WFCC NEWSLETTER AUGUST 2005

Biological Resource Centres (BRC)

The term Biological Resource Centre (BRC) was born when Japan raised the issue of long-term sustainability of culture collections with the Organisation for Economic Co-operation and Development (OECD). The OECD defined a BRC in its report *Biological Resource Centres – Underpinning the Future of Life Sciences and Biotechnology* (http://oecdpublications.gfi-nb.com/cgi-bin/oecdbookshop.storefront) dated 2001.

While some collections already call themselves BRCs, in its original context none exist until the Global BRC Network comes into being at the end of 2006. A paper presented to the *Committee for Scientific and Technological Policy* (CSTP) for the approval of the OECD member state Ministers entitled *Biotechnology for sustainable growth and development* (January 2004), describes the need for high-quality biological resource centres (BRCs), http://www.oecd.org/dataoecd/43/2/33784888.PDF. These form a vital element in a sustainable international scientific infrastructure, necessary to underpin the successful delivery of the benefits of biotechnology. They are fundamental to the harnessing and preservation of the world's biodiversity and genetic resources. They are part of the key infrastructure supporting biotechnology, bioprocessing and the development of new approaches in the prevention, diagnosis and treatment of disease. They also have a vital role in ensuring the safe and regulated use of organisms that are known pathogens to humans, plants or animals. The BRC is the next generation culture collection that keeps pace with user requirements functioning through internationally accepted operational criteria as well as meeting international rules, regulations and national legislation. Capacity building is essential to transform the culture collection into a BRC.

The European EBRCN project, European Biological Resource Centers Network (QLRT-2000-00221), was established and funded by the EU to help develop standards utilizing those that had been established by the UK National Culture Collection (UKNCC – http://www.ukncc.co.uk) and in particular the guidelines established by the Common Access to Biological Resources and Information (CABRI- http://www.cabri.org). Additional outputs of this project were helpful resource documents providing detailed information and guidance for culture collections in order to better cope with all the aspects of bio-legislation. A more general document on compliance with the law and a specialized document on deregulated transport regulations are offered here. Others are available on the EBRCN and WFCC websites (http://www.ebrcn.org; http://www.wfcc.info).

An information paper from the European Biological Resource Centres Network

An EU funded project to coordinate collection activities with the goal to address issues raised by the OECD global and virtual Biological Resource Centre initiative *http://www.ebrcn.org*

Did you know that there is extensive legislation governing the handling, use and distribution of microorganisms?

Microorganisms are isolated, grown, characterized, preserved for the long-term, stored and transported between laboratories. They are shipped by various means; by mail, courier or by hand, from one laboratory to another within countries and often across borders and continents. They are sent for identification, reference, research or for production purposes from colleague to colleague, from and to culture collections. All these actions involving dispatch must be carried out safely and in compliance with various legislations and regulations that control these matters. The existing legislation is regularly updated or added to (http://wdcm.nig.ac.jp/wfcc/wfccreports.pdf).

The importance of a laboratory's health and safety procedures stretches beyond its walls to all those who may come into contact with the substances and products dispatched from that laboratory. A microorganism in transit might put carriers, postal staff, freight operators and recipients at risk, some organisms being relatively hazard free whilst others quite dangerous. It is essential that safety and shipping regulations are followed to ensure safe transit. There are several other pieces of legislation that restrict the distribution of microorganisms of which a microbiologist must be aware.

A principal goal of the EBRCN project is to establish a European Standard for the operation of BRCs. Some examples of guidelines and quality management systems may be found at:

CABRI http://www.cabri.org/guidelines/gl-framed.html
WFCC http://wdcm.nig.ac.jp/wfcc/GuideFinal.html
UKNCC http://www.ukncc.co.uk/html/Information/docs/UKNCCQAP.doc

What should Biological Resource Centers or culture collections do to comply?

1. Health and Safety requirements
2. Classification of Micoorganisms on the Basis of Hazard
3. Quarantine regulations
4. Ownership of Intellectual Property Rights (IPR)
5. Convention on Biological Diversity
6. Safety information provided to the recipient of microorganisms
7. Regulations governing shipping of cultures

8. Control of Distribution of Dangerous Organisms

In the process of isolation, handling, storage and distribution of microorganisms and cell cultures there are many stages where compliance with the law, regulations or international conventions is required (Table 1).

1. Health and Safety

A risk assessment of handling and supply of organisms is required in all laboratories and should include an assessment of all hazards involved, not just infection, but also all others amongst which are the production of toxic metabolites and the ability to cause allergic reactions. Organisms that produce volatile toxins or aerosols of spores or cells present a greater risk. It is the responsibility of the microbiologist to provide such assessment data to a recipient of a culture to ensure its safe handling and containment.

Whether it is compliance with the law, or duties of a caring employer, the basic requirements in order to establish a safe workplace are:

- Adequate assessment of risks
- Provision of adequate control measures
- Provision of health and safety information
- Provision of appropriate training
- Establishment of record systems to allow safety audits to be carried out
- Implementation of good working procedures

Good working practice requires assurance that correct procedures are being followed and this requires a sound and accountable safety policy.

A BRC must put in place procedures to manage the health and safety of all those who may be put at risk by its activities. This requires a suitable and sufficient assessment of the risks to health and safety to which any person whether employed by them or not may be exposed to through their work (Anon, 1996a). These assessments must be reviewed regularly and additionally when changes in procedures or regulations demand, and must be recorded. The distribution of microorganisms to others outside the workplace extends these duties to protect others.

Table 1: Regulatory control of microbiology

Action	Requirement	Law, Regulation, Convention	Further information
Collecting in the field	Prior Informed consent from a recognized authority	Convention on Biological Diversity (CBD)	http://www.biodiv.org
	Mutually agreed terms on use	Convention on Biological Diversity (CBD)	http://www.biodiv.org
	Consent from the land owner	Property law	
Import	Non-indigenous plant pathogens require licenses from country authority	Quarantine regulations	
	Human, animal and plant pathogens can often only be imported to specified laboratories	Health and Safety	
Handling: Manipulation; Growth	Containment dependent on hazard	Control of Biological Agents - Health and Safety EC Directive 2000/54/EEC on Biological Agents	http://eur-op.eu.int/opnews/395/en/r3633.html
Genetic manipulation	Containment of manipulated organisms	EEC Directives 90/219/EEC. Contained use of genetically modified microorganisms (GMO's), *L117 Volume 33, 8 May 1990. EEC Directives 90/220/EEC. Release of GMO's, *L117 Volume 33, 8 May 1990. Cartagena Protocol on Biosafety	http://www.biodiv.org/biosafety/protocol.asp http://biosafety.ihe.be/Menu/BiosEur1.html http://biosafety.ihe.be/Menu/BiosEur1.html
Deposit as part of a patent process	Long-term storage and compliance with the Budapest Treaty	Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure	http://www.cnpat.com/worldlaw/treaty/budapest_en.htm
Storage	Appropriate containment	Health and Safety License to hold pathogens Security	
Export to another country	Some plant and animal pathogens require export licenses	Quarantine regulations	
	Dangerous organisms with potential for dual use	Export Licenses for dangerous organisms, Biological and Toxin Weapons Convention (BTWC)	http://binas.unido.org/binas/regs.php3 http://www.opcw.nl/fact/rel_conv.htm http://www.dfat.gov.au/isecurity/pd/pd_4_96/pd9.html
Distribution	Packaging and transport considerations	IATA Dangerous Goods Regulations (DGR), Universal Postal Union Convention (UPU) United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG)	http://www.iata.org/cargo/dg/dgr.htm http://www.upu.int/ http://www.unece.org/trans/danger/danger.htm
	Sovereign rights over the strains	Convention on Biological Diversity	http://www.biodiv.org
	Access and benefit sharing	Bonn Guidelines	http://www.biodiv.org
	Intellectual property Right ownership Customer licensed to receive organism?	Copyright	
	Dangerous organisms export	EU Council Regulation 3381/94/EEC on the Control of Exports of Dual-Use Goods from the Community	http://eur-op.eu.int/opnews/395/en/r3633.html See national Export Offices

2. Classification of Microorganisms on the Basis of Hazard

Various classification systems exist, which include the definitions for classification by the World Health Organization (WHO); United States Public Health Service (USPHS); Advisory Group on Dangerous Pathogens (ACDP); European Federation of Biotechnology (EFB) and European Community (EC). In Europe, the EC Directive (93/88/EEC) on Biological Agents sets a common base line, which has been strengthened and expanded in many of the individual member states. The definition and minimum handling procedures of pathogenic organisms are set by appropriate authorities in each country and are often the same or similar for all EC countries, in the UK the ACDP lists four hazard groups 1-4 with corresponding containment levels. Microorganisms are normally classified, on the basis of their potential to cause disease and their human pathogenicity, into four risk groups (Anon, 1995):

- Risk Group 1: A biological agent that is most unlikely to cause human disease.
- Risk Group 2: A biological agent that may cause human disease and which might be a hazard to laboratory workers but is unlikely to spread in the community. Laboratory exposure rarely produces infection and effective prophylaxis or treatment is available.
- Risk Group 3: A biological agent that may cause severe human disease and present a serious hazard to laboratory workers. It may present a risk of spread in the community but there is usually effective prophylaxis or treatment.
- Risk Group 4: A biological agent that causes severe human disease and is a serious hazard to laboratory workers. It may present a high risk of spread in the community and there is usually no effective prophylaxis or treatment.

A BRC must ensure that all strains are assigned to appropriate risk/hazard groups. This includes a positive assignment to risk/hazard group 1 unless otherwise considered hazardous. Hazard information must be recorded and made available to recipients of this material.

3. Quarantine Regulations

Clients who wish to obtain cultures of non-indigenous pathogens must first obtain a permit to import, handle and store from the appropriate Government Department. Under the terms of such a licence the shipper is required to see a copy of the Ministry permit before such strains can be supplied.

The BRC must do its best to ensure that non-indigenous pathogens are not distributed unless the recipient has a current license.

4. Ownership

On depositing a strain, BRCs must ascertain ownership and terms and conditions of further distribution, for example Intellectual Property rights or from Prior Informed Consent granted under the Convention on Biological Diversity.

The BRC must ensure that information on ownership of IP is passed on to third parties recipient of the organism

5. Convention on Biological Diversity

The Convention on Biological Diversity requires that microbiologists seek prior informed consent from the country in which they wish to collect organisms. They will be required to agree to terms on which benefits will be shared should they accrue from the use of the organisms. The benefit sharing may include monetary elements but may also include information, technology transfer and training.

A BRC must ensure transparency retaining the link between country of origin and end user of genetic resources. Biological materials must be received and supplied within the spirit of the CBD ensuring material transfer agreements are in place. A BRC must maintain contact and follow recommendations of its national CBD Contact Point and National Focal Point.

6. Safety Information provided to the Recipient of Microorganisms

A safety data sheet must be dispatched with an organism indicating which hazard group it belongs to and what containment and disposal procedures are necessary, in Europe, the Code of Practice for Biological Agents 1994 (Anon, 1994). Article 10 of the EU Directive 90/379/EEC regulates that manufacturers, importers, distributors and suppliers must provide safety data sheets in a prescribed format. A safety data sheet accompanying a microorganism must include:

- The hazard group of the organism being dispatched
- A definition of the hazards and assessment of the risks involved in handling the organism.
- Requirements for the safe handling and disposal of the organism.
    - Containment level
    - Opening procedure for cultures and ampoules
- Transport
- Disposal
- Procedures in case of spillage

A BRC issues an appropriate safety data sheet with every culture consignment.

7. Regulations governing Shipping of Cultures

The IATA Dangerous Goods Regulations (DGR) require that shippers of microorganisms of Risk Groups 2, 3 or 4 must be trained by IATA certified and approved instructors (every two years) if cultures are sent by air transport. Transport of highly pathogenic material classified in Category A, UN 2814 or UN 2900 (see definition of this new shipping Category and Table 3.6D, DGR 2005), requires shippers declaration forms, which accompany the package in duplicate. Cultures of infectious substances meeting the definition of the new shipping Category B, UN 3373 (majority of the Risk Group 2 organisms), can be transported under deregulated conditions. Different labels and packaging specification markings are used for organisms in transit by air, dependent on the shipping Category. IATA DGR also requires that packaging used for the transport of Risk Groups 2, 3 or 4 must meet defined standards of a UN combination package (see Addendum II to the current DGR 46th Ed., 2005 and IATA homepage http://www.iata.org). Category A shipments require a Packing Instruction PI 602 packaging whereas for Category B shipments PI 650 packaging are accepted. Packaging like European Standard EN 829 triple containment meets the requirements of UPU for the transport of Risk group 1 organisms (Anon, 1996b).

A BRC must ensure that staff responsible for distribution of infectious substances have a current IATA Shippers training certificate and ensure organisms are packed and shipped in accordance with IATA requirements, if applicable. Non-infectious microorganisms may be sent by (air) mail, acc. to the UPU requirements.

8. Control of Distribution of Dangerous Organisms

There is considerable concern over the transfer of selected infectious agents capable of causing substantial harm to human health. There is potential for such organisms to be passed to parties not equipped to handle them or to persons who may make illegitimate use of them. Of special concern are pathogens and toxins causing anthrax, botulism, brucellosis, plague, Q fever, tularemia and all agents classified for work at Biosafety Level 4 (Hazard Group 4). The 'Australia Group' of countries has strict controls for movement outside their group but has lower restrictions within.

A BRC has procedures to check the validity of customers that wish to receive dangerous organisms and if in doubt to decline the supply.

Useful References

1. Anon (1994). Approved Code of Practice for Biological Agents 1994. Health and Safety Executive. Sudbury: HSE Books.
2. Anon (1996b). European Standard EN 829:1996 E: Transport packages for medical and biological specimens, Requirements, tests. Brussels: CEN, European Committee for Standardization.

3. European Commission Directive 95/44/EC of 26 July 1995 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and work on variety of selections. Official Journal No. L 184, 03.08.1995, p. 34
4. European Commission Directive 2000/54/EEC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC.
5. European Council Decision 96/613/CFSP of 22 October 1996 amending Decision 94/942/CFSP on the joint action adopted by the Council on the basis of Article J.3 of the Treaty on European Union concerning the control of exports of dual-use goods. Official Journal No. L 278, 30.10.1996, p. 1
6. European Standard EN 829 - Transport packages for medical and biological specimens - Requirements, tests. CEN European Committee for Standardization, Brussels, 1996
7. IATA - International Air Transport Association (2005) Dangerous Goods Regulations. 46th edition. Montreal; Geneva: IATA.

Useful web sites:

MIRCEN Scholarships http://www.unesco.org/science/life/life1/rcenform.htm
CBD http://www.biodiv.org/
Biodiversity
Convention on Biological Diversity - http://www.unep.org/biodiv.html

Organisations

World Federation for Culture Collections http://wdcm.nig.ac.jp/wfcc/wfcc.html
World Data Centre for Microorganisms http://wdcm.nig.ac.jp/wdcm/wdcm.html
Microbial Strain Data Network - http://www.bdt.org.br/msdn/msdn.html
The Microbial Underground - http://www.ch.ic.ac.uk/medbact/.index.html
Biodiversity and Biological Collections Web Server http://muse.bio.cornell.edu/

Patents

Budapest Treaty for the Deposit of Micro-organisms http://www.wipo.org/eng/iplex/wo_bud0_.htm

Safety and Standards

Advisory Committee on Dangerous Pathogens - http://www.doh.gov.uk/bioinfo.htm
Binas Biosafety Site - http://www.un.org/binas
Control of Substances Hazardous to Health - http://www.open.gov.ac.uk/hse/hthdir/agents.htm
Cartagena Protocol on Biosafety - http://www.biodiv.org/biosafety/protocol.asp
EC Directive 93/88/EEC on Biological Agents – http://eur-op.eu.int/opnews/395/en/r3633.html

EC Directive 90/679/EEC setting mandatory control measures for laboratories - http://eur-op.eu.int/opnews/395/en/r3633.html for purchase through Celex
International Organisation for standardisation - http://www.iso.org/iso/en/ISOOnline.frontpage

Taxonomy and Nomenclature

Bacterial Nomenclature up-to-date - http://www.bdt.org.br/bdt/bacterianame/
Species 2000 Indexing Project - http://sunrae.uel.ac.uk/species2000/
CABI Bioscience fungal synonymy - http://www.cabi.org

Websites of interest for information on transport and shipping

Canadian Transport	www.rural-gc.agr.ca/e4.1_canutec.html
Biosafety on the internet Organisation for Economic Co-operation and Development (OECD) United Nations Industrial Development Organisation (UNIDO) Biosafety Information Network and Advisory Service (BINAS) International Service for National Agricultural Research (ISNAR) International Centre for Genetic Engineering and Biotechnology (ICGEB)	www.olis.oecd.org/bioprod.nsf www.binas.unido.org/binas/home.html www.cgiar.org/isnar/fora/biotech www.icgeb.trieste.it/biosafety www.aphisweb.aphis.usda.gov.biotech
US Animal and Plant Health Inspection Service (APHIS) Biotechnology Information Centre (BIC) of the US Department of Agriculture (USDA)	www.nal.usda.gov/bic/ www.vm.cfsan.fda.gov/ www.biosafety.ihe.be
US Food and Drug Administration (FDA) Centre for Food Safety and Applied Nutrition (CFSAN) Belgian Biosafety Server The Dutch Genetically Modified Organism Bureau UK Advisory Committee on Releases into the Environment (ACRE)	www.rivm.nl/csr/bggo.html www.environment.detr.gov.uk/acre/index.htm
EBIS	www.ivr.nl/ebis.html www.ccohs.ca/products/database/tdg.html
European Commission DGVII – Transport	http://europa.en.int/en/comm/dg07/index.htm
Harmonisation of UN documents etc.	www.hazmat.dot.gov/rules
International Air Transport Association	www.IATA.org/cargo/dg and www.IATA.org/cargo/dg/links.htm
International Civil Aviation Organization	http://hazmat.dot.gov/icao.htm www.volpe.dot.gov/ohm/icao.htm also www.cam.org/~icao/menu3.html

Websites of interest for information on transport and shipping (continues)

Maritime rules	www.eat.co.uk/ncec/complian/bibliog/bysea.html www.mdnautical.com/imo/cargoes.htm www.imo.org/pubs/pubcats.htm www.info.gov.hk/mardep/notices/mdn98149.htm www.hazmathelp.com/imdg.htm
National Chemical Emergency Response UK	www.eat.co.uk/ncec/complian/bibliog/bibliog.htm
OECD - Harmonisation Documents	
Chemical programme Classification and labelling Chemical testing Currently available test guidelines	http://www.oecd.org/ehs http://www.oecd.org/class http://www.oecd.org/test http://www.oecd.org/test/testlist
RID/ADR	http://hazmat.dot.gov/RIDADR.htm www.dsidat.com/products/undisk7.htm www.volpe.dot.gov/ohm/ridadr.htm
Transport – general German magazine	www.tci-transport.fr www.hazmathelp.com/dotlink.htm www.cefic.org www.storck-verlag.com/english/gela_e.htm
United Nations meetings agenda and minutes	www.unece.org/unece/trans/danger/meetdoc.htm
UN Model Regulations	www.ununece.org/unece/trans/main/dgdemo/intro.htm
UN Committee of Experts for the Transport of Dangerous Goods (UNSCETDG)	www.tc.gc.ca/tdgoods/consult/unlinks_e.htm
Universal Postal Union	http://ibis.ib.upu.org http://unicc/unece/tra www.de/facil/upustr.htm
USA Dept of Transport's Office of Hazardous Materials Management	http://hazmat.dot.gov
World Health Organization	www.who.org/emc/biosafe/index.htm

European Biological Resource Centers Network Information Resource

International Regulations for Packaging and Shipping of Microorganisms

This EBRCN information resource has been revised according to the 2005 changes

- ***In the UN Model Regulations on the Transport of Dangerous Goods 13th edition (ST/SG/AC.10/1/Rev.13), adopted by the UN SCETDG Committee***
- ***In Addendum Doc 9284-AN/905 to the ICAO Technical Instructions 2005-2006 Edition,***
- ***In Addendum II of March 2005 to the 46th Edition of the IATA Dangerous Goods Regulations***

INTRODUCTION

Before a consignment containing microorganisms is offered for transport, the decision as to whether it is an infectious substance or not is crucial as is the destination of the consignment. In order to select the correct type of packaging and the correct mode of transport/carrier (postal mail or courier), shippers of biological material must have a sound knowledge of all relevant packaging and transport regulations. They must have recurrent training according to the latest *IATA* Dangerous Goods Regulations (DGR, chapter 1.5) if infectious substances are to be transported by air. Air transport plays the dominating role when living biological materials are transported over long distances. Furthermore, the Dangerous Goods Regulations for air transport are most user-friendly making sure the responsible shipper is on the safe side and in conformity with international law. It is self-evident that the respective national or regional regulations for road transport have to be observed (e.g. ADR in Europe).

Infectious substances are by definition dangerous goods (Class 6, Division 6.2) and the Dangerous Goods Regulations for transport fully apply so that they do not pose a risk for the people involved in the transportation chain, animals or the environment. This usually does not apply to microorganisms classified in Risk Group 1. For the latter, consequently other regulations for packaging and transport are in place and have to be observed, they can usually be transported by postal mail services when packed in accordance with the respective packaging regulations laid down by the Universal Postal Union (UPU). Postal services usually differentiate between perishable (active) and non-perishable (dried, freeze-dried) biological substances. Shippers should be aware that any biological material is excluded from transport in postal parcels; UPU permits letter mail only. The term “freight” is used in connection with courier transport only, in contrast to postal parcels. Registered letter mail is generally recommended because of individual treatment and possible tracking. Also note that in general, postal mail systems exclude any dangerous goods, infectious substances classified in the new shipping Category B *might* be sent by national postal mail (on the road). The new deregulated transport requirements for Category B cultures imply that

administrational expenditure and costs have become much less problematic. However, there are still strict requirements on shipper's responsibility, training and packaging quality as well as on correct labelling and marking.

Although the recent changes relevant for shippers of infectious substances resulted in the definition of a new classification system with two new shipping Categories (A and B) instead of Risk Group definitions, the existing Risk Group allocation of an organism does help the sender to classify the material for transport purposes. Additionally, the regulations for shipping genetically modified organisms (GMO) have undergone a revision resulting in a clearer instruction for transport of safety level 1 GMO (class 9, miscellaneous dangerous goods, see below). Principally, the new deregulated requirements apply to the majority of Risk Group 2 microorganisms as the definition of this Risk Group conforms to the definition of the new Category B (see below): such cultures can be shipped under the same requirements as diagnostic specimens, using the new UN number UN 3373 and Packing Instruction PI 650 packaging. A Shipper's Declaration for dangerous goods is no longer required, neither a similar form for road transport nor a transport emergency card. However, with regard to strength and quality, UN packaging meeting the PI 602 requirements is strongly recommended as they withstand air vibrations, changes in temperature or high pressure during air transport. They have passed different tests compared to PI 650 packaging and growing market prices have dropped drastically.

The transportation chain begins in the packaging department of a Culture Collection, ends in the recipients' laboratory and may include transport by hand, postal or courier transport, within countries or across borders and continents. Only a correctly labelled and documented shipment reaches its destination quickly and safely, therefore the courier services require their customers to fulfil the regulations.

It is the responsibility of all laboratories supplying infectious substances to nominate a person, who receives recurrent training and takes on the responsibility for signing the shipping documents (in case of Category A shipments). The latter can **ONLY** be signed by a trained person (*IATA* DGR chapter 1.5, Training Requirements) who is thoroughly conversant with the regulations including the applicability, limitations (state or operator variations), classification, identification, packing, marking and labelling, and documentation. If substances meeting the definition of the new shipping Category A, UN 2814 or UN 2900 respectively, an experienced courier should be chosen, advance arrangements with the courier and with the consignee are necessary. Transport is mostly performed as individual transport due to recent total dangerous goods mass limitations on transport vehicles.

THE MOST IMPORTANT DEFINITIONS acc. to IATA DGR 46th Ed. 2005 and Addendum II to these DGR

3.6.2.2.1 Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

3.6.2.2.2 Infectious substances are divided into the following categories:

3.6.2.2.2.1 Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Indicative examples of substances that meet these criteria are given in Table 3.6.D (p. 96, IATA DGR 46th Ed.). Note: this Table is not exhaustive. It contains microorganisms that more or less meet the definitions of the Risk Groups 3 and 4.

3.6.2.2.2.2 Category B: An infectious substance, which does not meet the criteria for inclusion in Category A. Infectious substances in Category B, must be assigned to UN 3373.
Note: The Proper Shipping Name (PSN) of UN 3373 is "Diagnostic specimens", "Clinical specimens" or "Biological substance, Category B".

The exemption of the cultures under this paragraph has been withdrawn by IATA DGR Addendum II.

3.6.2.4 Genetically Modified Microorganisms and Organisms

3.2.6.2.4.1 Genetically Modified Microorganisms not meeting the definition of an infectious substance must be classified according to Subsection 3.9.

3.9.1.2 Genetically Modified Microorganisms (GMMOs) and Genetically Modified Organisms (GMOs) are microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

3.9.2.5.1 GMMOs and GMOs do not meet the definition of infectious substances but are capable of altering animals, plants or microbiological substances in a way which is not normally the result of natural reproduction. They must be assigned to UN 3245.

A NEW UN NUMBER, A NEW PROPER SHIPPING NAME (PSN)
The recent major breakthrough is that the majority of the Risk Group 2 organisms can now be sent under UN 3373 with the new PSN referring to a microbiological culture ("Biological substance, Category B"). This affects most Culture Collections. Addendum II to the DGR 46th Ed. admits, "On 1 January 2007, it is anticipated that the use of the shipping names Diagnostic specimens and Clinical specimens will no longer be permitted". The PSN has to be printed in letters at least 6 mm high and must be marked on the outer package adjacent to the diamond-shaped label UN 3373.

CATEGORY A AND CATEGORY B
The introduction of the two new Categories for transport purposes replacing the Risk Group definitions for shipping is a more realistic approach, it makes deregulated transport of a very large number of low-risk bearing cultures possible.

PACKING INSTRUCTIONS PI 650 and PI 602
All responsible shippers are asked to be conversant with both of these Packing Instructions. IATA PI 650 describes a UN-certified packaging system with less strength and smaller dimensions than IATA PI 602 (= UN/ICAO PI 620). See

recommendations in this text. Preferably, UN packaging fulfilling the PI 602 requirements should be used also for Category B, infectious substances.

THE PREMISES BEFORE DESPATCH OF CULTURES

The sender of a microorganism must be sure that the receiver is authorized to work with it and has adequate facilities:

1. Do NOT supply to private persons
2. Do NOT supply to new customers/unknown recipients who have not specified their institution
3. Supply infectious substances ONLY to recipients who have the appropriate laboratory safety level which corresponds with the Risk Group of the organism
4. Supply animal or plant pathogens or genetically modified organisms ONLY to recipients having an appropriate laboratory and the relevant permits for work

When shipping outside the country, the sender must also be sure that the microorganism does not fall under export restrictions like the Biological and Toxin Weapons Convention, Dual-use restrictions and other national legislation (relevant national Authorities are the national Export Office, Department of Commerce or the Foreign Office) and that, if applicable, quarantine requirements are fulfilled by the receiver and import permits (from Health Authorities) are ready to be shipped together with the organism. Please, also see the resp. EBRCN Information

Resource documents for further information.

It is important for Culture Collections to

1. Establish a well-organised shipping department with trained staff
2. Nominate a trained person who replaces the legal trained shipper in cases of absence
3. Have access to the latest *IATA* Dangerous Goods Regulations, to the latest regulations for road transport of dangerous goods and to all further relevant information sources
4. Develop a step-by-step checklist like below
5. Establish a computerised system for filling in the shipping documents in order to have a fast and reliable system that avoids mistakes

STEP-BY-STEP CHECKLIST FOR SHIPPERS

The following short instructions may be helpful in the proper packing and shipping of biological materials.

International shipments

1. **Is a permit or export license needed to distribute the ordered material outside the sender's country?**

   Only written orders should be accepted and in case of regulated/listed organisms an end user certificate is recommended if not required by law. If

unclear, contact your national authority (the Department of Commerce, Export Office or Foreign Office).

2. **Are there any import or quarantine restrictions of the customer's country?**

Some countries require an import permit for certain microorganisms (the recipient should provide this permit to accompany the consignment).

3. **Does the order include *any infectious substances (Risk Group 2 - 4 organisms)*?**

If YES, these are dangerous goods and therefore all packaging and shipping requirements must be adhered to e.g. ADR (road) in Europe or IATA (air) internationally. Continue with 4 and 5. If NO, see under 6.

4. **Is the recipient qualified and authorized to handle the ordered cultures?**

Recipients of cultures must confirm by a written statement that they are entitled to receive and handle infectious biological materials, especially those of Risk Group 3 and 4 organisms (in some countries this is also a requirement for Risk Group 2 organisms). An export license is required for the recipient culture (national biosecurity may restrict distribution of some organisms, their derivatives or products).

5. **Do the National Postal Authorities concerned (sender's, transit and customer's countries) accept infectious substances in the mail (observe IATA DGR 2.4 and UPU restrictions)?**

If YES, the order can be sent by mail (rarely permitted!). If NO, the order might be sent by (air) freight only. Category A infectious substances (UN 2814 or UN 2900, resp.) are excluded from any postal mail transport. Category B infectious substances (UN 3373) maybe sent by national postal systems on the road (see packaging sizes PI 650 and PI 602).

6. **Are *non-infectious perishable* cultures (agar or liquid "active cultures") to be included in the package?**

If YES, continue with 7. If NO, see under 8.

7. **Do the National Postal Authorities concerned accept non-infectious perishable biological substances in the mail?**

If YES, the order can be sent by registered airmail letter according to the relevant **UPU** packing requirements (see EXAMPLE cases). If NO, the order might be sent by (air) freight only.

8. **Does the shipment contain *only non- infectious and non-perishable* (dried or freeze dried) biological substances?**

   If YES, the shipment can be sent by (non-registered) airmail according to the relevant **UPU** packing requirements (see EXAMPLE cases).

National shipments

1. Does the order include *any infectious substances (Risk Group 2 - 4 organisms)*?

If YES, these are dangerous goods and therefore all packaging and shipping requirements must be adhered to e.g. ADR in Europe (road) or specific national requirements.

2. Is the recipient qualified to handle the ordered cultures?

Recipients must confirm by a written statement that they are entitled to receive and handle infectious biological materials and/or they are obliged to send a copy of the resp. working permit.

3. Does the National Postal Authority accept infectious substances in the mail (observe IATA DGR 2.4 if applicable and UPU restrictions)?

If YES (rarely permitted!), the order can be sent by mail if the required packaging is in conformity with the resp. national postal requirements. If NO, the order might be sent by courier only.

4. Are *non-infectious perishable* cultures (agar or liquid "active cultures") to be included in the package?

If YES, continue with 5. If NO, see under 6.

5. Does the National Postal Authority accept non-infectious perishable biological substances in the mail?

If YES, the order can be sent by registered letter mail according to the relevant **UPU** packing requirements (see EXAMPLE cases). If NO, the order might be sent by courier only.

6. Does the shipment contain *only non-infectious and non-perishable* (dried or freeze dried) biological substances?

If YES, the shipment can be sent by (non-registered) mail according to the relevant **UPU** packing requirements (see EXAMPLE cases).

EXAMPLE CASES

Case A

The organism to be sent is non-infectious, not genetically engineered (does not fall under UN 3245, see Case D) and its distribution is not restricted under law >> It may be sent nationally or internationally by postal letter mail, dependent on the regulations of the Postal Administration of the sender, transit and recepient countries. >> If permitted by Postal Administrations, the microorganism can be shipped by (registered) air mail letter according to the UPU Articles RE 2401 and RE 806 packaging requirements (also former European Standard EN 829 having a minimum strength of a triple packaging. There is no accepted packaging with less strength than EN 829. However, EN 829 will probably be withdrawn in order to avoid confusion with PI 650, which has similar quality). >> If not permitted by Postal Administration, freight (courier service) must be used.

Case B

The organism to be sent is infectious but if exposure to it occurs is not capable of causing permanent disability, life-threatening or fatal disease to humans or animals and does not meet the definition of Category A. It meets the definition of Category B, UN 3373 (the majority of Risk Group 2). >> Such organisms including laboratory cultures are dangerous goods of Class 6, Division 6.2 and can be sent according to PI 650, IATA DGR (see Addendum to the IATA DGR 46th Ed.). A Shipper's Declaration for Dangerous Goods is not required. The new Proper Shipping Name as given above can be used (alternatively to "Diagnostic specimens" or "Clinical specimens"). Shipment by airmail is usually prohibited; some national postal services may permit transport on the road.

Case C

The organism to be sent is an infectious substance, affecting humans (UN 2814) classified in Risk Group 3 or 4 and/or the definition of Category A applies or it is affecting animals (UN 2900) meeting the Category A definition >> Such an organism is to be shipped as a Class 6.2 dangerous goods by freight, national postal mail is excluded, air mail is prohibited (IATA DGR 2.4). When shipping infectious substances of Category A, independently of the net weight, the UN Model Regulations apply for <u>all</u> modes of transport requiring a UN certified combination packaging system acc. to IATA Packing Instruction 602. The shipper is a trained person and is responsible for the consignment including all documents (IATA DGR 1.5). Choose experienced courier services and clarify ALL steps before offering the consignment to the courier (destination manageable? , Door-to-door or door-to-airport delivery?). Make advance arrangements with the consignee (IATA DGR 8.1.6.11.3). Observe the IATA DGR Limitations chapter. Transport of these cultures is usually individual.

Case D

The organism to be sent is genetically engineered (GEM/GMO). The IATA DGR and other transport regulations distinguish between 2 kinds of GEMs: an infectious substance that is genetically engineered has to be shipped as >> UN 2814, UN 2900 (both Category A) or UN 3373, Category B, respectively (for the latter see Case B). Animals containing or being contaminated with GEMs or infectious substances, must not be transported by air unless exempted under IATA DGR

2.6.1. GEMs being not infectious substances but capable of altering animals, plants or microorganisms in a way which is not normally the result of natural reproduction must be classified in >> Class 9 (Miscellaneous Dangerous Goods) and assigned to UN 3245. >> Note: IATA Packing Instruction 913 applies; Class 9 label required (black and white stripes).

Case E

Carbon dioxide, solid, dry ice, is used for shipping an organism. >> Dry ice is classified as dangerous goods (Class 9, UN 1845) and has to be packed acc. to IATA Packing Instruction 904. Packaging systems for shipping UN 2814/UN 2900 or UN 3373 infectious substances together with dry ice are commercially available from several suppliers. Such packaging systems fulfil both packing requirements, for infectious substances and for dry ice and carry both dangerous goods labels and specification markings.

SOME GENERAL HINTS FOR SAFE PACKAGING

Petri dishes as primary receptacles should not be used for transport.
Screw caps, glass material and seals used for the purpose, as primary receptacle should be of good quality so that leakage is avoided during transport.
Only industrially available certified UN packaging systems are permitted, no other combinations.
When packaging is being re-used, it must not have any signs of any damage or previous leakage.

Associated example materials as appropriate

Labels as required (if not directly printed on outer packaging surface)
Shipper's declaration documents
Quarantine import permit
Information on categorisation of hazard group
Information sources
Images of packing materials and packages

International Organisations

- ***IATA***: the International Air Transport Association annually updates the Dangerous Goods Regulations (DGR), which are the legally binding basis for shippers and carriers of dangerous goods to be transported by air.
- ***ICAO***: the International Civil Aviation Organization Council uses the UN Model Regulations as the basis for its Technical Instructions for the Safe Transport of Dangerous Goods by Air (updated every two years).
- ***UN***: the United Nations Committee of Experts on the Transport of Dangerous Goods publish the Recommendations on the Transport of Dangerous Goods ("Orange Book"), being the basis = "Model Regulations" for international transport regulations for dangerous goods for all carriers (air, road, rail, waterways).
- ***UPU***: the Universal Postal Union publishes the International Postal Convention through the Compendium of Information (constantly updated).
- ***WHO***: the World Health Organization defines the Risk Groups scheme for classification of biological substances and has published the Laboratory Biosafety Manual.

Further Information

Canadian Transport	www.rural-gc.agr.ca/e4.1_canutec.html
EBIS	www.ivr.nl/ebis.html www.ccohs.ca/products/database/tdg.html
European Commission DGVII – Transport	http://europa.en.int/en/comm/dg07/index.htm
Harmonisation of UN documents etc.	www.hazmat.dot.gov/rules
International Air Transport Association	www.IATA.org/cargo/dg and www.IATA.org/cargo/dg/links.htm
International Civil Aviation Authority	http://hazmat.dot.gov/icao.htm www.volpe.dot.gov/ohm/icao.htm also www.cam.org/~icao/menu3.html
OECD - Harmonisation Documents	
Chemical programme	http://www.oecd.org/ehs
Classification and labelling	http://www.oecd.org/class
Chemical testing	http://www.oecd.org/test
Currently available test guidelines	http://www.oecd.org/test/testlist
RID/ADR	http://hazmat.dot.gov/RIDADR.htm www.dsidat.com/products/undisk7.htm www.volpe.dot.gov/ohm/ridadr.htm
Transport – general	www.tci-transport.fr www.hazmathelp.com/dotlink.htm www.cefic.org
UN Model Regulations, Committee of Experts on the Transport of Dangerous Goods, Meetings agenda and minutes	www.unece.org/trans/danger/publi/unrec/rev13/
Universal Postal Union	http://ibis.ib.upu.org http://unicc/unece/trade/facil/upustr.htm
USA Dept of Transport's Office of Hazardous Materials Management	http://hazmat.dot.gov

Useful References

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3. World Health Organization (1993) Laboratory Biosafety Manual, 2nd ed. (revised; interim guidelines). World Health Organization, Geneva, ISBN 92-4-154450-3
4. European Parliament (2000) Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work. OJ No.

L262, pp. 21-45 of 18.09.2000 Orange Book": UN Model Regulations on the Transport of Dangerous Goods, UN, New York, 13th ed. (2003)
5. IATA-International Air Transport Association (2004) Dangerous Goods Regulations. 46th Ed. Montreal, Geneva, ISBN 92-9195-318-0
6. Technical Instructions for the Safe Transport of Dangerous Goods by Air. Doc 9284-AN/905. Council of ICAO, International Civil Aviation Organization
7. ADR Accord européen relatif au transport international des marchandises dangereuses par route. English version (2005). Economic Commission for Europe (ECE)

The WFCC on Biosecurity

(DRAFT FOR COMMENTS FROM MEMBERS)

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The Word Federation for Culture Collections (WFCC) participates in international initiatives and fora on behalf of its members. These include discussions with the OECD on Biological Resource Centre establishment, operations and networking, the Global Biodiversity Information Facility and World Intellectual Property Organisation (see Box 1). A current issue subject to huge debate that has continued since 9/11 centres on biosecurity, it is imperative that the WFCC membership informs the Executive Board on their views on this topic so that they can adopt the appropriate position and take the necessary action. The WFCC has tackled the biosecurity issue previously making a public statement on its website, devoting a good part of its Newsletter Issue 34 January 2002 to the topic and in the Committee on Postal, Quarantine and Safety Report 2000-2004 produced for ICCC10. A key function of the WFCC is to provide information on such topics to its members and recently documents on legislation and regulation compliance have been placed on the web (http://www.wfcc.info/new/EBRCN_Resource_Legislation_file_WP5_2.htm).

The WFCC continues to try and keep pace with the large number of activities in the area. A number are covered below. The WFCC will continue to support the following principles

1. The WFCC supports the Biological and Toxin Weapons Convention of 1972 (BWC) that prohibits the development, possession, and use of biological weapons.

2. To the knowledge of the WFCC no culture collection of its membership is involved in active research on biological weapons. It is not the policy of the WFCC to influence the range of biological resources maintained and to interfere with research activities of member collections.

3. The control of access to organisms lies with the country in which the collection is based. The national governments are the enforcers of international and national legislation. The WFCC urges its members to strictly follow all national and international legislation concerning distribution of sensitive materials to third parties.

Box 1: International Organisations and Initiatives WFCC is collaborating or seeking collaboration with

BTWC	Biological and Toxic Weapons Convention
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CODATA	Committee on Data for Science and Technology
FAO	Food and Agriculture Organization
GBIF	Global Biodiversity Information Facility
IPGRI	International Plant Genetic Resources Institute
ISBER	International Society for Biological and Environmental Repositories
IUBS	International Union of Biological Sciences
IUMS	International Union of Microbiological Societies
OECD	Organization for Economic Co-operation and Development
UN	United Nations
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational Scientific and Cultural Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization

The WFCC requires its members to comply with legislation and procedures for the control of access to dangerous organisms in place, nationally and internationally.

The WFCC requires its members to adopt best practice in performing their role in the conservation and utilisation of biodiversity, in compliance with such legislation.

In line with its role, the WFCC have published guidelines http://www.wfcc.info/guideline.html and is working with the OECD Biological Resource Centre (BRC) Initiative to develop guidance for BRCs. This article addresses this issue and draws attention to a number of biosecurity initiatives and discussion fora (see box 2).

The WFCC has been invited to attend a number of meetings regarding some of the above and several individual members of the board are participating in these issues at a national level too. It is always difficult to ensure that the WFCC has a presence on such occasions and keep abreast of all relevant activities.

The Biological and Toxic Weapons Convention (BTWC) forms the baseline agreement that lays down the key principles internationally on disarmament and proliferation control measures. It came into force in its current structure thirty years ago, on March 26th 1975. However, there is still a threat from bio-weapons, resulting from bioterrorism or State bio-weapons programs. On the anniversary of the BTWC, a balance on international approaches to the fight against biological weapons was drawn up during a roundtable meeting organized by the cities of Hamburg and Berlin, Germany. The main questions were:

How successful is the BTWC?
Is there a realistic threat coming from bio-weapons?
Where does the highest risk come from?
What are the possibilities to control this threat?

Box 2: Some Biosecurity Initiatives

The New Defence Agenda (NDA): A forum where NATO and the EU, industries and academia, political figures and journalists gather to discuss the future of European and transatlantic defence policies. The NDA also serves as a networking centre of defence-related think tanks around Europe (http://www.newdefenceagenda.org).

The Chemical and Biological Arms Control Institute (CBACI) and the International Institute for Strategic Studies – US (IIS-US) charter: The aim is to create a global organisation of biotechnology companies, large pharmaceutical firms and other entities to focus on enhancing international standards of public safety and security on a global scale through responsible, ethical and sound business and scientific practices.

OECD Expert meetings on Biosecurity
Remit to deliver "Biosecurity Principles for BRCs", a meeting was held on 9-10 May, 2005 at the OECD Headquarters, in Paris, France and discussions will continue on 21-22 November 2005

The International Peace Research Association (IPRA)
IPRA is a world wide research organisation founded in 1964 to promote peace and peace education. The purpose of IPRA is to advance inter- and trans-disciplinary research into mechanisms of sustainable peace.

The Stockholm International Peace Research Institute (SIPRI)
SIPRI is currently conducting research into issues of non-proliferation and export control particularly comparing export control mechanisms for dual-use items.

The contribution of several initiatives needs to be investigated that lead toward a strengthened ban of bio-weapons.

80 Years ago, the Geneva Protocol on the prohibition of biological and chemical weapons was drawn up. In 1969, the way was paved for the BWC. Currently, 169 countries are signatories to the BTWC. African countries and the Middle/Near East are not yet among the signatories. Bio-weapons are an exception among the different types of weapons as since 1975 no state has ever admitted to possess biological weapons. These weapons have always been incompatible with the conscience of humankind and since 1945 there has been no state attack using bio-weapons. In 2001, there were five anthrax victims and the picture has changed completely and the term biosecurity has evolved. A code-of-conduct for scientists (“professional ethics”) is requested at different levels, e.g. during the recent Australia Group meetings, it was regarded necessary to protect the biological weapons control and prevent further possible erosion. It is considered that more effective control mechanisms, data protection and better information on relevant documentation and its tracking are required.

It is considered that there are inherent problems with the BTWC, for example, the verification regulations are difficult and national authorities admit that it was probably not optimum to use the same control mechanisms for both bio-weapons

and chemical weapons. Bioterrorism can extend beyond a threat directly on humans for example it might affect the food/nutritional chain. The sixth BTWC controlling conference will propose that States have to act if there are deficits in it's the BTWC's implementation. The outcome of the three-year follow-up process seems positive: Fifteen States have published their annual reports for control purposes.

The WFCC received an invitation to participate in The Inter-Academy Panel on International Issues (IAP), the International Council for Science (ICSU), and The National Academies of the United States *International Forum on Biosecurity*. The meeting was held 20-22 March, 2005 at the Centro Alessandro Volta in Como, Italy. The Forum's invitation-only sessions were informal, off the record, and were intended to foster discussion among leaders from the international scientific community and other stakeholders. The Forum grew out of the recommendations of a 2003 report by The National Academies, "Biotechnology Research in an Age of Terrorism" (http://www.nap.edu/books/0309089778/html/). The discussion reflected concern over the growing awareness that rapid developments in the life sciences and biomedical research, while offering great benefits, also pose the risk that the knowledge, tools, and techniques that enable these advances might be misused to cause deliberate harm. Any effort to address this "dual use" dilemma must ultimately be international, since biotechnology research is a genuinely global enterprise. The scientific community has an essential role in ensuring that efforts to manage the risks do so in a way that fosters both improved security and strengthened international collaboration to ensure scientific advances.

There have been numerous meetings at national and international levels; for example the meeting held jointly by the Royal Society and the Wellcome Trust *Do no harm: reducing the potential for the misuse of life science research*' on 7 October 2004. David Smith participated in a meeting *The Future of the Life Sciences: Reaping the rewards and Managing the Risks* in December 2004 organised by the Chemical and Biological Arms Control Institute (CBACI) and the International Institute for Strategic Studies – US (IIS-US) to present thoughts on Biosecurity and Biological Resource Collections. This followed attendance at their European Regional Workshop entitled: *The future of the Biotechnology Industry: Safeguarding the opportunities and managing the risks* which was held in London (July 2004).

The CBACI and the IIS-US are conducting a joint project to promote the engagement of the global biotechnology industry in issues of public safety and security with special attention to issues of biological weapons and bioterrorism. The project aims to create a global organization of biotechnology companies, large pharmaceutical firms and other entities to focus on such issues. The objective is to establish a self-sustaining enterprise that provides a mechanism for private industry to contribute to improved quality of life and to enhance international standards of public safety and security on a global scale through responsible, ethical and sound business and scientific practices. A second goal is to facilitate the development of effective partnerships between the life sciences industry, government, international organizations, the scientific community and other critical constituencies on these vital issues of common concern. As part of the process of achieving these objectives 3 regional workshops were organized, in

Asia (Singapore, April 2004), Europe (London) and the meeting for North America in Washington (December 2004).

Senator Sam Nunn, Co-chairman of the Nuclear Threat Initiative, opened the December 2004 meeting in Washington. He made eight key statements for the workshop to address:

- Biological, Chemical and Nuclear dangers are huge
- Terror groups can process biological agents for misuse
- Governments cannot address issues alone and need international collaboration
- The outcome of the event of an attack will depend on preparedness
- The treat goes beyond humanity concerns
- Pathogens must be kept out of the hands of those who may misuse them
- We must not sit back and wait for an event that will stimulate reaction, there is a need to be proactive in prevention and preparedness
- Health security will depend upon public/private co-operation

Dr. Ronald F. Lehman, Director, Center for Global Security Research, Lawrence Livermore National Laboratory set the scene discussing the capability and intent for bioterrorism. He looked at the problems there might be and the shortening in time lines between the idea, intent and potential to actual capacity and ability to carry out a bioterrorist act, fuelled by the availability of tools, technology and information. A draft charter to be adopted by the biotechnology companies, organizations and other producers and suppliers was provided and various speakers outlined key issues concerning the key elements of the charter:

- National/International Rules and Regulations
- Personnel Issues
- Information handling
- Safe and secure operation of facilities – included in a presentation on BRCs from David Smith
- Risk assessment
- Governance of research
- The International Council for the Life Sciences: Next steps

The initiative will set up the International Council for the Life Sciences as a self-sustaining global organisation for the life sciences community to contribute to improved quality of life and enhanced public safety. It will facilitate effective partnership between the various elements of the life sciences community, including private industry, academia and government on issues of public safety and security. Membership fees and corporate partnership will fund it.

New Defence Agenda

The WFCC was invited to the 4th Meeting of the New Defence Agenda: *Countering Bioterrorism: How can Europe and the US work together?* There was a broad mix

of participants who agreed that a key issue on this topic was the difference in perception of the risk. Many outside the NDA and similar groups believe the threat to life is there but that there are more important naturally occurring events that need immediate attention such as the numbers of people lost to infectious disease each year or dying through starvation.

The New Defence Agenda (NDA) has established itself as the only regular forum in Brussels where NATO and the EU, industries and academia, political figures and journalists gather to discuss the future of European and transatlantic defence policies and to contribute to a series of discussion papers that reflect key points raised in these debates. The NDA also serves as a networking centre of defence-related think tanks around Europe. The aim of the NDA is not to replicate more academic research-based projects but to give greater prominence to the complex questions of how the EU and NATO policies can complement one another, and to stimulate reaction within the international press. Bringing clarity and new ideas to the rapidly-changing defence policy scene has been the NDA's aim from its beginning. The NDA's activities range from monthly roundtables and international conferences to reports and discussion papers. One of its prime objectives is to raise the profile of defence and security issues among the Brussels-based international press. To encourage more in-depth coverage of these topics, the NDA holds regular, informal dinners for journalists. Its patrons Javier Solana and Chris Patten have backed this initiative from the start along with NDA's president, Eduardo Serra, former Spanish defence minister. The NDA's Advisory Board is comprised of some 20 prominent defence experts drawn from a cross-section of government, politics and industry-related fields.

The New Defence Agenda recommendations:

- Develop a stronger framework for sustained collaboration between G-8 (Global Partnership/Co-operative Threat Reduction (CTR) Kananaskis Agreement), the European Union (International Science and Technology Centres (ISTC)/Science and Technology Centre of Ukraine (STCU) and the United States (Bio Industries Initiative);
- Encourage ethical codes of conduct for scientists working in sensitive bio-technologies sectors;
- Implement bio-safety and bio-security standards in order to increase the likelihood of competitive international engagement of Russia in bio-technologies and pharmaceutical sectors;
- Implement regional programmes to secure pathogens and consolidate dangerous pathogen collections;
- Increase partnership opportunities with bio-industries to keep scientists with bio-defence expertise well paid and engaged in research that is peaceful but also market-orientated, to reduce the risk of intellectual flight to nations of concern.

There are over 80 signatories to the recommendations including David Smith on behalf of the WFCC. The NDA reports can be found on the NDA website http://www.newdefenceagenda.org.

The participants of the 4th meeting agreed that one of the key issues on this topic was the difference in perception of the risk between the EU and USA and also between different communities within. There were several speakers invited to introduce topics and stimulate debate. An introductory paper was read by Jill Dekker-Bellamy (NDA's Bio-Defence Consultant) who outlined problems in engaging all parties to a co-ordinated approach, the budgets involved and she also discussed the war games that have already been undertaken to test the response to a potential bio-terror event. The *Atlantic Storm* scenario postulated a release of smallpox, which in the 20th century killed an estimated 300 million. This highlighted discrepancies in smallpox vaccine stockpiling. Four major lessons were drawn:

- Difficulties involved in international exchange of information
- Lack of 'international perspectives'
- A requirement for common terminology to describe the magnitude and extent of a public health emergency
- The need for robust and reliable communication systems that are regularly tested

Michael Moodie, President of the Chemical and Biological Arms Control Institute (CBACI) introduced this meeting with five relevant statements:

1. The problem should be viewed as a misuse of the life sciences, a risk that must be managed
2. Risk of the deliberate misuse is part of a broader risk assessment e.g. on a spectrum of risk from natural events – events influenced by man (e.g. laboratory accidents, misadventure) – deliberate misuse
3. When we focus on misuse, single factor approaches are not adequate e.g. a focus on a pathogen such as smallpox. There is a lot that happens in the process of a bioterrorist act. The focus should not be on the actor, this is an oversimplification; we must also assess the mode of operation and then the targets (e.g. man, plants, animals, and the economy), is it a symbolic act? Looking to the worst-case scenario is not adequate a focus, it should be on the ability to act against all possible events
4. Whist the risk is permanent it can be reduced e.g. prevention, preparedness, response etc. and there is a need to integrate a wide range of players
5. All must be done in a fiscally restrained environment therefore there is a need to share tasks to maximize the limited resources

A practical approach was thought to be best by Ian Abbott, Chief of Policy and Plans Division, European Union Military Staff where he used the example of the 'white powder' attacks in the UK following events in the USA in 2001. The tools need to be designed and provided centrally but the event is local and needs local action. Annalisa Giannella, Personal Representative of the High Representative for matters of non-proliferation, Council of the European Union reported on the development of legal instruments to enable the USA and the EU to work together. The EU wanted to set up a Scientific Advisory Board to take into account the advancement in biotechnology; there was an obvious need for a threat assessment in this regard.

Christine Rohde interjected to broaden the ownership of these discussions. She suggested that the WHO should be the forum where such a debate should be held, as it was a truly international topic not just one for the EU and the USA. Unfortunately this was not responded to. It was obvious that there was a perception of common enemy between Europe and the USA. It was a very political debate that seemed to ignore the real statistics where deaths by terrorist acts (particularly bioterrorists) pale into insignificance compared to deaths through infectious disease and other causes. The threat is real, the outcome may be relatively small in terms of human loss but an event, even a potential event, has a disproportionately large psychological effect.

One of the key conclusions drawn was that there was need for good mechanisms to provide sound, proper and appropriate risk communication. The President of NDA, Giles Merritt invited written comment and reactions on the meeting content and in general on bioterrorism, risk management and preparedness. The WFCC should deliver an agreed statement and provide the NDA with copy of its Newsletter items and statements. The bioterrorism threat is something that culture collections must address but perhaps effectively dealt with alongside a number of similar issues that require similar controls e.g. compliance with national legislation and regulations and international conventions, the handling of new and emerging diseases, health and safety, access to genetic resources, security (in general), intellectual property rights and ownership, quarantine, shipping, genetic manipulation and quality management. Bioterrorism is a hot topic with impact on culture collection and Biological Resource Centre operations. It is clear that the WFCC and through its collaboration with the OECD, BRC initiative needs to reinforce its position, the requirements it places upon its members, acknowledge the level of its role and also to provide sound and consistent information. The WFCC will continue to keep a watching brief on NDA activities and discussions and contribute to sensible and appropriate debate.

OECD Biological Resource Centre Biosecurity Guidance

The OECD Biological Resource Centre (BRC) Initiative from its beginnings highlighted the need to ensure the new generation of culture collection complied with legislation, regulations and operated best practice. OECD State Ministers selected biosecurity as a key issue to address and draft guidance has been developed by the OECD BRC Task Force to deliver a practical approach that enables legitimate research and development but reduces the opportunity for misuse (OECD confidential document DSTI/STP/BIO(2005)8). It can be argued that less than 0.1% of holdings of BRCs are potential dual use biological agents and that only a minority of culture collections have the facilities to handle Risk Group 3 and 4 organisms, therefore the impact on most collections is limited. There are a defined number of human pathogens but even here an agreed international list of organisms will be difficult to achieve. The organisms of concern extend beyond the human pathogens to include crop and animal pathogens and those that can be used to threaten environmental and economic targets. The OECD BRC Task Force agree that guidance is necessary but that it should not be bureaucratic and applied to situations that don't require it. The basic principles of the guidance being discussed are that BRCs should:

- Be accredited/certified to handle organisms to a specific hazard level

- Comply with legislation over national boundaries
- Not increase the hazard level of holdings
- Enable full traceability of distribution ▪ i.e. the requirement for MTAs

It would therefore follow that only approved accredited BRCs could hold agents of concern and that exchanges across national boundaries would be between accredited BRCs of equal clearance.
The OECD has been gathering information in the area of biosecurity and specifically has held a meeting in Frascati, Italy in September 2004. The OECD has collated information on all such initiatives to reduce duplication and confusion and presented it on the web www.biosecuritycodes.org .. Charles Penn, Head of Research and Development Health Protection Agency Centre for Emergency Preparedness and Response, Porton Down and member of the Senior Advisory Panel to the ISS-US /CBACI project expressed his whole hearted support for the OECD BRC efforts. He was particularly supportive of restricting exchange of dangerous materials between dedicated BRCs.

Amongst other activities is that of The International Peace Research Association (IPRA) and the Stockholm International Peace Research Institute (SIPRI). IPRA is a worldwide research organisation founded in 1964 to promote peace and peace education. The purpose of IPRA is to advance inter- and trans- disciplinary research into mechanisms of sustainable peace. SIPRI is currently conducting research into issues of non-proliferation and export control particularly comparing export control mechanisms for dual-use items. They are focussing on biological weapons control and the "…efforts by the European Union to develop a coherent and effective approach to preventing and ending the spread of nuclear, biological and chemical weapons…" SIPRI's research is based on questions of international peace and security. Comprehensive information is disseminated regularly on its research activities and databases on past years' armaments and arms control, armed conflicts and security arrangements and gives an overview of the entire field of international security through its main publication, the SIPRI Yearbook which was established in 1969. This publication is used by governments, the United Nations, parliaments etc. Furthermore, SIPRI offers summary information about the export control systems of countries. The WFCC will examine the possibility to cooperate with SIPRI.

The WFCC position

It is important that a voice of reason be heard above the clamor that appears in the public media. Too often public policy is formulated in response to incomplete or inaccurate information. This is especially the case with biological agents and their potential use as weapons. This is affecting both the science as well as national scientific priorities. It is essential that the WFCC present a reasoned perspective in this issue. There is an argument that the threat is mostly economic, the target may not be human. In the light of what happened in Asia with SARS and bird-flu, a consequence of a disease outbreak (human, animal or plant disease), whether occurring naturally or with intended or involuntary human intervention, is economic loss. As national controls are put in place through national legislation, for example the Patriot Act in the USA and Security Act in the UK, the lists of organisms of concern differ. Although humans are present in all

countries, this is not the case for certain crops and what might be a threat in one country will not be in another. The lists will differ but many of these organisms will not be suitable and do we really believe that a bioterrorist will engage in genetic modification? Terence Taylor President of IIS-US speaks of a spectrum of risk spanning natural events from emerging disease through man's intervention e.g. laboratory accidents to deliberate acts, bioterrorism. The greatest risk comes from emerging disease.

Control of access to microorganisms and their safe handling has been in place for many years and is subject to national laws. Furthermore, these institutions/laboratories have to order the material repeatedly in order to follow the QM standards for authenticity of the biological material. The WFCC wishes to help put in place secure and safe systems for access and distribution but favours an approach that does not restrict legitimate use and demands the same rules for materials that present little risk.

The opinion of membership is requested on the biosecurity issue, information on events where the Executive Board should be present, comment on best practice and what statements the WFCC should be making on its membership's behalf.

Culture collections, Biosecurity and the Biological Weapons Convention

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Background

Microbial pathogens have been used in biological warfare for centuries. Among other examples, Roman soldiers ran their swords through rotting animal carcasses before battle, diseased cadavers were catapulted over castle walls during the 14th Century siege of Kaffa in an effort to spread disease and the British attempted to spread smallpox to American Indians during the 18th Century French-Indian War using infected blankets [1]. During the 20th century, also, the use of pathogens and biologically-derived toxins as biowarfare agents has been explored actively and, in some instances used [2], including for targeted assassinations [3].

The international norm against the development and deployment of biological weapons is well-established [4]. The use of *Bacillus anthracis* in letter attacks post 11 September 2001 reminded us of the threat posed by biological weapons, including through State-sponsored activity. The *B. anthacis* letter attacks also emphasized that biological weapons can potentially create widespread fear, wreak considerable economic and social damage, and attack a country's normal functioning and its collective confidence, even when they inflict relatively few deaths. Addressing threats posed by the misuse of biological agents requires a concerted response at international, national, facility and personal levels. Enhanced security of culture collections is one means of addressing the threat. Speculation that the *B. anthracis* used in the 2001 letter attacks is likely to have been sourced from a biodefence laboratory underlines the need for effective biosecurity at biotechnological facilities.

The 2003 SARS coronavirus infections of laboratory staff in Singapore and Taiwan also illustrates the need for those dealing with microbes to take personal interest in, and responsibility for, limiting the misuse of pathogenic organisms. Facilities that have poor biosafety procedures and protocols are vulnerable to those seeking to access pathogens and technology for hostile purposes. In the Singapore incident [5], poor record keeping made it difficult for a subsequent international investigation to determine whether live SARS virus was in the laboratory the day the infection occurred. In addition, poor laboratory practices led to contamination of samples with West Nile Virus — another hazardous pathogen being researched in the facility. Further, safety procedures differed between laboratories at the facility. If the biosafety culture and practices of the affected facilities were ineffective in ensuring the safety of staff, it is unlikely that they afforded adequate biosecurity. These examples demonstrate that life scientists

must actively support efforts to minimize risks that biological agents will be misused.

Biosecurity versus Biosafety

There is no agreed definition of 'biosecurity' and this has led to confusion with a related term, 'biosafety'. Some Governments and organizations interpret 'biosecurity' to comprise measures that minimize the risk of biological agents being deliberately misused to cause harm. Others use the term to reference actions that limit the incursion of exotic pests that may threaten agriculture and/or biodiversity. We understand the relationship between biosafety and biosecurity but, consistent with the trend internationally, consider that the concepts are distinct and that there are differences in associated practice.

We define 'biosecurity' as measures intended to prevent the **deliberate misuse** of biological pathogens and toxins. It is distinguished from 'biosafety', which we consider references measures taken to protect people and the environment from the **unintentional impact** of pathogens and toxins, and includes workplace health and safety issues and the prevention of the accidental release of such biological agents. While standard biosafety precautions may provide some security measures, such as restricting access to facilities to authorized people, additional measures are required to ensure effective biosecurity. Similar arguments are used to distinguish between chemical safety and security, and nuclear safety and security [6]. These arguments are widely accepted by personnel working in these respective disciplines.

In 2003, experts met in Geneva as part of a 3-year work program under the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (the BWC), to discus biosecurity and national legislative obligations of States Parties. Elements of a best-practice biosecurity model emerged from these discussions.

These were considered to be:

1. Establish agent control list
2. Risk assessments
3. Powers and penal legislation
4. Site and sales security
5. Export controls
6. Import controls
7. Secure transfers
8. Consequence management
9. Education and outreach
10. A national authority

As biosecurity is a relatively new field, many countries have yet to develop specific biosecurity measures. Some jurisdictions may develop biosecurity legislation by adapting existing laws, originally developed in relation to biosafety (e.g. quarantine, gene technology, occupational health and safety, public health, or biodiversity legislation). To date, however, few governments have introduced effective BWC-implementing legislation, let alone dedicated biosecurity legislation.

Notable exceptions include Canada, France, the UK and the USA [7]. Australia is currently reviewing controls over hazardous biological materials with a view to ensuring that regulations and their implementation and enforcement are effective, consistent and sufficient to prevent the procurement, possession or transfer of such goods for illegal purposes.

Biosecurity and Culture Collections

Microbial culture collections underpin much of the research undertaken in the biological, medical, veterinary and agricultural sciences. Such collections provide a source of material for scientific investigation and, thereby, contribute significantly to important biotechnological and medical advances. As a centralized source of microbial specimens, an increasingly important issue for culture collections is whether their security measures would prevent inappropriate access to, or use of, specimens or associated technologies. These may include human, animal and plant pathogens, and techniques used for their culture. A body of literature [8] attests to the interest of some governments and bioterrorists in each of these types of pathogens as bioweapons and underscores the need for vigilant security practices.

The World Federation of Culture Collections (WFCC) has published 'Statements on Biological Warfare' [9] and produced 'Guidelines for the Establishment and Operation of Collections of Cultures of Microorganisms' [10]. Paragraph 16.2 of these guidelines states that *"Particular attention needs to be given to the containment and security aspects of strains which are potentially harmful to man, animals or crops"*. These documents are very welcome and commendable, and emphasize that WFCC members must comply with national and international legislation and procedures for the control of access to dangerous organisms.

The WFCC's requirement that members 'adopt best-practice' in relation to their cultures [and associated biosecurity] is particularly important, given the scarcity of dedicated biosecurity legislation. Indeed, because of the scarcity of such legislation, we press the need for harmonised biosecurity practices between facilities researching and storing biological agents. As part of this effort, we encourage facilities to draw from the elements of biosecurity best-practice outlined at the 2003 BWC meeting of experts and learn from the 2003 SARS biosafety incidents in Singapore and Taiwan. Further, we suggest that compliance with internationally-recognised standards, such as the WHO Laboratory Biosafety Manual, the CDC/NIH biosafety guidelines and the Australian and New Zealand Standard (Microbiology) [11] is essential. Significantly, many of these standards are now being revised to provide specific guidance on biosecurity.

Biosecurity and the Global Biological Resource Centre Network (GBRCN)

The OECD recognizes that Biological Resource Centres (BRCs), including many that are registered with the WFCC as culture collections, are *"essential for R&D in the life sciences, for advances in the quality of the environment, agriculture, and human health, and for the commercial development of biotechnology"* [12]. Efforts to establish a Global Biological Resource Centre Network (GBRCN) have been endorsed by OECD Science and Technology Ministers [13] and are scheduled to

culminate in 2006. A key issue in the development of the GBRCN is biosecurity and, in this context, the OECD's Directorate for Science, Technology and Industry established an expert group under the auspices of the BRC Task Force to develop Biosecurity Principles for the GBRCN. The OECD approach starts from an understanding that for a global network of biological resource centres to contribute most effectively to scientific and economic development, the GBRCN must not only promote scientific openness but must also build-in security. The aim of the evolving principles is to reduce the possibility that dangerous pathogens held in culture collections around the world could be acquired and used for harm.

Many of the principles being considered by the Task Force echo the elements of biosecurity best-practice that emerged during the 2003 BWC meeting of Experts. Nonetheless, until dedicated biosecurity legislation is more prevalent internationally, we suggest that demonstrable compliance with the principles established by the OECD for GBRCN's should be a pre-requisite to joining the GBRCN. Further enquiries regarding the GBRCN, including potential membership, should be directed to the OECD [14].

International obligations

The international legal regime prohibiting biological weapons is clear [15]: the actual use of biological weapons is outlawed through the Geneva Protocol 1925 and the BWC prohibits all member States from developing, producing, stockpiling or otherwise acquiring or retaining biological weapons and their means of delivery. States Parties to the BWC must also prohibit their supply to, or acquisition by, all other entities ─ State and non-State. Highlighting widespread international acceptance of the norm against biological weapons is that 153 States are currently party to the BWC.

In 2004, UN Security Council Resolution 1540 [16] reinforced the objectives of the Geneva Protocol and the BWC. This resolution requires all member states to adopt and enforce criminal laws to prohibit the manufacture, acquisition, possession, development, transport, transfer or use of nuclear, chemical or biological weapons and their means of delivery, and requires all member states to introduce measures for controlling access to harmful chemical, biological or radiological materials. Enactment of effective laws is mandatory under international law.

Unlike other non-proliferation regimes such as the Chemical Weapons Convention and the nuclear Non-Proliferation Treaty and its associated protocols, the BWC lacks compliance and verification mechanisms. These shortcomings were underscored by revelations that some State Parties had extensive biological weapons programs. For example, the former Soviet Union admitted officially in 1992 to such a program, and UNSCOM inspectors uncovered an extensive program in Iraq during the early 1990's.

Negotiations towards an internationally-binding verification protocol to the BWC took place between 1995 and 2001. By early 2001, the negotiations had produced a draft composite text with legally-binding provisions. A number of key issues remained unresolved, however, and as a consequence, some States

Parties were unwilling to support the proposed Protocol. Negotiations broke down in mid-2001. States agreed, however, to continue to discuss measures to strengthen the BWC though an intersessional program of work from 2003-2005, based on agreed topics [17].

The absence of a verification protocol to the BWC emphasises the necessity for effective national implementation of the treaty, including through non-legislative means such as raising awareness and promoting security practices within the diverse communities of research scientists, industry groups (production, equipment and trade), public health, veterinary, military and other government experts ─ noting that any of these groups could inadvertently contribute to an illicit biological weapons program. In addition, objectives of the BWC are complemented by the work of the Australia Group (AG) [18], an informal arrangement which seeks to harmonize national export controls on materials and equipment suitable for the development of biological and chemical weapons. In participating countries, export permits are required prior to exporting AG-listed items.

Satisfying International Obligations

Effective and efficient implementation of international obligations arising from the BWC depends on a coordinated approach underpinned by three pillars, namely: comprehensive national legislation; effective implementation and enforcement arrangements, and self-regulation by facilities [19]. Where local circumstances challenge the development and implementation of effective national legislation, we encourage robust self-regulation to maximize biosecurity and demonstrate compliance with the BWC. Elements of self-regulation are outlined below.

Self regulatory measures

Improving attitudes to biosecurity

It is incumbent on life scientists to adopt practices which ensure that their research is not misused for hostile activities. There is a need for constant vigilance about suspicious or unusual activities and requests, and to bring these incidents to the attention of relevant authorities.

Implementation of best-practice biosecurity is a significant challenge and requires major changes to workplace attitudes, from the top of organisations down to individuals. This was reflected in discussions at the 2003 BWC experts meeting, during which it was noted that biosecurity is *"multi-faceted and could not be achieved simply with locks and keys and that biosecurity is a 'whole-of-life process', covering the acquisition, use, transfer and disposal of materials"*. This is difficult and requires awareness by both facility operators and regulators, and coordination and maintenance to ensure that exploitable weak links do not develop.

Responsibilities of researchers and Facility Operators

With rapid technological advances, researchers are in the best position to identify potential misuse of their research. Even with strong legislative and enforcement provisions, security will never be adequate unless there is an equally robust

commitment by researchers to assist the policy objectives of government. To this end, scientists working within culture collections are encouraged to take steps to prevent the transfer of specimens, technologies and research to recipients (individuals, groups and/or States) known to have misused biological agents in the past, or who are considered to pose a reasonable risk of misusing biological agents in the future. Deciding upon the latter can be challenging and, under such circumstances, consultation with relevant government authorities may be advisable. Some of the steps that would help to limit inappropriate transfers include, but are not limited to, strengthening physical security, including risk-assessment studies; restricting access to authorized workers only; effective stock auditing; checking intended use and appropriate chain of custody; developing codes of conduct and reporting thefts or suspicious incidents to appropriate authorities or agencies.

Conclusion

There is considerable pressure by, and expectation from, the international community to improve measures to control access to harmful biological agents and, thereby, deter their misuse. Because culture collections are a centralized source of many of the pathogens, specimens and technologies that are likely to interest those intent on malicious use of biological agents, these facilities have particular responsibilities to apply sound biosecurity practices. Accordingly, we strongly encourage facilities to consider the security implications of their work and ensure that measures are in place to minimize the risk of inappropriate access to, and use of, the collection. Given the absence in most countries of national biosecurity legislation, the need for high-level awareness of biosecurity issues and effective self-regulation is more important today than ever before.

NOTE: This article reflects the personal views of the authors and not, necessarily, those of the Australian Government Department of Foreign Affairs and Trade

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2. *ibid*
3. see *http://news.bbc.co.uk/1/hi/uk/2636459.stm*
4. A suite of international agreements relate to the norm against biological weapons. Key instruments include: the *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare* (the Geneva Protocol 1925), see *http://disarmament.un.org: 8080/TreatyStatus.nsf*; the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction* (BWC), see *http://disarmament.un.org:8080/wmd/bwc/*; and *UN Security*

Council Resolution 1540, see http://www.un.org/News/Press/docs/2004/sc8076.doc.htm

5. see http://www.moh.gov.sg/corp/sars/pdf/Report_SARS_Biosafety.pdf
6. For example, regarding nuclear safety and security, see the website of the International Atomic Energy Agency, http://www.iaea.org/.
7. For Canada, key legislation includes the *Public Safety Act 2002*, an element of which is to implement the *Biological and Toxic Weapons Convention Implementation Act* (BTWCIA); for France, key legislation is Ministerial Order published in the Official Journal of the French Republic JO/223; for the UK, relevant legislation includes the *Anti-terrorism, Crime and Security Act 2001*; and for the USA, key legislation includes the *Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001*, the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, and the *Agricultural Bioterrorism Protection Act of 2002.*
8. For example, *USAMRIID's Medical Management of Biological Casualties Handbook, 5th edition* (2004), see http://www.usamriid.army.mil/education/bluebook.htm; Madden & Wheelis (2003) *Annu. Rev. Phytopathol.* 41:155-76.
9. Culture Collection Statements on Biological Warfare, see http://wdcm.nig.ac.jp/biowarfare.html.
10. WFCC *Guidelines for the Establishment and Operation of Collections of Cultures of Microorganisms*, see http://wdcm.nig.ac.jp/wfcc/GuideFinal.html.
11. WFCC *Guidelines for the Establishment and Operation of Collect* for WHO guidelines, see http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf; for the CDC/NIH guidelines, see http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm; for the Australian and New Zealand Standard (Safety in Laboratories: Microbiology; AS/NZS 2243.3:2002) see http://www.standards.org.au/default.asp.
12. see http://www.wdcm.org/brc.pdf
13. Ministerial Meeting of the OECD Committee for Scientific and Technological Policy, 29-30 January 2004 - Final Communique; see http://www.oecd.org/document/15/0,2340,en_2649_201185_25998799_1_1_1_1,00.html.
14. OECD Directorate for Science, Technology and Industry; see http://www.oecd.org/department/0,2688,en_2649_33703_1_1_1_1_1,00.html.
15. refer to reference number 4
16. *ibid*
17. see http://disarmament.un.org:8080/wmd/bwc/pdf/bwccnfv17.PDF
18. see http://www.australiagroup.net/index_en.htm
19. The term 'facility' includes culture collections, whether in public, private or biodefence laboratories, and all entities handling, or potentially handling, biological agents and technologies in the facility.

Endangered Culture Collection Fund report: Saving a valuable bio-resource in Chiang Mai, northern Thailand

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Chiang Mai is the second largest province in Thailand after Bangkok. The province is located in northern part of the country and the population of Chiang Mai city itself is about 2 million. Chiang Mai University is a relatively new university and was established in 1965; the Faculty of Science being one of the seven faculties formed at that time. Now thirteen Faculties exist. The Faculty of Science has eight Departments including Biology, Chemistry, Computer Science, Geology, Mathematics, Physic, and Statistics.

Within the Department of Biology, three basic degree programs are taught specializing in Biology, Microbiology, Microbial technology, Biodiversity and Botany. The Biology department has 200 undergraduate students, 40 post-graduate students and 60 staff members. Each year 2000 students graduate from Chiang Mai University, most coming from northern region of Thailand.

The keen and ongoing interest in microbiology within the University has resulted in a modestly sized but unique collection of micro-organisms being built up representing a wide spectrum of biota from this part of the world. Within the Applied Microbiology Unit in the Department of Biology, Chiang Mai University there exists a collection of around 2000 strains of bacteria, actinomycetes, yeasts and filamentous fungi.

However, due to the current limitation of resources and in particular, a preservation facility, much of the collection which is of importance both as a local teaching tool and to the Thai network of culture collections, was in danger of being lost. We were therefore extremely grateful, having applied to the Society for Applied Microbiology Endangered Collections Fund, to secure a grant to enable our precious resource to be placed on a sounder footing, at least for the medium term. Strains maintained in our University culture collection are used in our undergraduate and post-graduate teaching and some may have commercial potential.

Current practice within the Chiang Mai culture collection is to preserve strains by active sub-culture, under mineral oil, and/or frozen at -20C. The collection is not fully characterized but is thought to contain many new taxa and novel isolates obtained from soils and plant materials of the region and other regions and unique habitats throughout Thailand. We also have an old freeze drier but lack the expertise to operate it efficiently. Consequently, the opportunity to have Dr Peter Green from the NCIMB Ltd. Culture Collection in the UK to come and visit and

advice on optimal preservation methods and to supply funds to enable the collection to continue was of immense value. This important biological resource is very important for research and development in Thailand. As we are a developing country most of our technology is originally bought in from developed countries, which involves significant amounts of money but the local people do not improve any of their skills by this route alone. Thailand is a tropical country and it is a good resource for a diversity of potentially valuable microbes, which can be important in the discovery of new bioactive compounds. If we can maintain these resources until we can fully study and exploit their potential, it will be of immense benefit to Thailand as well as to the international community. Thanks to the rescue, we will have time to discover if any of the micro biota within the Chiang Mai collection harbors useful compounds especially for the discovery of drugs against resistant disease pathogens such as MRSA, HIV, Tuberculosis and Bird flu.

Specifically, the cash part of the SfAM grant will be spent on a laboratory freezer, a dehumidifier, a small liquid nitrogen tank, glass ampoules for freeze drying culture, cryovials and culture media.

Dr. Peter Green's visit was therefore of extreme value in exploring various methods available to preserve our endangered strains. His lecture during the visit was useful in terms of methodologies for students and staff and to employ in our Lab making optimal use of the limited facilities available. We can improve our techniques more than before and collaborate with other research projects given the safeguarding of our resource. We also made use of Dr Green's visit to highlight the value of the culture collection to the senior administration within the university and to lobby for improved support in the future. Thanks again to the SfAM for your kind support.

Are the plant pathogens endangered?

WFCC Endangered Collections Committee

1] Collections and Germplasm Committee

Within the WFCC alone there are over 600 member collections. Out with this membership there exist thousands of private, institutional or industrial culture collections many of whom are financially unstable or which lack support in a number of different ways. From time to time it is inevitable that some of these collections should have difficulties in terms of their long or even short-term sustainability. It is the purpose of the WFCC endangered culture collection committee to try to assist such collections in any way it can via its contacts and expertise.

Although rarely will any direct financial assistance be available from committee, the members can assist those who are responsible for the curation or management of collections in various ways. Such assistance can take the form of simple advice or "political" intervention on your behalf e.g. lobbying your funding body or government department as a form of biological ombudsman.

If, on the other hand, you require advice on a more streamlined or cost effective maintenance of the collection in the wake of staff losses or additional training in some aspect of collection management; we can try to help or put you in contact with an appropriate person or persons who may be able to offer the required advice or assistance.

Similarly, if your collection requires to be relocated or is no longer supported by your parent organization, or is in imminent danger of being discarded or abandoned, then we can try to find a suitable recipient who is able and willing to help look after either the key strains or the collection in its entirety. Most importantly, the WFCC endangered culture collection committee acts as a first port of call for Curators and managers who are concerned about the sustainability of their collection.

It is part of the committees' remit to consider cases on an individual basis, in order to assess their degree of difficulty and to try to determine the most appropriate course of action. If collections are in imminent danger of being lost or their owners are voluntarily requesting relocation to another more stable collection, then a questionnaire has been designed to help assess the genetic resource "value" and relocation needs of that collection.

Realistically not all collections need to be or indeed can be saved, thus it is crucial that the committee are in possession of as much information about the collection in question to help with the assessment process. Wherever possible, it would also be viewed by committee as desirable to secure the continued existence of the endangered collection either *in situ* or in the same host country.

Please do not feel embarrassed or pensive about asking for help or advice. That is what we are here for. Your enquiry will be treated with confidence and

sensitivity. According to Dr. Peter Green, chair of the WFCC Endangered Collections Committee, in the last two years the committee has helped culture collections in Costa Rica and Thailand. This has taken the form of a short course or lectures by visiting experts to advise on collection management and preservation techniques and to provide limited funds for small items of equipment and urgently needed consumables.

http://www.wfcc.info/committee/endangered/home.html

2] International Stripe Rust Collection in the Netherlands

Dr. R. W. Stubbs at the Research Institute for Plant Protection (IPO), Wageningen, the Netherlands had maintained a good collection of international isolates of *Puccinia striiformis*, the fungal pathogen of stripe rust on cereal crops and grasses, before his retirement in early 1990s. After his retirement, the collection has not been used. It is not clear if the isolates in this collection are still viable.

3] Examples of Canadian fungal collections orphaned or vulnerable over 10 years*

Collection**	**Agency Type**	**Transferred to****	**Reason**
PRL	Government	CCFC	Retired or research priorities shifted
Waterloo	University	CCFC	Retired
J.W. Paden	University	CCFC	Died
E.G. Setliff	University	CCFC	Retired
D.W. Malloch	University	CCFC	Retired
Edible (S. Davies)	Government	UAMH	Research priorities shifted
J. Reid	University	UAMH	Retired
R.M. Danielson	University	UAMH	Retired
J.P. Tewari	University		Retired

**CCFC, Canadian Collection of Fungal Cultures, Agriculture and Agri-Food Canada, Ottawa, Ontario
PRL, Prairie Regional Laboratory, Saskatoon, Sask.;
UAMH, University of Alberta Microfungus Collection and Herbarium, Edmonton, Alta.

*Sigler, L. 2004. Culture collections in Canada: perspectives and problems. *Canadian Journal of Plant Pathology*, **26**: 39-47.

4] World *Phytophthora* Collection (Dr. Michael David Coffey, UC Riverside)

In 1962, the first accessions of the **World *Phytophthora* Collection** (WPC) were placed in glass culture tubes and a great adventure began. The origins of this important collection were in the research work of Professor Erwin and Professor Zentmyer at the University of California, Riverside. Erwin collected mainly isolates from alfalfa and Zentmyer isolates of *P. cinnamomi* and *P. palmivora*. An early collection of isolates representing different species came from Professor Mannon Gallegly at West Virginia University. By 1981 the collection was being maintained by Laura Klure in Professor Zentmyer's lab. With his retirement some of the accessions were sent to ATCC and provided them with a core collection. Many cultures were lost at this point due to the difficulty of maintaining them using traditional methods such as mineral oil preservation. From 1981 until 1986 a collection of about 600 isolates was maintained by Professor Michael Coffey. In 1986 a major development was the provision of funds to Professor Coffey by the UC Genetic Resources Conservation Program for Imperiled Microbial Collections to allow the WPC to be stored under liquid nitrogen using cryogenic techniques.

The WPC has grown in stature over the last 20 years increasing in size from 600 to nearly 6500 accessions (June 2005) of the 90 or so different species or taxa, which represent this most important plant pathogen. Many of the accessions have been intensively studied over the years and thus the WPC is not only unique in size but also in terms of its importance as a genetic resource. There is an increasing awareness of the importance of this collection now that a new species has been identified as the cause of Sudden Oak Death. The possible threat *P. ramorum* poses to the oak forests of the world cannot be underestimated. At the same time, other species of this most destructive of plant pathogens have resurfaced and threaten crop production. A new potentially destructive species *P. kernoviae* with the potential to impact forest ecosystems has recently been described in the UK. Without doubt the most important of the *Phytophthora* species is still the Late Blight fungus *P. infestans*, the cause of the Irish Potato Famine. Many new aggressive strains of this pathogen have emerged in the last few decades and seriously threaten potato and tomato production in many parts of the world. The WPC has a large and genetically diverse collection of this pathogen.

The World *Phytophthora* Collection at UCR is still threatened with extinction, urgent financial support is needed. With the drastic budget cuts facing the University of California this collection, which is over 40 years old, may be lost forever in the very near future. Funds are needed to replace aging equipment, some of it 20 years old, such as the programmed freezer (replacement cost ~$18,000) and the 5 liquid nitrogen refrigerators (replacement cost ~$84,000).

There is currently no technical help available and future operations are in potential jeopardy. Part-time technical help is urgently needed (cost ~$28, 000 per annum for salary and benefits a part-time lab assistant). The World *Phytophthora* Collection is in urgent need of financial support.

If you would like to make a donation please go to the World *Phytophthora* Collection Fund Webpage: http://www.geocities.com/m_d_coffey/phytophthora.html

The Eliava Phage Collection

Dr. Nina Chanishvili

The George Eliava Institute for Bacteriophage, Microbiology and Virology (GEIBMV) in Tbilisi, Republic of Georgia was founded in 1923 and has researched and developed bacteriophage medicines for over seventy years. These medicines formed a key element of the treatment of a wide range of bacterial infections during the Soviet era and the GEIBMV supplied the whole of the former USSR with bacteriophage therapeutics. The Institute survived the murder of Dr. Eliava, the first Head of the Institute, in 1937 and the civil war that followed the break-up of the Soviet Union in 1991.

Bacteriophage therapy is rapidly emerging as an important alternative to conventional chemotherapy for the treatment of bacterial infections at a time when antibiotic drug resistance threatens our continued ability to combat serious infections in our hospitals and in our communities, and at a time the pharmaceutical industry is drastically scaling down its development of the new antibiotics that we so badly need. The GEIBMV has amassed a unique and extensive collection of medically important bacteriophages; and the scientists and technicians within the Institute have unparalleled experience in research, development and clinical use of bacteriophage medicines.

All this is now under threat. The Georgian Academy of Sciences have revealed plans to merge the GEIBMV with five other Institutes in Georgia as a simple cost cutting exercise, and plan to disperse the resources and expertise currently residing under one roof in Tbilisi. Such a move will spell the end of this unique microbiological institution, with all that entails for the future development of unconventional but effective anti-infective medicines.

The proposal to merge the Institute has serious implications for the future, in particular:

- Loss of commercial funding opportunities
- Loss of key staff members
- Loss of external assistance in technical and commercial fields
- Disruption of collaboration agreements already in place
- Loss of new opportunities to develop commercial/joint ventures
- Potential repayment of some grants, which have been collected owing to, changed management and ownership.

Under this scenario this proposed move will result NOT in cost savings but in additional costs and the lost opportunities for Georgia in biotechnology on the world stage. No decision should be taken about the future merging of the Eliava Institute until a proper study is undertaken of all the economic, technical and financial implications.

Please help to ensure that this merger does not happen – sign this petition and send a message to the Georgian Academy of Sciences to say that the loss of this resource will not be a blow only to science in Georgia but will significantly

impoverish the global fight against the ravages of infectious disease – the biggest killer of mankind in the 21st century.

RESPONSE TO Dr NINA CHANISHVILI

Dr. Peter Green
Chair, WFCC Endangered Collection Task Group

The Eliava Phage Collection

The Eliava Institute in Tbilisi Georgia houses an important collection of bacteriophageS and this unique resource is currently under threat. Bacteriophages have many industrial and academic applications ranging from teaching to involvement in food production processes through to forms of alternative medical therapies. The article in this issue by Nina Chanishvili highlights the importance of the Eliava collection both nationally and to the wider international community. Clearly this is a very important phage collection and its continued existence is of the highest priority to the wider scientific community. Its plight has been brought to the attention of the WFCC and the Endangered Collection Task Group. The Task Group seeks to help endangered collections in the most appropriate way given local circumstances. This help can be limited short term monetary assistance for basic materials, advice on improved collection preservation or management issues, or lobbying national authorities to invest in the resource. As a last resort, The Task group can help in the relocation of the collections to a “safer” haven; however if at all possible, the desire is to save and improve the collection’s long term survival *in situ* or at least within the same country. In the case of the Eliava collection, the WFCC have been asked to lend support to lobby the Georgian government to invest in the future of this irreplaceable genetic resource. The best course of action will be considered by the Task Group and the full WFCC committee and a letter from the WFCC president to the appropriate contact within the Georgian government may prove the most fruitful course of action, in an area where there are sensitive political issues at stake. These issues must not be allowed to detract from the merits of the scientific case for investment in the continuance of this resource.

Myxobacteria – effective producers of bioactive compounds; Unique Reichenbach collection now available at the DSMZ

Dr Elke Lang

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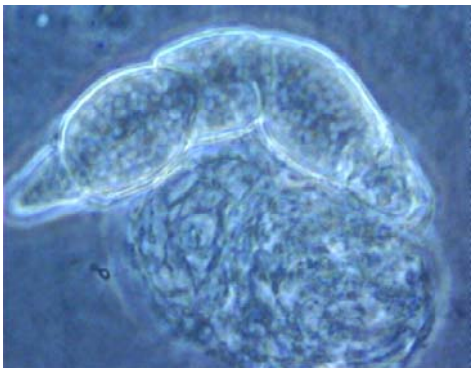
Myxobacteria are fascinating organisms because of their ability to produce fruiting bodies of different complexity. Under unfavourable conditions, billions of cells aggregate in a highly coordinated process to build up structures such as soft yellow spheres or coral like branches (genus *Myxococcus and "Corallococcus"*), or highly differentiated "trees" (*Stigmatella, Melittangium, Chondromyces*). These consist of fragile "stems" carrying on their top a bunch of drop- or bell-formed sporangioles containing the myxospores (Figs. 1-3).

Figure 1: Fruiting body of *Chondromyces apiculatus.* The treelet developing on top of the agar is about 500µm high. Each of the drop-shaped sporangioles contains several hundred myxospores

Figure 2: Fruiting body of *Stigmatella erecta*. The short, branched, cell-free stalk carries brown sporangioles, 30 – 50 µm in size.

Figure 3: The irregularly shaped fruiting bodies of *Nannocystis exedens* are built directly lying on or embedded in the agar. A rigid wall encapsulates the spherical myxospores (1 µm), which are still visible here



To understand how these fruiting bodies are built (i.e. coordinated morphogenesis in bacterial populations) is still an appealing matter of research.

About forty years ago, it was detected that the myxobacteria have another extraordinary capability: - producing various secondary metabolites of yet unknown structure and properties. The chemical structure of the compounds is diverse covering mainly peptides and polyketides or a combination of both, but also lactames, aromatics, polyethers and alkaloids are produced.

A high percentage of these compounds show distinct effects on other organisms. Antibacterial and antifungal effects as well as toxic effects to animal/human tissues were detected. The mechanism of interaction with other cells or tissues may be rare or novel in several cases. Among antibiotically effective compounds, a metabolite called Soraphen inhibits fungal acetyl-carboxylase. High attention attract the compounds interacting with the cytoskeleton of mammal cells, i.e. Rhizopodin effecting the organization of the actin skeleton and Epothilon fixing the microtubules thus inhibiting the construction of the mitotic spindle in eukaryotic cells. These interactions make some of the myxobacterial metabolites promising candidates for cancer medicals.

Since the chemical structure and the amount of secondary metabolites is strain dependent, a high-numbered collection of myxobacteria is an extraordinary rich source for the detection of novel (bioactive) compounds. Since the 1970s, the working group Natural Products Biology at the GBF (German Research Centre for Biotechnology), headed by H. Reichenbach, built up a comprehensive collection of *Myxococcales*, and it has already become the source for the isolation and characterization of many novel natural substances. The collection also built the background for studying the biotechnological properties of myxobacteria and for developing the fermentation processes for metabolite exploitation. Additionally, the strains were the basis for the description of 29 novel species, which will be published, in the forthcoming *Bergey's Manual of Systematic Bacteriology*, Vol II.

In cooperation with the GBF, the DSMZ GmbH makes this unique collection available to the public step by step. Currently, 2500 terrestrial strains, mainly members of the genera *Myxococcus*, *Cystobacter, "Sorangium"*, *Nannocystis* and

Melittagium, are offered as actively growing cultures. Hundreds more of strains will be added until the end of the year. Strain data are accessible at www.dsmz.de.

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Knowledge at the service of food security and prosperity for Africa

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Africa faces unparalleled development challenges. Some 70% of the poor live in rural areas and depend on agriculture for food and income. Agricultural development is central to improving livelihoods.

CAB International (CABI) an intergovernmental technical organization, established in 1913, brings a 'common wealth' of knowledge to support agricultural development in Africa. CABI is directly owned and driven by 41 Member Countries, including the UK and many African states.

African poverty reduction strategy plans increasingly seek to escape poverty through economic growth. In agriculture, this demands the development of local and international trade and added value through local processing. However, the shift to market economies is challenging as smaller producers lack knowledge, infrastructure and external connection. Through its Regional Center (Nairobi) and global resources, CABI works across Africa to overcome these challenges through the application of scientific knowledge and its conversion to goods and services.

- Realizing new resources – microbial biodiversity

Microbial biodiversity holds great promise for African countries. Often overlooked, fungi and bacteria sustain ecosystem function, while their antibiotic by-products underpin the world's pharmaceutical industry. CABI builds national capacities for the conservation, sustainable use and equitable benefit from biodiversity, resulting in novel, African-owned products such as a bio-pesticide against plague locusts.

- Empowering farmers through knowledge

In rapidly changing markets it is crucial that farmers can acquire and use external knowledge. CABI empowers poor farmers to understand market needs and the implications of improved practices. By forging new relationships between science and society, CABI helps farmers become equal partners in the development of innovative technologies.

Drawing on our extensive information resources, (nearly 8 million scientific abstracts in agriculture and human health), CABI promotes the effective access, use and dissemination of information through a wide range of ICTs and knowledge pathways including rural advisory centers, Internet portals, mobile phone systems and participatory video production.

- Enabling safe trade

Pests' impact heavily on yields both before and after harvest yet reliance on pesticides creates its own problems. CABI promotes Integrated Pest Management as a sustainable and beneficial alternative. Utilizing our wealth of expertise in biologically based control options and through participatory approaches we improve yields, quality and profitability.

Through the sanitary and phytosanitary provisions of WTO and increasing market emphasis on quality and risk management, science has become the main arbiter of agricultural trade. CABI maintains a unique skills base and microbial reference collection of 400,000 specimens underpinning the world's understanding of the occurrence and distribution of agricultural pests. With innovative information tools such as the Crop Protection Compendium, (detailing the biology and management of nearly 2,000 pests), these form an international resource enhancing the capacity of African countries to manage problems and engage effectively in trade negotiations.

Increased global mobility brings unprecedented risks of introducing invasive alien species (IAS) such as water hyacinth, threatening environments and agriculture. Many African countries lack the resources to control the spread of such pests. CABI fosters the national management of IAS through biological control, regional networks, capacity building and technology and information transfer.

CABI uses applied research, rural development projects and novel products and services to improve rural livelihoods. We address key needs as requested by our governments via practical partnerships with government bodies, NGOs and the private sector. As a not-for-profit organization, operating through just 3% core funding, we are highly focused and accountable, with our activities directly commissioned to enable delivery of valuable outcomes.

CABI forms a unique technical bridge between Europe and Africa. We seek to further strengthen these linkages and harness international knowledge for Africa's development.

China culture collection delegation visited CABI

A nine person delegation of culture collection of china composed of Prof. Jiang (Director, Agricultural Culture Collection of China, ACCC) Prof. Zheng (Director, China Center for Type Culture Collection, CCTCC), Prof. Fang (Deputy Director, China Center for Type Culture Collection, CCTCC) and Prof. Chen (Director, China Center for Industrial Culture Collection, CICC) along with Dr. Xu Zeng-tai (Ministry of Science and Technology of People's Republic of China) visited CABI Bioscience UK Centre (Egham) 2nd August 2005. David Smith, Matthew Ryan, Qiaoqiao Zhang and Joan Kelley explored opportunities for collaboration, introduced the work of CABI and conducted a tour of the living culture collection, research laboratories and the dried reference collection of CABI Bioscience. Presentations from Dr. Smith introduced CABI Bioscience and culture collection networks of the UK, Europe and the world. Dr. Zhang introduced the activities of CABI in China through its offices in Beijing. Dr. Ryan introduced the Structure and function of the CABI Genetic Resource Collection. Dr. Smith stated that CABI is an international organization owned by member countries and that China, as one of the members of CABI, was very important and collaboration in bioscience and agricultural was high on CABI's agenda. On behalf of the delegation, Prof. Jiang thanked Dr. Smith and colleagues for the warm welcome before presenting key information concerning culture collection networking in China. She introduced the progress being made on the national project on the microbial resources sharing platform. In the discussion, CABI and the Chinese delegation exchanged ideas on future cooperation in the project. When Dr. Smith introduced the work on the establishment of the Global Biological Resource Centre Network currently under the auspices of the OECD, the delegation expressed great interest in combining the work and collaborating with the BRC initiative. Collaboration has already begun between CABI and the ACCC, following lectures and discussions on the ACCC development by David in Beijing in 2003, arrangements for Mr Jingang Gu the Fungal Curator of the ACCC to conduct his current 3 month study visit to CABI were made.

Mr Gu's training includes: taxonomy of bacteria and *Trichoderma*, Characterisation techniques for fungi and bacteria, preservation technology, and culture collection management and projects covering: a desktop study on Genetic Resources for Food and Agriculture in China and preparation of a project proposal, which will lead to enhancement of the ACCC: through human resource development, facility enhancement, quality management, technology transfer and improved operational policy and procedures

David has identified a number of areas that CABI, ACCC, the Chinese National Project, the OECD BRC Initiative and the World Federation for Culture Collections can work together. Mr Gu is already preparing research and collaboration proposals during his stay at CABI. We look forward to long and fruitful collaboration.

Announcements

Book announcement: please, visit the website

http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf

We would like to announce and recommend the WHO Laboratory biosafety manual, third edition, World Health Organization, Geneva, 2004. This manual is still a must for all organisations and institutions working with biological materials including of course the culture collections. This basic manual was first published in 1983 and - as stated by Dr. A. Asamoa-Baah, Assistant Director-General in the Foreword - "it continues to provide international leadership in biosafety addressing biological safety and security issues facing us in the current millennium. The third edition stresses throughout the importance of personal responsibility and is a helpful reference and guide to nations that accept the challenge to develop and establish national codes of practice for securing microbiological assets, yet ensuring their availability for clinical, research and epidemiological purposes." The manual contains new information on risk assessment, safety in handling recombinant DNA and transport regulations and as a response to the recent world events, introduces aspects on biosecurity.

Microbial Genetic Resources and Biodiscovery
Edited by Ipek Kurtböke and Jean Swings
Printed by Queensland Complete Printing Services, Nambour, Australia
ISBN: 0-646-44048-9

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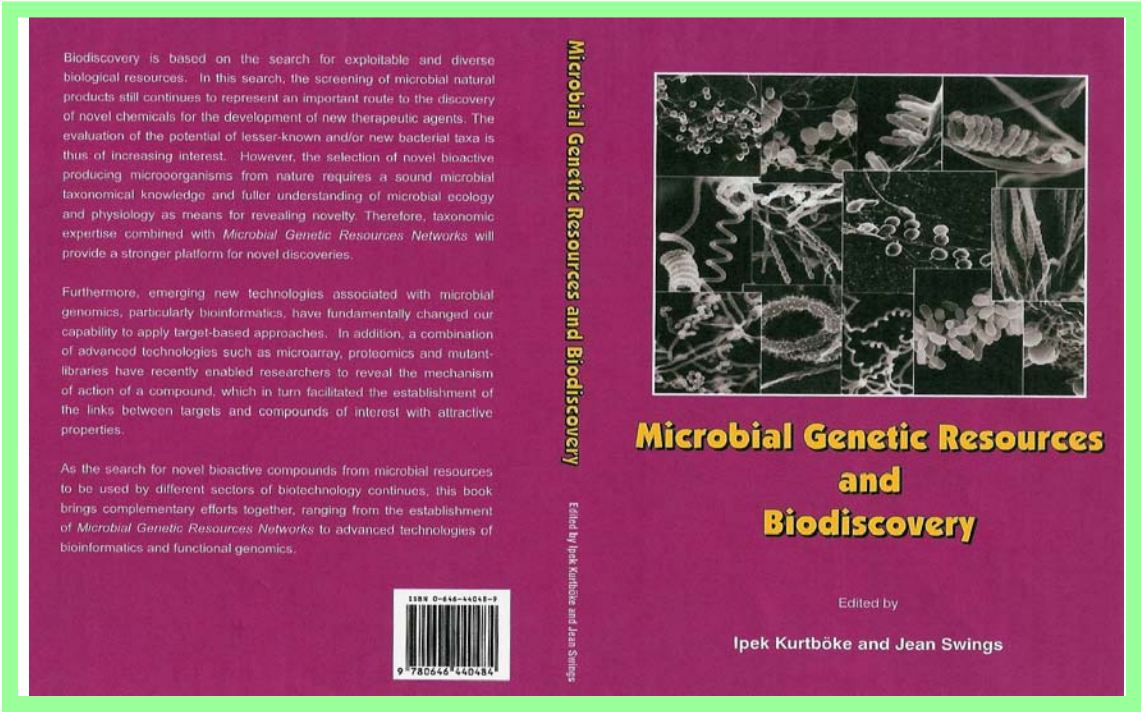

NATURAL PRODUCTS DISCOVERY COLLABORATION

Collaborations on Natural Products

KOSAN BIOSCIENCES

Kosan Biosciences, Inc. (www.kosan.com) is seeking collaborations with academic and industrial laboratories engaged in natural product discovery. Preferred collaborations will cover characterized compounds with therapeutic potential. Anti-tumor compounds are of special interest, but other indications, e.g. antibacterial, antifungal, etc. will also be considered. Kosan's expertise is in polyketides and mixed polyketide/non-ribosomal compounds, as well as in the chemistry and fermentation of other classes of natural products.

Kosan brings

1. Unique expertise in genetic manipulation of polyketide producing micro-organisms to introduce chemically intractable alterations in structures,
2. Cost-effective scalable fermentation production,
3. Chemical derivatization, and complete chemical synthesis of polyketide natural products and their derivatives,
4. Rigorous biology and preclinical development,
5. A strong and agile development organization capable of cost-effective management of many clinical trials.

Kosan Biosciences now has 4 drug candidates (derivatives of two polyketides, epothilone and geldanamycin) in clinical trials as anticancer agents.

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