the policy of exclusion towards foreigners to one of welcome. Naturalists, artists and scientists arrived from across Europe and begin to describe Brazil's vast resources, and important expeditions were mounted from several countries. They sought scientific knowledge and economically useful resources, but also exotic plants for ornamental horticulture and animals for zoos and menageries. Some collectors conducted their work via expeditions supported by governments and national academies, while others financed their explorations by selling their collections to Victorian enthusiasts building their cabinets of curiosities. Huge numbers of specimens were sent to European collections, to the growing dismay of Brazilian scientists, but some of the visitors took up residence in Brazil and became key figures in the development of Brazilian scientific institutions and endogenous science[9].

A few key 19th century expeditions and collectors should be mentioned, due to their contributions to European *ex situ* collections and their importance to the foundations of Brazilian botany and zoology[10].

2.3.1. Major expeditions

One of the first major expeditions was that of Auguste de Saint-Hilaire, following a diplomatic reconciliation between Louis XVIII and Jean VI of Portugal, Emperor of Brazil. The expedition (1816-1822) collected vast numbers of plant and animal specimens, many species described for the first time, and Saint-Hilaire published a number of important volumes on Brazilian natural history, including the *Flora Brasiliae Meridionalis*. The expedition's collections are largely deposited at MNHN, Paris.

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7 *Ibid.* 2 (Barman 1971)

8 Bastos, F.I. & Sá, M.R. (2011) The scientist as historian: Paulo Vanzolini and the origins of zoology in Brazil. História, Ciências, Saúde – Maguinhos. 18(4): 1021-1038. Available from www.ncbi.nlm.nih.gov/pubmed/22281957

9 *Ibid.*

10 Except where noted, collector information is drawn from the Global Plants Initiative webpages (http://plants.jstor.org/person...)

The Austrian Expedition to Brazil (1817-1821) carried out comprehensive studies of Brazil's natural resources and culture. Its two missions were led by Austrian-Czech botanist/zoologist/entomologist Johann Christian Mikan, and by German zoologist Johann Baptist von Spix and botanist Carl Friedrich Philipp von Martius. The Spix and von Martius collections are largely deposited in Munich, though von Martius's private collection was obtained by the government of Belgium. Other naturalists involved include Johann Baptist Emanuel Pohl, whose collections are now chiefly held in Naturhistorisches Museum Wien (Vienna Natural History Museum) and the National Herbarium of the Netherlands; Austrian botanist Heinrich Wilhelm Schott; Italian botanist Giuseppe Raddi; and Austrian zoologist Johann Natterer. All of these scientists made important contributions to the literature on Brazilian biodiversity.

Other major expeditions include that by German prince and naturalist Maximilian Alexander Phillip, Prinz du Wied-Neuwied (to southeastern Brazil in 1815-1817), whose resulting volume *Reise nach Brasilien* was another major contribution to knowledge of Brazil; the Russian Imperial Scientific Expedition to Brazil (1821-1829) led by German physician and naturalist Georg Heinrich Langsdorff and his deputy the German botanist and horticulturist Louis (or Ludwig) Riedel[11]; the Hassler expedition (1871-1872), mounted by Harvard University's Museum of Comparative Zoology, from which Austrian zoologist Franz Steindachner took back material for the Naturhistorisches Museum Wien[12]; and the Castelnau expedition to South America (1843-1845), coordinated by François Louis de la Porte, comte de Castlenau for the duc d'Orléans and the MNHN, which travelled through Brazil from Rio de Janeiro to the Brazil-Bolivia border, then returned through the Amazon rain forest. A critical reevaluation of this particular expedition's findings and interpretations led to the first Brazilian scientific expedition, the Comissão Científica do Império (Imperial Scientific Commission, 1859-1861)[13] [14].

2.3.2. Smaller expeditions and independent collectors

Institutions and companies also sent collectors to Brazil – for example the Royal Botanic Gardens, Kew (Kew) sent plant collectors out around the world with a mandate to discover new plants that could be useful to the British Empire – and some collectors were part-financed or fully financed by the selling of their specimens to wealthy collectors in Europe. Allan Cunningham and James Bowie collected for Kew in Brazil between 1814 and 1816 on their way to Australia. Scottish botanist George Gardner funded his 1836-1841 collections in the north and east of Brazil by selling duplicates to wealthy collectors through a London agent (many of his collections are now at NHM and Kew, among others)[15]; similarly, British naturalists Alfred Russel Wallace and Henry Walter Bates sold insect and bird specimens to support their 1848

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11 *Ibid.* 2 (Barman 1971)

12 Steindachner went on the coordinate the Austrian Expedition of 1903; www.nhm-wien.ac.at/en/research/_zoology_vertebrates/fish_collection_/history

13 *Ibid*. 8 (Bastos & Sá 2011)

14 Guimarães, M.R.C. (2013) A primeira viagem científica brasileira: a Comissão Científica do Império, História, Ciências, Saúde – Maguinhos 20(1): p.332-336, www.scielo.br/pdf/hcsm/v20n1/19.pdf

15 www.kew.org/science/tropamerica/gardner/index.html

expedition to Amazonian Brazil. Richard Spruce set out for the Amazon and the Andes in 1849 for Kew (in search of quinine and rubber), but again his main financial support came from 'subscribers' at home[16] [17].

Important horticultural collectors include William Lobb, who collected living plants and seeds and herbarium specimens in South America including Brazil over the course of two four-year voyages for the firm of James Veitch and Sons. His herbarium specimens are deposited in a number of major collections in Europe and the US.[18].

2.3.3. European collectors who remained in Brazil

Several prominent European-born collectors made Brazil their home. While they maintained scientific links to Europe, they also helped to build the strength of scientific institutions in the Empire of Brazil.

German botanist Louis (Ludwig) Riedel spent most his life in Brazil, collected important material for von Martius's *Flora Brasiliensis*, and was the first foreigner to be appointed within the National Museum of Rio de Janeiro, as director of the Herbarium and botanic garden. Danish zoologist and palaeontologist Peter Wilhelm Lund collected in and subsequently stayed in Brazil, where he hosted visiting naturalists (such as Peter Claussen in 1834) and contributed to Brazilian science, although his huge collection was donated to Denmark. The Swedish physician Anders Frederik Regnell immigrated to Brazil in 1840 and collected avidly in Minas Gerais until his death in 1884. He donated specimens to Swedish institutions, collected with visiting botanists (such as Gustaf Anders Lindberg in 1854-1855), and acquired other naturalists' collections; his personal collections were examined by Martius for *Flora Brasiliensis* and were eventually bought by the Swedish government.

French naturalist Auguste François Marie Glaziou lived in Brazil between 1858 and 1895, and as General Director of Public Gardens for Rio de Janeiro he collected widely across Brazil, and published *Plantae Brasiliae Centralis a Glaziou lectae*. His collections are deposited in major European herbaria and Rio de Janeiro, and he also sent live seeds and plants to European botanic gardens. The German biologist and physician Johann Friedrich Theodor (Fritz) Müller immigrated to the state of Santa Catarina in 1852, where he conducted botanical research, published papers on southern Brazilian zoology and evolutionary biology, and advised farmers. In 1876 he was appointed as Travelling Naturalist to the National Museum in Rio de Janeiro (then the Museu Imperial e Nacional), one of several foreign-born naturalists employed there, as well as Swiss zoologist Emil Goeldi and German zoologist Hermann von Ihering[19]. Ihring went on to found and become the first director of the Museu Paulista in São Paulo in 1894, while Goeldi went on to reorganise the Pará Museum of Natural History, now known as the Museu Paraense Emílio Goeldi.

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16 www.nhm.ac.uk/research-curation/research/projects/spruce/INTRODUCTION/introduction_spruce.dsml

17 Gribbin, M. & Gribbin, J. (2008) The Flower Hunters. Oxford University Press, Oxford, UK.

18 *Ibid*.

19 www.bbk.ac.uk/ibamuseum/texts/Andermann01.htm

2.3.4 Shared and conflicting interests

The actions of these and many other foreign collectors served to expand and enrich collections in Europe (and the US), but also to build knowledge of the immense complexity of Brazilian biodiversity at a time when Brazilian institutions were only just becoming established. Increasingly, European-born scientists were involved in developing and contributing to those institutions rather than returning to Europe.

However, the chief support for science and exploration came from commerce and intense competition between empires and nations to secure markets. The study, conservation and sustainable use of biodiversity was set back by overreaching actions taken by some institutions to secure valuable resources explicitly for their own nation's economic goals in direct opposition to those of Brazil. The most famous case involved the taking of rubber seeds by Henry Wickham for Kew and Britain's Indian Office, for establishment in British colonies in Asia and to thwart Brazil's near-monopoly on rubber export. The seeds were moved quickly and without declaration of their prized identity through Brazilian customs controls, where authorities were led to believe that the shipment was of delicate specimens for Cabinets of Natural History[20].

2.4 20th century exchange

Due to many factors, the mode of exploration and collection by large European expeditions declined after the 19th century. Most 20th century and recent collecting in Brazil has been carried out by individual collectors or for research projects, generally, though not necessarily, linked to Brazilian institutions.

For much of the 20th century, until the development in the 1960s of laws regulating the collection of material and the activities of foreign scientists, and the ABS regulations developed in 2000 in response to the CBD, private law covered most specimen collection and exchange. The concepts of national sovereignty over biological resources and prior informed consent had not yet been formally developed, and collectors were not required to negotiate benefit-sharing terms. Until 1969, there were no laws for the deposit of Brazilian material in national institutions, and consequently many taxonomic types were deposited abroad. Loans from foreign collections material allowed for some access to vital historic and type material (depending on those institutions' loan policies and the perceived historic value and fragility of the specimens), but in general Brazilian scientists wishing to consult historic and type specimens needed to find the resources to visit the foreign *ex situ* collections where the specimens were deposited - an expensive impediment to taxonomic research on Brazilian biodiversity.

The 'Law for protection of fauna' no. 5.197, of 3 January 1967, regulated the permissions for Brazilian and foreign scientists to collect zoological material. Botany and microbiology did not have any laws regarding collection of such material, or its import into, or export from, Brazil.

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[20] Jackson, J. (2008) The Thief at the End of the World: Rubber, Power, and the Seeds of Empire. Penguin Books.

In 1968, the National Council for Scientific and Technological Development (CNPq) was determined by Decree 62.203 to be the responsible body for authorisation of collecting and research by foreigners. CNPq is an agency of the Ministry of Science and Technology and is still, even after the CBD, the responsible body for such authorization.

In 1969, Decree 65.057 defined CNPq as the responsible body for the authorization and supervision of scientific expeditions or any other activities involving the exploration, survey, collecting, filming or recording of scientific material, effected by foreign or national private institutions or individuals. This Decree also establishes the decision that the material collected and associated collecting data must be sorted by the parties working on the project and deposited by agreement in a national institution, and a subsample may be taken by or sent to the international collection involved. When a new taxon is described, the holotype shall be kept in Brazilian official institutions.

In 1990, Decree 98.830 revoked the Decree from 1969, and provided a more complete regulation on collection of scientific data and material by foreigners in Brazil, and with a retrospective ordinance (Portaria 55, March, 14th) the regulation of the deposit of taxonomic material was also added, with the following determination : '*The Ministry of Science and Technology, through the Brazilian institution co-participant and co-responsible, will retain the material collected for disposal in the Brazilian scientific institutions, the following items: a) holotypes or syntypes and 50% of the paratypes, animals or plants; b) all plant unicates; c) neotypes that may be chosen; d) collections, specimens and ethnographic pieces that are rare or that are not represented in national institutions; e) all of the type material fossils; f) at least 30% of the copies of each taxon is identified at any time; g) other specimens, data or materials considered of national interest should stay.'*

Information on the Brazilian regulatory response to the 1992 United Nations Convention on Biological Diversity will be provided in a separate paper.

3. Development of Brazilian collections

Biological collections in Brazil started in 6 June 1818, when the Museu Real (Royal Museum) was created by decree - with the aim of spreading knowledge and studies of natural sciences in the country. Today, the Royal Museum, the first Museum of Natural History in South America and also in Brazil, is known as the National Museum of Quinta da Boa Vista[21].

After the second half of the nineteenth century, museums and collections emerged that encompassed activities related to the natural history, and today constitute the following institutions: Goeldi Museum (1866), Museu Paranaense (1883), and Museu Paulista (1895), which became, in 1969, the Museum of Zoology, University of São Paulo. Nowadays, the most important collections in Brazil are held in those museums and also at the National Institute for

[21] Nascimento Junior, J. do & Chagas, M. De S. (2008) Panoramas dos Museus no Brasil. Iberus 1. Panoramas museológicos da Ibero América. IPHAN, Brasília

Amazonian Research (INPA), Botanical Garden in Rio de Janeiro, Butantan Institute, Fundação Instituto Oswaldo Cruz, Fundação Zoobotânica, in public and private universities and at the Brazilian Agricultural Research Corporation (Embrapa). The university-held collections are responsible for the majority of research and capacity-building on taxonomy and systematics in Brazil. Embrapa's collections are especially important for agricultural research and also seed and germplasm collections (see Section 6).

In general, for many years, collections grew in a haphazard manner, depending on the interests and preferences of successive curators. Following the CBD, more initiatives have arisen and the collections have been treated as the core of the biodiversity studies. The best examples are the Research Program in Biodiversity (PPBio)[22] and the Biota Fapesp[23]. Other initiatives have concentrated their effort towards gathering the collections into networks and releasing the biological information via the internet, such as SpeciesLink[24] and Taxonline - Network of Biological Collections in Paraná State[25].

As a result of the international requirements of the CBD and the need for a National Program on taxonomy and collections, in 2005-2006, under the coordination of the Ministry of Science, Technology and Innovation (MCTI), the project 'Guidelines and Strategies for the Modernization of Brazilian Biological Collections and Consolidation of Integrated Biodiversity Information Systems' was carried out by the Brazilian Societies of Botany, Microbiology, and Zoology and the Reference Center on Environmental Information (CRIA). 29 documents and technical notes were produced and presented in two workshops with more than 80 participants, including international specialists[26]. The specific objectives included: carry out a critical analysis of the transformations that biological collections, taxonomy, and informatics for biodiversity are undergoing; make recommendations that will lead to an increase in our capacity to answer the challenges presented associated with the use of natural resources and its impacts to biodiversity; recommend guidelines and strategies to modernize and consolidate an integrated network of biological collections associated to an infrastructure for data and information sharing. The results were published and presented at the COP-8 in Curitiba by the MCTI[27].

As a result of this initiative, in 2005 the Technical Chamber of Biological Collections (CTCB) was established under the National Biodiversity Commission (CONABIO/MMA) to be the responsible body for proposing actions regarding Brazilian collections. In 2008 the CTCB sent CONABIO a new format of the Project 'Guidelines and Strategies for the Modernization of

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22 http://ppbio.inpa.gov.br/colecoes

23 www.biota.org.br/

24 http://splink.cria.org.br

25 www.taxonline.ufpr.br

26 See www.cria.org.br/cgee/col/

27 http://www.sbzoologia.org.br/subcategoria.php?idsubcategoria1=25

Brazilian Biological Collections and Consolidation of Integrated Biodiversity Information Systems' for approval and it was published as Deliberation number 53[28].

Two important programs arose from these actions: PROTAX - Project for capacity building in taxonomy, and SiBBr - Information System on Brazilian Biodiversity, the latter intended to integrate information on biodiversity in Brazilian ecosystems and to support researchers and decision-makers in the creation and implementation of public policies. PROTAX is a joint program of the MCTI and Ministry of Education, launched in 2005. SIBBr launched in 2012 and is a program of MCTI responsible for the project in cooperation with the United Nations Program for Environment and the Global Environment Facility. It is still in its initial phase of implementation: more than 220 institutions, including universities, research centres and other scientific organisations were invited to join it.

It is still very difficult to give a precise figure for the number of collections in Brazil and consequently the number of specimens deposited. The Brazilian Network of Herbaria (RBH), established by the Botanical Society of Brazil holds data on Brazilian collections; currently 218 herbaria are recorded[29]. There is no specific formal list or catalogue for zoological collections.

The only formal list of Brazilian collections (across all areas of biodiversity) is the one of 'Instituições Fiéis Depositárias' (Trustee institutions), maintained by the Ministry of Environment[30]. Accredited by CGEN, these are the institutions authorised to conduct activities and to receive subsamples of genetic resource accessed under art. 16, § 3 of the Medida Provisora 2.186-16/2001.

This situation will change when Project SIBBr begins to gather all the collections and biodiversity information in Brazil into one system. By providing access to a national register of biodiversity, this initiative will enable Brazilian scientists and policymakers to expand and organise biodiversity research and also plan the future of the biological collections in Brazil.

4. Collections communities in Europe and Brazil

Centuries of exploration, empire-building and scientific research have produced a multitude of diverse institutions. A more recent focus on biodiversity conservation and civic engagement continues to drive the worldwide creation of new museums, gardens and zoos, the needs of a growing global population are driving the creation and expansion of agricultural and forest genebanks, while advances in science and industry are rapidly widening an array of collections of microbes, biological compounds and extracts, and increasingly, synthetic forms.

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28 Marinoni, L. & Peixoto (2010). As Coleções Biológicas Como Fonte Dinâmica e Permanente de Conhecimento Sobre a Biodiversidade. Ciência e Cultura, 62(3)

29 www.botanica.org.br/rede_herbarios.php

30 www.mma.gov.br/images/arquivo/80043/fiel%20depositario/instituicoes_fieis_depositarias_04-2013.pdf

Given that range, it is extremely difficult to provide a definitive figure for the number of *ex situ* collections in the EU and Brazil, especially in the case of private or corporate collections. Few EU ABS national focal points are able to provide comprehensive information on the extent of *ex situ* collections in their countries, although the NP and the discussions around the draft European Regulation on ABS are prompting new assessments[31]. A very rough indication of the number of natural history museums, herbaria, university collections and public research institutes holding preserved collections can be obtained from the Biodiversity Collections Index[32] (BCI), which draws from the Index Herbariorum, the Insect and Spider Collections of the World and Biorepositories.org. Larger institutions may hold very diverse types of collections beyond those currently recorded in BCI[33].

Many, though not all, public and university *ex situ* collections are members of global, regional and/or national networks, whose websites and databases provide some information as to numbers of individual collections, and such networks are also integral to the successful dissemination of relevant sectoral information on ABS, so this section will identify and focus on those networks.

4.1 Botanic gardens

There are over 3000 registered botanical living collections globally, including botanic gardens, arboreta, research institutes, and zoo gardens[34]. Around 800 of these collections are in the EU, and 40 in Brazil. Botanic garden governance systems vary widely: there are very many small municipal and private collections, although the majority of the prominent historical and international collections are held in national or state institutions, or associated with universities. Networks often include arboreta, zoo gardens and large estates. Many gardens also have associated herbarium collections – and herbaria are also maintained by a huge range of societies, universities and conservation agencies, as well as natural history museums. An increasing number of gardens are employing other *ex situ* conservation techniques, such as seed banks, field genebanks, and tissue banks for micropropagation. BGCI GardenSearch data

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31 Pers. comm.; attempts to contact all EU ABS national focal points were made during the preparation of this paper.

32 The BCI was accessed via www.biocol.org during this paper's preparation (April 2013) but is in transition to a full merger with Biorepositories.org. BCI both overestimates the number of collections institutions (a single institution may contain several collections listed under separate acronyms), and underestimates the number (e.g. in the UK, where collections other than herbaria are not included).

33 For example, in addition to its plant and fungal herbaria and economic botany collections, Kew holds living collections, plant tissue cultures, a seed bank and a DNA bank.

34 BGCI GardenSearch database, www.bgci.org/garden_search.php

indicate that, in EU countries, 98 botanical institutions hold seed banks[35] and 33 have plant tissue culture facilities; a few gardens also maintain DNA banks (see 5.1).

There are two major international botanic garden networks, the International Association of Botanic Gardens (IABG)[36], and Botanic Gardens Conservation International (BGCI)[37]. BGCI is a global membership organisation that supports the delivery of conservation objectives by botanic gardens and is a key nexus for botanical collections. There are 203 BGCI member institutions in the EU and 5 in Brazil[38].
Most EU countries have established garden networks. Convened by BGCI, the European Botanic Gardens Consortium[39] links national networks and promotes initiatives such as the International Plant Exchange Network. In Brazil, the national network is the Rede Brasileira de Jardins Botânicos (RBJB).

The key European botanic gardens with herbaria that hold important Brazilian historical material are largely also part of, or linked to, institutions in the Consortium for European Taxonomic Facilities (CETAF; see 4.2 and Table 2), although others can be identified via their participation in the Latin American Plants Initiative, now part of the Global Plants Initiative. Although some institutions acquire material directly from fieldwork projects and active partnerships with provider countries, traditional seed exchange between botanic gardens is the principal source of material for most small European gardens. An active European horticultural trade has also served to disseminate living plants widely. Table 1 shows the distribution of botanic garden collections in the EU.

4.2 Natural history museums

A precise figure for the number of natural history museums is difficult to obtain, as there is considerable overlap with university research collections and museums with wider mandates. There is no overarching association or network for the majority of European natural history museums, although many projects link them. The Consortium of European Taxonomic Facilities (CETAF) [40] is a network of scientific institutions that promotes training, research and understanding of systematic biology and palaeobiology, and access to its members' information and expertise. Its 33 members from 18 countries together hold very substantial

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35 Many have a focus on native plant species; the ENSCONET (European Native Seed Conservation Network) Consortium coordinates native seed plant conservation in Europe http://ensconet.maich.gr/

36 There is currently no website for IABG with information on membership numbers (Apr-Jun 2013)

37 www.bgci.org

38 Although 17 Brazilian institutions are International Agenda registrants

39 www.botanicgardens.eu

40 www.cetaf.org

collections and include almost all of the major repositories for historic Brazilian material[41], and CETAF members are committed to cooperate on objectives that include the digitisation of collections, development of information services, training for systematists and improvement of access to collections for visiting researchers. CETAF members are also engaged with ABS issues and discussions towards European regulations.

The founding membership of Scientific Collections International (SCICOLL), a new global interdisciplinary coordinating mechanism, includes a small subset of the major CETAF institutions[42]. Table 2 lists current CETAF and SCICOLL members in the EU (as well as other EU collections that have contributed data from Brazilian specimens to the Global Plants Initiative).

4.3 University research collections and research institutes

Many museums and botanic gardens are associated with universities, but university departments may also maintain their own living and/or preserved collections of plants, animals, fungi and microbes. Short-term research specimens may also be accessioned into larger museum, botanic garden or microbial collections after their primary use, for permanent storage. Boundaries are hence difficult to draw, but university collections and research institutes are considered together as a collections community in this paper, following the approach of two UK reports on ABS[43] [44]. The 2005 review of UK access and benefit-sharing stakeholders indicated that within the publicly-funded sector, research institutes and universities are collectively the most prominent users of genetic resources, carry out both academic research and commercially-oriented research, and often act as intermediaries for industry by collecting material. A 2006 Belgian federal ABS survey found that a division between public and private sector stakeholders was not very meaningful, but noted that the research sector involves many private collections, acquisition of material from countries of origin and ex-situ sources, and exchange between research organisations[45].

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41 The V.L. Komarov Botanical Institute in St. Petersburg Russia is the largest exception.

42 SCICOLL's 10 founding members include 6 EU institutions (see Table 3) and 1 Brazilian institution (Fundação Oswaldo Cruz), although many other institutions and countries are represented on the steering committee. See www.scicoll.org and http://scicoll.org/sites/default/files/Sci_Coll_Brochure.pdf.

43 Defra (2012) UK Implementation of the NP: Assessment of the Affected Sectors. Final Report to Defra from ICF GHK. UK Department for Environment Food and Rural Affairs. http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=17827

44 Latorre, F. (2005) Review of the Experience of Implementation by UK Stakeholders of Access and Benefit sharing Arrangements under the Convention on Biological Diversity. UK Department for Environment, Food and Rural Affairs.

45 Frison, C. & Dedeurwaerdere, T. (2006) Belgian Federal Survey: Public infrastructure and regulations on access to genetic resources and the sharing of benefits arising out of their utilisation for innovation in life sciences research – access to, conservation and use of biological diversity in the

The BCI listed 290 collections (preserved botanical/zoological/mycological specimens) linked to universities in EU countries (likely an underestimate). No single network connects the many activities of university collections and research institutes across Europe.

4.4 Culture collections

Microbes of one kind or another have been used for millennia, but culture collections were first established in the late 19th century. The term 'culture collections' can refer to collections of bacteria, viruses, microscopic fungi and algae, and other microorganisms, as well as animal and plant cell lines. The world's many collections are used for a vast range of purposes and an extensive array of sectors, including health services, environmental bioremediation, biological control, and fermentation industries. Types of collection include research collections, service collections, patent collections (collections established as International Deposit Authorities for patent cultures) and safe deposits (where a culture can be deposited by a laboratory to be maintained under conditions of secrecy), as well as public deposits, and one collection can fulfill several of these roles[46].

Culture collections have high ABS relevance, as the major trend in natural product research is towards microorganisms for a number of reasons, including that: they are easier to source (they can be grown in culture rather than collected from the wild or cultivated, as the case for plants); their genomes can be more easily sequenced; even 'backyard' species can be profitably mined for secondary metabolites (avoiding many ABS issues); and their DNA can be extracted from environmental samples via metagenomic technology. Compounds produced from the complex interactions of symbiotic microbial species with other organisms are also of high interest[47].

The parent organisations of culture collections may be public or private, governments, universities, or industries, but as a sector there is relatively good communication. Many microbial collections are members of The World Federation for Culture Collections (WFCC). The WFCC is concerned with the collection, authentication, maintenance and distribution of microbial and cell line collections, and it helps to support, link and foster information exchange between collections and users[48]. The WFCC World Data Centre for Microorganisms (WDCM)

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general interest. Federal Public Service of Public Health, the Safety of the Food Chain and the Environment – Directorate General of the Environment, Belgium.

[46] Dedeurwaerdere, T., Iglesias, M., Weiland, S. & Halewood, M. (2009) The use and exchange of Microbial Genetic Resources for food and agriculture. Commission on Genetic Resources for Food and Agriculture Background Study Paper no. 46, ftp://ftp.fao.org/docrep/fao/meeting/017/ak566e.pdf

[47] Secretariat of the Convention on Biological Diversity (2008) Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors. Technical Series No. 38. Montreal. See also www.cbd.int/abs/policy-brief/default.shtml/

[48] www.wfcc.info/about

compiles and provides online access to data on culture collections world-wide; its CCINFO database, a world directory of all registered collections, lists 162 culture collections in EU countries and 65 in Brazil[49].

In Europe, the European Culture Collections' Organisation (ECCO, established in 1982) promotes regional collaboration. Currently there are 61 members from 22 European countries (52 from 19 EU countries)[50]. The Microbial Resources Research Infrastructure (MIRRI) is a new pan-European research infrastructure to provide microorganisms and facilitate access to high quality microorganisms (and derivatives and associated data) for research development and application. The project currently includes 16 European public microbial culture collections and resource centres[51], as well as collaborating parties from 18 other ECCO members. The European Consortium of Microbial Resources Centres (EMbaRC) is another network (EU-funded, involving 10 institutions), aiming to improve, coordinate and validate microbial resource centre delivery to researchers (European and international) from public and private sectors through standardised practical approaches to compliance with international standards, national policies and biodiversity-related national legislation.[52]

The Brazilian Ministry of Science, Technology and Innovation (MCTI)-funded capacity building program for biological collections infrastructure is implementing quality management procedures in selected microbial service collections and consolidating a distributed network of centres. The Reference Center on Environmental Information (CRIA) is developing the network information system (SICol), with the adoption of internationally agreed standards and protocols to allow dynamic access to the Brazilian Virtual Catalogue of Biological Materials[53].

The Global Biological Resource Centre Network (GBRCN)[54] is a demonstration project that aims to provide an infrastructure to support more collaborative globalised research and development, with high quality biological material and related data, working to best practice and commonly agreed procedures and principles. There are currently 23 global partners, 9 in the EU and one in Brazil (CRIA). Table 3 lists the EU members of ECCO, MIRRI, EMbaRC and GBRCN.

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49 www.wfcc.info/ccinfo

50 www.eccosite.org; member collections provide a professional public service on demand and without restriction, accept cultures for deposit, provide catalogues and are housed in countries with microbiological societies affiliated to the Federation of the European Microbiological Societies and registered with the WFCC.

51 www.mirri.org

52 www.embarc.eu

53 www.gbrcn.org

54 *Ibid.* and www.gbrcn.org/fileadmin/gbrcn/media/downloads/GBRCN_Final_Report/GBRCN-FinalReport2012.pdf. Partners include Centro de Referência em Informação Ambiental (CRIA), Campinas.

4.5 Zoos and aquaria

Zoos and aquaria are traditionally involved in maintaining living wild species for public display, and increasingly for conservation, education and research. Although animals were originally commonly collected from the wild, and often acquired via wildlife traders, supply is now normally from managed breeding programmes and exchange between collections, often as part of international conservation programmes[55]. The genetic resources in animals in zoos and aquaria are not typically 'utilized' for research and development in the sense of the NP, and this sector was largely absent from the ABS negotiations leading to the Protocol. However a few zoos (largely outside Europe) do hold important cryo-preserved collections of embryos, semen, oocytes, blood and tissue samples, cell cultures and DNA (see 5.1), for conservation and research purposes.

The major global network for zoos and aquaria is the World Association of Zoos and Aquaria (WAZA), which helps to link regional and national associations. The European Association of Zoos and Aquariums (EAZA, a WAZA member) represents 345 institutions (including national associations) in 41 countries, including 299 institutions in EU countries[56] (an underestimate of zoo numbers, since national associations also include institutions that are not EAZA members). The Asociación Latinoamericana de Parques Zoológicos y Acuarios (ALPZA, also a WAZA member) has 4 Brazilian members[57].

5. Agricultural collections

Global and national food security is a high priority for governments, and consequently they have relatively good knowledge of their public collections holding plant, animal, aquatic, forest, invertebrate and microbial genetic resources, for food and agriculture, and sectoral cooperation is strong.

European countries hold a vast range of *ex situ* collections. European national genebanks hold approximately one quarter of the world's *ex situ* plant germplasm accessions, and are also involved in the conservation of crop wild relative diversity. The majority of recent acquisitions of germplasm by European countries was collected nationally or from nearby countries. Most European states have long-, medium- and short-term seed storage facilities as well as field

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55 *Ibid* 44 (Latorre 2005)

56 www.eaza.net

57 www.alpza.com/index.php

genebanks[58]. The Nordic countries (Denmark, Finland, Iceland, Sweden and Norway) coordinate their efforts via NordGen, the Nordic Genetic Resource Centre[59].

The European Cooperative Programme for Plant Genetic Resources (ECPGR) is a collaborative programme involving national institutes in most European countries (including all EU countries but Luxembourg), contributing to national, sub-regional and regional programmes in Europe. ECPGR is coordinated by a secretariat hosted by Bioversity International and structured into Crop and Thematic networks; national coordinators link back to each country's national institutes. ECPGR also offers web access to crop and multi-crop databases[60]. The EURISCO web catalogue receives data from the national inventories[61] and provides access to all public *ex situ* plant genetic resources information in Europe. Countries vary widely in the number of accessions that they hold[62] and the extent to which the focus is on native plant genetic resources or resources from other countries.

The European Forest Genetic Resources Programme (EUFORGEN) is a platform for European cooperation to promote conservation and sustainable use of forest genetic resources; Bioversity International also hosts its secretariat[63]. Focus in EU countries is on agriculturally and horticulturally important species and conservation of native forest species – resources that can be maintained in outdoor gene reserve forests in European climates, so of rather less relevance to Brazil than many other types of *ex situ* collection.

The regional platform to support conservation and sustainable use of animal genetic resources for food and agriculture is the European Regional Focal Point for Animal Genetic Resources[64]. However, unlike plant genetic resources, few livestock animal genetic resources are held in the public domain, transfer tends to take place using private contracts between companies or individuals, and the transfer of genetic material from the developed 'North' to the developing

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58 Commission on Genetic Resources for Food and Agriculture (2010) The Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture. Food and Agriculture Organization of the United Nations, Rome. http://www.fao.org/docrep/013/i1500e/i1500e.pdf

59 www.nordgen.org

60 including those maintained at the National Botanic Garden of Belgium and the Millennium Seed Bank at Kew; www.ecpgr.cgiar.org

61 http://eurisco.ecpgr.org/about/the_network/online_national_inventories.html

62 Germany reports 155,000 accessions of more than 3000 species, held in 11 institutes, while Slovenia's 3 institutes hold 3100 accessions of 40 species

63 www.euforgen.org

64 www.rfp-europe.org

'South' between regions of the North, and South to South is currently much more significant than transfer from South to North[65].

In Brazil, the national organisation for pure and applied agricultural research is Embrapa[66], the Brazilian Agricultural Research Corporation, affiliated with the Ministry of Agriculture. Embrapa's mission is to provide feasible solutions for the sustainable development of Brazilian agribusiness through knowledge and technology generation and transfer. Embrapa contains many different research centres, including the Genetic Resources and Biotechnology Centre.

Until 2008, Brazil's National Network of Genetic Resources (RENARGEN), created in 1984, helped to coordinate the activities of Embrapa research centres, state agricultural research institutions and universities to support more efficiently their research on and conservation of food and agriculture. RENARGEN was made up of eleven research projects. RENARGEN's major activities concern: (a) enrichment: germplasm collection, introduction, exchange and quarantine; (b) conservation *in situ* (either in nature or on-farm) and *ex situ* (*in vitro* plant cultures; microbial cultures; cryopreservation of seed, semen, embryos and oocytes); (c) phenotypic and genetic characterization; and (d) information exchange. The network maintained a Curatorship System and an Information System called Sibrargen (Brazilian Information System for Genetic Resources)[67].

In early 2009, Brazil launched an innovative structure for the conservation and sustainable use of its genetic resources, known as the Brazilian Platform of Genetic Resources, under the leadership of the National Research Centre for Genetic Resources and Biotechnology (Cenargen), one of the 47 Research Centres of the Brazilian Agricultural Research Corporation (Embrapa). This Platform replaced RENARGEN.

This Platform comprises four networks. The first one is responsible for the utilization and conservation of plant genetic resources; the second one for animal genetic resources, and the third for genetic resources of microorganisms. The fourth one is a horizontal network, and comprises six research projects that are integrated with the other three networks. Among these six projects, the first one deals with the management of the Platform as a whole, while the others are research projects: Germplasm Curatorship System; Documentation of Genetic Resources; Germplasm Exchange; Germplasm Quarantine; and Implementation of ABS.

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65 Commission on Genetic Resources for Food and Agriculture (2009) The use and exchange of Animal Genetic Resources for food and agriculture. Commission on Genetic Resources for Food and Agriculture Background Study Paper no. 43, ftp://ftp.fao.org/docrep/fao/meeting/017/ak222e.pdf

66 www.embrapa.br

67 Mariante, A.S., Albuquerque, M.S.M., Egito, A.A., McManus, C., Lopes, M.A. & Paiva, S.R. (2009) Present status of conservation of livestock genetic resources in Brazil. *Livestock Science* 120:204-212; http://plataformarg.cenargen.embrapa.br/pnrg/rede-animal/publicacoes/Artigo%20Presente%20Status%20of%20Conservation-2008.pdf

The Plant Network comprises one Management project, with 10 projects that deal with the conservation, characterization and utilization of the different products (Cereals, Oily Crops, Vegetables, Forages, Fruits, Medicinal, Ornamental, Forests and Palm Trees, Industrial Crops, and Roots and Tubers), as well as three cross-cutting projects (Base Collection, Germplasm Collection, and *In Situ* On Farm Conservation). Currently, the base collection has almost 110,000 accessions, making it the 7th largest world collection.

The Animal Network comprises six research projects: Management of the Animal Network; *Ex situ* Conservation; *In situ* conservation of Large Livestock Species; *In situ* conservation of Small Livestock Species; Genetic Characterization; and Conservation of Wildlife with Economic Potential. This network is composed of Conservation Nuclei of locally adapted livestock breeds of eight different species (cattle, horses, buffaloes, sheep, goats, pigs, donkeys and chickens), that are distributed all over the country. The Animal Gene Bank stores over 65,000 semen samples and about 500 embryos, as well as 12,000 DNA samples.

The Microorganisms Network comprises five research projects: Management of the Network; Multifunctional Microorganisms; Biological Control Agents; Phytopathogenic Microorganisms; and Microorganisms of Importance to the Agro-industry and to Animal Production. This network is formed by 34 collections with an approximate total of 45,000 accessions.

The Brazilian Genetic Resources Platform, as a whole, includes 31 research projects and 170 action plans, being developed at 35 Embrapa Research Centres as well as in 70 partner institutions, by a total of 520 researchers. Such a structure shows the high priority that the country gives to the conservation and sustainable use of its genetic resources.

5. Collections of derivatives, extracts, and genetic information: DNA and tissue banks, compound libraries and genetic sequence databases

5.1. DNA and tissue banks

Storage in DNA banks allows for DNA to be readily available to researchers for the characterisation and utilization of biodiversity. DNA banks are not yet commonplace in gardens, zoos and agricultural genebanks due to the expensive requirements for equipment, supplies and trained personnel[68]. However their numbers are growing worldwide, especially with the development of the International Barcode of Life (IBOL) project[69], which necessitates the extraction and isolation of DNA. A 2004 global survey of the Plant Genetic Resources

[68] Although these costs vary, depending on whether DNA is isolated and stored in aliquots in -80C freezers, or more simply stored as plant samples in silica gel at -20C, as at Missouri Botanical Garden

[69] www.ibol.org. Brazil participates in IBOL via the BrBOL Project (Brazilian Barcode of Life), a Brazilian consortium of almost one hundred institutions: see www.brbol.org.

community found that only 20% of 243 respondents stored DNA, and 98% of those institutions stored DNA in order to ensure its availability for research activities, rather than as a gene/genome conservation measure (29%) or duplicate safety measure (8%)[70].

New networks for tissue and DNA banks are being created to coordinate efforts and increase their availability, representing a large range of organisation types and research foci. The International Society for Biological and Environmental Repositories (ISBER)[71] aims to address harmonisation of scientific, technical, legal and ethical issues relevant to repositories of biological and environmental specimens. Its European regional chapter, the European, Middle Eastern & African Society for Biopreservation and Biobanking (ESBB), currently has 37 members, 33 in the EU[72]. ESBB members are chiefly health-care related institutions, although the intended scope of ISBER and ESBB includes environmental specimen and museum biobanks. There is currently no regional ISBER chapter for South America.

Closer to the focus of this paper and the workshop, several CETAF institutions hold important DNA banks, such as BGBM, Kew and the Royal Botanic Garden Edinburgh[73]. Five Polish institutions have established the National Plant, Fungi and Animal DNA Bank[74]. BGBM coordinates the DNA Bank Network, which currently includes the DNA banks of 5 German collections, the Austrian Institute of Technology and the New York Botanical Garden, representing all kingdoms of life. The network can accept the deposit of samples after project completion or data publication, and enables other researchers to use material remaining from previous studies[75].

In Brazil, the Rio de Janeiro Botanical Garden holds a DNA Bank of Brazilian Flora Species, storing DNA from the garden's collections, special taxonomic groups, flagship and endangered species, and species from endangered ecosystems (especially Atlantic rainforest species)[76]. In the field of food and agriculture, Embrapa's Laboratory of Animal Genetics (LGA) maintains a

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70 Andersson, M.S., Fuquen, E.M. & de Vicente, M.C. (2006) State of the art of DNA storage: results of a worldwide survey. In: de Vicente, M.C. & Andersson, M.S. (eds) DNA banks – providing novel options for genebanks? Topical Reviews in Agricultural Biodiversity. International Plant Genetic Resources Institute, Rome, Italy. http://cropgenebank.sgrp.cgiar.org/images/file/learning_space/dna_banks.pdf

71 www.isber.org

72 www.esbb.org/biobanks.html

73 www.bgbm.org/bgbm/research/dna/; http://apps.kew.org/dnabank/homepage.html; www.rbge.org.uk/science/scientific-and-technical-services/molecular-laboratory-facilities

74 www.bankdna.pl

75 http://wiki.bgbm.org/dnabankwiki; see also its non-exhaustive list of other non-human DNA banks

76 http://www.jbrj.gov.br/pesquisa/div_molecular/bancodna/sobre_ing.htm

DNA bank of native breeds of major domestic animal species in the country. Many of the breeds sampled are at risk of extinction and have been preserved in Cores of Conservation under RENARGEN[77]. Several Brazilian universities also hold important and diverse DNA and tissue collections[78], principally the University of São Paulo, the Federal University of Amazonas, São Paulo State University (UNESP), University of Campinas (UNICAMP) and the Federal University of Espírito Santo. EMBRAPA amongst its other collections maintains a DNA bank for Pantanal fish diversity.

The Global Genome Biodiversity Network (GGBN) is new network of 'well-managed cryopreserved collections of genomic tissue samples from across the Tree of Life.' It currently involves over 20 collaborators including the DNA Bank Network, the Natural History Museum of Denmark, and the Natural History Museum, as well as institutions in the US, Colombia, China, Australia and South Africa[79].

5.2. Extracts and compounds

A wide range of organisations use and store extracts and isolated compounds derived from genetic resources, though these 'collections' are predominantly are held in the private sector, and are not the focus of this *ex situ* collections workshop. They include collections of extracts used in many products (such as cosmetics, medicinal products, health foods and other health products), and compound libraries of stored chemicals for use in high-throughput screening for drug discovery.

Raw material for the natural personal care and cosmetics sector is generally supplied via trade networks (with varying levels of ABS-awareness, using wild-harvested or cultivated sources), and various companies then develop and test the extracts and products. In some cases the supply chain is very short, but more often larger companies use intermediaries, such as for-profit brokers and research institutions. The lists of ingredients used and supplied by this sector are most often derived from already well-known species (on health authorities' approved lists), but the industry is characterised by its secrecy towards its ingredients and sources[80]. The botanical medicines sector can be similarly summarised. European-based companies have been very dominant in the botanical supply industry, and within Europe the trade is dominated by a few wholesalers[81].

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77 http://plataformarg.cenargen.embrapa.br

78 See CGEN list of Instituições Fiéis Depositárias (Trustee institutions): www.mma.gov.br/images/arquivo/80043/fiel%20depositario/instituicoes_fieis_depositarias_04-2013.pdf

79 http://ggbn.org/

80 ten Kate, K. & Laird, S.A. (1999) The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing. Earthscan, UK.

81 *Ibid*.

The Union for Ethical BioTrade (UEBT)[82] is a relatively new (2007) association that promotes the 'Sourcing with Respect' of ingredients that come from biodiversity and has members in the food, cosmetics and pharmaceutical sectors. A significant proportion of UEBT's 10 provisional, 31 trading and 18 affiliate members globally to date are Brazilian companies and organisations. Few European companies are involved at this stage; of those, most are from France.

Pharmaceutical companies have greatly reduced their reliance on in-house collections of natural products and extracts for their research due to the development of mass-produced compound libraries produced via combinatorial chemistry and the manipulation of biosynthetic pathways in microbes using combinatorial biosynthetic techniques, as well as the increased legal uncertainty related to ABS. Most pharmaceutical companies closed their natural products research programmes. However the industry is looking again to natural products, using genome mining (often in microbes), and solving some supply issues by using advanced synthetic chemistry technology – and effectively outsourcing the discovery of hits and leads to universities, public institutes, and smaller discovery companies[83].

Many compound libraries are held by European pharmaceutical companies represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA)[84], which has participated actively in European ABS discussions and the NP negotiations. EFPIA members include 33 national pharmaceutical industry associations (in all EU countries) and 40 leading research-based pharmaceutical companies. Also in Europe, EuropaBio (the European Association for Bioindustries) around 1800 small and medium sized biotech enterprises across Europe (56 corporate and 14 associate members and 19 national biotechnology associations)[85].

At the global network level, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)[86] has 13 European pharmaceutical association members and 12 member companies. There are no Brazilian IFPMA member companies, but the Brazilian association member, INTERFARMA (the Brazilian Research-based Pharmaceutical Manufacturers Association)[87] currently has 47 member companies, many of which are Brazilian subsidiaries of Europe-based multinationals.

5.3. Genetic sequence databases

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82 www.ethicalbiotrade.org

83 Secretariat of the Convention on Biological Diversity (2008)

84 www.efpia.eu

85 www.europabio.org/members

86 www.ifpma.org

87 www.interfarma.br

Genetic (and increasingly, genomic) information is now a central tool for identification, taxonomy, conservation, environmental monitoring and many other areas of biodiversity research, and is becoming integral to the activities of all the *ex situ* collections communities detailed above. Permanent storage of such information is important, and required by publishers of genetic research, and patent authorities.

The many partners and projects involved in the IBOL initiative are generating DNA barcode data, which can then be submitted to the Barcode of Life Database (BOLD)[88]. The BOLD platform is a bioinformatics workbench aiding the acquisition, storage, analysis and publication of DNA barcode records. BOLD is not itself a primary repository: it makes block transfers to GenBank using a high-throughput database-to-database protocol[89].

GenBank (under the US National Institutes of Health) is one of the three giant genetic sequence databases for long-term storage of genetic information, as well as the DNA DataBank of Japan (DDBJ), or the European Molecular Biology Laboratory (EMBL). All three cooperate via the International Nucleotide Sequence Database Collaboration (INSDC)[90] and exchange data on a daily basis, although they use slightly different data submission and retrieval tools. All three have agreed to the data standards of the Consortium for the Barcode of Life (CBOL) for barcode records[91].

The European Bioinformatics Institute (EBI) is part of EMBL, and maintains the world's most comprehensive range of freely available molecular databases; it also conducts basic research, and trains scientists in academia and industry on bioinformatics. The databases and tools span the full range of molecular biology, covering DNA and RNA sequences, protein sequences, gene expression, chemical biology and metabolomics, and full systems[92].

7. Collections and the Nagoya Protocol

Many *ex situ* collections from the diverse communities described above have gradually developed or are developing responses to the CBD's core provisions on ABS – particularly the needs for prior informed consent, mutually agreed terms and benefit-sharing. However the NP presents new challenges that current policies and systems may not yet address. The NP establishes a framework (more detailed than that of the CBD) for actions by countries, and also a clearing house that will share ABS information internationally, including information on

88 www.boldsystems.org

89 www.barcoding.si.edu/CBOLDatabasesBOLD.htm

90 www.insdc.org

91 www.barcoding.si.edu/PDF/DWG_data_standards-Final.pdf

92 www.ebi.ac.uk

permits. This section identifies some of the new terms and provisions that have particular relevance for collections.

It is still too early to know how individual countries' Nagoya implementation measures will affect collection management, but European implementation will certainly be shaped by the draft European regulation on ABS, and Brazilian implementation will be shaped by Brazilian legislation. The European draft proposes measures to address user compliance, identifies collections as potential intermediaries and assigns to them key responsibilities to undertake due diligence.

This paper will then survey the standards, codes and tools that are currently used by different collections sectors, to provide a background for discussion of their suitability or otherwise to meet the requirements of the NP and enable stronger cooperation between European and Brazilian collections.

7.1 New Nagoya implications for collections

7.1.1 Utilisation

The NP to a certain extent uncouples 'access' from 'benefit-sharing' and focuses on benefit-sharing arising from the 'utilisation' of genetic resources, which also includes the benefits from derivatives (Article 2). Collections will need to examine the Protocol definition of 'utilisation' and decide how it may affect their policies and practices. Taxonomy – at least the growing field of molecular systematics – is included, as a form of research: the investigation and study of the genetic and/or biochemical composition of genetic resources in order to establish facts and reach new conclusions[93], while some other uses such as conservation, and propagation and cultivation in the form received, which do not necessarily involve research (or development) on the *genetic* aspect of genetic resources, are somewhat less clearly covered by the 'utilization' concept.

7.1.2 Temporal scope and other ABS instruments

Collections must already consider how they will handle material acquired pre- and post-CBD, but will also need to consider how to handle material collected post-CBD but before the entry into force of the NP, as well as, potentially, the date of ratification of the Protocol by the particular country providing the resource. In the case of resources on Annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture held in public collections in ITPGRFA Parties and requested for food- and agriculture-related purposes, the

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[93] See Greiber, T., Peña Moreno, S., Åhrén, M, Nieto Carrasco, J., Kamau, E.C., Cabrera, J., Oliva, M.J., & Perron-Welch, F., in cooperation with Ali, N. & Williams, C. (2012) An Explanatory Guide to the NP on Access and Benefit-sharing. IUCN, Gland, Switzerland.

date of acquisition and access are irrelevant – but collections managers will still have to be able to navigate the patchwork of ABS regulations for the various potential situations.

7.1.3 Non-commercial research and changes in intent

Countries are expected to create conditions to promote and encourage research related to conservation and sustainable use, and may use simplified measures on access non-commercial research purposes, while also addressing possible changes in intent (Article 8(a)). To some extent 'the need to address a change of intent' is simply a re-stating of the general CBD/NP requirement for prior informed consent (PIC) and mutually agreed terms (MAT), but where simplified measures are developed, collections acquiring material under these terms will need to record the limits of the terms and remain alert to any changes in researchers' and subsequent users' interests.

7.1.4 Monitoring, certificates and checkpoints

The Protocol introduces specific requirements to monitor the utilisation of genetic resources (Article 17), and these provisions have high relevance to collections. Documentation of basic scientific information is neither new nor difficult. Scientific collections almost always necessarily maintain information relating to original collection (such as collector's name, date and location). However, not all have developed fail-safe, user-friendly means to keep track of evidence of PIC and MAT and to pass this information to other users – let alone means to track individual uses of specimens. As more specimens are databased and digitised, and electronic means of annotating specimens are developed[94], the capacity to track their use and movements (including of samples and extracts) will increase, but currently there is a very wide range of practices, and despite intensive efforts in the last decade, few of even the relatively well-resourced major collections are well-digitised at the specimen unit level.

Institutions currently use a huge range of different database systems for collections management, some developed in-house, some by third parties. Database designers across the board will need to work with collections personnel to create interfaces that will allow the easier input of (and user access to) links to relevant CBD-related data and documents, such as internationally recognised certificates of compliance, and agreements that set out mutually agreed terms.

Certificates of compliance, if well- implemented, may prove helpful for collections: a document that pulls together all of the ABS-relevant information on PIC and MAT and is assigned a unique identifier that can be easily added to labels and database fields will be much simpler to keep linked to specimens as they are used and transferred than a mass of separate documents.

The NP also requires Parties to designate checkpoints to receive and provide information on prior informed consent, source, mutually agreed terms and/or utilization. Some countries may

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94 For example via the FilteredPush network project, http://wiki.filteredpush.org/wiki/

decide to involve *ex situ* collections as checkpoints, which in most institutions would require the development and maintenance of new mechanisms to cope with high levels of information exchange.

7.1.5 Associated traditional knowledge

Traditional knowledge associated with genetic resources is thoroughly knit into the substance of the NP (Articles 5, 7, 11, 12, 16). Many *ex situ* collections do hold specimens that are accompanied with some information relating to their traditional use, either on specimen labels, or in specialised ethnobotanical collections. However, very few *ex situ* collections have policies or practices that address how TK is handled, shared or used, and a huge amount of capacity-building is needed for users. It is to be hoped that NP Parties will work actively to support indigenous and local communities to develop community protocols, and are also supportive of efforts by user and provider communities to develop model contractual clauses and practical advice that can assist collections to handle and curate this information appropriately.

7.1.6 Codes of conduct and model contractual clauses

On a very positive note, the NP recognises that different sectors access, use and supply genetic resources in very different ways, and Parties should encourage sectors to themselves develop appropriate model contractual clauses and voluntary codes/guidelines/best practices to meet the requirements of the Protocol and their own practical needs and constraints (Articles 19 and 20). Section 6.3 explores the range of ABS codes and models that have so far been developed and/or used by European collections.

7.1.7. Cooperation, technology transfer and capacity-building

The CBD contains provisions on technology transfer, exchange of information and technical and scientific cooperation (CBD Articles 16-18), many of which are highly relevant to *ex situ* collections. The NP reiterates and re-emphasises the importance of such cooperation: Article 23 emphasises the importance of collaboration and cooperation in technical and scientific research, and access to technology by, and transfer of technology to, developing countries, for the development of a viable scientific base for the attainment of CBD and NP objectives.

The NP also identifies key areas for ABS-related capacity-building (Article 22) that countries may need to address, again with relevance to *ex situ* collections, such as capacity to negotiate MAT and capacity to develop endogenous research capabilities, as well as numerous possible measures such as bioprospecting, associated research and taxonomic studies; technology transfer and capacity to make technology transfer sustainable; and enhancement of the contribution of ABS activities to conservation and sustainable use. The NP encourages the sharing of information on capacity-building initiatives via the ABS Clearing-House to promote synergy and coordination.

7.2 Draft European Regulation on ABS and its implications for collections

Exchange between collections in the European Union and those in other countries is currently affected by national and regional regulations relating to endangered species and trade (e.g. CITES regulations), animal and plant health, and transportation of dangerous goods, but European governments have not yet developed specialised ABS regulations relating to use and exchange of genetic resources in collections. A proposal for a 'Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union' is presently being discussed by EU member states and the Council, with the aim of agreeing commitment in time for the next CBD COP in 2014. The current draft Regulation puts a strong emphasis on the role of *ex situ* collections, proposing a system of 'Union Trusted Collections'[95] .

The European participants of this workshop are aware of the substance of discussions and the possible implications for their institutions. In brief, a register of such trusted collections will be kept by the European Commission, and to be considered as a trusted collection, a collection will need to (a) apply standardised procedures for exchange; (b) only supply material and related information with documents providing evidence that they were accessed legally, with PIC and MAT as appropriate; (c) keep records of all samples and information supplied to third parties; (d) use unique identifiers for samples supplied; and (e) use appropriate tracking and monitoring tools for exchanging samples with other collections. When users acquire material from 'trusted collections', they will be considered to have exercised due diligence with respect to ABS. The draft Regulation's preamble notes that collecting of genetic resources in the wild is mostly undertaken for non-commercial purposes, and that in the majority of cases and across user sectors, access to newly-collected resources is gained via intermediaries, collections or other agents. In effect, the draft Regulation positions EU collections firmly between providers and users. Consequently *ex situ* collections in all sectors are in the process of determining whether, and how, they will need to change their practices to account for a possible increase in demand from commercially-orientated users, and whether the costs (of implementing comprehensive monitoring mechanisms, and of negotiating with providers terms that might need to extend to later commercialisation) involved in being a 'trusted collection' outweigh the benefits.

Once the Regulation is adopted, it will have effect in member states, which will each then need to decide on what changes are needed at the national level. However, the draft Regulation provides no prescription as to exactly how collections should implement ABS, as long as those that are registered as 'trusted' can fulfill the legal and tracking requirements, and (like the NP) suggests complementary measures, such as the development of sectoral codes of conduct, model contractual clauses, guidelines and best practices. Hence ABS measures will likely continue to be developed and implemented on a voluntary sector-specific basis.

7.3 ABS measures developed by collections communities

[95] http://ec.europa.eu/environment/biodiversity/international/abs/index_en.htm

Recognising that they need to understand and comply with the CBD in order to continue and build their international activities, *ex situ* collections sectors have developed an extensive array of voluntary responses, ranging from awareness-raising and guidance tools, to institutional policies and policy frameworks, to model agreements, to multilateral systems with standard documentation. Sectors and collections differ in the extent to which they maintain documentation that allows material to be tracked (followed up from the end user back to the provider) or traced (where every single movement of a resource is registered), in part depending on the level of perceived risk of misappropriation of the specific material, and the resources available to invest in tracking systems and personnel.

7.3.1 Botanic gardens

The botanic gardens sector was one of the first to recognise the importance of developing ABS policies and implementation measures, and European gardens have led these efforts. A four-year pilot project coordinated by Kew and funded by the UK Department for International Development brought together 28 botanical institutions (including the Jardim Botânico do Rio de Janeiro) from 21 developed and developing countries, and agreed on Principles on Access to Genetic Resources and Benefit-Sharing and Common Policy Guidelines to assist with their implementation[96] [97]. Several model agreements were also developed. The one-page Principles cover acquisition, use and supply of genetic resources, use of written agreements, curation, and benefit-sharing, and are intended to be used by gardens to structure an institutional policy that covers all of their ABS-relevant activities and collections (including any commercial activities such as plant sales). The North-South nature of the pilot project helped to build trust and awareness in biodiverse developing countries, and the Principles on ABS have been formally endorsed by 22 institutions, from 13 countries (5 developed countries, though only 2 in the EU, and 8 developing countries), including several of the world's major biodiversity collections such as Kew, BGBM, the Royal Botanic Garden Edinburgh, the Missouri Botanical Garden, the New York Botanical Garden, Jardim Botânico do Rio de Janeiro and the South African National Biodiversity Institute[98].

However, the more detailed Common Policy Guidelines were perceived by many European institutions as being overly cumbersome, especially for the many small gardens with few staff, as was the Principles' requirement for gardens to develop their own institutional policy. Institutions vary widely in their capacities and resources for monitoring, and the Principles do not prescribe how resources should record terms and conditions, or track resources, or record supply. There is currently no requirement to make publicly available the policies or practices

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96 www.bgci.org/resources/abs_principles/; www.kew.org/conservation/principles.html

97 Latorre, F., Williams, C., ten Kate, K. & Cheyne, P. (2001) Results of the Pilot Project for Botanic Gardens: Principles on Access to Genetic Resources and Benefit-Sharing, Common Policy Guidelines to assist with their implementation and Explanatory Text. Royal Botanic Gardens, Kew.

98 www.kew.org/conservation/endorsements.html

that are developed under the Principles, and there is no organisation that assists endorsing institutions to put them into practice, or monitors compliance, so although the Principles on ABS can provide helpful guidance, it is not clear how effective an implementation measure they have proved to be.

The International Plant Exchange Network (IPEN) is a registration system developed by the Verband Botanischer Gärten (association of gardens in German-speaking countries) to facilitate the exchange of living plant material for non-commercial use between member gardens while respecting the CBD provisions on ABS[99]. It has been formally endorsed by the European Botanic Gardens Consortium and has a Task Force for its implementation.

IPEN member gardens sign and abide by a Code of Conduct that sets out gardens' responsibility for acquisition, maintenance and supply of living plant material and associated benefit-sharing. Each plant put into the IPEN system receives an IPEN number from the garden that first accessions it. The IPEN number contains four elements – a code for the country of origin, a code to indicate restrictions for transfer, the first garden's code, and an identification number, the accession number of the garden – and is a unique identifier for that material. The accession's full information (including scientific data and permits) is maintained by the first institution (the 'maximum documentation'), but the plant and its descendants, with the same IPEN number, can be exchanged between IPEN members without using Material Transfer Agreements (MTAs), and only the 'minimum documentation'. Acquisition or supply of material with extra terms and conditions or any use for commercial purposes is outside the scope of IPEN and requires the use of the IPEN MTA. Herbarium material, DNA extracts and other non-living specimens are not covered by IPEN, so the IPEN MTA is used to transfer them. In the case of commercialisation, new prior informed consent must be obtained from the original provider by the prospective user before any material is supplied from an IPEN garden[100].

There are currently 157 IPEN members, from 25 countries (140 members from 21 European countries, including 135 members from 17 EU countries). IPEN awareness and membership in the US is likely to expand now that Missouri Botanical Garden has joined. IPEN has not yet been taken up by gardens in any developing countries, possibly due its European grass-roots origins, or perhaps to the difficulty of accommodating more restrictive terms from permits, or to providers' concerns about relatively free exchange within a multilateral system with less direct 'personal' links to the provider country – although the IPEN system ensures that the original link to provider countries is maintained during all transfers.

IPEN cannot be used for material collected with very restrictive terms, and does not cover other types of collections often found in European botanic gardens, such as herbaria (or, increasingly, DNA and tissue banks), except to the extent that the MTA is used. Thus, the full range of an IPEN member's activities and collections may not carried out within IPEN's

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99 www.bgci.org/resources/ipen/

100 www.bgci.org/resources/Description_of_IPEN/

multilateral, facilitated-access system – but the tracking system itself, with its unique identifiers, could certainly be extended for use with all collections (as is the intention at Missouri Botanic Garden[101]).

Regardless of their membership or endorsement of particular ABS systems, several botanic gardens have made available their institutional policies on ABS, including Kew[102], the National Botanic Gardens Glasnevin, Ireland[103], Royal Botanic Garden Edinburgh[104] and BGBM (which sets out how IPEN is used to implement the Principles on ABS)[105].

MTAs are commonly used for transfer of specimens (hence the development of IPEN for gardens that struggled with the amount of documentation involved in traditional seed exchange), enabling some tracking, although MTAs themselves do not necessarily communicate all of the original terms and conditions of acquisition. To handle large flows of specimens, Kew, among other institutions, uses MTAs with standard terms of use and transfer, including non-commercialisation, which may sometimes be more restrictive than the provider's original terms (though where original terms are more restrictive, those terms are recorded and respected). Furthermore, such institutions routinely handle preserved specimens (perceived as having lower risk of misappropriation) in batches[106], without recording individual specimen movements, except in the case of type or historic material, so responsibility falls onto collectors and researchers to ensure that provider country details and any restrictive terms are clearly recorded on labels/database fields that travel with the specimens.

Given that individual curators, researchers and horticulturalists have the responsibility to ensure that specimens are acquired, used and supplied appropriately and that specimens and terms are kept linked, awareness-raising is extremely important at all levels of an institution. The botanic gardens sector has developed a range of CBD guidance tools materials that provide user-friendly information on ABS, such as the CBD for Botanists, a plain-language guide

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101 A. Wyatt, pers. comm. (2012)

102 www.kew.org/conservation/docs/ABSPolicy.pdf

103 www.botanicgardens.ie/educ/accnosho.pdf

104 www.rbge.org.uk/assets/files/science/Herbarium/Destructive_sampling_policy.pdf; www.rbge.org.uk/assets/files/databases/RBGEcond.pdf

105 www.bgbm.org/BGBM/research/colls/garden/CBD.HTM

106 See case study by K. Davis, P. Middlemiss, A. Paton & C. Tenner: The Royal Botanic Gardens, Kew: Herbarium and Millennium Seed Bank. In Tobin, B., Cunningham, D. & Watanabe, K. (2004) The feasibility, practicality and cost of a certificate of origin system for genetic resources : preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme. UNEP/CBD/WG-ABS/3/INF/5, www.cbd.int/doc/meetings/abs/abswg-03/information/abswg-03-inf-05-en.pdf

and training tool (with a focus on ABS) for people working with botanical collections[107], and the CBD Manual for Botanic Gardens[108], which contains a practical ABS checklist.

BGCI has recently updated the International Agenda for Botanic Gardens in Conservation, a policy framework for botanic gardens to contribute to biodiversity conservation, to include post-Nagoya information on ABS and a list of key tasks for consideration by gardens developing their implementation plans[109]. Currently there are 110 International Agenda registrants in EU countries[110], though this number does not indicate ABS activity. BGCI also maintains ABS webpages that provide information on the Principles on ABS and IPEN, case studies and useful resources[111].

7.3.2 Natural history museums

To date there is no overarching set of ABS-related standards, codes or guidance tools for natural history museums, although general policy frameworks such as the Principles on ABS and guidance tools such as the CBD for Botanists and the Swiss Academy of Sciences Good Practice Guide (see 6.2.3) are quite applicable. Generally, individual institutions have developed their own collections policies and loan agreements, and these are increasingly likely to cover ABS. Documentation such as loan agreements allows for a certain amount of tracking of basic information, if the transaction is recorded in sufficient detail.

Based on the loan policies of 13 European natural history museums, the European Distributed Institute of Technology (EDIT) project[112] developed common loan principles, which have been since been adopted by the wider array of institutions involved in the Consortium of European Taxonomic Facilities as 'CPB principles for research loans between natural history collections'[113]. The principles aim to facilitate access to collection material through loans while maximising their long-term preservation. The general policy statements include the provision

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107 Williams, C., Davis, K., & Cheyne, P. (2003 and updates) The CBD for Botanists: an introduction to the Convention on Biological Diversity for people working with botanical collections. Royal Botanic Gardens, Kew, UK. www.kew.org/data/cbdbotanists.html

108 Davis, K. (2008) A CBD Manual for Botanic Gardens. Botanic Gardens Conservation International, Richmond, UK. www.bgci.org/resources/cbdmanual

109 BGCI (2012) International Agenda for Botanic Gardens in Conservation: 2nd edition. Botanic Gardens Conservation International, Richmond, UK. www.bgci.org/files/Worldwide/News/SeptDec12/international_agenda_web.pdf

110 BGCI GardenSearch database

111 www.bgci.org/resources/abs

112 www.e-taxonomy.eu/

113 EDIT principles: http://www.e-taxonomy.eu/files/EDIT%20Common%20Loan%20Principles_vfinal.pdf

that the signatory institution is committed to abiding to all international and national agreements covering the transfer of biodiversity specimens and products such as CBD, CITES and other agreements on access and benefit-sharing, e.g. the Bonn Guidelines. There are five key principles: (1) the availability of all specimens for research loan (but institutions reserve the right to refuse to lend any material at its discretion for transparent reasons , including unacceptable risk to items such as type and figured specimens, and specimens of high historical significance); (2) no charge for research loans; (3) the institution where the loan is to be housed must be safe and secure; (4) material will only be used for research, not for commercial purposes without prior agreement; and (5) the borrowing institution accepts that title to and ownership of loaned items remains with the lending institution. There are further requirements for sound documentation, restrictions relating to DNA/tissue sampling and destructive sampling, and specific statements covering molecular collections such as return of samples, notification of data sent to GenBank, and intellectual property rights related to molecular collections.

Most CETAF institutions hold very large numbers of diverse kinds of specimens, and often manage loans and exchanges on a batch basis – these institutions are generally not yet prepared for detailed monitoring and tracking of individual specimens and their movements using unique identifiers, unless significant new resources are located. In the case of insect samples collected and stored *en masse* in containers, it may take decades before specimens are individually identified to species, although provider details and terms and conditions for the batch can still be passed on via labels and databases[114].

The Museums Association Ethics Committee guidelines, although not designed specifically to cover the needs of natural history collections, stress the importance of using due diligence to acquire specimens legally, without infringing the national laws in countries of origin or international regulations such as CITES, and with documentation[115].

7.3.3 University research collections and research institutes

There have been no overarching ABS guidelines, codes, or systems designed specifically for the use of university or research institute collections, but there are general guidance tools aimed at academic researchers. The 2005 UK stakeholder survey indicated that awareness of ABS provisions of the CBD (although not the Bonn Guidelines) seemed much higher in research institutions, universities and botanic gardens than in commercial organisations. Universities

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[114] See case study by L.P. Hirsch & A.C. Villegas: The Smithsonian Institution: the life of natural history museum specimens. In Tobin, B., Cunningham, D. & Watanabe, K. (2004) The feasibility, practicality and cost of a certificate of origin system for genetic resources : preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme. UNEP/CBD/WG-ABS/3/INF/5, www.cbd.int/doc/meetings/abs/abswg-03/information/abswg-03-inf-05-en.pdf

[115] www.museumsassociation.org/ethics/ethical-guidelines

also appeared to be the only organisations who mainly acquired biological material from *in situ* sources[116]. As universities and research institutes are becoming important players in biodiscovery projects, supplying leads and hits to industry, ABS awareness is vital.

The German Research Foundation (Deutsche Forschungsgemeinschaft, DFG), the self-governing funding organisation for science and research in Germany, actively promotes cooperation in science, as well as the interaction of science with industry and society[117]. The DFG has produced guidelines, including an ABS checklist with indication as to when ABS tools such as MTAs or ABS agreements are necessary to cover the proposed research. Funding applicants are required to 'describe specifically which competent authorities you have contacted or intend to contact, how the access procedure works in the host country, and how you rate the prospects for success. In addition please confirm that you have familiarised yourself with these CBD Guidelines and intend to conduct the project according to the principles described herein'[118]. The guidelines also prompt researchers to check whether their proposal involves a plant species covered by the ITPGRFA – in which case the guidelines do not apply.

The Swiss Academy of Sciences has produced a good practice manual for non-commercial academic researchers[119] that provides basic information on the CBD (and has been partially updated for the NP), considers case studies across diverse research areas (agriculture, ecology, botanical inventories, medicine and ethnobotany), sets out the basic steps for researchers to take regarding ABS requirements, and provides checklists to aid in the preparation of research projects. Working with models and examples provided by a range of international institutions, the Swiss Academy of Sciences has also developed a model ABS agreement for non-commercial research[120], which includes options regarding the terms for storage or deposition of material in public collections, and use/transfer from those collections. The model agreement also includes options related to handling traditional knowledge.

Universities and research institutes with commercial interests, as well as private sector organisations and other users who are considering developing more complex projects with commercial potential and/or working with indigenous communities and traditional knowledge,

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116 *Ibid*. 44 (Latorre 2005)

117 www.dfg.de/en/dfg_profile/mission/index.html

118 www.dfg.de/download/programme/sonstige/antragstellung/1_021_e/1_021e.pdf

119 Biber-Klemm, S. & Martinez, S.I. (2012) Access and Benefit Sharing: Good practice for academic research on genetic resources. Swiss Academy of Sciences, Bern, Switzerland. http://abs.scnat.ch/downloads/documents/ABS_GoodPractice_2012.pdf

120 Biber-Klemm, S., Martinez, S.I., Jacob, A. & Jevtic, A. (2010) Agreement on Access and Benefit Sharing for Non-Commercial Research : Sector specific approach containing model clauses. Swiss Academy of Sciences, Bern, Switzerland. http://abs.scnat.ch/downloads/documents/NonCommResearch_ABS_Agreement.pdf

can use the ABS Management Tool[121]. The ABS-MT is a best practice standard and handbook that provides voluntary guidance to help companies, researchers, indigenous and local communities and governments to understand and comply with the ABS requirements of the CBD and the NP. The tool provides elements for an MTA based on the Bonn Guidelines, but its focus is on guiding the overall process of negotiation and decision-making, not addressing practical issues such as specimen exchange. Its post-Nagoya update focuses on national implementation.

Unless institutions have developed their own MTAs and loan agreements, the standard agreement that is most likely to be used for academic transfer of biological material between universities and research institutes is probably the Uniform Biological Materials Transfer Agreement (UBMTA)[122]. The UBMTA was published in 1995 by the US National Institutes of Health for the transfer of biological materials for teaching and academic purposes, and contains ABS-relevant terms relating to transfer, ownership and intellectual property, if not to key CBD concepts such as linkage to country of origin and benefit-sharing. Institutions that have signed the UBMTA Master Agreement can transfer materials to each other under the UBMTA once they have signed the Implementing Letter. The Association of University Technology Managers is the repository for the signed agreements and maintains the list of signatories to the Master UBMTA Agreement; there are currently 494, including a range of EU universities and research institutes, though US institutes are in the majority[123]. The AUTM has identified a set of principles to distinguish the legitimate expectations of the primary stakeholders in the technology commercialisation process – but with no ABS-related content. In an effort to make the sometimes overly complex UBMTA terms more user-friendly and applicable to more situations, the Science Commons (now Creative Commons) Biological Materials Transfer Project has been developing alternatives[124], though it is not clear whether specific ABS concerns are being considered.

7.3.3 Culture collections

The culture collections community was also an early adopter of ABS measures. Unlike European botanic gardens, whose collections are predominantly used for non-commercial purposes, culture collections provide services to a diverse range of commercial users, as well as to academic researchers. The Belgian Coordinated Collections of Microorganisms (BCCM) led an EU project to develop the Microorganisms, Sustainable Access and Use, International

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121 Stratos Inc., Burton, G. & Cabrera, J. (2012) ABS Management Tool : Best Practice Standard and Handbook for Implementing Genetic Resource and Benefit-Sharing Activities. Swiss State Secretariat for Economic Affairs, Switzerland. www.sib.admin.ch/en/nagoya-protocol/abs-management-tool/index.html

122 www.ott.nih.gov/NewPages/UBMTA.pdf

123 www.autm.net

124 http://sciencecommons.org/projects/licensing/details/

Code of Conduct (MOSAICC)[125], involving representatives from commercial and not-for-profit organisations, and like the project that produced the Principles on ABS, representatives from North and South (including collections in Brazil, Costa Rica, Indonesia and South Africa.

MOSAICC provides full guidance on procedures and terms of access to both *in situ* and *ex situ* microbial genetic resources, and model documents – an MTA and different PIC application forms for *in situ* and *ex situ* situations. The *in situ* origin of the material is always mentioned when transfer occurs. Collections' MTAs may differ in detail but should contain at least (1) information about the *in situ* origin or source of material; (2) information about provider and recipient; and (3) mutually agreed terms for the access to and the transfer of resources, access to and transfer of technology, benefit-sharing and technical and scientific cooperation. MOSAICC also recommends that Global Unique Identifiers (GUID) should be issued and attached to samples when they have been isolated, to help document their transfer, or (if not already assigned) when they are deposited for long-term storage. The World Data Centre for Micro-organisms (WDCM, the international database developed by the WFCC) has developed a registration system that provides culture collections with a unique acronym and numerical identifier; if collections then catalogue and assign GUIDs to their cultures, then resources, their movements and related publications can be tracked through the collections network.[126] MOSAICC was revised in 2011 and is currently being revisited in the light of the NP via the TRUST project (Transparent User friendly System of Transfer for Science and Technology).

ECCO member collections now employ the ECCO core Material Transfer Agreement (approved in 2009) for the supply of biological material from their public collections, which reflects common positions on traceability, fair and equitable benefit-sharing, intellectual property rights, and quality, safety and security. ECCO collections also agree to continue 'exchange of cultures between culture collections adhering to equivalent and compatible core conditions of supply'[127]. The MTA allows for use 'in any lawful manner for non-commercial purposes', but that if the recipient wishes to use the material commercially, it is required to, 'in advance of such use of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the material.' Collections may need to use special MTAs for other situations, for example when a depositor wishes to exclude any commercial use, or requires prior informed consent before transfers to third parties[128].

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125 http://bccm.belspo.be/projects/mosaicc/docs/code2011.pdf

126 Desmeth, P. & Smith, D. (2011) Tools to implement the NP on Access and Benefit Sharing in microbiology: ABS, an intrinsic preoccupation of the World Federation for Culture Collections. Information document for ICNP1. www.cbd.int/abs/doc/protocol/icnp-1/wfcc-en.pdf

127 www.eccosite.org

128 Verkley, G.J.M. European collections partner to the Microbial Resource Research Infrastructure (MIRRI) develop common approaches to answer the NP. Presentation given at NBRC 10th Anniversary Symposium, Tokyo, December 6, 2012.

The MIRRI, EMBarC and GBRCN networks are all actively engaged in developing sound best practices for the microbial resources sector, aiming for approaches that will meet the concerns of a wide range of international stakeholders and users while also encouraging facilitated access to collections. The new MIRRI partnership is currently developing a policy on Intellectual Property Rights and ABS, analysing the problems and deficiencies in the MTAs in current use, and the minimal requirements for CBD compliance. It welcomes the EU Regulation proposal, which could increase users' trust in culture collections, increase traceability and reduce non-compliant use of resources, and provide an incentive for users to choose resources held by Union Trusted Collections because they will be able to demonstrate due diligence without additional administrative burden. Concerns identified by MIRRI include the need to clarify how material that is post-CBD but pre-Nagoya will be covered (ideally using the ECCO core MTA approach, negotiating benefit-sharing before commercial use), how to handle material that has missing or incomplete documentation, the need to keep type and reference strains unrestricted, and the need for Member States to support collections that meet the trusted collections criteria but lack the resources to fulfil the tasks[129].

The global culture collections community is moving towards the concept of establishing a Microbial Commons, establishing basic common use principles for access to both material and information, in a way that is complementary to national ABS regulations and IPR laws. In this demarcated open commons space, material and information would be relatively freely accessible provided that outputs are returned to the commons space to be shared again. Benefits would include depositing in collections, publication of associated data, and making material and information easily available to stakeholders including the country of origin. Other benefit-sharing measures would apply in the case of commercial exploitation, such as access, milestone and royalty/license payments. Outside the commons space, ABS would be governed by national and international laws[130].

7.3.5 Zoos and Aquaria

A review of UK stakeholders indicated that the acquisition of animals from wild populations for the zoo sector is generally covered by written agreements following the guidelines of the UK Federation of Zoos and the World Zoo Conservation Strategy, which are not specifically ABS-related, but ban illegal and unethical trade[131]. Draft guidelines on ABS were discussed by WAZA

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129 Response of MIRRI to the "Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union", prepared by E. Stackebrandt & G. Verkleij, 14 March 2013.

130 *Ibid*. 126 (Desmeth & Smith); for more discussions on the Microbial Commons concept see National Research Council (US) Board on Research Data and Information, Uhlir P.F. (ed) (2011) Designing the Microbial Research Commons: Proceedings of an International Symposium. National Academies Press, Washington DC. www.ncbi.nlm.nih.gov/books/NBK91499

131 *Ibid*. 44 (Latorre 2005)

member organisations in 2006[132]. The draft laid out core commitments covering PIC, MAT, benefit-sharing, conservation and sustainable use, traditional knowledge, community participation, and information and transparency, and incorporated the Principles on ABS (see 6.2.1). WAZA members would be expected to record the terms and conditions of acquisition, track and audit the use of those resources and benefits arising from use, record disposal to third parties, including terms, and should develop an institutional policy. However it is not clear whether these guidelines were further developed and released.

7.3.6 Agricultural genebanks

In both Brazil and the EU, the agricultural collections sectors were deeply engaged in the negotiations leading to the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[133], which establishes a specialised instrument for access and benefit-sharing, with a commons space. All EU countries and Brazil are Parties to the ITPGRFA, and so collections of local, national and international gene banks and under the direct control of the Parties share a set of rules for facilitated access, as do the collections in the Consultative Group for International Agriculture Research (CGIAR) research centres. Those that hold Annex I material are required to make that material available to the Multilateral System using the Standard Material Transfer Agreement (SMTA) for transfers, if the intended use is related to food and agriculture, greatly reducing transaction costs.

However not all material is on Annex 1, and not all access is strictly for food and agriculture purposes, so much of the material in gene banks must be transferred outside the commons of the Multilateral System, and a patchwork of ABS rules apply, depending on the countries of origin and the terms of acquisition. Some ITPGRFA Parties have chosen to extend facilitated access and the use of the SMTA to other crops, but institutional ABS awareness is needed to prevent inappropriate use of the SMTA, as it can only be used as a 'default' when there are clearly no CBD-related restrictions on material. Bioversity International and other partners have produced updated technical guidelines[134] and a guide to the use of the SMTA[135]that remind germplasm collectors that they should always ensure that they seek prior informed consent from the country where they are collecting, and adhere to the conditions that are set.

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132 www.zoosprint.org/ZooPrintMagazine/2006/June/15-17.pdf

133 www.planttreaty.org

134 Moore, G. & Williams, K.A. (2011) Legal issues in plant germplasm collection. Ch. 2 in: Guarino, L., Ramanatha Rao V., Goldberg, E. (eds) Collecting plant genetic diversity: Technical Guidelines – 2011 Update. Bioversity International, Rome, Italy. http://cropgenebank.sgrp.cgiar.org/images/file/procedures/collecting2011/Chapter2-2011.pdf.

135 Guide for the CGIAR Centres' Use of the Standard Material Transfer Agreement www.bioversityinternational.org/fileadmin/bioversityDocs/Policy_module/eng.policy_module/Reference_Material/Guide_SMTA.pdf

The approach taken by the Centre for Genetic Resources (Netherlands) is to refrain from claiming legal ownership of, or intellectual property rights on, the germplasm (and related information) in its genebank, and to keep it as unrestrictedly available as possible, passing on these same obligations to future recipients. It uses Memoranda of Understanding to cover its collection missions, and the SMTA as a basis for collecting material[136].

7.3.7 DNA and tissue banks

A 2004 global survey of the (agricultural) plant genetic resources community found over 70% of DNA storage in the developed world was performed by private firms, while in the developing world only a few public sector institutions had the research capabilities, and additionally, that almost half of the institutions that supplied DNA to others did not account for legal issues regarding ownership and international transfer, and only one quarter had official policies or MTAs[137] – but it is likely that this situation has much improved, given the international, multi-stakeholder involvement in the negotiations for the NP.

The DNA banks held by botanic gardens and natural history collections (mentioned in 5.1) are governed by those institutions' policies and practices, and are using MTAs that reference the CBD. The Global Genome Biodiversity Network program of work includes the development of a values statement in support of member organisations' work on ABS by (1) being aware of the CBD and the NP and working to respect those agreements, maintaining transparency, and working towards goals of mutual benefit sharing; (2) being aware that biodiversity-rich countries consider their biodiversity as National Assets and working with those countries towards mutual benefit-sharing; and (3) considering a proactive role in the sharing of information and the use of tracking systems[138] .

The International Society for Biological and Environmental Repositories (ISBER) provides updated best practices for repositories[139]. Guidance is provided on the importance of obtaining appropriate collecting and export permits, and repository managers are reminded that the benefits derived from international transfer of biological material extend beyond the physical specimen to include benefits such as training and capacity building. Best practices set out in the document include that use of specimens and associated data should be consistent with informed consent and authorisation; that resources should have a well-documented and clearly defined process for sharing specimens and data; that repository procedures for collection, storage, distribution, use and disposal of specimens should respect the perspectives

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136 *Ibid.* 43 (Defra 2012)

137 *Ibid*. 70 (Anderson et al. 2006)

138 http://ggbn.org/taskForce_Policies.html

139 ISBER (2011) Best Practices for Repositories: Collection, storage, retrieval, and distribution of biological materials for research. Biopreservation and Biobanking Vol. 10, no. 2. Mary Ann Liebert, Inc. www.isber.org/bp/documents/ISBERBestPractices3rdedition.pdf

and traditions of donors from whom the specimens were obtained and minimise risks to communities, populations and groups; that repositories that import specimens and data from other countries should respect the autonomy of the providing country and ensure that fair and equitable benefits are made available to the providing country; and that MTAs (or similar documents) should be used to document the obligations and responsibilities of parties involved in the transfer of materials from a repository prior to shipment.

7.3.8 Collections of extracts and compounds

The most stringent ABS measure that has been developed for companies that trade in natural products is the Union for Ethical BioTrade (UEBT)'s internationally-recognised standard, revised in 2012[140]. The standard covers all natural ingredients in the organisation's portfolio, and sets out principles, criteria that must be met, and indicators. The ABS-related measures cover negotiations, equitable prices and recognition of traditional practices, and members are required to gain access subject to PIC and on MAT, and to share benefits, regardless of whether or not there are national ABS laws and regulations. Trading members must demonstrate working knowledge of the principles of the CBD, NP and CITES, and must prepare work-plans and report annually on their implementation.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) has been an active participant in the NP negotiations, and has produced 'guidelines' on ABS that list certain best practices that should be followed by companies[141], such as the need to obtain PIC (disclosing intended use of the resources) and the use of formal contractual benefit-sharing agreements to set out mutually agreed terms (which may contain conditions on permitted uses and transfers to third parties). They do not provide detailed guidance for collections. INTERFARMA, the Brazilian Research-based Pharmaceutical Manufacturers Association, has produced a new code of conduct (2012)[142] but it does not extend to ABS issues.

EuropaBio has developed Core Ethical Values, which include as a general principle 'we support the principles embodied in the United Nations Convention on Biological Diversity (CBD) to protect biological diversity including adherence to the principles of access and benefit-sharing'[143] .

7.3.9 Genetic sequence databases

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140 http://ethicalbiotrade.org/news/wp-content/uploads/STD01-Ethical-BioTrade-Standard-2012-04-11_.pdf

141 www.ifpma.org/innovation/biodiversity.html

142 http://www.ifpma.org/fileadmin/content/About%20us/2%20Members/Associations/Code-Brazil/Brazil_-_Interfarma_Code_of_Conduct_2012_-_English_version.pdf

143 Available at www.basf.com/group/corporate/en/products-and-industries/biotechnology/europabio

The International Nucleotide Sequence Databases do not currently require information depositors to supply ABS information such as country of origin, or evidence that prior informed consent was obtained and mutually agreed terms were established[144]. In GenBank, 'source' field refers to the biological source of the sequence (the organism's name, and the type of molecule), not to geographic source, and the 'origin' field, not required, refers to the sequence start in older records[145]. Some qualifiers are available, for example an optional institution code and collection code for where the material is currently stored.

To gain a 'BARCODE' flag in one of the INSDs, barcode sequence records from IBOL-related projects require much more stringent and unambiguous information, such as a country code and a unique identifier for a voucher specimen in a biorepository[146], and the barcoding community is currently in the process of developing model ABS agreements for the acquisition, use and transfer of DNA and voucher specimens (particularly important for those institutions that do not yet have other ABS measures in place that would cover barcoding activities).

8. Information-sharing and cooperation between *ex situ* collections

Although there are clearly many legal and practical impediments to exchanging physical specimens between *ex situ* collections, there has been an astounding increase in global access to the biodiversity information that they hold, thanks to the growth of the Internet and the decreasing costs of digitisation and information storage. Collections worldwide are joining forces and building networks to make available resources such as catalogues of holdings, taxonomic bibliographic databases and species-focused resources such as floras and monographs. In particular, the last decade has seen the development of initiatives to share high-quality digital specimen images, which greatly help to address the uneven physical distribution of specimens in international collections. There has been a parallel development of aggregators that can draw together data on many taxa from many separate sources[147]. The numbers of species that are not yet known and specimens that are not yet digitised or even catalogued are still very great (and projects involving flat herbarium specimens far outnumber those attempting to capture images of zoological specimens), and institutional resources are limited, but huge advances have been made on a project-by-project basis on many different levels. European and Brazilian institutions have been centrally involved in many of these developments.

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144 The DDBJ/EMBL/GenBank Feature Table: Definition. Version 10.2 November 2012. ftp://ftp.ebi.ac.uk/pub/databases/embl/doc/FT_current.html#7.1.1

145 Sample GenBank Record. www.ncbi.nlm.nih.gov/Sitemap/samplerecord.html

146 Hanner, R. (2009). Data Standards for BARCODE Records in INSDC (BRIs). http://barcoding.si.edu/pdf/dwg_data_standards-final.pdf

147 Lughadha, E.N. & Miller, C. (2009) Accelerating global access to plant diversity information. Trends in Plant Science, 14(11): 622-628.

8.1. Database networks and data aggregators

Aggregators include the intergovernmental Global Biodiversity Information Facility, a mega-science project that encourages free and open access to biodiversity data through the creation of a global decentralised network of interoperable databases that contain primary biodiversity data held by biodiversity information facilities around the world[148]. The data include information associated with specimens documented in *ex situ* collections, as well as records from *in situ* studies. The Catalogue of Life is another important aggregator, a quality-assured checklist of more than 1.3 million species of plants, animals, fungi and micro-organisms[149]. Complete databases across all groups of organisms are being created in some regions, including Europe and Brazil (the Catalogo da Vida Brasil), in part with EU funding for the 4D4Life (Dynamic Distributed Databases for Life) project[150] and EU-Brazil OpenBio, a project to deploy an open-access platform from the federation and integration of existing European and Brazilian infrastructures and resources (2011-2013)[151].

In Europe, the BioCASE (the Biological Collection Access Service for Europe) network[152] has helped to increase access to heterogeneous European collection and observational databases of unit-based data, as well as metadata on non-databased collections[153].

The microbial collections community has developed strong networks for data-sharing. The WFCC-MIRCEN World Data Centre for Microorganisms (WDCM) links microbial resource centres, as well as their customers. Its databases include Culture Collections Information Worldwide (CCINFO), a database management system for all registered culture collections, which currently covers 643 collections from 73 countries and regions, including 64 collections in Brazil and 167 in EU countries[154].

The Global Catalogue of Microorganisms (GCM), another WFCC initiative, is a new system to help culture collections to manage, disseminate and share the information related to their

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148 www.gbif.org

149 www.catalogueoflife.org

150 www.4d4life.eu

151 www.eubrazilopenbio.eu

152 www.biocase.org/index.shtml

153 The BioCASE metadata network was replaced by the more global Biodiversity Collections Index, which in turn has been merged with Index Herbariorum and Biorepositories.org (which links DNA barcode voucher specimens to barcode data records in GenBank) www.biorepositories.org/merger_announcement

154 www.wfcc.info/ccinfo/statistics/

holdings[155]. As is the case for other types of *ex situ* collections, many collections have not yet put their data online – currently around one-sixth of registered in CCINFO have an online catalogue. GCM currently contains data from 25 countries and regions, 50 collections (1 in Brazil, 22 in the EU), 37,382 species and 253,981 strains.

8.2. Specimen images and data

Earlier specimen data repatriation projects involved exchange of catalogue data and cibachrome prints, such as the first phase of the Northeastern Brazilian Repatriation Project (a partnership between RBG, Kew and three local Brazilian herbaria, IPA, CEPEC and HUEFS, and part of the Biodiversity Subprogramme of the Plantas do Nordeste Project, between RBG Kew and the Associação Plantas do Nordeste[156]), but the availability of lower-cost digital scanners and digital photography revolutionised the possibilities for sharing specimen images and data.

The Global Plants Initiative (GPI) is a major international collaboration to digitise and make available plant type specimen images, funded by the Andrew W. Mellon Foundation and hosted via JSTOR Plant Science[157]. The project involves more than 166 herbaria in 57 countries (including 56 in 13 EU countries, and 6 herbaria in Brazil). The Latin American Plants Initiative is the second stage of the global project (after the first, the African Plants Initiative), involving partners already active from the African initiative and new ones with Latin American interests[158].

Project Reflora is a large-scale research and data-sharing collaboration initiated by CNPq, involving data capture in Brazilian and European herbaria, software development, infrastructure enhancement, and research support for Brazilian botanists and capacity-building. The scope extends beyond the digitisation of types and historic specimens (the focus of the GPI), aiming to capture data from some one million Brazilian plant specimens held in foreign collections in Europe and the US. The major collaborating collections in Europe are MNHN and Kew, which together house an estimated 600,000 Brazilian specimens[159] [160].

Other smaller, but highly significant projects have focused on capturing images and data from the specimens gathered by particular European collectors, as well as other objects, such as their field notes, maps, illustrations and bibliographic data. In connection with Project Reflora and with support from CNPq, the A. de Saint-Hilaire Virtual Herbarium is aiming to make

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155 http://gcm.wfcc.info/mission/

156 www.kew.org/science/tropamerica/repatriation.htm

157 http://gpi.myspecies.info/content/all-vascular-types-line-global-plants-initiative

158 http://plants.jstor.org/action/community

159 www.kew.org/science-research-data/directory/projects/Reflora.htm

160 www.scidev.net/en/news/brazil-to-repatriate-its-botanical-data.html

available images of Auguste Saint-Hilaire's 30,000 specimens as well as his field notes from his travels in south and central Brazil between 1816 and 1822. At the time of this paper's preparation, 6197 specimens had been captured from the MNHN collections and 636 from the Institut des Herbiers Universitaires, CLF, Clermont-Ferrand[161].

The Martius Project, a prototype for larger networking efforts, made available a selection of digital images of type specimens from the Martius collection types that were cited in the *Flora Brasiliensis*, held in the National Botanic Garden of Belgium, the National Herbarium of the Netherlands and Herbarium Botanische Staatssamlung Muenchen, Germany. The project fits into larger networking efforts between Brazilian, North American and European herbaria to expand the digitisation of the Martius collections to cover all relevant collections and link to key illustrated works including the *Flora Brasiliensis*[162].

The Richard Spruce project was a joint initiative between Kew and the NHM (London) that resulted in the digitisation of over 6000 specimens and notebooks from Spruce's 15 years of travels from Amazon to Andes[163].

8.3 Cooperation and capacity-building

Although the organisation of field collecting trips and the acquisition and exchange practices have become much more complex since 1992, and national and international laws and regulations are continuing to develop post-Nagoya, *ex situ* collections continue to provide a vital base for conservation, research and development. European collection and research in biodiverse countries has not stopped: instead, institutions and companies (at least those that are aware of ABS developments) have needed to consider their options, resources and strengths, and focus their activities in fewer countries and deeper partnerships, working with knowledge of the relevant ABS legislative framework.

Among CETAF institutions, MNHN and Kew are prominent examples of large institutions that have put significant effort into deepening their research and conservation partnerships in Brazil. They have built collaborations with a range of Brazilian institutions and have developed imaginative initiatives to share information that was previously in effect locked away[164] [165].

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161 http://hvsh.cria.org.br/project

162 In total 1089 types were found and digitised, from eight target plant groups. http://projects.bebif.be/enbi/martius/

163 www.kew.org/science-research-data/directory/projects/RichardSpruceCollectn.htm

164 See projects illustrated in 'The Muséum National d'Histoire Naturelle (France) in Brazil' (brochure), and presentations from meeting 'La Biodiversité en question: Coopération entre le Museum National d'histoire Naturelle et le Brésil', 2009. www.mnhn-brasil.info/program_fr

165 www.kew.org/news/kew-projects-brazil.htm

Kew, MNHN and other European institutions are also actively involved in more general capacity-building initiatives for professionals and students from many different developed and developing countries including Brazil. At the higher education level, MNHN (among other institutions) offers Masters and Doctoral programmes, while Kew runs a suite of professional development courses for botanists, horticulturalists and plant conservation specialists[166] (including two in association with BGCI). The Distributed European School of Taxonomy (DEST), established during the EDIT project and managed by the Royal Belgian Institute of Natural Sciences, continues to organise training sessions in European institutions for international students[167].

9. Conclusions and questions

The history of exchange, and non-exchange, between Brazil and Europe shows the clear need for enlightened balance and cooperation on all sides to further the three objectives of the Convention on Biological Diversity. The knowledge necessary for conservation and sustainable use comes from research and development, but the research-enabling collections and tools have been heavily concentrated in some places while the research subject, the diversity of life, is often concentrated in others. Stringent rules to stem the flow of valuable genetic resources at risk of use without benefit-sharing can also stem the flow of cooperation that generates most of the benefits, while ignorance of the concerns and lack of will or actions to address them provides justification for tough measures. This workshop will try to bridge the science-policy gap and identify and overcome barriers to research and cooperation.

This paper highlights action at the network level, because capacity to track ABS developments and develop new measures is spread very unevenly at the institution level in both regions, and because network- and community-level approaches are more likely to facilitate ABS-aware exchange and research. Individual institutions still need to take responsibility for their own actions and practices (such as sound agreements with providers), but networks can help to share knowledge, ideas and tools to fill the gaps in capacity. The draft EU Regulation on ABS would allow for user associations (such as these networks) to propose a specific combination of procedures, tools or mechanisms overseen by the association as 'best practice', but designation as a Union Trusted Collection would apply at the level of individual collections.

The workshop group might wish to consider whether the already existing codes of conduct, guidelines and model documents could be adopted more widely to harmonise and facilitate exchanges and increase scientific collaboration between Brazil and Europe – and if, and how, such measures need to be adjusted to meet the requirements of post-Nagoya legislation/regulation. Clearly there is a need for ABS capacity-building for collections

166 www.kew.org/learn/specialist-training/continuing-professional-development/index.htm

167 www.taxonomytraining.eu/

personnel in both regions in order to ensure that facilitating exchange systems are used appropriately and that cooperation is truly enhanced.

Tracking is an important practical issue for collections in both regions. The NP will require all institutions to consider how they monitor their use of genetic resources. The draft EU Regulation requires the use of unique identifiers for transfers to third parties; the proposal for a new Brazilian regulation would also involve registration in a national online system, and the use of unique identifiers to monitor transfer to third parties. At the moment, only a few collections sectors in Europe and Brazil are tracking individual specimen/sample use. Until very significant resources can be directed towards new systems and more staff, and a greater proportion of holdings are registered in databases, some natural history collections will likely fail to meet those requirements. IPEN (a network that includes small gardens with few staff) shows how a unique identifier system can actually help to reduce documentation costs for exchanges of living plants. It would be useful to explore whether that type of documentation could realistically be applied at a large scale for preserved herbarium and natural history specimens (bearing in mind the need to honour more restrictive terms for some specimens).

Change of intent of use, from non-commercial research to commercial development, is another key issue for collections in Brazil and Europe, especially for those with links to universities and industry. This multi-sectoral group can consider whether this issue can be tackled in a consistent, harmonised manner that will build trust and cooperation – and ideally develop a best practice that can be taken into account by regulators. Although the microbial collections community welcomes the concept of 'Union Trusted Collections', other EU institutions that, post-CBD, generally acquire and supply material on strictly non-commercial terms may not be comfortable with a system that positions them as sources of material for small- and medium-sized commercial enterprises, and some may choose not to become 'Union Trusted Collections'. A Brazil- and EU-developed common approach to change of intent issues that could still allow collections to use simpler access procedures for non-commercial use might possibly motivate more collections to seek EU 'trusted' status. Brazilian authorities and collections may wish to consider how significant they would find 'trusted' designation when choosing whether to exchange material with European collections.

Regardless of the 'trusted collections' discussions, and collections' readiness to apply unique identifiers to individual specimens, it is clear that almost all of the collections communities surveyed are gaining experience in using agreements such as MTAs, and that they would be capable of curating certificates of compliance. As long as provider PIC and MAT continue to travel with specimens (and specimen information, e.g. for IBOL projects) and benefit-sharing expectations are met, participants might wish to consider the extent to which specimen-level tracking or tracing is necessary for Nagoya implementation. Could standard terms and agreements be used as a basis for facilitated exchange, even if those standard terms do not guarantee tracking?

This workshop also provides a space for participants from both regions to consider creatively what other roles, beyond monitoring and control, collections play in NP: for example what are

the opportunities for innovative cooperation and technology transfer, and what responsibilities do collections have related to traditional knowledge?

The challenge for workshop participants is to find insightful and practical ways to balance the diverse needs and recognise the common interests of European and Brazilian collections communities and European and Brazilian regulators in a way that biodiversity research and sustainable use can be enabled in an equitable and collaborative manner.

Abbreviations and acronyms

ABS	Access to genetic resources and benefit-sharing
ABS-MT	ABS Management Tool
AUTM	Association of University Technology Managers
BCCM	Belgian Coordinated Collections of Microorganisms
BCI	Biodiversity Collections Index
BGBM	Botanic Garden and Botanical Museum Berlin-Dahlem
BGCI	Botanic Gardens Conservation International
BioCASE	Biological Collection Access Service for Europe
BOLD	Barcode of Life Database
CBD	Convention on Biological Diversity
CBOL	Consortium for the Barcode of Life
CCINFO	Culture Collections Information Worldwide
CENARGEN	National Research Center for Genetic Resources and Biotechnology
CETAF	Consortium for European Taxonomic Facilities
CEPEC	Herbário Centro de Pesquisas do Cacau
CITES	Convention on International Trade in Endangered Species of Fauna and Flora
CGEN	Genetic Heritage Management Council
CGIAR	Consultative Group for International Agriculture Research
CNPq	National Council for Scientific and Technological Development
CONABIO	National Biodiversity Commission
CRIA	Reference Center on Environmental Information
CTCB	Technical Chamber of Biological Collections
DDBJ	DNA DataBank of Japan
DFG	German Research Foundation
EAZA	European Association of Zoos and Aquariums
EBI	European Bioinformatics Institute
ECCO	European Culture Collections' Organisation
ECPGR	European Cooperative Programme for Plant Genetic Resources
EDIT	European Distributed Institute of Technology
EFPIA	European Federation of Pharmaceutical Industries and Associations
ELF	European Lead Factory
EMbaRC	European Consortium of Microbial Resources Centres
EMBL	European Molecular Biology Laboratory
Embrapa	Brazilian Agricultural Research Corporation
ESBB	European, Middle Eastern & African Society for Biopreservation and Biobanking
EU	European Union
EUFORGEN	European Forest Genetic Resources Programme
EURISCO	European Search Catalogue
EuropaBio	European Association for Bioindustries
GBIF	Global Biodiversity Information Facility
GBRCN	Global Biological Resource Centre Network

GGBN	Global Genome Biodiversity Network
GPI	Global Plants Initiative
GUID	Global Unique Identifier
HUEFS	Universidade Estadual de Feira de Santana
IABG	International Association of Botanic Gardens
IBAMA	Brazilian Institute for the Environment and Natural Resources
IBOL	International Barcode of Life
INSD	International Nucleotide Sequence Database
INSDC	International Nucleotide Sequence Database Collaboration
IPA	Empresa Pernambucana de Pesquisa Agropecuária
IPEN	International Plant Exchange Network
IPR	Intellectual Property Rights
ISBER	International Society for Biological and Environmental Repositories
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually Agreed Terms
MCTI	Ministry of Science, Technology and Innovation
MIRRI	Microbial Resources Research Infrastructure
MNHN	Musém National d'Histoire Naturelle, Paris
MOSAICC	Microorganisms, Sustainable Access and Use, International Code of Conduct
MTA	Material Transfer Agreement
NHM	Natural History Museum, London
NordGen	Nordic Genetic Resource Centre
NP	Nagoya Protocol
OECD	Organisation for Economic Co-operation and Development
PIC	Prior Informed Consent
PPBio	Research Program in Biodiversity
PROTAX	Project for Capacity Building in Taxonomy
RBH	Brazilian Network of Herbaria
RENARGEN	National Network of Genetic Resources
SCICOLL	Scientific Collections International
SIBBR	Information System on Brazilian Biodiversity
SMTA	Standard Material Transfer Agreement
TK	Traditional Knowledge
TRUST	Transparent User friendly System of Transfer for Science and Technology
UBMTA	Uniform Biological Materials Transfer Agreement
UEBT	Union for Ethical BioTrade
WAZA	World Association of Zoos and Aquaria
WDCM	World Data Centre for Micro-organisms
WFCC	World Federation for Culture Collections

Table 1: Numbers of EU botanic gardens and other botanical institutions with living collections, and affiliations

Country	Number of gardens	with seed bank	with tissue facilities	BGCI members	IPEN members	Endorsed Principles on ABS
Austria	22	1	0	4	8	0
Belgium	28	4	0	7	3	0
Bulgaria	10	0	0	1	0	0
Cyprus	0	0	0	0	0	0
Czech Republic	27	2	3	4	1	0
Denmark	10	2	1	3	0	0
Estonia	10	0	0	2	0	0
Finland	8	0	2	4	3	0
France	95	18	6	23	6	0
Germany	103	9	4	16	48	1
Greece	11	2	1	6	3	0
Hungary	14	3	1	6	2	0
Ireland	16	1	2	6	0	0
Italy	107	8	1	21	10	0
Latvia	2	0	1	1	0	0
Lithuania	9	3	3	4	0	0
Luxembourg	1	1	0	1	1	0
Malta	1	0	0	1	0	0
Netherlands	44	6	0	6	20	0
Poland	32	2	0	6	0	0
Portugal	13	7	1	8	7	0
Romania	15	2	0	3	2	0
Slovakia	10	0	1	2	0	0
Slovenia	5	1	0	2	0	0
Spain	29	14	3	12	9	0
Sweden	9	1	0	4	3	0
United Kingdom	182	11	3	50	6	3
EU total	**813**	**98**	**33**	**203**	**132**	**4**

Sources: BGCI GardenSearch database http://www.bgci.org/garden_search.php; IPEN www.bgci.org/resources/ipen/; Principles on ABS www.kew.org/conservation/endorsements.html)

Table 2: Major EU taxonomic institutions (members of CETAF/SCICOLL/GGBN) and contributors of Brazil specimen data to the Global Plants Initiative

Country	Institution	CETAF	SCICOLL/ GGBN	Brazil specimens digitised for GPI
Austria	Biologiezentrum der Oberösterreichischen Landesmuseen, Linz	C		
Austria	Naturhistorisches Museum, Vienna	C		
Austria	Karl-Franzens-Universität, Graz			587
Belgium	Royal Belgian Institute of Natural Sciences	C	S	
Belgium	National Botanic Garden, Meise	C		9990
Belgium	Royal Museum of Central Africa, Tervuren	C		
Belgium	Herbarium, Laboratory of Botany, Gent University			5
Czech Republic	National Museum (Natural History), Prague	C		
Denmark	Natural History Museum of Denmark, Copenhagen	C	G	1040
Estonia	Estonian Academy of Sciences, Tartu	C		
Finland	Finnish Museum of Natural History, Helsinki	C		233
France	Muséum National d'Histoire Naturelle	C	S	16412
France	Herbier de l'Université Montpellier			1307
Germany	Botanischer Garten und Botanisches Museum, Berlin-Dahlem	C		2832
Germany	Senkenberg, Forschunsinstitute & Naturmuseum, Frankfurt	C		18
Germany	Museum für Naturkunde	C	S	
Germany	Staatliches Museum für Naturkunde, Stuttgart	C		
Germany	Staatliches Naturwissenschaftliche Sammlungen Bayerns	C		5818
Germany	Zoologisches Forschunsinstitut und Museum Alexander König, Bonn	C		
Germany	Universität Göttingen			522
Germany	Martin-Luther-Universität			969

Germany	Biozentrum Klein Flottbeck und Botanischer Garten der Universität Hamburg			423
Germany	Friedrich-Schiller-Universität Jena			556
Hungary	Hungarian Natural History Museum, Budapest	C		
Ireland	Herbarium, Trinity College, Dublin			2161
Italy	Museo Civico di Storia Naturaledi Milano	C		
Italy	Museo di Storia Naturale dell'Università degli Studi di Firenze	C		394
Italy	Museo civico di Storia Naturali di Genoa	C		
Netherlands	Centraalbureau voor Schimmelcultures, Utrecht	C		
Netherlands	Nederlands Centrum voor Biodiversiteit NCB Naturalis, Leiden	C	S	(number not obtainable from GPI)
Poland	Museum and Institute for Zoology PAN, Warsaw	C		
Slovakia	National Taxonomic Facility of Slovakia	C		
Spain	Consejo Superior de Investigaciones Científicas, Museo National de Ciencias Naturales, Madrid (MNCN/CSIC)	C	S	
Spain	Real Jardin Botánico, Madrid	C		62
Sweden	Naturhistoriska Riksmuseet, Stockholm	C		3724
United Kingdom	Royal Botanic Gardens, Edinburgh	C		1750
United Kingdom	Royal Botanic Gardens, Kew	C		21622
United Kingdom	Natural History Museum London	C	S,G	6777
United Kingdom	Linnean Society of London			90

Sources: Consortium for European Taxonomic Facilities (CETAF) institutions www.cetaf.org/; Scientific Collections International (SCICOLL) founders www.scicoll.org/; Global Genome Biodiversity Network (GGBN) collaborators www.ggbn.org; data on Brazil specimens digitised for the Global Plants Initiative http://plants.jstor.org (accessed 23/4/13)

Table 3: EU microbial collection networks: European Culture Collections' Organisation (ECCO), Microbial Resources Research Infrastructure (MIRRI), European Consortium of Microbial Resources Centres (EMbaRC) and Global Biological Resource Centre Network (GBRCN)

Country	ECCO members	MIRRI participants (P) & collaborating parties (C)	EMbaRC	GBRCN
Austria	ACBR VIENNA, Austrian Center of Biological Resources and Applied Mycology. Hyphomycetes & yeast strains			
Belgium	BCCM Belgian Co-Ordinated Collections of Microorganisms, Belgium: consortium of 7 Biological Research Centres coordinated by central team at Belgian Science Policy. Includes: BCCM/IHEM Scientific Institute for Public Health - biomedical fungi & yeasts BCCM/LMBP Ghent University - plasmids & DNA libraries BCCM/LMG Ghent University - bacteria BCCM/MUCL Catholic University of Louvain - (agro)industrial fungi & yeasts BCCM/DCG Ghent University - diatoms BCCM/ITM Institute of Tropical Medicine - mycobacteria BCCM/ULC University of Liège - polar cyanobacteria	P C C (& P as UGENT) C	E E E E	G
Bulgaria	NBIMCC SOFIA, National Bank for Industrial Microorganisms and Cell Cultures. **Bacteria**, **actinomycetes, plasmid bearing microorganisms, yeasts, fungi, animal and plant viruses,** and **animal cell cultures**			
Czech Republic	FCCM Federation of Czechoslovak Collections of Microorganisms. 17 collections http://web.natur.cuni.cz/fccm/collecze.htm . In ECCO: CAPM Collection of Animal Pathogenic Microorganisms CCF Culture Collection of Fungi, Charles University. CCM Czech collection of Microorganisms, Masaryk University. Bacteria and fungi. CNCTC Czechoslovak National Collection of Type Cultures, National Institute of Public Health. Deposited strains.	C		
Denmark	SCCAP The Scandinavian Culture Collection of Algae and Protozoa. Representatives from most algal divisions. IBT (no data)			
Estonia	CELMS Collection of Environmental and Laboratory Strains, Institute of Molecular and Cell Biology, University of Tartu. Non-medical environmental and laboratory microbial strains. HUMB Human Microbiota Biobank, Institute of Microbiology, University of Tartu			
Finland	HAMBI University of Helsinki, Faculty of Agriculture & Forestry, Division of Microbiology; non-profit. Total no. cultures ~5500. Includes: HAMBI / BAC for bacteria HAMBI / FBCC for fungi HAMBI / UHCC for cyanobacteria VTT VTT Culture Collection, under VTT Technical Research Centre. Yeasts, filamentous fungi and bacteria	C		G
France	CCRB French Comité Consultatif des Ressources Biologiques : CRBIP Centre de Ressources Biologiques de l'Institut Pasteur. Bacteria, fungi, cyanobacteria, viruses, plasmids, probes & transposons, culture media. CIRM International Centre of Microbial Resources, Institut Micalis, INRA/AgroParis Tech; 5 sites. Food bacteria, pathogenic bacteria, lignocellulotytic filamentous fungi, phytopathogenic bacteria, hemiascomycetous yeasts. CIRM-CFBP French Collection for Plant-Associated Bacteria, Institut for Horticulture and Seeds. Bacteria. BRC-oenology CRB-Leish LCP	P P	E E	G
Germany	DSMZ Leibniz-Institut DSMZ - Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, Braunschweig. Microorganisms, plant cell cultures, plant viruses, human and animal cell lines. CCAC Culture Collection of Algae at the University of Cologne. 85% from freshwater/terrestrial habitats. Also has strains from ASW (Algenkultur-Sammlung Wien). SAG : Culture Collection of Algae at Göttingen University. Microscopic algae	P C	E	G
Greece	ACA-DC Laboratory of Dairy Research at the Agricultural University of	C		

Sources: ECCO (www.eccosite.org), MIRRI (www.mirri.org), EMbaRC (www.embarc.eu) and http://www.gbrcn.org websites.

ANNEX 5. Brazil's Legislation on Access and Benefit Sharing. Author: Eliana Fontes

Brazil's Legislation on Access and Benefit Sharing

Brazil was one of the first countries to put in place – over ten years ago – domestic legislative, administrative and policy measures designed to implement this objective at national level.

However, there was a common understanding from the beginning that the international regime depended on the third objective of the Convention to be met. Provider countries should enact legislation that would enable benefit sharing from users of genetic resources.

Brazil is a biologically megadiverse country, with a rich population of indigenous and local communities holding valuable traditional knowledge about their genetic resources. The country also possesses significant scientific and technological capacity. A functioning and fair ABS system is crucial to develop new biodiversity-based activities that will generate benefits for the nation, including for further conservation and sustainable use of our biological resources.

Brazil's interest in developing a functioning and fair ABS system derives from its position as a megadiverse country of continental proportions – a terrestrial area of 8.5 million km^2 and a marine area of 4.5 million km^2. Two-thirds of the country are still covered by native vegetation. It is home to six continental biomes (Amazon, Caatinga, Cerrado, Pantanal, Atlantic Forest, Pampas) and 15 per cent of known species (and possibly 25 per cent of all species).

Brazil is a culturally megadiverse country too. It has a population of 190 million, multi-ethnic par excellence, including 220 indigenous peoples speaking 180 different languages, as well as numerous categories of non-indigenous traditional communities whose livelihoods depend upon the sustainable use of biodiversity. Overall the national population is made up of Brazilians with ethnic backgrounds originating from all continents.

Brazil produces 6 per cent of the science on biodiversity and has significant genomics and biotechnology programmes. It is the world's second largest exporter of agricultural commodities and producer of biofuels.

As a provider of genetic resources, Brazil seeks to use this potential wealth to foster research and development that will build scientific and technological capacity, create wealth and promote sustainable human development. This will contribute to the conservation and sustainable use of its natural capital.

Provisional Measure 2.186-16 establishes the ABS legal framework in Brazil. Its main provisions require:

- Previous authorization by CGEN (Council for Genetic Heritage Management) in order to access genetic resources and associated traditional knowledge for research, bioprospecting and technological development.
- Prior Informed Consent from indigenous and local communities as a necessary condition for accessing their genetic resources and/or traditional knowledge associated to genetic resources.
- Benefit sharing with the providers when any product or process that results from the access to genetic resources or associated traditional knowledge arrives at the market.
- The signing of benefit sharing contracts and their submission for approval by CGEN.

Simultaneously, Decree 3.945/2001 provided overall complementary regulation. It designated the Council for Genetic Heritage Management (CGEN) as the ABS national competent authority and the Department of Genetic Heritage (DPG) to operate as Secretariat for CGEN. DPG functions within the Ministry of the Environment.

Subsequent Decrees have amended the requirements for obtaining authorization for access, regulated the application of administrative penalties and regulated the use of public funds for benefit sharing.

Since its establishment in April 2002 CGEN has approved a number of norms to clarify and promote the implementation of the legislation, including 40 Resolutions and 7 Technical Orientations. The Council has also certified over 300 public *ex situ* collections.

To increase CGEN's capacity to manage the ABS system, the council may accredit other institutions to concede access authorizations. The Federal Environment Agency -IBAMA, the National Science Research Council - CNPq, and the National Institute of Historic and Artistic Heritage - IPHAN have been accredited by CGEN.

The Brazilian National Patent Office (INPI) has begun refusing patent requests which do not fulfill the requirements of Provisional Measure 2.186-16. This is an important step towards meeting the requirements of Article 17 of the Nagoya Protocol which requires Parties to designate one or more checkpoints to ensure compliance by monitoring and enhancing transparency about the utilization of genetic resources.

The regulatory system as established in 2001 has proved to be very difficult to implement, notwithstanding the clarifications and adjustments made by CGEN over the succeeding eleven years. This is not surprising given that Brazil was a pioneer in the attempt to incorporate the provisions of Article 15 of the CBD into a national legislative, administrative and policy framework. There were no existing models to be followed.

The rationale of the system put in place twelve years ago revolved largely around command and control principles. This is understandable in light of Brazil's longstanding concern to forestall biopiracy in the absence of any international benefit sharing framework. However one of the consequences of this focus is that the required procedures may have resulted as a disincentive to applied research and development for both academic researchers and industry.

Despite the difficulties, there has been significant progress. By 2012, CGEN and accredited institutions had registered more than 600 access authorizations. Institutions and companies, mainly cosmetic and pharmaceutical, are sharing benefits, sometimes through capacity building and training, but mostly in monetary form. Over 70 contracts have been registered by CGEN, generating benefits for local communities and landowners. However, that is still well short of the existing potential.

Nevertheless the experience accumulated over the past twelve years is very valuable. The imminent adoption of a legally-binding global regime on ABS in the form of the Nagoya Protocol provides a unique window of opportunity. Brazil is now able to refocus its domestic ABS regime from command and control to encouraging cooperation in scientific research, within Brazil and with international partners, thereby generating more benefits and reinforcing conservation and sustainable use of biodiversity. Indeed, the government is working on a new bill to be sent to the Congress. The elaboration of this bill is well in advance, after thorough consultation to the many stakeholders involved.

Brazilian regulation on ex situ conservation and on transfer of biological samples for ABS

The legislation regulates activities of *ex situ* collections. Foreign institutions or companies that wish to access genetic resources must be associated with a Brazilian institution. For identification purposes 'sub-samples' of material sent abroad must be lodged with an accredited Brazilian *ex situ* collection. Furthermore, authorization from CGEN or accredited institutions (CNPq, IBAMA, and IPHAN) is required for the shipment abroad.

Notably for *ex situ* collections, the technical guidelines clarified that the term 'collection' refers to removal of an organism (or parts of it) from *in situ* conditions, whilst the term 'access to the component of genetic resource' refers to access at molecular level – isolating, identifying or utilising information stemming from genetic origin – or of substances stemming from living organisms' metabolism and extracts obtained from organisms.

CGEN's Resolution 32 sets guidelines for Prior Informed Consent and benefit-sharing requirements to access material in most *ex situ* collections that was collected *in situ* before, and since the Provisional Measure was enacted: for material collected after 2001, PIC should be sought from the original provider, as identified by the collection (CGEN will evaluate cases where the provider cannot be found), while the *ex situ* collection holding the material should handle PIC for pre-2001 specimens[168].

Regarding transfers and shipment of genetic resources, the minimum requirements are:

- information on intended use
- collecting data
- deposit of a "sub-sample" on a trusted depository collection;
- PIC and Material Transfer Agreement in the form of a benefit sharing contract (BSC).

BSCs are not required for access to genetic resources for research purposes, but are required for bioprospecting and technological development.

CGEN keeps working towards improving guidelines and norms to promote a better regulatory environment for researchers, industry, indigenous peoples and local communities. Many challenges still lie ahead. Transparency and wide interlocution with all stakeholders involved are paramount to promote the necessary conditions for innovation to thrive, benefits to be fairly shared and sustainable development to take place.

[168] https://www.cbd.int/abs/measures/measure.shtml?id=68321

ANNEX 6. Provisional Agenda

WORKSHOP AGENDA

The Role Played by Scientific Biological Collections under the Nagoya Protocol

18 to 20 June 2013,
Álvaro Barcellos Room, Brazilian Agricultural Research Corporation,
Brasília, Brazil

Context

In 2008, the EU-Brazil Sector Dialogues Support Facility was created as part of a bilateral cooperation programme spanning 2007-2013, signed between the Brazilian government and the European Community.

The present meeting is part of the EU-Brazil Sector Dialogues Support Facility. It seeks to explore and build upon the history of interactions between Brazilian and European *ex situ* collections, and the current practices that were developed in response to the Convention on Biological Diversity, and how such practices are suitable or adaptable to the new realities brought by the Nagoya Protocol.

Moreover, the main goals of this meeting are to discuss possible roles that collections could play in the implementation of the Nagoya Protocol, and explore common interests and mechanisms to promote more effective cooperation towards facilitation of research, traceability of genetic resources, and mechanisms to deal with the change of purpose in the use of genetic resources.

It is well known how diverse are the *ex situ* collections: plant, animal and microbial resources; maintained in preserved or living form; utilized for non-commercial or commercial purposes by public or private bodies. Nevertheless, this dialogue will focus predominantly on publicly-held collections and non-agricultural collections and their relation to the Protocol.

Furthermore, one of the outcomes of the present high level meeting is to assist in the implementation of Articles 8a, 9, 19, 20, 22 and 23 of the Nagoya Protocol. In that sense, this opportunity aims to bridge the science – policy gap by gathering researchers and curators of biological collections to engage in an insightful exchange of ideas.

Working Time:

- 09:00 – 12:00 and 13:00-17:30.

1. Opening of the Meeting

2. Research Needs and Barriers Related to ABS Legislation

Introductory presentations:

***Ex situ* conservation under the Nagoya Protocol and under the Brazilian ABS legislation**

- Larissa Costa – Brazilian *Ministry of Foreign Affairs*

Brazilian trusted depository institutions

- Ana Yamaguishi – *Ministry of the Environment*

The E.U. Commission's legislative proposal on implementing the Nagoya Protocol

- Kathryn K. Davis, Project's Senior Consultant

Report of the Brazilian workshop "O papel das coleções biológicas no cenário do Protocolo de Nagoia"

- Luciane Marinoni, Project's Senior Consultant

Suggested issues for discussion:

- Needs and barriers for research, including exchange and transfer of biological material, in the face of current national/regional legislation, guidelines, and rules of procedure; what will change under the new scenario of the Nagoya Protocol;
- Challenges and opportunities for facilitation of research collaboration, traceability of genetic resources, monitoring of utilization, changes of intent (where access for non-commercial purposes leads to interest in use for commercial purposes);
- Issues raised by the proposed European and Brazilian ABS regulations/legislation on the role played by *ex situ* collections on access

to genetic resources;

- Innovative roles that biological collections can play in the implementation of the Nagoya Protocol to promote access to genetic resources and the conservation and sustainable use of biological diversity.

3. Good ABS Practices for Research Facilitation and Cooperation

Introductory presentations:

Activities of science, technology and innovation for the systematization of knowledge and information on biodiversity

- David Oren – Ministry of Science and Technology

Collecting, use and supply of plants at Kew

- Natasha Ali – Royal Botanic Gardens, Kew

Exchange of genetic resources under the ITPGRFA

- Filipe Teixeira, Brazilian Agricultural Research Corporation

Suggested issues for discussion:

- Identification of best practices for the exchange of biological material between collections for non-commercial scientific research purposes, and the monitoring of utilization;
- Practical measures to facilitate the cooperation and sharing of benefits between Brazilian and European collections;
- Practical measures to address access to genetic resources in *ex situ* collections for commercial purposes;
- Considerations and possible measures for appropriate collection, use and transfer of traditional knowledge associated with genetic resources;
- Future developments: how *ex situ* collections can adapt to cutting-edge and future scientific developments, including the transfer and use of genomic and epigenomic information, and associated capacity-building, aiming at better knowledge of biodiversity.

4. Recommendations

5. Closure of the Meeting

6. Guided visit to a Brazilian collection

- Thursday 20 June 2013. From 14:00 to 18:00. Visit to EMBRAPA/CENARGEN *ex situ* collections

ANNEX 7.
RESOLUÇÃO CGEN Nº 21, DE 31 DE AGOSTO DE 2006

Dispõe sobre as pesquisas e atividades científicas que não se enquadram sob o conceito de acesso ao patrimônio genético para as finalidades da Medida Provisória no 2.186-16, de 23 de agosto de 2001.

Provides for the research and scientific activities that are not under the concept of access to genetic resources for purposes of the Provisional Measure 2,186-16 of August 23, 2001.

O CONSELHO DE GESTÃO DO PATRIMÔNIO GENÉTICO, tendo em vista as competências que lhe foram conferidas pela Medida Provisória nº 2.186-16, de 23 de agosto de 2001, e pelo Decreto nº 3.945, de 28 de setembro de 2001, e o disposto no art. 13, inciso I, do seu Regimento Interno;

THE BOARD OF MANAGEMENT OF GENETIC HERITAGE, considering the powers conferred by Provisional Measure No. 2,186-16 of August 23, 2001, and Decree No. 3,945, of September 28, 2001, and the provisions of art. 13, paragraph I, of its Rules of Procedure;

Considerando que diversos tipos de pesquisas e atividades científicas poderiam enquadrar-se sob o conceito de acesso ao patrimônio genético para fins de pesquisa científica simplesmente pelo fato de utilizarem ferramentas metodológicas moleculares para a sua execução de modo circunstancial e não propriamente porque seus objetivos ou perspectivas estejam relacionados com o acesso ao patrimônio genético;

Considering that various types of research and scientific activities could be under the concept of access to genetic resources for scientific research purposes simply because they use methodological molecular tools for their implementation in a circumstantial manner and not because your objectives or intentions are related to access to genetic resources per se;

Considerando que a finalidade dessas pesquisas e atividades, assim como seus resultados e aplicações, não interferem no principal objetivo da Medida Provisória no 2.186-16, de 2001, que é a garantia da repartição justa e equitativa dos benefícios resultantes da exploração econômica de produto ou processo desenvolvido a partir de amostras de componentes do patrimônio genético, resolve:

Considering that the aims of such research and activities, as well as their results and applications, do not interfere with the main objective of Provisional Measure 2.186-16, 2001, which is the guarantee of fair and equitable sharing of benefits arising from economic exploitation or product process developed from samples of genetic heritage components, determines:

Art. 1º As seguintes pesquisas e atividades científicas não se enquadram sob o conceito de acesso ao patrimônio genético para as finalidades da Medida Provisória no 2.186-16, de 23 de agosto de 2001:

Article 1. The following research and scientific activities are not under the concept of access to genetic resources for the purposes of Provisional Measure No. 2.186-16 of August 23, 2001:

I - as pesquisas que visem elucidar a história evolutiva de uma espécie ou de grupo taxonômico a partir da identificação de espécie ou espécimes, da avaliação de relações de parentesco, da avaliação da diversidade genética da população ou das relações dos seres vivos entre si ou com o meio ambiente;

I - research that aims to elucidate the evolutionary history of a species or taxonomic group from the identification of species or specimens; the evaluation of phylogenetic relationships; the assessment of the genetic diversity of the population or the relationship of living beings with each other or with the environment;

II - os testes de filiação, técnicas de sexagem e análises de cariótipo que visem a identificação de uma espécie ou espécime;

II – paternity tests, sexing techniques and karyotype analyses intended to identify a species or specimen;

III - as pesquisas epidemiológicas ou aquelas que visem a identificação de agentes etiológicos de doenças, assim como a medição da concentração de substâncias conhecidas cujas quantidades, no organismo, indiquem doença ou estado fisiológico;

III - epidemiological research or research that aims to identify the etiologic agents of diseases, as well as measurement of the concentration of known substances whose relative quantities in the body indicate disease or physiological state;

IV - as pesquisas que visem a formação de coleções de ADN, tecidos, germoplasma, sangue ou soro.

IV - research intended to build DNA, tissues, germplasm, blood or serum collections.

§ 1º As pesquisas e atividades científicas mencionadas neste artigo estão dispensadas da obtenção de autorização de acesso a componente do patrimônio genético.

§ 1 The research and scientific activities mentioned in this article are exempted from obtaining authorization for access to genetic heritage components.

§ 2º O critério estabelecido nesta Resolução tem a finalidade exclusiva de orientar o enquadramento destas atividades sob a Medida Provisória no 2.186-16, de 2001, sem

prejuízo do atendimento das exigências estabelecidas em outros instrumentos legais, bem como em tratados internacionais dos quais o Brasil seja Parte.

§ 2 The criteria established in this Resolution have the sole purpose of guiding the framework of these activities under the Provisional Measure 2186-16, 2001, subject to compliance with the requirements established in other legal instruments, as well as in international treaties to which Brazil is a party.

Art. 2 º Esta Resolução entra em vigor na data de sua publicação.

Article 2 This Resolution shall come into force on the date of its publication.

Annex WP9-6

To:
Mrs Linda Colette
Secretary Commission on Genetic Resources for Food and Agriculture
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00153 Rome
Italy

Utrecht, March 14, 2014

Your ref: Invitation to report on voluntary codes of conduct etc. in relation to ABS

Dear Madam Secretary,

On behalf of the Microbial Resource Research Infrastructure, I am sending you an overview of voluntary codes of conduct, best practices and standards developed and adopted by the community of microbial resource centres in Europe. The relationships between Food and Agriculture sectors and the public service collections of pure cultures of microorganisms are manifold, and we highly appreciate this opportunity to provide the Commission on Genetic Resources of the FAO with this information. We hope that this will be useful.

If you have any questions or need more information, I am at your disposal.

With highest regards,

Gerard Verkleij

Leader MIRRI Workpackage 9 (Legal Operational Framework)

Curator CBS Collections

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Overview of model contractual clauses, best practices and standards for in relation to access and benefit sharing for the community of Microbial Resource Centres in Europe

Microbial Resource Centres (MRCs) hold *ex situ* collections of authentic, high-quality and well-identified cultures of living microorganisms which are available for global research in agriculture, food production, plant health and numerous other sectors. These microorganisms are, for example, used as reference materials in pathogen research, discovery of effective agents for pest control, new bio-active compounds, and improving food and beverage production. Agriculture and food security are facing the major challenges of globalisation, consumer demands and environmental concerns. The Microbial Resources Research Infrastructure [1] (**MIRRI**) brings together European MRCs with users of the resources, policy makers, potential funders, and other stakeholders, aiming at coordinating improved services, facilitating the deposit of important new microbial material and improving access to microbial resources in an appropriate legal framework. MIRRI's efforts will strongly build upon the existing links to the Global Biological Resource Centre Network (GBRCN-Demonstration Project) with partners and their respective regional and national networking activities e.g. in Brazil, China, Japan, Kenya, Taiwan and other links to e.g. USA and Australia.

Since the entry into force of the Convention on Biological Diversity (CBD), the community of MRCs has worked to reach compliance and harmonise practices. Several initiatives emerged, often leading to EU-funded projects aiming to develop model contractual clauses and best practices. Some projects are now completed, others are currently underway using output of earlier projects that will be updated and supplemented with new elements for best practices, that are in compliance with the Nagoya Protocol on Access and Benefit Sharing (ABS). A summary of the work done is presented below. Footnotes provide further detailed information.

A first voluntary Code of Conduct

The project **MOSAICC**[2], which was financially supported by European Commission DG Research, aimed to develop a voluntary **Code of Conduct** that provides a set of **model clauses for PIC and MAT** for providers and recipients of microbial genetic resources (MGRs), and for **Material Transfer Agreements** (MTA) for the deposit in public collections (also referred to as Material Accession Agreements) and supply of MGRs by these collections to users. Key elements identified for MTA included (i) description of the MGRs, (ii) specifications of terms of use (commercial or non-commercial) and, (iii) terms of benefit sharing (monetary or non-monetary). MOSAICC was completed in 1999, became listed on the CBD website in the Nagoya Protocol webpage and also appears on the WIPO list of sources of model contractual clauses in the context of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore. MOSAICC also influenced the drafting process for the CBD Bonn Guidelines. The latest version of the MOSAICC document is available on the BCCM website. The follow-up project **MOSAICS**[3], also funded by the EU, aimed at the development of an Integrated Conveyance System, offering (i) tools to evaluate the economic value of MGR, (ii) standard provisions to

enable uncomplicated tracking of MGR, and (iii) a way of balanced benefit sharing for those that are entitled to be rewarded for the services and products they provide to society.

The practice of sharing MGRs and related information by scientists world-wide for research purposes, known as **Microbial Commons** [4, 5, 6] has been key to the development of microbiology over more than a century. Collections have been involved in several recent studies and meetings on the subject of microbial commons, which aimed at analysing current practices of sharing MGRs and information by collections, researchers and their networks, and how this practice could be placed on a more solid scientific, and legally sound, institutional basis. The complicated issues of ownership was also addressed and a "**bundle of rights**" [7] attached to MGRs was proposed, which should be regulated by law and managed through agreements and contracts between stakeholders.

Best practice and the ECCO-Core MTA

Even years after the publication of the Bonn Guidelines in October 2001, many Parties to the CBD still failed to set in place authorities with competence for processing requests for PIC and MAT. Meanwhile, the collections continued their efforts to find ways to enhance compliance under these quite difficult circumstances.

After considerably discussion in various meetings, most public collections adopted a best practice for deposit and supply of MGRs. The main elements for this best practice are:

- Accession forms to be completed by the depositor of the MGR where information on the PIC and MAT should be provided, if applicable
- No acceptance of MGRs without information about the country of origin
- Supply by the collection of MGRs to users under MTA settling the most important conditions for supply and terms of use

Collections recognised that a highly harmonised MTA for supply by all European collections would contribute to improving legal certainty and transparency to both users and suppliers of MGRs. Therefore, the European Culture Collection's Organisation [8, 9] (**ECCO**) developed the **"ECCO-Core MTA"** [10], taking recommendations of MOSAICC into account. The Core MTA answered to the need of collections to have a harmonised MTA that settles terms for use of supplied MGRs, and also effectively raises awareness with the users of MGRs about their obligations under the CBD, especially with regard to benefit sharing. The Core MTA was agreed upon by the ECCO members in 2009, and subsequently implemented in many European collections.

Next steps to prepare for the entry into force of the Nagoya Protocol

Member collections of ECCO and other participants in the Global Biological Resource Centre Network (**GBRCN**) Demonstration Project[11], joined in an endeavour to establish MIRRI. In its EC funded three-year Preparatory Phase (2012-2015), MIRRI is focussing on **the preparation of a legal operational framework** for the RI. MIRRI has been following the development of a Regulation for ABS in the European Union closely, provided a formal response to the draft EC proposal for the regulation, communicated directly with European Parliament Rapporteur and other MEPs, and is currently evaluating the outcome of the trilogue negotiations.

MIRRI will take the output of previous projects and initiatives into the next process of formulating minimal requirements for compliance and use these to develop a new common policy for ABS and IPR for MGRs. Alongside, partners of the MOSAICC project have started to review its set of model clauses and recommendations with the help of other experts to make it fully compliant with the Nagoya Protocol.

Global efforts

The World Federation of Culture Collections (**WFCC**) submitted an overview of efforts and novel approaches to COP9 in 2011[13]. The European MRCs are currently also involved in discussions about the

consequences of the NP with collection institutions outside Europe. During international meetings[14] addressing these issues where curators of European as well as non-European collections and representatives of various governments were also present, considerable interest and positive responses were seen to the proposal to set up a **Register of collections** in the EU, as proposed by the EC in the draft Regulations. On the basis of growing consensus among MRCs world-wide on how to achieve compliance, the "**TRUST**" initiative was coined by the WFCC. The acronym stands for "TRransparent User-friendly System of Transfer for Science & Technology". TRUST aims to create an effective global system of trusted sources for microbiology, which could be supported by further development of its pioneering database system which is maintained by the World Data Centre for Micro-organisms[15] (**WDCM**). In the WDCM CCInfo-database, collections can register through a unique acronym and numerical identifier in its official list of MGRs. Today, some 656 culture collections are registered in CCInfo, holding over 2 300 000 cultures of microorganisms. The WDCM system will use the recent technology of electronic markers called "Globally Unique Identifiers (GUIDs)" that could be used to set up a robust system to organise transfers of (micro) biological items, tracking the flow of resources and related information.

Conclusions

The community of microbial collections in Europe has been very active and continues to be so. The final result of the process of developing the EU Regulation on ABS will largely determine next steps to be taken towards the development of best practises suited for the new situation that will come into existence in the course of 2014. Based on its long-standing cooperation in ECCO and WFCC, the community of microbial collections is ready to go forward and contribute to a successful implementation of the NP. It is hoped that it will bring more legal certainty and also justice to the goals of the CBD.

Contact person:
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[1] Microbial Resource Research Infrastructure (MIRRI) is an EU funded project that aims to build one pan-European infrastructure for microbial collections that will more effectively facilitate access to high-quality microorganisms, their derivatives and associated data and services, for research, development and applications. After its acceptance on the European Strategy Forum on Research Infrastructures road-map, MIRRI obtained funding from the European Commission and on Nov 1st, 2012 it entered a three-year Preparatory Phase, in which partners will focus on governance and structure, and technical, legal, and financial issues to build the network. This will establish the links across the distributed RI and between the RI microbiological resource centre (MRC) community, its users, policy makers and potential funders. http://www.mirri.org/

[2] MOSAICC stands for Microorganism Sustainable use and Access regulation International Code of Conduct (http://bccm.belspo.be/projects/mosaicc/). MOSAICC recommendations facilitate access to MGRs and help partners to make appropriate agreements when transferring MGRs, in the framework of the CBD and

other applicable rules of international and national laws. A version that was updated in 2011 is provided at theBCCM website.

[3] MOSAICS stands for "Microorganisms Sustainable use and Access management Integrated Conveyance System". It was funded by Directorate General Research of the European Commission under the Sixth Framework Program. The consortium of the MOSAICS project is made of partners from developed and developing countries, including culture collections, international organisations, branch federations and specialised research institutes. Already in 1999, the MOSAICC project had identified three necessary features for a system to implement coherently the CBD provisions on ABS. MOSAICS central objective is the development of such an integrated conveyance system that:

- has reliable tools to evaluate the economic value of microbiological resources;
- disposes of validated model documents with standard provisions to enable tracking via an uncomplicated procedure, widely applied by microbiologists;
- combines valuation and tracking in one system for trading of microbiological resources, with balanced benefit sharing for those that are entitled to be rewarded for the services and products they provide to society.

[4] Dijkshoorn L, de Vos P, Dedeurwaerdere T (2010). Understanding patterns of use and scientific opportunities in the emerging global microbial commons. Research in Microbiology 161: 407-413.

[5] Dedeurwaerdere, T (2010). Global microbial commons: institutional challenges for the global exchange and distribution of microorganisms in the life sciences. Research in Microbiology 161: 414-421.

[6] Dedeurwaerdere, T (2010). Self-governance and international regulation of the global microbial commons: introduction to the special issue on the microbial commons. International Journal of the Commons 4: 390-403. URN:NBN:NL:UI:10-1-100217.

[7] The innovative concept of "bundle of rights" is a dynamic model of ownership management moving away from the static concept of ownership towards a flexible allotment of rights. Ownership constitutes a "bundle" of use and decision rights that are attributed to a number of stakeholders / economic agents. It is a set of operational and collective choice rights defining respectively who decides upon the use that one can make of a resource, and who decides upon the future exercise of the rights on the resource. Such scheme allows multi-ownership of a gradual level of use and decision rights. These rights can begin with basic access rights, encompassing research delivering outputs to the public domain, distribution on to third parties, exploitation rights to develop intellectual property and its ownership which may include reach through rights. Furthermore, the application of the "bundle of rights" makes possible the enforcement of the "sovereign rights of States over their natural resources" without prejudice to private rights. Unambiguous allotment of rights in advance will facilitate rightful benefit sharing "at the end of the pipe". See also Dedeurwaerdere, T : Understanding ownership in the knowledge economy: the concept of the bundle of rights. BCCM News Edition 18 - Autumn 2005.

[8] The European Culture Collections' Organisation (ECCO, http://www.eccosite.org/) was established in 1981. ECCO comprises 61 members from 22 European countries, holding over 350.000 strains of yeasts, filamentous fungi, bacteria and archaea, phages, plasmids, animal cells including human and hybridoma cell lines, viruses, plant cells, algae and protozoa. The aim of the ECCO is to promote collaboration and exchange of ideas and information about all aspects of culture collection activity. ECCO meetings are held annually and are a valuable forum for discussion and innovation on the future development of member collection activities.

[9] Fritze D (2010) A common basis for facilitated legitimate exchange of biological materials, proposed by the European Culture Collections' Organisation (ECCO). International Journal of the Commons 4: 507-527. URN:NBN:NL:UI:10-1-100222.

[10] Janssens D, Tindal B, Green P, Garay E, Fritze D, Stalpers J, Smith D, Bimet F, Desmeth P (2009). The ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection.

Article 7 of this standard MTA is cited here: "If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSE(S), it is the responsibility of the RECIPIENT, in

advance of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the MATERIAL, as indicated by the COLLECTION's documentation." The full MTA text is downloadable from http://www.eccosite.org/.

[11] Global Biological Resource Centre Network Demonstration (GBRCN) Project was supported by the German Federal Ministry of Research and Education (BMBF) following work in the OECD to improve access to high quality biological resources and information to support research and biotechnology as a platform for a knowledge-based bioeconomy. Partners included collections from 15 countries, with representatives of the WFCC, a global network and regional networks, ECCO and the Asian Consortium for Microorganisms (ACM). The final report of the project which was completed in 2012 can be downloaded at http://www.gbrcn.org/.

[12] Response of MIRRI to the "Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union" E. Stackebrandt & G. Verkleij, March 14, 2013.

[13] Desmeth, P., Kurtböke, I. & Smith, D. (2011). Tools to implement the Nagoya Protocol on Access and Benefit Sharing in microbiology; ABS, an intrinsic preoccupation of the World Federation for Culture Collections (WFCC); http://www.cbd.int/abs/doc/protocol/icnp-1/wfcc-en.pdf

[14] For example: NITE-NBRC 10th Anniversary Symposium "Impact of Nagoya Protocol on management of Biological Resource Centers", Tokyo, Japan, Dec. 6, 2012.

[15] The World Federation for Culture Collections (WFCC) has developed a pioneering database system by registering its members through a unique acronym and numerical identifier in its official list and urging them to catalogue their microbiological resources. This system is maintained and improved by the World Data Centre for Micro-organisms (WDCM). Combining the WDCM system and the use "Globally Unique Identifiers (GUIDs)" set up a robust system to organise transfers of (micro) biological items, tracking the flow of resources and related information. This system also facilitates the application of ABS since it can potentially retrieve all kinds of information about microbiological resources, including information related to the location and movements of the resource. The WDCM portal acts as an information broker between all online catalogue entries of the culture collections. See http://www.wdcm.org/.

MIRRI WP 9.2 Questionnaire on biosecurity implementation

For filling out this questionnaire, please, use the Code of Conduct on Biosecurity for Biological Resource Centres (BRCs) as attached here and answer as detailed as possible. Your individual response will be highly appreciated.

Please, also see the MIRRI Statement at the end of this document.

(1) BIORISK MANAGEMENT

- Is implementation of export control a key issue of biosecurity and general security and visible through your documentation?

- Does the institution have biorisk management in place, is it a mandatory part of the institution's operational practices and is it documented?

- What support do you think would be useful to facilitate biorisk assessment?

- Does your collection hold organisms of risk groups 2, 3 or 4; toxin producers, animal pathogens, plant pathogens etc.? If so, please specify which.

(2) RAISING AWARENESS

- Is there an expert in the institution who is responsible for organising in-house training and information flow for staff to maintain an appropriate level of biosecurity consciousness?

- Does the institution provide adequate training and information on biosecurity and is this documented?

- Are related third parties identified and informed regarding awareness of relevant biosecurity issues?

(3) REPORTING MISUSE

- Is reporting of suspicion of misuse in the context of biorisk facilitated in anyway in your institution?

- Is protection of reporting persons and confidentiality guaranteed by the institution's administrative bodies?

(4) INTERNAL AND EXTERNAL COMMUNICATION

- For facility protection, does the institution restrict access to sensitive information and data on potential dual-use research or material; are authorised / unauthorised persons defined?

- Does the institution regulate sensitive communication in the biosecurity context?

(5) RESEARCH AND SHARING KNOWLEDGE

- Are research projects checked for possible dual-use potential at an early stage (before project application)? In case yes, who is involved in performing such checks, in-house experts, a commission, an authority?

- Does the institution screen manuscripts intended for publication for content about potential or listed dual-use organisms that could be potentially misused?

- Is critical know-how transfer in the dual-use context regulated by the institution (examples: customer requests, business travel, training courses, visitors and guests)?

(6) ACCESSIBILITY

- Are listed or potential dual-use organisms properly locked away?

- Is physical access control available in the institution? Is access control defined and how is authorization of persons limited?

(7) SUPPLY, SHIPMENT AND TRANSPORT

- What control measures do you have in your institution to make sure all recipients of material are authorised to receive it? Are there computerised and manual check systems in place? How does the institution make sure all requirements are met? Are the relevant authorities to be contacted known and contacted if necessary?

- Is the transport chain secure, are couriers professional and legally authorised, especially to transport dangerous goods of class 6, division 6.2, infectious substances?

- Can you explain how export control is verified in such a way that the risk of a breach is minimal? Does your organisation use IT systems to support the export control regime and what are its key-functionalities?

The above questions that constitute the MIRRI WP9.2 biosecurity questionnaire directly correspond with the sub-issues of the respective seven key issues of the Code of Conduct on Biosecurity for Biological Resource Centres, BRCs, (please see attached) and may lead to YES / NO responses or to more detailed responses. In all cases, answers are necessarily individual for institutions, institutions cannot be compared with regard to the details of practical implementation. The level of security and implementation of security measures for "biosecurity" will depend on the outcome of risk assessment and would be minimal if the organisms held by the BRC are of low risk; as long as a sound system for risk assessment and review of current national legislation and international requirements is in place that may well be sufficient for the respective BRCs. It will be essential to investigate the level of risk assessment that exists in the BRCs (what capacity do they have, what is done practically); most BRCs should be able to address biosecurity issues easily based upon their national regulations. It is fundamental, however, that the seven key issues of the Code of Conduct are covered by BRCs or, in a broader context, by institutions in the life sciences.

This biosecurity questionnaire aims at identifying gaps, possibly in a graded manner: which are the most frequent and the most dangerous gaps (with legal consequences), what makes implementation most difficult, where is help needed? While considering that in most institutions the situation regarding personnel, finances and tools as well as room/space is problematic and never optimal, the gap analysis becomes even more important. As a consequence, it will finally be an important goal of MIRRI to find harmonised ways to implement biosecurity and the code of conduct. This questionnaire will be treated confidentially and will remain within the MIRRI WP 9.2. When finally the feedback is summarized, neither names of persons or institutions will be mentioned, nor their locations in countries.

The Biosecurity Quest is one of the Surveys that will help to define the function and content of the Microbial Resource Research Infrastructure, MIRRI

Statement on use, access and protection of collected data

1. What information will be collected, for what purpose and by what means?
The MIRRI surveys gather information from European microbial/genetic Resource Centres and their Users, aiming to define the function and the content of MIRRI and to provide means for efficient and coordinated access to the microbial/genetic resources, their derivatives, and associated data and services. The survey results will also be used to improve quality standards, harmonization in data storage and collection management.
For this survey the following data will be collected:
Information from microbial/genetic Resource Centres about their structure, services offered, Quality Management System, legal issues related to their activity, etc.

2. Who has access to your information and to whom is it disclosed?
The raw data gathered in this survey are accessible only to a strictly limited number of members of the MIRRI preparatory phase consortium, responsible for the data analyses.
The identity of the persons filling in the questionnaire and of their Company/Institution will not be made public, and will only be divulged within the MIRRI consortium and only to those MIRRI partners on a need to know basis for further direct communication/contact in the frame of the MIRRI project.
The information freely communicated within and outside the MIRRI project shall be visible as read only documents and shall be digested and anonymised both at the level of the personal names as at the level of the company/institution name.
The digested and anonymised information will be delivered to the European Commission, as an output (Deliverable) from the MIRRI preparatory phase project.

3. How do we protect and safeguard your information?
Access to the Questionnaire contents is limited to the members of MIRRI Work package 9.

4. How long do we keep your data?
Individual responses (raw data) will be deleted at the latest 1 year after the digested output (Deliverable) has been reported to and accepted by the European Commission.

5. How can you access, verify, modify or delete your data?
To verify, modify, correct or delete any personal data you can contact Christine.Rohde@dsmz.de, by sending an e-mail giving details of your request.

Code of Conduct on Biosecurityfor Biological Resource Centres (BRCs)

I. PREAMBLE

Accumulated and advancing knowledge on biological systems offers substantial benefits to mankind, to research and to development in all areas of basic and applied bio-medical and bio-technological sciences. However, this improved knowledge is intrinsically associated with the potential for dual application: for beneficial or malicious purpose. The possibility of using scientific knowledge for peaceful or non-peaceful purposes reflects the *dual-use dilemma* and confers a responsibility on both those with the knowledge and with the biological resources. The responsibilities of those engaged in the life sciences have an increasing role for in-depth implementation of the Biological and Toxin Weapons Convention (BTWC). Scientific openness and a sense of security are prerequisites for freedom of scientific work, publication of findings and exchange of bio-resources to carry out activities in the life sciences. This Code of Conduct on Biosecurity is to help microbial Biological Resource Centres (BRCs) promote a basic ethical understanding of science compliant with the BTWC and raise awareness to prevent misuse in the life-sciences context.

This Code intends to raise awareness on biosecurity within and outside BRCs and to clearly demonstrate that BRCs are fully compliant with national and international legislation and support the BTWC as an international norm prohibiting biological weapons. It is not the aim of this Code to influence the range of bio-resources maintained or life science activities performed at BRCs. Above all, this Biosecurity Code of Conduct is meant to complement legislative procedures.

II. SCOPE

The aim of this Code of Conduct is to prevent microbial BRCs from directly or indirectly contributing to the malicious misuse of biological agents and toxins, including the development or production of biological weapons.

BRCs commit themselves to this Code of Conduct on Biosecurity considering their specific situation and key role as an essential part of the international infrastructure underpinning biotechnology: providing the world-wide scientific and industrial communities with authentic biological materials required in research, application and teaching as well as related information and services. Being part of the scientific community they conduct activities in the life sciences, offer training courses, expertise and knowledge and they support the bioeconomy.

Many BRCs are entrusted with the collection and controlled supply of potentially hazardous bio-resources. This requires high responsibility, well-established biorisk analyses and management, and appropriate BRC internal infrastructures, profound knowledge of relevant bio-legislation including export control and respective protective measures. This Code calls for implementation and compliance of awareness, accountability and oversight and targets all those engaged in life sciences activities, laboratory workers, managers, stakeholders and others.

III. CODE

(1) BIORISK MANAGEMENT

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

(2) RAISING AWARENESS

- Devote specific attention in the education and further training of all staff on:
  - the dual use dilemma i.e. the risks of misuse of biological material, information and life sciences research

- the requirements of regulations in this context.

- Provide regular training and carry out auditing to maintain up to date knowledge on biosecurity.
- Raise awareness of related third parties on their responsibilities.

(3) REPORTING MISUSE

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

(4) INTERNAL AND EXTERNAL COMMUNICATION

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

(5) RESEARCH AND SHARING KNOWLEDGE

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

(6) ACCESSIBILITY

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

(7) SUPPLY, SHIPMENT AND TRANSPORT

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