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Abstract	Many microbial Biological Resource Centres are entrusted with the collection and controlled supply of potentially hazardous bio-resources. This requires high responsibility, well-established risk analyses 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.
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Contents



Workshop

on

Biosecurity

EMbaRC - GBRCN

2011, September 1-2, Hotel Mitland, Utrecht, The Netherlands

Aims of the Workshop

Finalize and agree on the Biosecurity Code of Conduct for BRCs (CoC) (EMbaRC WP NA1.3 and GBRCN WP 3 MS3.5)

Agree on approaches for ratification of the CoC by the EMbaRC and GBRCN Partners

Put the CoC in context to different laws and provisions on Biosecurity

Evaluate practicalities of the implementation of national and European legislation and the OECD Biosecurity Guidelines

Workshop program

THURSDAY September 1

Session 1. Introductions
Chair: D. Smith & J. Stalpers

09:00-09:15	Welcome and introduction to the workshop goals – Joost Stalpers
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09:30-10:00	Setting the scene on Biosecurity: Legislation & Regulations – Cathy Bollaert
10:00-10:15	Discussion on key aspects of paper
10:15-10:45	Codes of Conduct, a comparative overview and the EU CBRN Action Plan – Volker Beck
10:45-11:00	Discussion on key aspects of paper
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Session 2. Code of Conduct
Chair: D. Smith & J. Stalpers

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12:30-13:00	Discussion on the text of the CoC and the adjoining texts
13:00-14:00	Lunch
14:00-16:00	Continued Discussion on the text of the CoC and the adjoining texts
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Session 3. Practicalities
Chair: D. Smith & J. Stalpers

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16:45-17:45	Discussion on the implementation of BPG
17:45-18:00	Break
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FRIDAY September 2

Session 4. Practicalities (continued)
Chair: D. Smith & J. Stalpers

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09:00-10:00	Discussion risk assessment and revision of the CoC and accompanying documentation in light of the previous day's discussions.
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Session 5. Practicalities (continued)
Chair: C. Rohde

10:20-10:50	Establishment of export control in institutions – Dunja Martin
10:50-12:00	Discussion: practicalities of implementation relative to national and European legislation
12:00-13:00	Summary discussions and development of an action plan
13:15	Lunch

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

I. PREAMBLE

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

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. This Code intends to raise awareness within the BRCs and outside 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.

II. SCOPE

The aim of this Code of Conduct is to prevent 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.

Biological Resource Centres 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 risk analyses 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 OF CONDUCT

(1) BIORISK MANAGEMENT

- Integrate biorisk management throughout the organization, provide adequate resources and identify opportunities for improvement and prevention.
- Assign 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 to the risks of misuse of biological material, information and life sciences research and the requirements of regulations in this context.
- Maintain attention for and update knowledge on biosecurity by regular training and auditing.
- Raising awareness of related third parties on their responsibilities.

(3) ACCOUNTABILITY

- Report any finding or suspicion of misuse of biological material, information and technology directly to competent persons or commissions.
- Protect persons reporting on misuse and ensure that they do not suffer any adverse effects from their actions.

(4) INTERNAL AND EXTERNAL COMMUNICATION

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

(5) RESEARCH AND SHARING KNOWLEDGE

- Screen for possible dual-use aspects during assessment or application procedures and during 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

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

(7) SHIPMENT AND TRANSPORT

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

Biosecurity Code of Conduct for BRCs to strengthen the BTWC

General thoughts before finalising and agreeing upon the Code under EMbaRC and GBRCN – Workshop Utrecht 01./02. September 2011

September 2011, by Christine Rohde (this text contains in part statements of the OECD Best Practice Guidelines on Biosecurity for BRCs, 2007)

Over the past decades, the developments in the life sciences and related technologies have been revolutionary fast. Accumulated and advanced knowledge on biological systems offer substancial benefits to mankind, to research and development in all areas of basic and applied bio-medical and bio-technological sciences. Whereas improved knowledge contributes essentially to all such beneficial processes, it is associated with the potential for dual application, for beneficial or malicious purpose, constructive or destructive activities. The possibility of using scientific knowledge for peaceful or non-peaceful purposes reflects the dual-use dilemma and affects both, knowledge (critical know-how) and biological resources and their data. The association between science and the international political debate on arms control is playing an increasing role, even more because the Geneva negotiations over a verification protocol to the 1972 ***Biological and Toxin Weapons Convention (BTWC)*** failed. Scientific openness and a sense of security must be prerequisites for freedom of scientific work, publication of findings and exchange of bio-resources to carry out research. Biosecurity Codes of Conduct will promote ethics of science and awareness raising to prevent misuse in the life-sciences context and will strengthen the BTWC during its intersessional process started in 2002 so that proliferation and malicious use of potential bio-weapons cannot have a chance.

Biological Resource Centres (BRCs) under the global network ***GBRCN*** are essential in the international infrastructure underpinning biotechnology. They commit themselves to an agreed Biosecurity Code of Conduct considering their specific situation and key role: they have great importance to the developments in the "biological revolution" as they provide the world-wide scientific community with authentic biological materials required in research, application and teaching. BRCs keep bio-resources stable for the future, being turntables and reliable suppliers, many of them are certified by official certification bodies, according to international standards like the ISO 9001 system. However, BRCs are not only suppliers of bio-resources and related data, they conduct research, offer training courses and consultation, 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 (micro)biological diversity and data and information on these resources.

To fulfill all these missions, the security of BRCs was considered vital by the ***Organisation for Economic Co-operation and Development (OECD)*** to protect 1. the BRCs' individual facilities and their staff, 2. the organisations' and stakeholder networks they are embedded in: universities, states' institutes, scientific societies, private institutions etc., 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 requires high responsibility, well-established risk analyses and appropriate BRC infrastructures, profound knowledge of relevant bio-legislation including export control and respective protective measures. The Biosecurity Code of Conduct is no alternative to legislative procedures but will raise awareness within the BRCs and outside – towards Best Practice - and clearly demonstrates that BRCs fully support the BTWC as an international norm prohibiting biological weapons 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.*"

This all applies to BRCs and forms part of the Biosecurity Code of Conduct. Individual BRCs will tailor the implementation of the Code to their specific needs: while biosafety

means ensuring appropriate containment of biological substances at the workplace and providing all required health and safety protection mechanisms, biosecurity is more: biosecurity 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 have to be controlled and protected including the area of synthetic biology and bio-informatics. This all is of special relevance when dealing with hazardous bio-resources or such that are listed on national or international export lists (dual-use items; see List of Biological Agents for Export Control by the ***Australia Group***). Before delivering hazardous bio-resources to third parties, BRCs will check the recipients and ensure transport 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 for BRCs to principally influence the range of bio-resources maintained or research activities performed.

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 process, evaluate possible consequences of research projects performed within their institutions because national law is not necessarily able to norm the risks and misuse potential of research. This includes know-how transfer as BRCs are repositories of knowledge. BRCs are aware of the fact that national law of the country the BRC is located applies to activities of guests from foreign countries and additionally the guest's country's legislation might apply.

This Biosecurity Code of Conduct for BRCs considers and supports the statement and principles by the ***InterAcademy Panel (IAP Statement on Biosecurity)***: 1. Awareness, 2. Safety and Security, 3. Education and Information, 4. Accountability and 5. Oversight. Further, this Code for BRCs fully supports the International Union of Microbiological Societies ***(IUMS) Code of Ethics against Misuse of Scientific Knowledge, Research and Resources***.

This Biosecurity Code of Conduct for BRCs will be prepared to be set in force shortly before the 7th BTWC Review Conference in 2011, as a signal to strengthen the Convention.

Codes of Conduct The need for unpinning of awareness and education in dual-use biosecurity

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Codes of Conduct are unlikely to be successful unless underpinned by awareness and education of life scientists. This presentation reviews a series of activities to promote global biosecurity education which the University of Bradford has been involved in. Firstly, the presentation brings to attention the problem and the need for a wider understanding of biosecurity and summarises key findings from international surveys on biosecurity education. Secondly, it provides an overview of the educational resources that have been developed as a result of this. This includes a summary of the scope and content of the freely available online Education Module Resource (EMR) which was jointly developed by the University of Bradford in UK, the National Defense Medical College in Japan and the Landau Network Centro Volta in Italy is illustrated; and an outline of the online Applied Dual-Use Biosecurity/Bioethics Train-the-Trainer module/course that was developed as an expansion of the EMR. The module is designed to provide life scientists with information about biosecurity and bioethics to raise awareness about the dual-use dilemma, and seeks to facilitate cultural change in life science education and practice. The module pursues a twofold objective namely to disseminate information to trainers about biosecurity and dual-use concerns and to transfer awareness and knowledge acquired by the trainers for subsequent dissemination throughout their life science communities.

Construction of the Code of Conduct on Biosecurity for BRCs

The aim of this accompanying text to the circulation of the draft of the Code of Conduct on Biosecurity for BRCs is to provide information on why the Code takes the form it does. There will be a document *Biorisk, Prevention and Assessment: The practical implementation of the Code of Conduct on Biosecurity for BRCs* written soon to provide practical advice on how it might be implemented.

Aim of the Code: to help BRC's 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 require the implementation of OECD BRC Best Practice[1] 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 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 code 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[2].

- **Aspirational (codes of ethics)** – set out ideals that practitioners should uphold.

[1] OECD (2007) *OECD Best Practice Guidelines for Biological Resource Centres*, OECD publications, 2, rue André-Pascal, 75775 Paris Cedex 16, France.
[2] Rappert, Brian (2004), ***Towards a Life Sciences Code: Countering the Threat from Biological Weapons***, Bradford Briefing Papers, University of Bradford Department of Peace Studies, Bradford , UK .

- **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 Interacademy 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"[3]. Dando was present at the International Conference for 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 Resource Centres, BRCs holding microorganisms**.** The Code preamble contains the ethical reasons and background that forms the Code and this is followed by specific actions relevant to BRCs. 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 BRCs 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 collections/BRCs.

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.

[3] Dando, M. (2008). The Dutch experiment with a biosecurity code of conduct. Bulletin of the Atomic Scientists 170, p1-3. http://www.thebulletin.org/node/170

Biosecurity risk assessment concept for BRCs (special focus Europe)
A suggestive risk assessment for biological material
Background document for the Biosecurity Code of Conduct for BRCs
for discussion at the Workshop 01./02. September 2011, Utrecht

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The following draft is considering biosecurity risk assessment in routine practice and includes
* Biosafety: the risk group as by WHO definition and by the risk group allocation acc. to EU Directive 2000/54/EC (or national law)
* Dual-use potential: by 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 fulfill the requirements of the BTWC, the Australia Group, the EU or other regional legislation, national legislation and additional regulations/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. This is in order to implement biosecurity and biosafety and using biosafety considerations as the basis for biosecurity.

Main official basis documents in the practical process of biosecurity risk assessment

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

"Risk assessment" as defined by the OECD BPG

"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 are

- The difficulty to quantify,
- The lack of data,
- Difficulties in establishing causality in biological systems,
- The fact of multiple risk factors (incl. the 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 a best practice. This draft concept is focused on the biological biosecurity risk assessment and does not consider biosecurity management options. The latter are under the obligation of each individual BRC and can hardly be generalized.

The EU CBRN Action Plan

And its EU List of high risk biological agents: Threats to humans, animals, plants; toxins
aims, among other preventive measures, at developing lists of high-risk CBRN (chemical, biological and radionuclear) 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. The list is shorter than other lists mentioned here.

The OECD Best Practice Guidelines on Biosecurity for BRCs (2007)

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" (p. 8-9) using those biogenic/intrinsic factors that are known for a biomaterial. It becomes clear that biosecurity risk assessment is a multifactorial complex process with difficulties, see above.
This matrix seems difficult to work in practice, it 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 are Best Practice (not more but not less); risk evaluation of biological systems will never be complete.

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

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, in addition, perform appropriate 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 are securely kept. Situations requiring risk assessment should be described. In the biosecurity risk assessment context, intelligence forces are complementing biosafety risk assessment with local threat assessments.
Laboratory biosecurity
"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:
"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 extraterrestrial 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.
Potential conflicts between biosafety and biosecurity:

- Cases of emergency (unrestricted access to sensitive VBM)
- Protection of sensitive VBM by reducing signage (biohazard signs on doors etc)

The difficulties of risk assessment of microbiological systems

The following is taken from the risk assessment procedure acc. to M.E. Coleman, B.K. Hope, H.G. Claycamp, and J.T. Cohen (2007), Microbe 2, 13-17:
Microbial Risk Assessment Scenarios, Causality and Uncertainty: Risk assessments are iterative, whether for evaluating infectious agents or other matters that affect regulatory policies
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. Guidance is meager and microbial risks are not always fully understood. Adequacy of current methods to distinguish between subjective opinion or belief remains controversial, particularly given the hypothetical nature of many microbial risks >> biothreat: intentional release, accidental release, natural outbreaks"

Suggestions for effective laboratory biosecurity risk assessment procedures under the Biosecurity Code of Conduct for BRCs

* Focus on biosecurity/biothreat, according to the aim of the Code of Conduct, not on broader VBM definition
* Use the biosafety risk group allocation and claim all 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 RG2 biomaterial
* Compare all biomaterial with applicable lists of dual-use goods – lists are "incomplete" but legal basis!
* Look also at potential economic harm by a given RG1 microorganism (certain plant pathogens)
* 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 nearly always 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, it goes beyond the biological risk assessments and potential threats.

Checklist of practicality items (from GBRCN enquiry, prepared by Dunja Martin)

This checklist is for personal use only, to adress specific problems in the own environment, which can be brought up in the discussions.

Assessing biosecurity risks of biological material

-Can the BRC ensure that a detailed inventory of the different biological materials it holds is available?
- Did the BRC conduct a risk assessment of the biological materials in their inventories for the purpose of assigning such materials to biosecurity risk levels, which may be assigned as high, moderate, low or negligible?
- Is the level of biosecurity risk of biological material determined according to the best available information on its potential for malicious misuse as well as its virulence?
- Does the risk assessment address the potential of biological materials (should they be obtained and misused by unauthorised persons, to cause harm to the health of humans, crops, livestock or infrastructure)?
- Does the BRC engage in developing expert networks that can contribute to the provision of risk analysis?
- Does the BRC share its experience with other BRCs regarding the results of qualitative risk assessment and the reasons for assigning the biosecurity risk level of a particular biological material and does the BRC make all such documentation available to competent national authorities?
- Does the BRC determine a biological material's biosecurity risk level as a function of its potential for malicious misuse and its virulence?
- Does the BRC assess the potential for misuse based on the following key factors:
1. Availability: the number of facilities that stock the biological material and their geographical distribution
2. Amplification: the case with which the biological material can be replicated, for example whether it can be grown in culture and its growth rate
3. Skills and knowledge: the ubiquity or rarity of the skills and knowledge necessary to amplify and/or genetically modify the biological material
4. Dispersal: the ease and effectiveness with which the biological material can be dispersed, such as by air, water, food or by other means into the environment.
This might include (but not be limited to) a biological material's aerosolisation and inhalation characteristics
5. Environmental viability: the hardiness of the biological material across a range of temperatures, humidity levels, light exposures
6. Countermeasures: the existence of and ease of access to prophylaxis, post-exposure treatments and detection and decontamination measures
7. Economic consequence: the extent to which the biological material may be used to bring about harmful economic consequences for humans, crops, livestock or infrastructure?
- Does the BRC assess virulence based on the following key factors:
1. Infective dose: the smallest quantity of the biological material necessary to cause infection
2. Pathogenicity: the disease-causing ability of the biological material
3. Lethality: the ability of the biological material to cause death to the host.
4. Transmissibility: the ease with which the biological material can spread either by vector to host or host to host
- Where factors that could materially affect the assessment of a biological material's potential for malicious misuse as well as its virulence are known, does the BRC ensure that due account is taken of them in determining the overall biosecurity risk level of a biological material?
- Does the BRC carry out the risk assessment in such a manner that risk factors are

weighed?
- In conducting the risk assessment, if there is doubt as to whether a particular factor of a biological material should be characterised as high, moderate, low or negligible, does the BRC consider assigning that factor to the higher of the two possible levels?
- Does the BRC see the development of common methodologies for risk assessment as a priority?
- Does the BRC seek to develop quantitative and qualitative tools and assessments that assist in completing appropriate and comparable risk assessment?
- In developing common tools and methodologies with the broader scientific community, does the BRC draw on appropriate existing tools and methodologies (including international)?

New acquisitions/ re-assessment of inventory
-Does the BRC make biosecurity risk assessment part of the acquisition process of new biological material?
- When being transferred between BRCs, is a summary of a biological material's risk assessment made available to the recipient of the BRC?
- Is a new risk assessment only then being conducted if, after reviewing the summary, there appears to be new circumstances or information that affects the original assessment?
- Does the BRC re-assess the biosecurity risk level of materials for which there is new information about their virulence or potential for malicious misuse?

Biosecurity risk management Practices
- Does the BRC establish a timetable for internal audits to check for the level of compliance with the risk management practices?
- Do such evaluations conform to the rolling audit and review programme as described in the document "General Best Practice Guidelines for all BRCs Section"?
- Does the BRC designate a biosecurity officer at operational level within the BRC, whose responsibility is to ensure internal compliance with the biosecurity best practice guidelines?

NOTE: The biosecurity officer need not be a separate, full-time position; its functions may belong to the responsibilities of the BRC manager or another employee of the BRC.

Physical security of BRCs
- Does the BRC conduct all activities with biological materials in an area that corresponds to the appropriate biosecurity risk level resulting from the application of the biosecurity risk assessment?
- Does the BRC supplement the general security area by additional layers of physical security within the facility, if they possess biological material that presents a high or moderate biosecurity risk level?
- Does the biological material present a moderate biosecurity risk being stored and worked with primarily in a restricted area?
- Does the biological material present a high biosecurity risk being stored and worked with in a high security area?

NOTE: The purpose of physical security measures is to minimize opportunities for unauthorized entry into BRCs and to prevent the unauthorized removal of materials from their facility. Physical security measures can be manual, such as locks on internal and external doors, freezers and storage cabinets, or electronic, such as electronic access and biometric access controls, or they can be based on manpower (private security guards).

Intrusion detection sensors and cameras, although not physical barriers, can provide an instant alert in the case of a security breach. In exceptional circumstances biometric controls may be deemed appropriate.

Physical security of BRCs: General security area
- Does the BRC implement physical security measures that provide a general security barrier against theft and persons gaining unauthorised access to facilities and the material therein?
- Is the general security barrier equipped with access controls, available to all staff at the facility?

Physical security of BRCs: Restricted area
- Is access to a restricted area limited by an additional access item that is only available to individuals who are authorised to access the materials held within?
- Are all restricted areas enclosed on all sides within the general security area? (restricted areas should not share a boundary with a public area)
- Are restricted areas equipped with a 24-hour intrusion detection system?

Physical security of BRCs: High security area
- Is the high security area nested within a restricted area? (it should not under any circumstances share a physical boundary with the general security area)
- Is the access to the high security area limited by an additional access item that is only available to individuals who are authorised to access the materials held within?
- Does the access item signal that the individual has a different level of access than staff with access to only general or restricted areas?
- Is the high security area equipped with a 24-hour intrusion detection system?
- Is the construction of restricted and high security areas as such that any apertures (windows, ventilation, shafts) that are sufficiently large for a person to gain entry through are secured to prevent this?
- Are emergency exit doors releasable only from the inside, unless prevailing safety codes provide otherwise?
- Does the BRC maintain equipment /facility maintenance logs of the security areas, including names and affiliation of maintenance personnel?

Security management of personnel
- Does the BRC manager ensure that attentive management practices in the supervision of staff are the norm?
- Does the BRC institute security screening, in line with national privacy law, and set in place best practice guidelines describing how decision on appointments should be taken according to the nature of the facts that emerge about the individual?
- Are background checks of staff whose duties require them to have access to material that presents a high or moderate biosecurity risk conducted prior to the granting of access to such biological materials?
- Has all staff been issued with an identification token? (preferably equipped with a photograph of its issued holder and providing information as to their level of access)
- Are identification tokens being worn at all times, except in circumstances where doing so would present a health and safety risk (when wearing a biohazard)?
- Are identification tokens being surrendered upon termination of employment at the BRC?
- Does BRC keep records of current and former employees, while paying due respect to their privacy?

Security management of visitors
- Has the BRC established a system of security controls for visitors?
- Does the BRC system of security controls include a list of the types of visitors that are

allowed to enter the facility and does it classify whether the visitor should be escorted or not?
- Are unescorted visitors subject to the same security management procedures as BRC personnel?
- Does the BRC alternatively choose to accept the security clearance conferred to the visitor by a government agency, or other appropriate body, provided that security clearance is current?
- Do escorted visitors have access to restricted or high security areas?
- Does the BRC maintain visitor logs to ensure that visitors do not enter the facility with prohibited items?
- Does the BRC issue colour coded badges for visitors, according to the level of biosecurity risk to which they have access?
- Do these badges either automatically expire when the visitor leaves or is it taken from the visitor on exiting?
- Have appropriate visitor-to-escort ratios been established for different security areas?
- Is the permission to visit the facility being granted by the manager of the BRC or a designee?
- Are decisions on visits to restricted and high security areas being taken in consultation with the biosecurity officer?
- Are visitors within restricted and high security areas being only escorted by personnel with an appropriate level of access?

NOTE: BRCs possessing high or moderate biosecurity risk material should develop a policy addressing prohibited items for both staff and visitors and inform staff about what particular items are prohibited.

Incident response plan
- Does the BRC devise and adopt an incident response plan, which sets forth a protocol to be followed by the BRC staff for recording, reporting and investigating security breaches?
- Has the BRC determined how to report investigations of security breaches, guided by applicable laws?
- Has the BRC ensured that every staff member is fully notified of the incident response plan and trained in the actions they should take in the event of a security breach?
- Does the incident response plan indicate the reporting requirements in case of a security breach?
- Has the BRC alerted the responsible national authorities if a security breach involving biological material with a high or moderate biosecurity risk level has occured? In such a case, is the BRC prepared to communicate information on associated risks to the local community if so requested by competent national authorities?
- For security breaches involving biological material with a high or moderate biosecurity risk level, does the internal response plan identify the internal staff and external national authorities to whom the security breach is to be reported, in what order and any other actions they need to take?
- Do these actions include immediately instigating appropriate biosafety measures to reduce any health and safety risks to laboratory staff and the local community arising from the breach and to avoid disturbing the scene of the breach and any evidence until authorities arrive?
- Does the incident response plan identify individuals responsible for retrieving and compiling information that may assist investigating authorities, including where relevant, a list of people who have legitimate access to the material, the biosecurity risk level assigned to the biological material or compromised data and the inventory of requests received for the material?

NOTE: The severity of a security breach should be evaluated in accordance with risks that arise as a consequence of it. For example, a missing link in the documented chain of custody should be considered a less severe security breach than unauthorized entry into the facility or misappropriation of biological material.

Staff training and developing a biosecurity-conscious culture

- Has the BRC devised and implemented a biosecurity training course to instruct relevant staff in the biosecurity procedures of the facility?
- Does the training course explain to staff the key elements of the Risk Management Practices and ensure that staff are aware of their responsibilities and procedures that should be followed during the course of their work?
- Does the course give staff specific instruction on what constitutes a breach of security procedures and if appropriate, provide information about disciplinary sanctions that will be applied if a staff member deviates from the BRC's biosecurity policy?
- Does the course particularly instruct on the Incident Response Plan, ensuring that all staff are fully aware of the actions they should take if they detect a security breach, or witness activity that they deem suspicious on security grounds?
- Does the biosecurity training course comprise one element of the general orientation course that new staff typically undergo?
- Does the BRC also concern itself with appropriate risk communication and the creation of a biosecurity conscious culture?
- Does the BRC conduct its activities in a transparent manner and does it strive to build trust with the local community?

NOTE: BRCs should seek to raise awareness of the need to secure biological materials against their unauthorised acquisition and misuse by holding seminars, information campaigns and other activities as they consider appropriate to the nature of the facility and the tasks performed by their staff. An important component of developing a biosecurity-conscious culture is the development of a code of conduct by staff.

Material control and accountability

- Has the BRC established a system of material control and accountability, which includes conducting and maintaining inventories of biological materials in their collections and identifies individuals who have access to or custody of biological materials at any point in time?
- Does the system provide accurate knowledge of what biological materials exist in a BRC, where those materials are and who has access to them or custody of them at any given time?
- Does the BRC respect the principles of material control and accountability, that apply to all biological material held by the BRCs, including those with only negligible or low biosecurity risk associated with them?

Supply of material

- Does the BRC grant requests from facilities that seek to acquire, use and maintain biological material that presents a negligible or low risk, subject to national legislation?
- Is biological material that presents a moderate or high biosecurity risk only being transferred to facilities that ensure biosafety and where biosecurity measures appropriate to handle such material are in place?
- Does the BRC document all acquisition requests, in particular for high and moderate biosecurity risk level materials, including requests refused and the reason for refusal?
- Is the BRC able to provide competent national authorities with a record of all acquisition requests for such materials, whether the request was accepted or declined , if requested by such national authorities?

- Does the BRC condition the dispatch of biological material with a high or moderate biosecurity level upon agreement of the receiving party to provide notice of successful receipt in their as agreed timeframe?

NOTE: It is incumbent on the requesting facility, not the BRC, to prove to the BRCs satisfaction that it has put in place biosafety and biosecurity measures appropriate to handle high and moderate biosecurity risk level materials.

Transport security
- Does the BRC institute procedures that secure material during packaging and transport to reduce the risk of theft?
- For internal and external transfers of biological material that present a negligible or low biosecurity risk, does the BRC apply the required national or regional/international regulations?

Transport security: Internal transport
- Has the biological material that poseses a high biosecurity risk been left unattended or temporarily stored outside the high security area?
- Has the BRC employed a strict chain of custody approach to the internal transfer of biological material that presents a moderate or high biosecurity risk and movement from one high security or restricted area, via a restricted or general security area, to another high security or restricted area?
- Has the BRC worked on making this procedure as minimally burdensome as possible while allowing subsequent analysis of the transactions and transfers made within the scope of the preceding paragraph?

Transport security: External transport
- Does the BRC follow the WHO Guidelines on International Regulations for the Packaging and Transport of Infectious Substances to ensure safe and secure packaging and transportation of biological material?
- Is biological material exempt from the WHO Guidelines if it is sent by (air) mail or other means of transport according to the Universal Postal Union requirements?
- Does the BRC follow the International Air Transport Association Dangerous Goods Regulations and other applicable regulations including those for road transport, to ensure that all regulations for packaging and shipping dangerous goods on ground and air are met?
- Does the BRC ensure that staff responsible for the distribution of biological material have the necessary knowledge and training to comply with applicable national and regional / international laws and regulations?
- Does the staff responsible for the distribution of dangerous goods via air have the shipper's training certificate in possession as required by IATA?

Security of information
- Is information that could be reasonably used to facilitate the loss or theft of biological materials with a high or moderate biosecurity risk level being protected by proportionate measures to ensure the security of this information?
- Is the information being secured against unauthorised access by appropriate physical and/or electronic means (depending on the format in which the information is stored and the resources available to the BRC)?
- Is access to information pertaining to biological materials associated with high or moderate biosecurity risk levels being granted on a need-to-know basis and only to those individuals with security clearance to access material at the same biosecurity level as the information sought?

NOTE: This includes information pertaining to the facility (physical plans detailing the layout of the facility and the location of the master control of electrical and communication services that are essential for keeping security barriers in place), personal information on employees that could be used for blackmail, sensitive documentation such as a review that points to weaknesses in a facility's security programme and information that could potentially assist in gaining unauthorised access to biological materials and inventories.

The key question in conducting the information risk assessment is whether possessing the information would permit the holder to severely compromise the health of humans, crops, livestock or infrastructure.

Security of information: Information that relates to the collection

- Has the BRC developed a policy to guide it in deciding what kinds of information relating to the collection should purposefully be withheld from entering the public domain?
- Is the BRC staff aware of the fact that its repository of knowledge could present a security risk?
- Has the BRC encouraged staff to adopt a code of conduct specific to biosecurity?

NOTE: Information that relates to the collection includes detailed information on organisms, such as that relating to environmental hardiness, aerosolisation, cultivation method, sequence data etc. Such information, in particular that relating to organisms that present a high or moderate biosecurity risk, can present a security risk itself.

End-user Certificate
(Formblatt EVE - Endverbleibserklärung - EG-nationale Sonderverfahren)

please fill in boxes

Address of the end-user in the country of destination

Name/address of the supplier in the Federal Republic of Germany

DSMZ-Deutsche Sammlung von Mikro-
organismen und Zellkulturen GmbH
Inhoffenstraße 7B
38124 Braunschweig
Germany

CERTIFICATE

In accordance with the regulations of the Federal Republic of Germany concerning the prevention of biological warfare proliferation which state that granting of individual export licence is dependent on the presentation of an end-use certifcate, we (I) declare that the goods supplied by

Name of the supplier: DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH

Specifications of the product (Name and strain designation): ***Staphylococcus aureus* subsp. *aureus* DSM 19040**

Quantity: 1 **Value in Euro** EUR 50.00

Weight: less than 1 g of viable organisms

is intended to remain in: _____
(country of final destination)

and will only be used for non-military, peaceful, civil scientific or industrial purposes, like test/assay, research, quality control, teaching, production, and/or others (please specify):

Detailed purposes: __ Test/assay __ Research
__ Quality control __ Teaching __ Production
Others (*please specify*) _____

In no case will the goods be resold or used for other purposes than the above mentioned.

Re-exporting the goods is definitely excluded.

_____ _____

Place, date **end-user stamp and original signature of the legal representative**

Biosecurity
Code of Conduct

Joost A. Stalpers
Centraalbureau voor Schimmelcultures

Why? The 2001: Anthrax letters

- Bruce Edwards Ivins, mad scientist nightmare
- 22 infected, 5 deceased: equivalent of Saturday night traffic victims in New Jersey
- Overreaction public and authorities
- Increase funds biological warfare
- Radiation of biological material
- Lost trust in Culture Collections and scientific institutions
- Image damage: great

Some CoC history

- EMbaRC agrees to produce a Code of Conduct for BRC's (february 2009). (NA 1.3)
- GBRCN joins the project. (WP 3 MS3.5)
- Production of bibliography on Biosecurity
- Choice for Code of Conduct, similar to KNAW model
- Development of a biosecurity database
- Production of draft CoC and Preamble
- Meeting in Braunschweig 26-27 october 2010
- OECD workshop Paris december 2010
- Workshop Utrecht september 1-2 2011

Workshop Goals

- Finalize and agree on the Biosecurity Code of Conduct for BRCs (CoC) (EMbaRC WP NA1.3 and GBRCN WP 3 MS3.5)
- Agree on approaches for ratification of the CoC by the EMbaRC and GBRCN Partners
- Put the CoC in context to different laws and provisions on Biosecurity
- Evaluate practicalities of the implementation of national and European legislation and the OECD Biosecurity Guidelines

Types of Code

- Code of ethics
  - Aspirational, set ideals
- Code of conduct
  - Voluntary, but supporeted by guidelines
- Code of practice
  - Enforceable, embedded in regulations

Code of Conduct

- Biorisk management
- Accountability
- Raising awareness
- Research and knowledge exchange
- Internal and external communication
- Accessibility
- Shipment and transport

Biosecurity: classes

- **Biowarfare:** military conflict between nations: Iraq against Kurds
  - short to long term goals
- **Bioterrorism:** religion/ political/ ideological/ environmental groups attacking civilians: Aum Shinrikyo, metro attacks
  - short term goals
- **Bioattacks:** on individuals, e.g. HIV + man deliberately infects women (or vice versa), assassination (political), murder (personal), revenge etc.
  - short term goals

Targets

- Humans (direct)
- Economical/environmental (indirect)
  - lifestock
  - crops
  - human environment

•viruses
•bacte
•fungi

Controled of Dual-use Goods

A BRC has procedures to check the validity of customers that wish to receive dangerous organisms and if in doubt does not supply

- Australia Group (1990), now 41 members
  - to prevent supply of substantial harmful organisms to mala fide third parties
- Biological and Toxin Weapons Convention (BTWC), now 171 signatories
  - prohibits the development, possession and use of biological weapons

Accessibility

- Physical containment
- Employees
- Guests
- Customers
- Information

Biosecurity principles for BRC's

- Physical security
- Security management of personel
- Security management of visitors/guests
- Material control
- Material supply
- Transport security internal and external
- Information security
- Risk assessment

Biosafety Classification of Hazardous Micro-organisms

- 1. Most unlikely to cause human disease
- 2. May cause human disease
  - a possible hazard to laboratory workers but unlikely to spread in the community. Laboratory exposure rarely produces infection and effective prophylaxis or treatment is available
- 3. May cause severe human disease
  - a serious hazard to laboratory workers. Presents a risk of spread in the community but usually effective prophylaxis or treatment.
- 4. Causes severe human disease

  a high risk of spread in the community and there is usually no effective prophylaxis or treatment

Hazard classification for biosecurity

- 4 categories: Neglegible, Low, Moderate, High.
  - Problem: it is not only the organism potential, but also the available techniques.

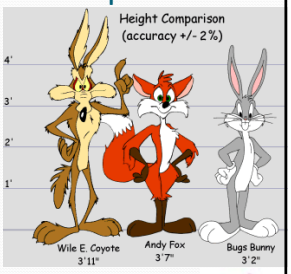
In practice based on threats against humans, not lifestock, crops or environment. However, Q-lists, Dual use lists contain plant pathogens

No common lists for human or animal diseases (no agreement among countries)
No uniform evaluation for plant pathogens possible (host, presence, possible occurrence, invasion risk etc.)

However, these organisms can be obtained in many countries

Risk Assessment, current practice

- Intended for biosafety, not biosecurity
- Assessment by comparison
  - Substrate
  - Relatives
  - Tests (toxin production)
  - Stay on the safe side
- It worked, up to now



Expected Risk Assessment by BRC's

- Identify sources of potential harm
- Assess potential misuse
  - availability, amplification, necessary skills and knowledge, dispersal, environmental viability (survival chances), effective countermeasures
- Assess virulence
  - infective dose, pathogenicity, lethality, incubation time, transmissibility

What do BRC's need?

- Information
  - Appropriate legislation in various countries
  - Lists of quarantaine organisms (WFCC, GBRCN)
  - Access to external experts
- Testing
  - Access to testing laboratories or possibility to delegate such tasks

Biosecurity Database MicroBioRisk GBRCN

- Legislation: import and export regulations for microorganisms per country
- Transport regulations per country
- Quarantine organisms per country
- Biosafety and biosecurity regulations per country
- List of human pathogens
- List of animal pathogens
- Lists of plant pathogens per country (long term). EPPO lists
- List of experts that could advise on biosecurity items (risk assessment; quarantine regulations; biosecurity regulations)
- Addresses of authorities per country that control quarantine; biosecurity; biosafety

rst version available

Structure of database

- Fields
  - Name organism
  - Name country (what about EU? Only under the various countries?)
  - Pathogen type
  - Toxin
  - Legislation identity
  - Biosafety classification
  - Biosecurity classification
  - BSL (handling) classification
- Connections between fields
  - Country - Legislation
  - Organism – various classifications, pathogen type, toxin
  - Legislation – various classifications

Surveys of Biosecurity Awareness

- Analysis of interactive seminars conclude that *there is **little evidence** that participants:*
  a. regarded bioterrorism or bioweapons as a substantial threat;
  b. considered that developments in life sciences research contributed to bio-threats;
  c. were aware of the current debates and concerns about dual-use research; or
  d. were familiar with the BTWC
- Lack of biosecurity awareness requires explanation:
  One possible explanation: it does not feature in their university education.

University Education Surveys

Results of biosecurity education in life science degree courses in Europe:

- Only 3 out of 57 Universities offered some form of specific biosecurity module (all optional modules)
- Similar results were found in Israel and in the Asia-Pacific Region

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Solving the Problem: Bottom-up Approaches

National Defense Medical College IWG-LNCV

Education Module Resource

– **Main Concept**
  - A free (open-source/shareware) on-line educational resource for facilitating the training in Ethics and Dual-Use issues of Life Science Students in Higher Education.

– **No one size fits all**
  - Content of the resource can be tailored by users for specific academic contexts.

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National Defense Medical College IWG-LNCV

Education Module Resource

- EMR 21 Lectures: Broader Concept of Biosecurity
  - A. Overview (Lecture1).
  - B. The Threat of Biological Warfare and Bioterrorism and the International Prohibition Regime (L2-10).
  - C. The Dual-Use Dilemma and the Responsibilities of Scientists (L11-18).
  - D. National Implementation of the BTWC (L20).
  - E. Building a "Web of Prevention" (L21).

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National Defense Medical College IWG-LNCV

EMR Translations

- **Implementation:** Being tested in Italy, the Netherlands, Poland, Portugal, Spain, Sweden, the UK and Japan.
- **Language:** Available in English, Japanese, Russian, French and Romanian/Moldovan. Will shortly be available in Spanish, Urdu, Polish, Georgian and Arabic…

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MAKING KNOWLEDGE WORK
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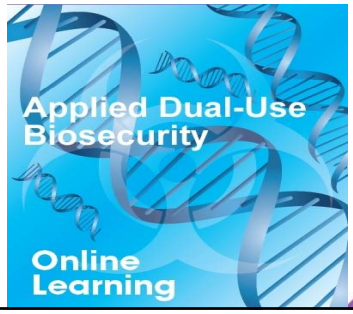
Online Train-the-Trainer Courses



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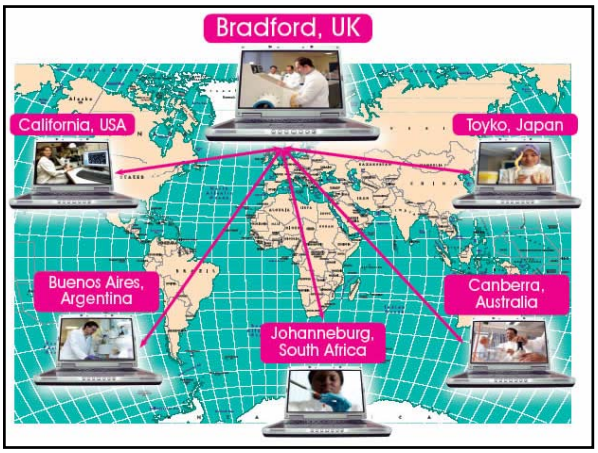

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Course Participants

Egypt	Disease Surveillance Research Laboratories (DSRL), Global Disease Detection & Response Program
Egypt	Veterinary Serum and Vaccine Research Institute(VSVRI),
Egypt	Central Public Health Lab
Indonesia	Department of Microbiology, Medical Faculty, University of Indonesia
Indonesia	Eijkman Institute for Molecular Biology
Jordan	Princess Haya Biotechnology Center/Jordan University of Science and Technology
Jordan	Jordan University of Science and Technology
Jordan	Jordan University of Science and Technology
Jordan	Head, Dept. of Biological Sciences, Yarmouk university
Kenya	Kenya Medical Research Institute/Centers for Disease Control and Prevention
Kenya	UNIVERSITY OF NAIROBI/ NATIONAL BIOLOGICAL AND TOXIN WEAPONS COMMITEE
Kenya	Centre for Biotechnology Research and Development, Kenya Medical Research Insitute
Kenya	International Livestock Research Institute (ILRI)
Kenya	National Council for Science and Technology, Ministry of Higher Education, SCience, and Technology
Morocco	University Sultan Moulay Slimane
Morocco	Université Hassan II
Morocco	Faculty of Sciences Dhar El Mahraz
Morocco	National Institute of Hygiene, Ministry of Health
Nigeria	College of Peace and Social Sciences,Salem University
Pakistan	University of Karachi
Pakistan	Armed Forces Institute of Pathology, Combined Military Hospital
Pakistan	Dept. Plant Sciences, Quaid-i-Azam University, Islamabad
Philippines	College of Public Health, UP Manila
Philippines	Foreign Service Institute
Philippines	University of the Philippines Manila
Qatar	Consultant Medical Microbiologist, Hamad medical Corporation
Qatar	National Commitee for the Prohibition Of Weapons
Qatar	Qatar University, Department of Health Sciences
Russia	I.I.Mechnikov Research Institute for Vaccines and Sera:
UAE	Abu Dhabi University
Uganda	National Airport Services, Medical Laboratory
Yemen	National Center for Public Health Laboratories

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Applied Dual-Use Bioethics/Biosecurity: Online Distance Learning Train-the-Trainer Course

Learning Outcomes: to build capacity of participants to develop:

1. Knowledge & Understanding
- Review and appraise ethical/biosecurity themes and methods relevant to dual-use.

2. Discipline Skills
- Integrate dual-use biosecurity issues and concerns into their own training programmes.

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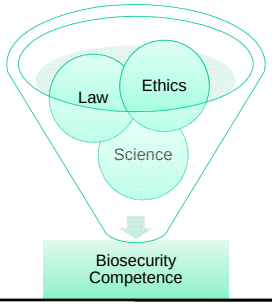
Key Themes of the Course

A. The Threat of Biological Warfare (BW) and Biological Terrorism (BT)
B. International Prohibition Regime
C. The Dual-Use Dilemma
D. Responsibilities of Life Scientists
E. National Implementation of the BTWC
F. Building an Effective Web of Prevention to Ensure Benign Development



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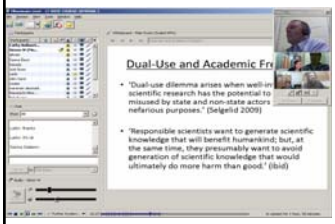
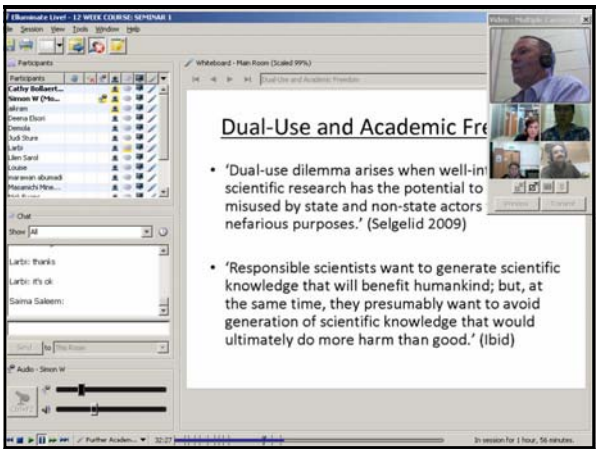
Tools: Elluminate, NING and Blackboard

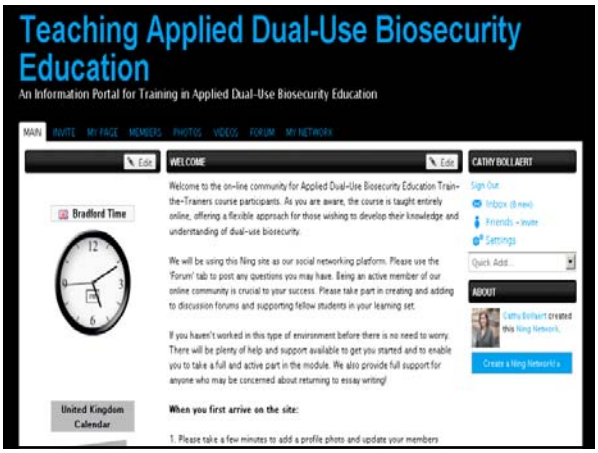


- ***Elluminate***
  - Live platform for lectures and seminars,
  - Virtual classroom enabling the interaction amongst participants backed up by (PPTs, Webcam, Audio equipment),

- ***NING***
  Induction and social networking platform outside of lectures

- ***Blackboard***
  Archives of the course: lecture PPTs, videos, hand books





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Course Structure and Assessment

Two types of courses

1x 30 Credit Module (UK Higher Education Master's level credit):
12 Lectures + 12 Seminars-Real-World Scenarios based discussions
1x Certificated Course: 6 lectures in 6 weeks

Assessment: 30 Credit Module

1. Coursework: 50%
Reflective applied written individual assignment: 3,500 - 4,000 words.

2. Groupwork Report: 50%
Online group-work presentation (25%) and one related written group-work assignment (25%) of 2,000 words

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Seminar Scenario

As members of a research team you find a method of rapid synthesis viruses. Presumably it would also allow you to (re)create potentially dangerous pathogens.

In a 2000-word report outline what your further actions would be, taking into account biosecurity, biodefence and ethical considerations.

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What do Course Participants get?

They get:

- A qualification - 30 (transferable) Master-level Credit from a UK HE institution
- Evidence of awareness and education on biosecurity
- Membership of a supportive network that seeks to build sustainable capacity in dual-use biosecurity

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Acknowledgements

IWG-LNCV — Landau Network Centro Volta, Italy.

National Defense Medical College — National Defense Medical College, Tokyo, Japan.

Bio Engagement Program, Department of State, USA.

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Thank you!

Facebook: http://tinyurl.com/bioseced

Twitter: http://twitter.com/#!/DualUseBioSec

Skype: dual.use.biosecurity

http://www.brad.ac.uk/bioethics/

Codes of Conduct -
A Comparative Overview and the EU CBRN Action Plan

Biosecurity Workshop
EMbaRC-Project
Utrecht, 1-2 September 2011

Dr. Volker Beck
Germany

Codes of Conduct – International Activities

- The Policy Working Group on the United Nations and Terrorism, October 2001
- Inter-Agency Consultative Meeting, UNESCO 2003:
  … encouraging ethical codes of conduct for scientists and engineers [and] promoting ethics of science education and awareness …
- BTWC Intersessional process 2005 and 2008
  - 2005: *… promote common understanding and effective action on codes of conduct for scientists …*
  - 2008: *… 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 …*

EU CBRN Action Plan

COUNCIL OF THE EUROPEAN UNION 15505/1/09 REV 1,
12 November 2009

- Prevention
  Goal 1: Lists of high-risk CBRN materials
  Goal 2: Enhance the security of high risk CBRN materials and facilities
  Goal 3: Enhance control over high risk CBRN materials
  Goal 4: Contribute to the development of a high security culture of staff
  Goal 5: Improve the identification and reporting of suspicious transactions
  Goal 6: Enhance the security of transport
  Goal 7: Improve information exchange
  Goal 8: Strengthen the import/export regime
- Detection
- Preparedness and response

EU CBRN Action Plan Measure B.5

- Measure B.5 :
  The Commission together with the Member States should encourage professional and other relevant associations working with bio-issues to develop and adopt codes of conduct for their members.
- Proposed Implementation*:
  The Commission will
  - facilitate the exchange of information and collect information,
  - provide funding in form of grants to organisations developing and adopting the codes of conduct.

  Member States should provide support in spreading the information of the financing possibilities and encourage the organisations at national level to apply for funding.

* Report of the first meeting of the Sub-Group, June 2010

Codes of Conduct – National Activities

- Round-table discussions 2004, 2005 and 2008 with representatives from academia, industry, research facilities, professional associations, ministries and government agencies (organized by the Federal Foreign Office)
- 2009: Exchanges of views with synthetic biology industry representatives and US government representatives (organized by the Federal Foreign Office)

What is a Code of Conduct ?

- Code of Conduct
  - is a formal statement of values and professional practices of a group with a common focus either on occupation, academic field, industrial field, or social doctrine,
  - defines the expectations and directs the actions of a group,
  - contributes to raising awareness of possible misuse of science and technology.
- Code of Conduct is not an alternate for necessary legislative measures.

Code of Conduct – Examples

- Deutsche Forschungsgemeinschaft – German Research Council
  - organisation for funding research projects
- Bio Deutschland – Bio Germany
  - more than 260 biotech/pharma/bioinformatics/bio-equipment/ bio-consultant companies
- IASB – International Association for Synthetic Biology
  - six German and two Chinese companies
- Max-Planck-Gesellschaft – Max-Planck-Society
  - independent non-profit research organisation that primarily promotes and supports research at its own institutes
- Other German biology, biosciences and biomedicine associations

German Research Council*
DFG Code of Conduct: Work with highly pathogenic microorganisms and toxins

- Experiments to be relevant with regard to the dual-use dilemma
- Project leaders should be more aware of sensitive aspects of the dual-use dilemma in their proposals
- Review Boards should give thorough consideration to proposals which touch on the dual-use dilemma
- Publication in peer-reviewed journals
- Laws and regulations must be respected
- Best practices process to be further developed

---
* Deutsche Forschungsgemeinschaft (DFG): biggest German research projects funding organisation

Bio Deutschland*
Position Paper Biosecurity – The Dual-Use Problem

- addresses the risk of dual-use of results that cannot only be used for increasing scientific knowledge but also for the development of bio-weapons,
- borrows from the code of the German Research Council,
- argues for
  - increasing the sensiblility for the dual-use problem,
  - peer review of publications,
  - further development of best practices.

Bio Deutschland: More than 260 biotech/pharma/bioinformatics/bio-equipment/bio-consultant companies, etc

The IASB* Code of Conduct for Best Practices in Gene Synthesis

- General consideration
  - Synthetic Biology can also create the risk of abuse
- Risk assessment and risk management
- Cooperation with authorities
- Sequence screening
- Response to identified threats
- Customer screening
- Cooperation on biosafety and biosecurity issues

---
* International Association for Synthetic Biology: six German and two Chinese companies

Max-Planck-Gesellschaft
Advice and Rules for Responsible Handling of Freedom of Research and Risks of Research

- Addresses the dual-use problem in general terms, not bio-specific, but names biological weapons,
- Recognizes that not all risiks and potential misuse can be regulated by legal norms
- Self-regulation based on ethical norms shall prevent misuse of science and risks
- Respect existing laws and regulations
- Project related risk analysis and impact assessment
- Minimize risk of release or theft of dangerous materials from laboratories
- Review results before publication
- Wave irresponsible research

Other German Biology, Biosciences and Biomedicine Associations

- Society of more than 30 professional lifesciences associations:
  - review work done on existing laws/regulations/codes of conduct:
    - - assesses existing legal mechanisms as being adequate
    - - sees presently no need for a code, but will keep track of developments
    - - argues for academic lectures on „best practices and ethics“
- Other professional/industry associations share more or less the a.m. view
- More work needs to be done to convince associations to develop and implement codes of conduct, but codes must also be put in practice.

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Workshop
on
Biosecurity for BRC's

Session 3: Practicalities – The implementation of OECD Best Practice Guidelines on Biosecurity

Dunja Martin, Global Biological Resource Centre Network (GBRCN)
Demonstration Project Secretariat, Braunschweig, Germany

OECD Best Practice Guidelines for BRCs

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

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

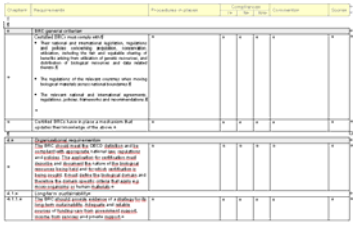
Best Practice Guidelines for the Micro-Organism Domain
- Staff-qualifications and training
- Hygiene und biosafety
- Equipment use, calibration, testing and maintenance records
- … … … …
- Preparation of samples
- Information provided with the biological material supplied

Best Practice Guidelines on Human-Derived Material
- … … …

Self-Assessment on OECD Best Practice Guidelines

To evaluate conformity to the specific requirements **an internal audit** can be performed **following a matrix** and a scoring system:

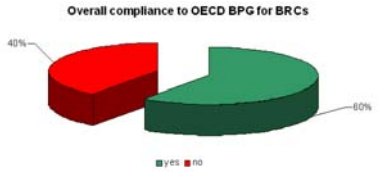
- Chapter of the guide
- Requirement
- Procedure in Place
- Compliance
- Comments
- Score



- full compliance = 2
- Compliance with minor rework = 1
- non-compliance = 0

Results of Self-Assessments

- 10 GBRCN Pilot Project Partners performed an Internal Audit according to the OECD BPG checklist:
- 66% of the partners countries responded to the call and demonstrate an overall compliance to the OECD Best Practice Guidelines of 60 %
- The future work of GBRCN will be dedicated to continuously increase the compliance level amongst BRCs and to deliver a library of standard operating procedures based on the OECD Guidelines

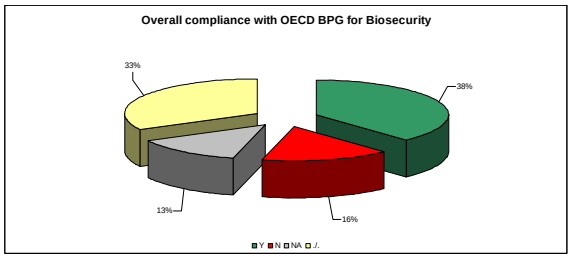


Result of the self assessment on OECD BPG for Biosecurity

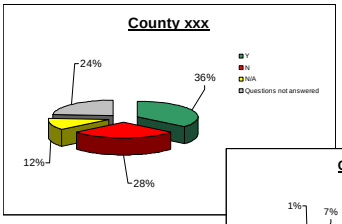
Main results:

- **Highest compliance** with mostly no deviation **are shown in the traditional management factors of culture collections**:
  - transport security and internal transport
  - supply of material
  - material control and accountability
  - staff training and developing a biosecurity-conscious culture
- **The lowest compliance** with most deviations are shown in aspects like:
  - biosecurity risk assessment
  - incident response plan
- **The most undetermined aspect** by indicating compliance is:
  - security management of personnel and visitors
  - request for security of information
- **The most problematic biological material** with respect to risk assessment are:
  - plant pathogens

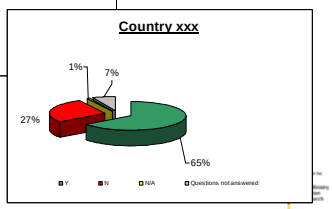
Results of the self assessment on OECD BPG for Biosecurity



Result of the self assessment on OECD BPG for Biosecurity



- Between the different participating BRCs a different level of compliance is reached, which can be used for mutual support and for creating a SOP library



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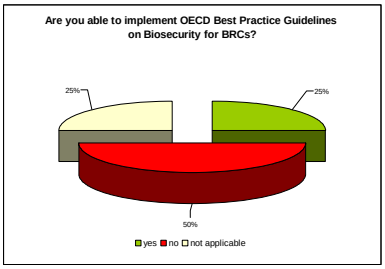
Survey on Biosecurity in 2011 (Utrecht)

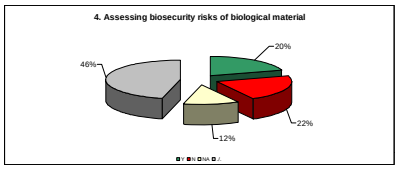


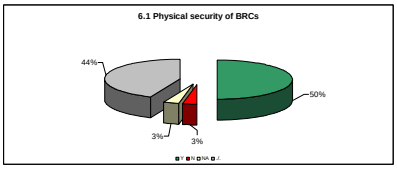
Result displays the returns of the self evaluations:

- Survey in 08/2011: 50 % of responses indicate that implementation is not possible
- Self Assessment until 10/2010: 16 % of responses indicate non-compliance + 33 % gave no answers = 49 %

8

Results of the self assessment on OECD BPG for Biosecurity



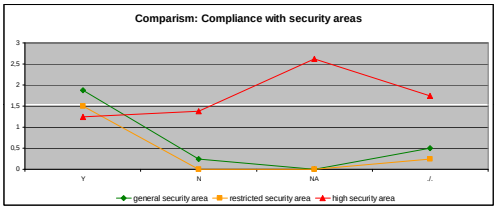


A high percentage of over 45 % were not answering thisquestions :

- A high factor of **uncertainty is associated with biosecurity risk assessment and physical securing** of laboratory infrastructure

9

Result of the self assessment on OECD BPG for Biosecurity



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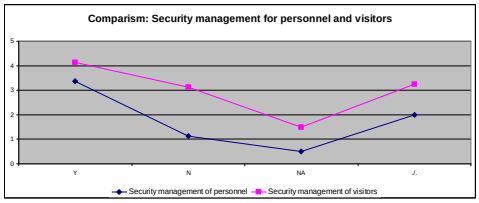

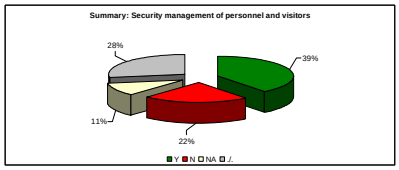

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Result of the self assessment on OECD BPG for Biosecurity

Remaining questions:

- **What part of the OECD BPG on Biosecurity need the most significant changes / improvement?**
  - e. g. physical security
- **Which type of information / information source is missing mostly?**
  - e. g. harmonised hazardous classification
  - e. g. uniform export control lists
- **What exactly is hindering BRCs from compliance**:
  - e. g. financial help (e. g. for high security areas)
  - e. g. conflictive laws like Data Protection Acts hindering from screening staff members
  - e. g. additional personnel and special training for Biosecurity
- **Is there a paragraph in the OECD BPG on Biosecurity which should be deleted completely?**

12

Workshop
on
Biosecurity for BRC's

Session 4: Practicalities – Risk Assessment in the Context of Risk Management

Dunja Martin, Global Biological Resource Centre Network (GBRCN)
Demonstration Project Secretariat, Braunschweig, Germany

1

OECD Best Practice Guidelines for Biosecurity

The frameworks for risk assessment and risk management contained herein provide tangible tools for biosecurity. These are necessary but not sufficient to ensure biosecurity, however. 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.

The OECD guidelines identified three key aspects related to Biosecurity:

- BRCs should demonstrate a culture of responsibility
- BRCs should perform risk assessment
- BRCs should manage through balancing, measuring and considering all relevant factors

Thus BRCs are requested to implement a complementary **system** of different routines **providing a functional management** for Biorisks.

2

Three Components of Managing Risks

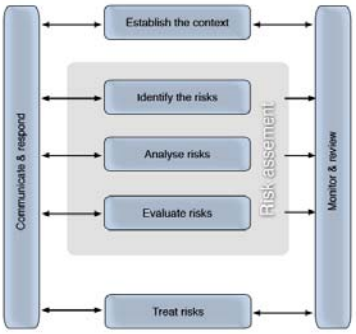
The triangle to manage risk contains the interactive components:

- **Risk management** is setting up a policy for a sustainable reduction of risks and is selecting and implementing appropriate options.
- **Risk assessment** is the determination of quantitative and qualitative value of risk related to a concrete situation and a recognized hazard.
- **Risk communication** is to improve collective and individual decision making and means an interactive exchange of information and opinions .

3

Risk Assessment – Flow Chart

Risk management according to ISO 31000 considers this triangle:



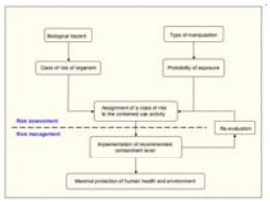
Complete Risk Assessment includes:

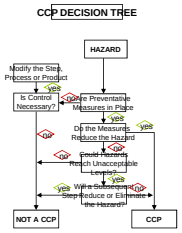
- Agent Characterization (Risk Group RG)
- Personnel Factors (experience) Work Activity Factors
- Environmental Factors
- Equipment Factors
- Risk Consequences
- Probability Profile

Detailed view:

4

Risk Assessment & Risk Management in Laboratories

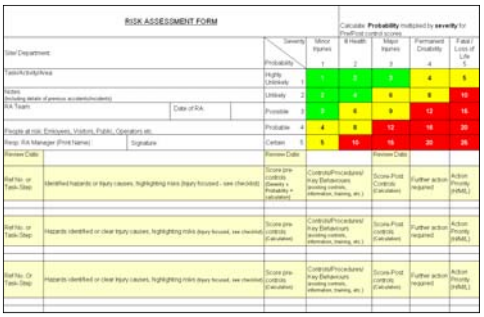




5

Risk Assessment Documentation

Risk assessment form (example only!):



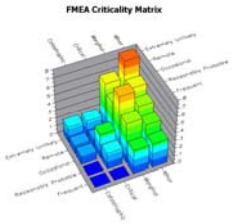
6

Tools for Risk Assessment

FMEA:
Failure Mode and Effect Analysis

HACCP:
Hazard Analysis and Critical Control Points

SWOT Analysis:
Strengths, Weakness, Opportunities and Threats



Federal Ministry of Education and Research

7

Thank you very much for your attention!

For further questions please contact:

Dunja Martin
gmb@dsmz.de

Federal Ministry of Education and Research

8

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MAKING KNOWLEDGE WORK
School of Social & International Studies

Codes of Conduct: The Need for Underpinning of Awareness and Education in Dual-use Biosecurity

Workshop on Biosecurity
1-2 September 2011
Utrecht, The Netherlands

Cathy Bollaert
Bradford Disarmament Research Centre,
University of Bradford, UK

www.bradford.ac.uk

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Outline

1. Codes of Conduct: Introducing the problem
2. Towards a solution: Online Awareness-Raising and Education
3. Further Developments

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Biological Threats Spectrum

- Natural Disease
  - Public Health
- Accidental Disease
  - Biosafety
- Deliberate Disease
  - Biosecurity
    - Laboratory
    - **Wider**

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Education to Strengthen Codes of Conduct

Codes of Conduct

Important but difficult to implement

Education

informed scientists and policy makers = effective biosecurity policies *including* CoC

Lack of expertise/teachers to provide biosecurity education

Train the Trainer

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Why is there a Problem?

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School of Social & International Studies

B10. University Education in: Europe, Japan, Israel and the Asia-Pacific (AP) Region*

Region/ Countries	Year	Sampled Courses	Main Results
Europe	2008	142 courses in 29 countries	3 out of the universities in the survey currently offered some form of specific biosecurity module.
Japan	2009	197 courses in 62 universities	Implementation of ethics education for scientists rarely include dual-use issues.
Israel	2009	35 courses in 7 universities	Biosecurity act, a report on bioterrorism by its national academy and security council but no education course.
AP	2010	197 courses in 58 universities	Few biosecurity education courses, and nascent but growing interest for regional cooperation to promote education.

The EMbaRC-GBRCN Biosecurity Code of Conduct

Initial Thoughts on its Practicability and Implementation

Codes of Ethics

Codes of Practice

Codes of Conduct

Why a Code of Conduct has been developed under EMbaRC NA1.3 to feed into GBRCN

Why a Code of Conduct?

Codes in the multiform international regulative world:

Treaty > Code > Guideline > Principle

A Code is the previous step below an international agreement

Codes of Ethics: are outlining ground lines and ideals of behaviour, they reflect the „basis“, can be a possible basis in a „stepwise“ plan

Codes of Conduct: are outlining principle actions: committing to a binding maxim, to common agreements, to demands in practice

Codes of Practice: are governing the practical level, the operative actions in detail

Codes of Conduct are „between“ Ethical Codes and detailed advice

Why a Code of Conduct?

OECD BPG on Biosecurity for BRCs:

„The BRC staff should be aware that their repository of knowledge could present a security risk. BRCs may choose to address this issue through encouraging staff to adopt a code of conduct specific to biosecurity.“

BRCs are the „official“ turntables of biomaterial that is delivered to global destinations in the scientific community. Loss of reputation shall be avoided.

Scientists are responsible for and shall protect

•Themselves

•Their institution

•Their umbrella/hosting society

Why a Code of Conduct?

The scientific and the technical world bear risks and need to evaluate the risks and potential scenarios, to communicate the potential risks and to set in place appropriate risk management.

BRCs hold a huge diversity of biological resources and are active in scientific research, both is bearing potential for misuse.

A Code of Conduct might ideally focus on the principal issues of the OECD BPG. It provides BRCs with the opportunity to demonstrate self-control.

Self-control, the BRC way of quality & global thinking

•To protect workers

•To protect animals and the environment

•To obey all relevant rules & regulations on biosafety and biosecurity

•To adhere to a „long-lasting“ agreed, binding Code in the sense of best practice

What are the key topics of a Biosecurity Code of Conduct for BRCs?

These are addressed by the OECD BPG.

Any Code shall not limit scientific freedom, it shall not replace any national or regional laws and regulations, it shall offer clear practical advice in form of principles, it shall respect and consider globally relevant regulations including the requirements by the UN, WHO and WTO.

The Code will require to evaluate risks and will require to follow the principle „security first“. The basis of the Code will be ethical.

One Code of Conduct for all?

The Code of Conduct shall be designed in such a manner that **all** Culture Collections/BRCs can adopt it, independent of their holdings and facilities:

It shall outline principal practice, short, simple and clear. Procedural details are not desirable, but an accompanying background document is offered.

It shall strengthen responsibility and awareness within and throughout an institution.

Necessarily, risk assessment is a key issue.

Risk Assessment as a key issue of the Biosecurity Code of Conduct

In what depth can we perform risk assessment for the bioresources?

What is possible and realistic in this respect?

Where can we start, which guidance is available?

Is risk assessment necessarily list-based or more free?

Can the risk be „managed“?

How can responsibility be delegated in a BRC and its hierarchy?

Which role does biosafety play for the Code of Conduct?

Main issues covered by the Biosecurity Code of Conduct for BRCs

BIORISK MANAGEMENT
RAISING AWARENESS
ACCOUNTABILITY
INTERNAL AND EXTERNAL COMMUNICATION
RESEARCH AND SHARING KNOWLEDGE
ACCESSIBILITY
SHIPMENT AND TRANSPORT

Biosecurity Risk Assessment

Is a **list-based approach** feeding into a scheme (matrix) desirable, realistic and sufficient (high, moderate, low, negligible risks)? Lists like the EU Dual-use or select agents lists are fundamental, not only for export purposes because „listed“ biomaterial is for good reasons listed.

OECD BPG: „*The frameworks for risk assessment and risk management provide tangible tools that are necessary but not sufficient to ensure biosecurity*“.
OECD BPG suggests strong **cooperation of BRCs** with regard to risk assessment and risk management to share collectively the burden and to develop expert networks including external experts.

Limits of Biosecurity Risk Assessment

Microorganisms

See background document:

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 are
The difficulty to quantify,
The lack of data,
Difficulties in establishing causality in biological systems,
The fact of multiple risk factors (incl. the dose of a pathogen after intake, uncertainty of dose-response predictions).

>> Risk assessment as a process of Best Practice acc. to the *state-of-the-art* and best knowledge

Microorganisms

Thank you very much for your attention!

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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.