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Abstract	The aim of a Code of Conduct for Biosecurity for European Microbial Domain Biological Resource Collections is to prevent Microbial Domain Biological Resource Collections (mBRCs) from directly or indirectly contributing to the development, production or preservation of biological weapons, as described in the Biological and Toxin Weapons Convention (BTWC), or to any other misuse of biological material or derivatives. This task (NA1.3) was to draft, seek community opinion and finalise a Code of Conduct that: • Raises awareness of risks and regulations within the BRCs • Addresses risk assessment • Considers accessibility to material and information, accountability and responsibilities, information and communication and considers shipment and transport of potential dual use materials. A first draft of a Code of Conduct was opened for collection community feedback, it was subsequently revised and its practicability was assessed at a workshop held in Utrecht in September 2011. As a result the code was finalised and presented to mBRC owner organisations. The code was well-received by the Biological and Toxic Weapons Convention 7th Review conference and accepted in principle by the European Culture Collections Organisation (ECCO)]
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Revision table

Date	***Version***	***Revised by***	***Main changes***
27/07/2012	1.0	Danielle Janssens on behalf of BCCM	Reference throughout the document to microbial domain Biological Resource Centres (mBRCs) as opposed to microbial resource centres or BRCs
			Reduction of stringent requirement of not to allow dangerous organisms to get into the wrong hands to reducing the potential of this
			Page 10: removal of reference to GBRCN
			Page 10: BRCs have yet to commit to the code so the text has been altered to “They will be invited to commit”
27/07/2012	1.0	Smith	Added Annexe: Statement to BTWC conference
06/08/2012	1.0	BCCM/LMBP	Added statement on the Code’s usefulness to all microbiologists and non-microbial BRCs
16/08/2012	1.0	Christine Rhode	Page 19 shipping training requirements specified

Contents

Abbreviation key

BRC	Biological Resource Centre
BTWC	Biological and Toxin Weapons Convention
CABRI	Common Access to Biological Resources and Information
CBRN	Chemical, Biological and Radio Nuclear
EBRCN	European Biological Resource Centres Network
ECCO	European Culture Collections' Organisation
EMbaRC	European Microbial Resources Consortium
EU	European Union
GBRCN	Global Biological Resource Centre Network
IAP	Inter-academy Panel
ISO	International Standards Organisation
IUMS	International Union of Microbiological Societies
mBRC	microbial domain Biological Resource Centre
OECD	Organisation for Economic Co-operation and Development
RG	Risk Group
VBM	Valuable Biological Materials
WFCC	World Federation for Culture Collections
WHO	World Health Organisation

1 Background and Objectives

The aim of a Code of Conduct for Biosecurity for European Microbial Biological Resource Collections is to prevent Microbial Biological Resource Collections (mBRCs) from directly or indirectly contributing to the development, production or preservation of biological weapons, as described in the Biological and Toxin Weapons Convention (BTWC), or to any other misuse of biological material or derivatives. Although the principles of the Code provide a useful basis for all microbiologists and non-microbial BRCs the scope in the EMbaRC context is restricted to mBRCs. This task (NA1.3) was to draft, seek community opinion and finalise a Code of Conduct that:

- Raises awareness of risks and regulations within the mBRCs
- Addresses risk assessment which involves several categories requiring different procedures:
    a. humans
    b. livestock
    c. crops
    d. environment (invasive potential)
    e. toxins
- Considers accessibility to material and information, accountability and responsibilities, information and communication and considers shipment and transport of potential dual use materials.

A first draft of a Code of Conduct was opened for collection community feedback, it was subsequently revised and its practicability was assessed at a workshop held in Utrecht in September 2011. As a result the code was finalised and presented to mBRC owner organisations, the Biological and Toxic Weapons Convention 7th Review conference and submitted to the European Culture Collections' Organisation (ECCO).

The key principle is that all scientists who use and exchange microbial domain biological resources have a responsibility to reduce the potential of the inherently dangerous ones to get in the wrong hands and be misused. They need to be aware of the regulatory environment and their responsibilities in the prevention of malicious use of microorganisms, their toxins and other derivatives. It is particularly important that culture collections and Biological Resource Centres (BRC) put in place practices to ensure biosecurity and that they support the scientific community in their duty of care. To ensure this, the EMbaRC and GBRCN Demonstration projects have defined the Code of Conduct on Biosecurity for BRCs. The following presents the code and provides information on its construction and describes the regulatory and working environment in which the microbiologist and public service culture collections work. It goes on to define the responsibilities in preventing misuse and provides practical advice in implementation of best practice. The focus in this document is BRCs which are the modern day culture collections that have agreed to implement OECD best practice and follow international conventions, regulations and law. However, the recommendations and advice is useful for all. The Code of Conduct on Biosecurity addresses the key aspects of work of BRCs, describes the issues that are of importance and controls or practices that should be in place.

2 International conventions and activities

2.1 BRCs and the BTWC context

The **Geneva Protocol** of 1925 took the first step to demonstrate international condemnation of chemical and bio-weapons. It paved the way for the **BTWC,** the **Biological and Toxin Weapons Convention.** The BTWC demands a complete prohibition of bio-weapons. After World War II, this convention was not only the first armament control but the only true disarmament convention. National governments are the enforcers of national and international legislation on the distribution of sensitive materials, usually controlled by the Export Offices. Their experts are important contact partners for BRCs. The BTWC is the legal international basis for an implementation and control regime but it lacks lists of restricted material.

The **Australia Group,** established in 1985 currently with 41 members including the European Commission encourages countries to impose export measures for control of dual-use goods. This

globally important initiative is an informal group of countries committed to combating the proliferation of chemical and biological weapons and defines common control lists of potential dual-use materials. Several more items including microorganisms might be added to the existing dual-use list. Consequently, this will influence regional and national export control regulations (www.australiagroup.net/).

As these lists will never be globally harmonised, there cannot be one binding list. With respect to plant pathogens there are climatic differences that are leading to different requirements in the regulative status of a plant pathogen whether or not it may be harmful to crops and cause economic damage because of the availability of the host plants and host spectrum in a country's environment. Comparable to that, the allocation of some organisms to the four pathogenicity risk groups as defined by the **WHO** is not internationally harmonised because of factors like vaccination and health status of the public community of a country and some other factors of infrastructure. In the context of biosecurity risk assessment, there are more aspects to be considered than the infectious potential and allocation to a pathogenicity risk group, toxin production is one of several properties that imparts potential dual-use.

The possibility of using scientific knowledge for peaceful or non-peaceful purposes reflects the dual-use dilemma and affects knowledge (critical know-how), biological resources and their data. The association between science and the international political debate on arms control is playing an increasing role in science and society. Even more now because the Geneva negotiations over a verification protocol for the demands of the BTWC require a more successful inter-sessional process. In a previous inter-sessional programme to enhance the BTWC, representatives of the UN State Parties published recommendations (press release DC05044E, 9 December, New York, NY, USA: United Nations, 2005) to discuss "common understanding and effective action on the content, promulgation, and adoption of codes of conduct for scientists". Also in 2005, the Inter-academy Panel on International Issues (**IAP**) published a statement pointing out that "scientists have a special responsibility when it comes to problems of "dual-use" and "the misuse of science and technology". The BTWC prohibits development, possession and use of biological weapons. However, the scientists' responsibilities in the life sciences are split, on the one hand the need for scientific openness and on the other a sense of security. These must both be prerequisites for scientific work, the publication of findings and the exchange of bio-resources. The Code of Conduct on Biosecurity for Biological Resource Centres (BRCs) will promote awareness and strengthen the BTWC so that proliferation and malicious use of potential bio-weapons can be prevented. Furthermore, the Code will promote freedom of research. To support this, the EMbaRC project has also compiled a list of relevant documents and references on legislative and regulatory requirements (EMbaRC Deliverable D.NA1.3.1.Definitions).

2.2 The EU CBRN Action Plan

The European Union action plan on chemical, biological, radiological and nuclear (CBRN) security and its EU List of high-risk biological agents: Threats to humans, animals, plants; toxins aims at developing lists of high-risk CBRN materials ("all-hazards approach") to strengthen safety and security within the European Union. The EU Commission adopted the CBRN Action Plan in 2009. Note: it deals with high-risk material and risk-based concepts and scenarios, with prevention, detection and reaction.

2.3 The OECD BRC initiative

The Organisation for Economic Cooperation and Development (OECD) established a task force on Biological Resource Centres which focused also on developing a set of guidelines in biosecurity in order to address compliance with the regulatory environment. In order to meet modern demands for the further advancement of biotechnology and life sciences, the OECD in 2001 introduced a new concept of repositories and providers of high quality biological materials and information: Biological Resource Centres (BRCs). BRCs are considered to be one of the key elements for sustainable international scientific infrastructure, which is necessary to underpin successful delivery of the benefits of biotechnology, and in turn ensure that these advances help drive growth. OECD member countries, together with a number of key partner countries, under the auspices of an expert Task Force established by the OECD Working Party on Biotechnology, developed, a series of best practices for BRCs in extensive consultation with culture collection managers, curators and other representatives of the scientific community. The best practices, including those concerning biosecurity, were intended to serve as a target for the quality management of collections and published in 2007 (OECD, 2007).

The Biosecurity guidance provided by the OECD stated that BRCs espouse openness of information and the ability to exchange material quickly; they therefore need to provide certain safeguards that such material and information will not be misused for nefarious purposes. The prospect of bioterrorism generates the need to secure facilities that work with, store or transfer dangerous biological material to ensure that such materials are not susceptible to misuse for malevolent ends. Thus, to contribute most effectively to scientific and economic development, BRCs should not only promote scientific openness but also a sense of security. The two goals are equally important and should be balanced and should be mutually reinforcing.

To deliver such a balanced and mutually reinforcing effect the aim of biosecurity best practice guidelines for BRCs is to reduce the probability that potentially dangerous biological material could

be obtained by unauthorised persons and deployed to cause harm, without unduly hindering research or being financially burdensome. Such best practice guidelines should be clearly articulated and grounded in an understanding of the biological material and the operations of BRCs. These best practices are available for download from the OECD website and remain the fundamental document for compliance for BRCs (http://www.oecd-ilibrary.org/science-and-technology/oecd-best-practice-guidelines-for-biological-resource-centres_9789264128767-en).

The biosecurity best practice guidelines provide a basis for establishing best practices to secure the maintenance and provision of biological materials held by BRCs. They are designed to be implemented in conjunction with the general operational guidelines for all BRCs and the applicable specific domain best practices for BRCs. They also provide the guidance to implement the code. BRCs should implement these biosecurity best practice guidelines in a manner that does not conflict with obligations under national, local and/or international laws and regulations. The guidelines propose a framework for risk assessment of materials held within a BRC as well as a framework that sets out best practices for management of such risk. The frameworks for risk assessment and risk management contained provide tangible tools for biosecurity. These are necessary but not sufficient to ensure biosecurity. Just as important will be a demonstrable culture of responsibility and awareness of security throughout a BRC. The assignment of an individual within a BRC who has, as part of his/ her responsibilities, the general oversight of procedures within a BRC to ensure biosecurity is essential to achieve best practice and will contribute towards the said culture of security. The management and staff of a BRC should also share a sense of responsibility for biosecurity and a BRC should be able to demonstrate that this is the case.

2.3.1 Definitions

Relevant definitions are provided in the OECD Best Practice Guidelines on Biosecurity for BRCs and are provided below.

"*Biosecurity*": Institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens, or parts of them, and toxin-producing organisms, as well as such toxins that are held, transferred and/or supplied by BRCs.

"*Risk assessment*": The process of identifying sources of potential harm associated with the loss, theft, misuse, diversion or intentional release of pathogens, or parts of them, and toxin-producing organisms, as well as such toxins that are held, transferred and/or supplied by BRCs, assessing the likelihood that such harm will occur and the consequences if that harm occurs

"*Risk management*": The process of weighing policy alternatives, considering risk assessment and other factors relevant for biosecurity, and selecting appropriate prevention and control actions.

"*Security breach*": A security breach is any violation of the biosecurity best practice guidelines where these are intended to be in place as best practices.

"*Risk communication*": The interactive exchange of information and opinions among personnel of the BRC and, where appropriate, other parties, concerning risk-related factors and risk perceptions.

The OECD guidance goes on to describe how to address the aspects of management of microbial resources that are of concern. They cover:

- Assessing biosecurity risks of biological material
- New acquisitions/re-assessment of inventory
- Biosecurity risk management practices
- Physical security of BRCs
- Security management of personnel
- Security management of visitors
- Incident response plan
- Staff training and developing a biosecurity-conscious culture
- Material control and accountability
- Supply of material
- Transport security (within a BRC and outside)
- Security of information

The implementation of these guidelines requires a microbiologist to be aware of the information available to assist particularly in risk assessment; this in itself can be difficult as not all information is easily accessible. What is required in this context is that the risk assessment takes into consideration all that is known about the organisms and does not require the BRC to carry out specific new research. It is therefore essential that networks and communities of BRCs work together to ensure that the necessary information is available for implementation of best practices; some guidance is given below and it is envisaged that the BRC community will develop a database to help in this regard.

3 Operational arena - Biological Resource Centre (BRC) mission and research

3.1 The mission of BRCs

BRCs and their networking are essential in the international infrastructure underpinning biotechnology. They are invited to commit themselves to the agreed Biosecurity Code of Conduct; considering their specific situation and key role: they have great importance in the developments of the "biological revolution" as they provide the world-wide scientific community with authentic biological materials required in research, application and teaching. BRCs protect investment in research by keeping the bio-resources used stable for the future, being reliable suppliers; many of them are certified by official certification bodies, according to international standards like the ISO 9001 system. However, BRCs also conduct research, offer training courses and consultation, and provide expertise and knowledge. They are part of the scientific community and enhance the bio-economy, BRCs also support beneficial progress in the developing world. BRCs are custodians of the constantly growing (micro) biological species diversity and data and information on these resources. To fulfil all these missions, the security of BRCs was considered vital by the **Organisation for Economic Co-operation and Development (OECD)** to protect 1) the individual BRC facilities and their staff, 2) the organisations and stakeholder networks they are embedded in: universities, state institutes, scientific societies, private institutions etc. and 3) the countries the BRCs are located in so that the countries support the world's freedom.

Many BRCs are entrusted with the collection and controlled supply of hazardous bio-resources, this endows high responsibility and requires well-established risk analyses and appropriate infrastructures, profound knowledge of relevant bio-legislation including export control and the respective protective measures. The Code of Conduct on Biosecurity for Biological Resource Centres (BRCs) is no alternative to legislative procedures but will raise awareness within the BRCs and outside – towards Best Practice - and demonstrates that BRCs fully support the BTWC as an international norm prohibiting biological weapons so that "*each state party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic or other peaceful purposes.*"

All this applies to BRCs and forms part of the Code. Individual BRCs will tailor the implementation of the Code to their specific needs: biosafety means ensuring appropriate containment of biological substances at the workplace and providing all required health and safety protection mechanisms, but biosecurity additionally involves institutional and personal security measures and procedures to prevent the loss, theft, misuse, diversion or intentional release of pathogens or parts of them, toxin

producing organisms and toxins. Access and supply of bio-materials, information and critical know-how must be controlled and protected including the area of synthetic biology and bio-informatics. This is all of special relevance when dealing with hazardous bio-resources that are listed on national or international export lists (dual-use items; see List of Biological Agents for Export Control by the **Australia Group**- www.australiagroup.net/). Before delivering to third parties, BRCs must take care that recipients are legitimate as far as is possible (normally a State Authority responsible for export control will help with this) and ensure as far as possible that the transport chain is safe. BRCs will implement best practice on all safety and security aspects accordingly, including tracking of their holdings. It is not the aim of this Code to influence the range of bio-resources maintained or research activities performed.

Some bioresources available from a BRC are subject to the provision of relevant permits and licenses and must be released only to *bona fide* users in compliance with legislation. Procedures must be followed to identify potential illegal requests and to minimize the risk of inappropriate distribution. Traceability of cultures has to be ensured, especially of those capable of causing substantial harm to human or animal health or the environment.

3.2 Research

The possibility of "dual-use" causes problems in evaluating *bonafide* or *malafide* research activities, civil or military, defence or attack, peaceful or terroristic aims. Research results and their application are often not predictable. Therefore, BRCs will, in a process of ethical self-regulation and in a transparent way, evaluate possible consequences of research projects performed within their institutions and externally within collaborative projects to help control the risks of misuse of research. Controls must extend to know-how transfer as BRCs are repositories of expertise and knowledge which could also be misused. BRCs are aware of the fact that national law of the country the BRC is located applies to activities of guests from foreign countries, but additionally the guest's country's legislation might apply.

4 Development and structure of the Code of Conduct on Biosecurity for Biological Resource Centres (BRCs)

The Code of Conduct on Biosecurity for Biological Resource Centres (BRCs) considers and supports the statement and principles by the ***Inter-Academy Panel (IAP Statement on Biosecurity)***: 1) Awareness, 2) Safety and Security, 3) Education and Information, 4) Accountability and 5) Oversight. Further, the Code for BRCs fully supports the **International Union of Microbiological Societies *(IUMS) Code of Ethics against Misuse of Scientific Knowledge,***

Research and Resources. The IUMS Code of Ethics reflects the most important Code in the developmental process of the Code as most BRCs are member collections of the **WFCC (World Federation for Culture Collections),** WFCC being a IUMS federation. The Code presented here was prepared as an output of the GBRCN and EMbaRC projects to be adopted by the culture collection community.

Culture collections' activities on the biosecurity issue are remarkable (see www.wfcc.info). The WFCC Newsletter 34, 2002, was dedicated to the bio-terrorism topic with two articles: "WFCC's Handling Bioterrorism Issues" and "The Implication of the Biological and Toxin Weapons Convention and other related initiatives for WFCC members" to elucidate the WFCC standpoint as a response to the anthrax letters in 2001. Long before this time, the **WFCC Guidelines** first published in 1989 and now in the third edition, included seven paragraphs dealing with controlled access/supply of bioresources and the legal background. Documentation and tracking and using end-user certificates are indicators of quality and reliability of WFCC member collections. European culture collections under the **EBRCN**- European Biological Resource Centres Network project developed information resource documents on various relevant bio-legislation issues including biosecurity ("Controlled Distribution of Dangerous Microorganisms-The Control of Dual-use Goods") to function as a helpful guidance for culture collections and the scientific community (see www.wfcc.info).

The Code of Conduct on Biosecurity for Biological Resource Centres (BRCs) in its version of September 2nd 2011 was agreed during the EMbaRC-GBRCN ***Workshop on Biosecurity***, Utrecht, September 2011 (EMbaRC WP NA1.3 and GBRCN WP 3 MS3.5). Along with the Code, the accompanying document **Construction of the Code of Conduct on Biosecurity for BRCs** (see below) was agreed with the aim to demonstrate why and how this Code had been developed in the form it has, a Code of Conduct. Three months later, in December 2011, the Code was introduced at the 7th Review Conference to the Biological and Toxin Weapons Convention (BTWC), United Nations, Geneva, together with an announced NGO statement (see ANNEX I).The idea of the Code was well received by the Review Conference. The NGO statement was a milestone in the history of the Code and has the meaning of additional background information. Recently at the European Culture Collections' Organisation (ECCO) 31stAnnual General Meeting the principle of the code was endorsed by the ECCO members.

4.1 Structure of the Code – the key issues

Aim of the Code: to help BRCs to avoid any direct or indirect contributions to the development and production of potential biological weapons. The Code would also raise awareness of potential dual use and the need to prevent malicious misuse.

The GBRCN and EMbaRC insist on the implementation of OECD BRC Best Practice which includes the Biosecurity Guidance as well as aspects of biosafety, particularly in regard to implementation of national legislation. Concerns exist by BRCs/culture collections on their abilities to implement best practice regarding biosecurity, particularly with the requirements of risk assessment in the manner as described by the OECD BRC Best Practice. This will be addressed in future work. The Code of Conduct will help to focus BRC efforts on the relevant key issues.

The Code of Conduct on Biosecurity for BRCs, together with the accompanying procedural document will facilitate the easier and focussed access to national and international relevant regulations and other information. It is evident that culture collections adopt compliant procedures firstly governed by national laws but specifically compliant with the Biological and Toxin Weapons Convention (BTWC). They must endeavour to reduce the potential for misuse of biological agents, toxins or associated information or technologies. The Code of Conduct on Biosecurity for BRCs sets out an undertaking by BRCs to tackle their responsibilities and provides a base line for the operation.

There are many examples of codes and the first task was to determine exactly what form was needed for the BRC community. The OECD have created a web based information resource (http://www.biosecurity.org) which provides an analysis of the different types of codes and provides many examples: http://www.biosecuritycodes.org/codes.htm. In starting this work the EMbaRC/GBRCN work group faced the question: What is a code of conduct? The OECD had shed some light on this for us. In the context of biosecurity, a code is a set of conventional principles and expectations that are considered binding on any person who is a member of a particular group, whether or not membership in that group is voluntary. A code is a unique regulatory instrument that should not be mistaken with a treaty, guideline, or principle. There are also a number of different words that can be used in place of codes (e.g. – charter, oath, declaration, etc…) but mean essentially the same thing as evidenced by some of the examples provided on the OECD web site.

Types of Codes (in the broader context): Codes can either be voluntarily binding or involuntarily binding. A code could be said to be voluntarily binding on a participant that chooses to be a member of any society or group that sponsors a code. While codes which have concrete consequences regardless of one's voluntary entry into compliance can be said to be involuntarily binding. Some researchers have further categorized codes by their objectives and the level at which the code is binding.

- Aspirational (codes of ethics) – set out ideals that practitioners should uphold.
- Educational / Advisory (codes of conduct) – go further than "Aspirational codes" by tying actions to guidelines which suggest how to act appropriately.

- Enforceable (codes of practice) – seek to further codify what is acceptable practice. Rather than attempting to sway or guide behaviour, enforceable codes are embedded within wider systems of professional and legal regulations.

There is much debate as to the effectiveness of "aspirational" and "educational" codes that are voluntary and unenforceable, specifically when one is determined to act against the code. However, a key aim of a code is prevention, and this is focussed by the code. Codes are used to guide people's actions in a variety of different sectors and activities. Key to this EMbaRC and GBRCN activity was the examination of different codes in order to incorporate their successful characteristics. There is no "universal" code to guide the conduct of those involved in the life sciences.

Key texts consulted to form the preamble were: the Inter-academy panel on international issues, a global network of science academies, IAP http://www.interacademies.net/ - Statement on Biosecurity http://www.interacademies.net/Object.File/Master/5/399/Biosecurity%20St..pdf

And the DFG Code of Conduct: Work with highly pathogenic microorganisms and toxins http://www.unog.ch/80256EDD006B8954/(httpAssets)/618DD849160CEBB8C12574A200422AC0/$file/Germany+DFG+Code+of+Conduct+WP.pdf. Malcolm Dando reviewed the Dutch experiment with a biosecurity code of conduct in March 2008 coming to the conclusion that the key element was the attention paid to raising awareness, going on to state "only when we have a widely informed, and involved scientific community will we be in a position to contribute effectively to preventing the hostile misuse of the modern life sciences". Dando was present at the International Conference on Culture Collections (ICCC12) participating in the debate on how culture collections should address the biosecurity issue. He was very impressed by the network approach and he praised this in a recent publication and how culture collections were taking up the challenge of compliance and raising awareness http://thebulletin.org/web-edition/columnists/malcolm-dando/science-development-and-security-the-global-biological-resource.

The conclusion is that we need a binding code of conduct specific to our needs. The Code of Conduct on Biosecurity for BRCs should itself be short, simple, clear and address the community of microbial domain Biological Resource Centres (mBRCs) holding microorganisms. The Code preamble contains the ethical reasons and background that forms the Code and this is followed by specific actions relevant to mBRCs. The Code offers a way to reconcile the various national and international approaches to biosecurity. Not by superseding national legislation, as the Code adopts all the key principles, but by setting a ground level for actions associated with the specific activities of mBRCs and culture collections to enable the reduction of the possibility of malicious misuse of their holdings and associated information. It offers clear benefits and delivers awareness. Entities adopting the Code become trusted partners and demonstrate their awareness

of the responsibilities of conducting safe science. Sharing the Code with users raises their awareness of their need to be responsible in how they conduct their activities. The Code sets a baseline for responsible actions in carrying out the duties of microbial collections/mBRCs.

Input is welcome on the content but importantly the Code needs to be tested to ensure that it is acceptable to BRCs and that it can be practically implemented.

The Code is a brief two pages document without delivering details on its implementation and without citation of any legislation because of its global relevance: Preamble, Scope and the Code itself; the Code covers seven key issues in the biosecurity context having the most obvious relevance to protect the individual facilities (BRCs), their employees, all possible third parties involved and finally the countries, to protect the world's freedom from misuse of biomaterial, associated data and know-how.

4.2 Code of Conduct on Biosecurity for microbial domain Biological Resource Centres (BRCs)

I. PREAMBLE

Accumulated and advancing knowledge on biological systems offers substantial benefits to mankind, to research and to development in all areas of basic and applied bio-medical and bio-technological sciences. However, this improved knowledge is intrinsically associated with the potential for dual application: for beneficial or malicious purpose. The possibility of using scientific knowledge for peaceful or non-peaceful purposes reflects the *dual-use dilemma* and confers a responsibility on both those with the knowledge and with the biological resources. The responsibilities of those engaged in the life sciences have an increasing role for in-depth implementation of the Biological and Toxin Weapons Convention (BTWC). Scientific openness and a sense of security are prerequisites for freedom of scientific work, publication of findings and exchange of bio-resources to carry out activities in the life sciences. This Code of Conduct on Biosecurity is to help microbial domain Biological Resource Centres (BRCs) promote a basic ethical understanding of science compliant with the BTWC and raise awareness to prevent misuse in the life-sciences context.

This Code intends to raise awareness on biosecurity within and outside BRCs and to clearly demonstrate that BRCs are fully compliant with national and international legislation and support the BTWC as an international norm prohibiting biological weapons. It is not the aim of this Code to influence the range of bio-resources maintained or life science activities performed at BRCs. Above all, this Biosecurity Code of Conduct is meant to complement legislative procedures.

II. SCOPE

The aim of this Code of Conduct is to prevent microbial domain BRCs from directly or indirectly contributing to the malicious misuse of biological agents and toxins, including the development or production of biological weapons.

BRCs commit themselves to this Code of Conduct on Biosecurity considering their specific situation and key

role as an essential part of the international infrastructure underpinning biotechnology: providing the world-wide scientific and industrial communities with authentic biological materials required in research, application and teaching as well as related information and services. Being part of the scientific community they conduct activities in the life sciences, offer training courses, expertise and knowledge and they support the bioeconomy.

Many BRCs are entrusted with the collection and controlled supply of potentially hazardous bio-resources. This requires high responsibility, well-established biorisk analyses and management, and appropriate BRC internal infrastructures, profound knowledge of relevant bio-legislation including export control and respective protective measures. This Code calls for implementation and compliance of awareness, accountability and oversight and targets all those engaged in life sciences activities, laboratory workers, managers, stakeholders and others.

III. CODE

(1) BIORISK MANAGEMENT

- Integrate biorisk management throughout the organization and seek its continuous improvement.
- Assign adequate resources and responsibility to guarantee compliance with legal requirements, communication to staff and relevant third parties, and carry out reliable and appropriate risk assessment.

(2) RAISING AWARENESS

- Devote specific attention in the education and further training of all staff on:
  - the dual use dilemma i.e. the risks of misuse of biological material, information and life sciences research
  - the requirements of regulations in this context.
- Provide regular training and carry out auditing to maintain up to date knowledge on biosecurity.
- Raise awareness of related third parties on their responsibilities.

(3) REPORTING MISUSE

- Encourage a culture of reporting misuse.
- Report any finding or suspicion of misuse of biological material, information or technology directly to competent persons or commissions.
- Protect persons reporting on misuse and ensure that they are not targeted for retribution as a consequence.

(4) INTERNAL AND EXTERNAL COMMUNICATION

- Prevent access by unauthorised persons to internal and external e-mails, post, telephone calls and data concerning information about potential dual-use research or potential dual-use materials.
- Regulate the communication of sensitive information.

(5) RESEARCH AND SHARING KNOWLEDGE

- Assess possible dual-use aspects of research during the application for and the execution of research projects.
- Minimize the risk that publication of results on potential dual-use organisms will contribute to misuse of that knowledge.
- Consider biosecurity implications when sharing knowledge.

(6) ACCESSIBILITY

- Ensure physical security of and access control to stored potential dual-use material in accordance with its risk classification.
- Implement access control for staff and visitors where potential dual-use biological materials are stored or used.

(7) SUPPLY, SHIPMENT AND TRANSPORT

- Screen recipients of potential dual-use biological materials, in consultation with the relevant authorities and parties.
- Select transporters suitable to handle potential dual-use biological materials.
- Perform export control in accordance with applicable regulations.

4.3 Overview of the code

This Code delivers more than a Code of Ethics because of the nature and the mission of the institutions implementing it, the mBRCs (see above). It is important to mention that the mBRCs' primary mission includes service which is beyond pure scientific research.

Codes do not replace any legal regulations. Their main characteristics are that they demand commitment to compliance and professional behaviour, related to occupational, academic or industrial activities and/or social engagement. The Code and all accompanying documents do not intend to focus on any national or regional regulations or fora. Instead, it is the aim to focus at a global level. A broad outreach of this Code is desirable; it is designed in such a way that it can be implemented in bio-scientific and bio-medical institutions outside the mBRC community.

5 The difficulties of Biorisk Assessment – Balancing the risks (an overview)

There are numerous important web links and publications including books on the biosecurity and dual-use problem. This large body of information resources cannot be cited here. This document provides a helpful guidance how to implement the Code with focus on the seven key issues (see above) and being based on the ***OECD*** *Best Practice Guidelines on Biosecurity for BRCs*, also considering the ***WHO*** *Laboratory biosecurity guidance* (WHO/CDS/EPR/2006.6). Therefore, this document is not more than and not less than a basis for Best Practice.

5.1 Suggestive biosecurity risk assessment approach for biological material for BRCs (with European focus) – a compilation

The following considers biosecurity risk assessment for routine practice and includes

* Biosafety: the risk group of a bioresource according to the WHO definition and the national risk group allocation

* Dual-use potential: according to the official lists of

  - The Australia Group, including Australia Group Warning List

  - EU Directive 428/2009/EC with Annex I, dual-use export list

  - The EU CBRN Action Plan: EU List of high risk biological agents

  - National laws

It is crucial to fulfil the requirements of the BTWC, the Australia Group, the national/regional legislation and additional regulations and recommendations on the basis of e.g. agreements by umbrella organizations hosting a BRC and Codes of Practice, Codes of Conduct or Codes of Ethics, if applicable. The aim is to implement biosecurity along with biosafety and using biosafety considerations as the basis for biosecurity.

5.2 Official key documents in the practical process of biosecurity risk assessment

- WHO *Laboratory biosecurity guidance* (WHO/CDS/EPR/2006.6),
- OECD *Best Practice Guidelines on Biosecurity for BRCs* (2007)

5.3 "Risk assessment" as defined by the OECD Best Practice Guidelines

"The process of identifying sources of potential harm associated with the loss, theft, misuse, diversion or intentional release of pathogens or parts of them, and toxin-producing organisms as well as such toxins that are held, transferred and/or supplied by BRCs, assessing the likelihood that such harm will occur and the consequences if that harm occurs". Therefore**, risk assessment involves**

* The biological intrinsic risk,
* The risk of harm after loss or misuse,
* The likelihood and consequences if harm occurs

Main problems of biosecurity risk assessment

- Difficulty to quantify
- Lack of data
- Difficulties in establishing causality in biological systems
- Multiple risk factors (incl. dose of a pathogen after intake, uncertainty of dose-response predictions).

While this must be accepted, biosecurity risk assessment under a Code of Conduct can be performed according to best practice. Risk assessment should be based upon what is publicly available knowledge; discovering new facts about the potential use of an organism is not required. Therefore, Best Practice in the biosecurity context depends on the extent of known information on an organism to the best of our knowledge.

In contrast, Biosecurity management options concerning the organizational infrastructure and practical processes, for example export control, are subject to national legal requirements to which BRCs must comply. These obligations and procedures cannot be fully generalized in detail but they are not compromised by adoption of the principles of the Code.

Sometimes assessing the risks outside the BRC is difficult for example in regard to the whole shipping trail and this is where the selection of competent well-known transporters becomes essential. Transporters do not have specific remits to carry dual-use organisms and therefore selecting specialists in transporting dangerous goods is normally sufficient because by far the majority of dual-use organisms fall under the regulations on transport of dangerous goods (UN Model Regulations). For transport by air, ICAO and IATA have clear regulations for Dangerous Goods Security: IATA DGR 2012, chapter 1.6 deals with General Security Provisions, Dangerous Goods Security Training and Security Plans, the latter under DGR 1.6.3 with 1.6.3.2: Elements of a Security Plan and 1.6.3.3: List of High Consequence Dangerous Goods: it is important to note that Class 6.2 Category A (UN 2814 and UN 2900) is affected.

The IATA DGR precisely define the training required for all categories of shippers, operators, forwarders etc. BRCs, as shippers of such goods, have to make sure that these requirements are fulfilled. Thus BRCs must confirm that transporters of their materials have the correct certificates and in turn must ensure that they are able to provide valid training certificates for responsible staff to their dangerous goods shippers.

5.4 Risk assessment as described in the OECD Best Practice Guidelines on Biosecurity for BRCs (2007)

The OECD biosecurity expert group developed a scheme of physical security applicable to biosecurity risk levels within BRCs and define a matrix on biosecurity risk levels and physical security in a graded manner:

Biosecurity risk level:	Physical security:
Negligible or low	> General security area
Moderate	> Restricted area
High	> High security area

The OECD BPG describe a model on "Assessing biosecurity risks of biological material" using those biogenic/intrinsic factors that are known for a biomaterial. Clearly, biosecurity risk assessment is a multifactorial complex process.

This matrix could mean that physical/technical safety and security should play a major role for covering all requirements because of biological uncertainties and causalities. The OECD BPG reflect Best Practice; risk evaluation of biological systems can hardly be complete.

The WHO Laboratory biosecurity guidance document WHO/CDS/EPR/2006.6

This goes beyond the dangerous pathogens and addresses "VBM, Valuable Biological Materials":

In summary, taken from the WHO document, it aims to strike a balance between biosafety procedures and the broader biosecurity concepts. It introduces the overarching "biorisk management" approach to minimize the occurrence and consequences of human error within the laboratory:

The WHO biorisk management approach is composed of biosafety, laboratory biosecurity and ethical responsibility. Biosafety practices reinforce and strengthen laboratory biosecurity. Biosafety recommendations outlined in the *WHO Laboratory Biosafety Manual (2004)* provide levels of protection for VBM (VBM, see below). Laboratory biosecurity is a complement to laboratory biosafety.

Laboratory biosecurity risk assessment under the Laboratory Biosecurity Programme is mentioned as "associated agent-based microbiological risk assessment and laboratory biosecurity risk assessment": the backbone of biosafety measures is a microbiological risk assessment, but laboratory biosecurity programmes additionally perform biosecurity risk assessments and strategies for their managements. This is part of the biorisk assessment efforts; regular re-

evaluation is necessary to respond to national and institutional standards. Risk assessments for research projects should be performed and records securely kept. Situations requiring risk assessment should be described. In biosecurity risk assessment, intelligence forces are complementing biosafety risk assessment with local threat assessments.

Laboratory biosecurity (WHO)

"describes the protection, control and accountability for VBM within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release." >> Safekeeping of all VBM, not only pathogens and toxins, but also scientifically, …economically important biological materials such as collections and reference strains …, vaccines …".

VBM definition (WHO)

"Biological Materials that require…administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historic (archival) value, and/or the population from their potential to cause harm. VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, GMOs, cell components, genetic elements, and extra-terrestrial samples." The classification of biological materials as VBM should be left to their caretakers…who should be able to address and define the level of protection required. Pathogens and toxins are an important subset of VBM. No "biosecurity risk assessment matrix" is given by the WHO.

5.5 The difficulties of risk assessment of microbiological systems

Microbial risk assessment scenarios, causality and uncertainty: risk assessments are iterative (*M.E. Coleman et al. (2007), Microbe 2, 13-17*):

Framework for risk assessment with four elements:

- Hazard identification
- Exposure assessment
- Dose-response relationship
- Risk characterization

What can go wrong, how likely is it to go wrong, what are the consequences?

"These questions seem simple, the analytical process is not, it involves compiling and validating evidence and models, developing assumptions and extrapolations, making predictions for complex systems, assembling interdisciplinary teams…." >> team efforts, can take years. Such efforts should be transparent and the process should provide opportunities for stakeholders to comment.

Microbial risks are not always fully understood, particularly given the hypothetical nature of many microbial risks >> biothreat: intentional release, accidental release, natural outbreaks

5.6 Suggestions in brief for effective laboratory biosecurity risk assessment procedures under the Code of Conduct on Biosecurity for mBRCs

* Focus on biosecurity/biothreat, according to the aim of the Code of Conduct, with priority over the broader VBM definition

* Use the biosafety risk group allocation and claim all human pathogens of RG3 and RG4 as principally highly dangerous with all consequences re. biosecurity

* Apply an appropriate physical security standard for all RG2, regardless of any known biosecurity threats/hazards of a specific RG2 biomaterial

* Compare all biomaterial that is kept in an institution with applicable lists of dual-use goods – lists are “incomplete” but legal basis

* Look at potential economic harm by certain plant pathogens (guided by quarantine threat)

* If a BRC has a collection of specialized GMOs or other special collections, individual risk assessments per individual biological substance should be performed

Important consequences

Risk assessments are by nature iterative, knowledge is mostly incomplete >> Risk assessments need to be re-assessed as knowledge advances, e.g. on host-pathogen interactions. >> Only the physical, technical, procedural and facility-specific operational measurements can implement biosecurity, beyond the biological risk assessments and potential threats.

Conclusion

The code has attracted a significant amount of interest in its development and has been well received at various levels. It was constructed to establish the principles of biosecurity as defined in the OECD Best Practice Guidelines on Biosecurity for BRCs (in OECD 2001) and consultation has ensured it complies with national laws and regulations. It has recognized at the Biological and Toxic Weapons Convention’s seventh review conference and adopted in principle by the European Culture Collections’ Organisation (ECCO). There remain some difficulties for BRCs to carry out risk assessments. However, as outlined above risk assessment is based on existing knowledge by ensuring BRCs (and all microbiological practitioners) are provided with the relevant data risk

assessment can be carried out effectively. It is essential that BRCs make sure they maintain a dialogue with their relevant national authorities.

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ANNEXE 1 Global Biological Resource Centre Network: statement to the BTWC seventh review conference by Christine Rohde, Leibniz-Institut DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH

A Biosecurity Code of Conduct for Biological Resource Centres
A Signal to strengthen the global implementation of the BTWC

Mr. President, Excellencies, Distinguished Representatives, Ladies and Gentlemen,

I would like to express my gratitude to you for the opportunity to make a statement on behalf of the GBRCN, this is the Global Biological Resource Centre Network.

The Final Declaration of the Sixth Review Conference in regard to Article IV reaffirmed *the commitment of States Parties shall take the necessary national measures under this Article* and that *necessary national measures under this Article … would strengthen the effectiveness of the Convention*. We welcomed the call that you made for *States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed … to ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins*.

In 2008, the Meeting of States Parties devoted several *working sessions to national, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins (agenda item 6) and to oversight, education, awareness raising and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention (agenda item 7).*

We especially endorse the outcome of the Meeting of States Parties in 2008 when you recognized that *biosafety and biosecurity measures contribute to preventing the development, acquisition or use of biological and toxin weapons and are an appropriate means of implementing the Convention*.

In order to take such measures, it is necessary to enhance awareness and create a biosecurity-conscious culture. We noted that in your MSP 2008 report *biosecurity refers to the protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorized access to, retention or transfer of such material.* And furthermore, agreed on the value of *…applying appropriate risk assessment and risk management strategies*.

The problem in the life sciences is the dual-use potential of bio-resources, associated data and know-how. These can be misused maliciously whether by non-States actors/terrorists or by States. Shortcomings in the effective implementation of the Convention have their origin in ignorance and lack of concern.

Consequently, careful export control, tracking of biological material and observing all transport requirements including the *Recommendations on the Transport of Dangerous Goods-Model Regulations* (16th rev. ed.) are essential. It includes security plans for transport of *High Consequence Dangerous Goods* like infectious substances Category A, UN 2814/UN 2900. There is no doubt that the *WHO Biorisk management Laboratory biosecurity guidance* (2006) is an invaluable tool to implement biosecurity. The document uses the expression *valuable biological materials* pointing out strongly the value of biological resources for research and progress.

This alone is not enough to implement effective biosecurity: adequate preventive measures help avoid reactive measures. Biosecurity on the whole is highly complex and it is often difficult for scientists to perceive the dual-use potential of their profession and work. Scientists tend to believe wholly in the bona fide use of bioresources, associated data and know-how. Know-how transfer does not seem critical. The scientific world proclaims total freedom of research and world-wide exchange is essential.

But, biosecurity needs to become an integral part of human activity in the life sciences. Several international, regional and national scientific associations of the life sciences have developed Codes of Conduct or Ethical Codes; generally biosecurity plays an important though not outstanding role in those Codes. Scientific best practice primarily addresses the ethics of the science undertaken; special biosecurity Codes are infrequently found.

Therefore, several Biological Resource Centres decided to elaborate a practice-related Code of Conduct devoted specifically to biosecurity in order to protect their facilities and staff and the world's freedom:

The OECD Directorate for Science, Technology and Industry and the Task Force on Biological Resource Centres (BRCs) realized as early as 1999 that there was a gap to be filled to cover bio-legislation (www.SourceOECD.org). In 2007, the OECD published the *Best Practice Guidelines on Biosecurity for BRCs* including detailed *Qualitative Risk Assessment* and *Risk Management Practices.* This document postulated the development of a Biosecurity Code of Conduct.

With support by the European Commission, the project EMbaRC (**E**uropean Consortium of **M**icro**b**i**a**l **R**esources **C**entres) developed the Biosecurity Code of Conduct (CoC) as it is presented here, in cooperation with the GBRCN, the Global Biological Resource Centre Network, an umbrella initiative for many microbial resource collections around the world. GBRCN has dedicated a task force to address biosecurity, the dual-use problem, export controls and the BTWC. Your MSP 2008 report agreed on the value of *building networks between scientific communities and academic institutions… for appropriate risk communication strategies and tools*. GBRCN is such a network. Its members are legal entities and providers of biological materials which fulfil their mission of delivering bio-resources to authorized recipients within their countries and across borders and continents.

As we recognize the present and future value of the effective national implementation of the BTWC with its high global relevance, and recognizing the rapid scientific and biotechnological developments, we would like to express to the States Parties that the CoC presented here will add value to the objectives of the BTWC. The aim of the CoC is to prevent microbial resource centres from directly or indirectly contributing to malicious misuse of biological agents and toxins, including the development or production of biological weapons and shall promote a basic ethical understanding of science compliant with the BTWC. We also consider that such a generally applicable type of a Code can substantially help all States Parties because awareness raising is

absolutely crucial in the scientific world. The Code as presented is far-reaching, going beyond the GBRCN community. Indeed most countries have microbial resource collections, with different holdings, infrastructure and risk potential. However, BRCs are not only biological resource centres but also biological research centres.

The GBRCN require that this CoC shall be implemented by BRCs all over the world. It is designed in such a manner that similar scientific and bio-medical institutions and, on a higher level, scientific associations and societies can use the CoC to demonstrate their will to strengthen the BTWC.

In conclusion, our message and recommendation to the Seventh Review Conference is that States Parties should, as part of their consideration of improving the national implementation of the Convention, agree to adopt a comparable Code of Conduct for their national microbial resource collections and other institutions in the life sciences because of the awareness raising focus on biosecurity that it provides. We recommend that States Parties activate and involve their legal authorities in a top-down process of communication with their life sciences institutions.

Thank you again for the opportunity to give a statement on behalf of GBRCN

This GBRCN statement was prepared by

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Significance of this deliverable

This Code of Conduct on Biosecurity is to help microbial Biological Resource Centres (BRCs) promote a basic ethical understanding of science compliant with the Biological and Toxin Weapons Convention and raise awareness to prevent misuse in the life-sciences context. It aims at preventing microbial BRCs from directly or indirectly contributing to the development or production of biological weapons or to any other malicious misuse of biological agents and toxins.