DURC 101

Web Based Training

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Introduction

Biological research has progressed considerably over the last decades thanks to remarkable and rapid technological advances (e.g. „genome editing“). These innovations and their rapid global dissemination have however increased the risk of a potential misuse of novel research findings. Research which has a significant potential to be misused for criminal and/or harmful purposes, i.e. (bio)terrorism or biological warfare, and therefore gives reason for particular concern is designated as „Dual Use Research of Concern (DURC)“.

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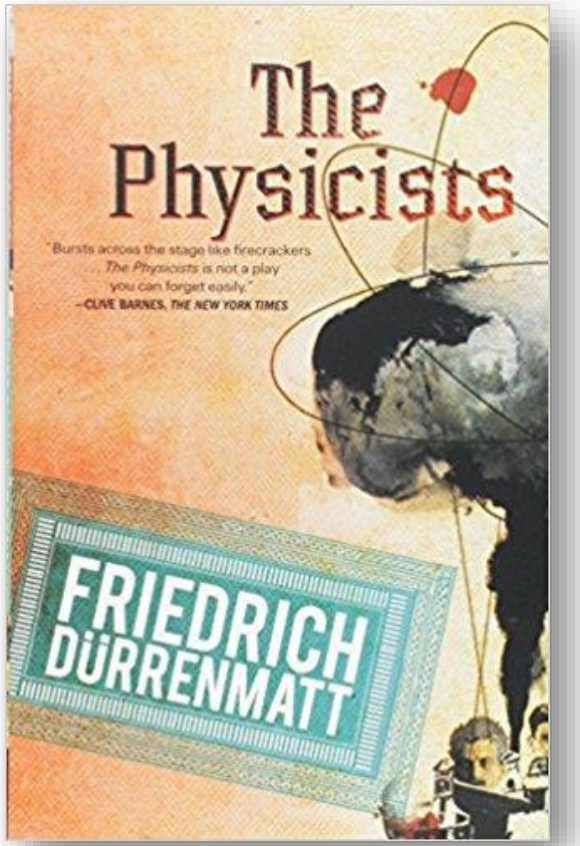
I. DURC – Definition and Relevance

In simple terms this means that techniques that are necessary to construct a bioweapon sometimes are the same ones that are needed to conduct legitimate research in basic and applied science. Ultimately, this instruction module deals with the responsible handling of such research by the scientist in terms of biosecurity.

The fact that scientific knowledge is associated with risks and can become a threat is no new experience. A succinct symbol for the threat posed by scientific experience and knowledge is the atomic bomb, and the problem was transposed into literature in Dürrenmatt's drama „The Physicists".



I. DURC – Definition and Relevance

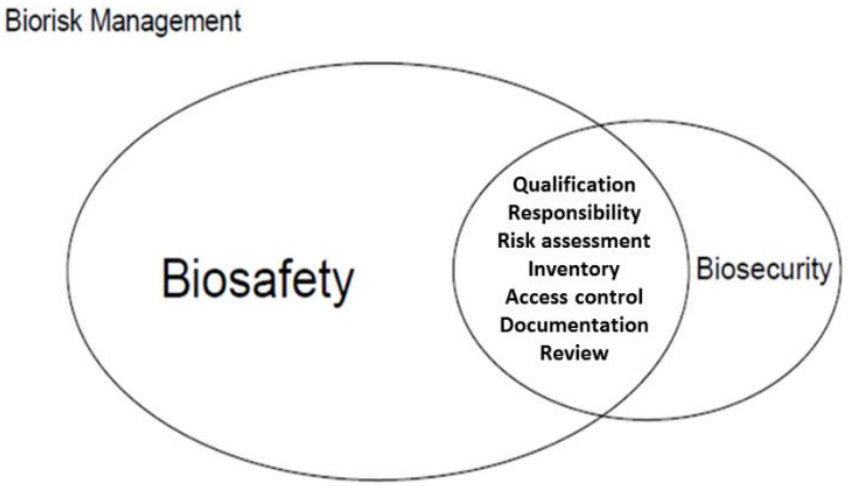
In the 21st century a new group of researchers has moved into this ambiguous spotlight: life scientists. Microbiologists, biomedical scientists, including virologists are now the focus of DURC.

Responsibility is borne not only by established scientists, but also by postdocs, PhD and diploma students as well as by the scientific and technical staff involved in planning, preparing, realizing and/or publishing experiments.

II. Biosafety and Biosecurity

In general, **biosafety** and **biosecurity** relate to the systematic protection of humans, animals, plants, and the environment from threats associated with handling biological agents.

The term „biorisk“ describes the combination of the likelihood of a damaging event and the possible consequences of such an event caused by a biological agent. Complex biosafety and biosecurity measures should be implemented into a management system. The task of Biorisk Management is to balance the different requirements of „biosafety“ and „biosecurity“ depending on the risk analysis or risk assessment and the objectives of the respective institution.



Decision 36/2011 of ABAS – ABAS position paper on „Biosecurity from an occupational health and safety perspective – assessment of interfaces“

II. Biosafety and Biosecurity

The principles of biosafety and biosecurity have been combined in the CEN Workshop Agreement (CWA) 15793:2011(14). This agreement summarizes in detail all biologically relevant safety and security aspects in terms of quality management in order to increase effectiveness of the overall laboratory management.

II. Biosafety and Biosecurity

The terms „Biosafety“ and „Biosecurity“ describe different concepts and objectives, but also have some commonalities. *Biosafety* focusses on the protection of persons and the environment, whereas *Biosecurity* aims at the protection of biological agents and information to prevent misuse and criminal acts.

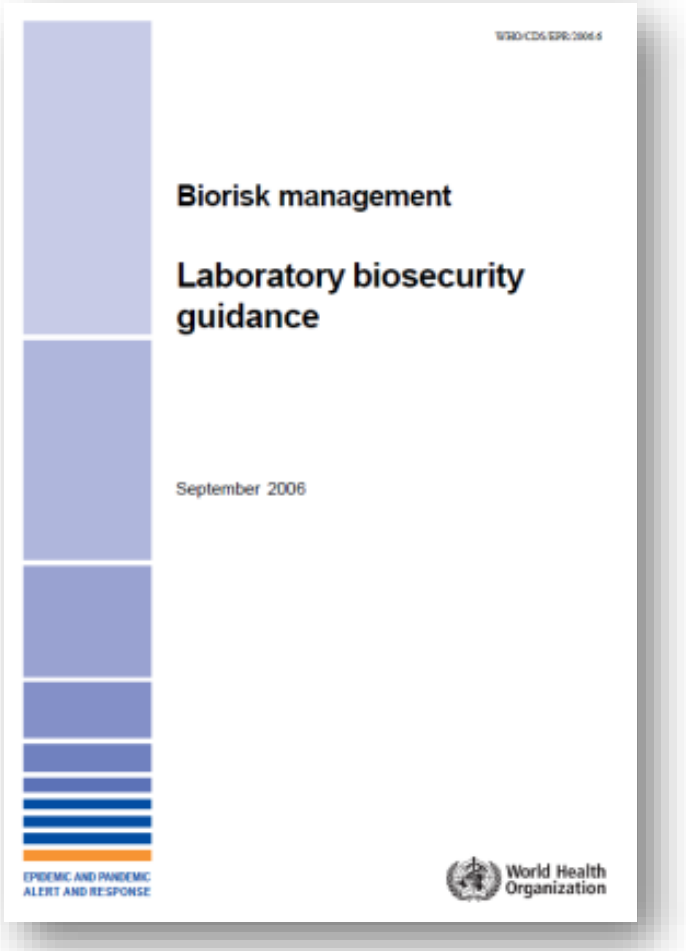
https://cdn.shopify.com/s/files/1/0329/0333/products/BIOSECURITY_AREA_AUTHORISED_PERSONNEL_ONLY.png?v=1476939633

II. Biosafety and Biosecurity

"Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release."

"Laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release."

(World Health Organization, CDS/EPR/2006.6)



II. Biosafety and Biosecurity

Biosecurity measures in particular aim at preventing the loss, theft, or misuse of microorganisms, biological agents, or scientific information, findings and research results. Based on the assessment of the risk of misuse this can e.g. be achieved by restrictions placed on persons and their activities, restrictions on the use and fate of biological agents, and targeted limited access to essential information.

Biosecurity programs are in particular required for laboratories working with biological agents and biogenic toxic substances that are part of the War Weapons List of the War Weapons Control Act, the "EU list of high threat pathogens", the American USDA list of „Select Agents and Toxins", or the Australia Group "List of Human and Animal Pathogens and Toxins for Export Control". Furthermore, the WHO recommends biosecurity considerations include all laboratories of safety levels 3 and 4.

Legal foundations of biosecurity requirements can be found in Annex II of the Biological Agents Regulation

(Control of access to biological agents) and in the Security Screening Act (Reliability of staff members).

II. Biosafety and Biosecurity

From a legal point of view „biosecurity and biosafety“ are regulated by different areas of law depending on the focus:

- *Occupational health and protection (Biological Agents Regulation - BioStoffV)*
- *Infection protection (Infection Protection Act - IfSG)*
- *Genetic engineering (Genetic Engineering Act - GenTG)*
- *Animal diseases (Animal Pathogen Regulation - TierSeuchErV)*
- *Hazardous materials (e.g. UN,IATA,IMO,ADR)*
- *Anti-terrorism measures and protection of critical infrastructures (Security Screening Act - SÜG)*

Pure „security“ measures are not included in these regulations, as legal regulations cover risks and threats arising from free research only to a limited extent.

II. Biosafety and Biosecurity

Elements of a biosecurity program

1. *Assessment of the risk of misuse ("Threat assessment")*
2. *Protection, inventory, and control of biological agents*
3. *Security screening of staff members*
4. *Access control*
5. *Information security*
6. *Transfer and transport security*

II. Biosafety and Biosecurity

The freedom of scientific research is protected by Art. 5 Paragr. 3 of the German Basic Law is an essential basis for the increase of knowledge and for the progress and wealth of society.

Scientifically successful research requires transparency, in particular through the free exchange of information and the publication of research findings.

II. Biosafety and Biosecurity

Freedom of knowledge-oriented basic research has enabled scientific developments that have made it possible to eradicate fatal diseases through the production of vaccines. Biological knowledge however can also be misused (e.g. the anthrax letters).

A newly arising problem is that not only the agents can be used in different ways, but also knowledge, the information itself, can be misused in the context of synthetic biology.

III. Freedom of scientific research, ethical responsibility, and knowledge transfer

Due to their knowledge, experience and freedom, all scientists bear a particular ethical responsibility that goes beyond these basic legal obligations and regulations.

The scientist must be aware of the risk of misuse of research findings. In critical cases they must decide personally if a research activity can be justified ethically based on their knowledge and experience. The benefits of the research must be weighed up against the risks for human dignity, life, and other important goods. Risk analysis and decision making are supported by a Committee for Ethics in Security Relevant Research (CER)*, which should be established at the respective research institution.

At the FLI, the "Institutional Biorisk Committee" acts in this capacity.

* CER = KEF: Kommission für die Ethik sicherheits-relevanter Forschung

III. Freedom of scientific research, ethical responsibility, and knowledge transfer

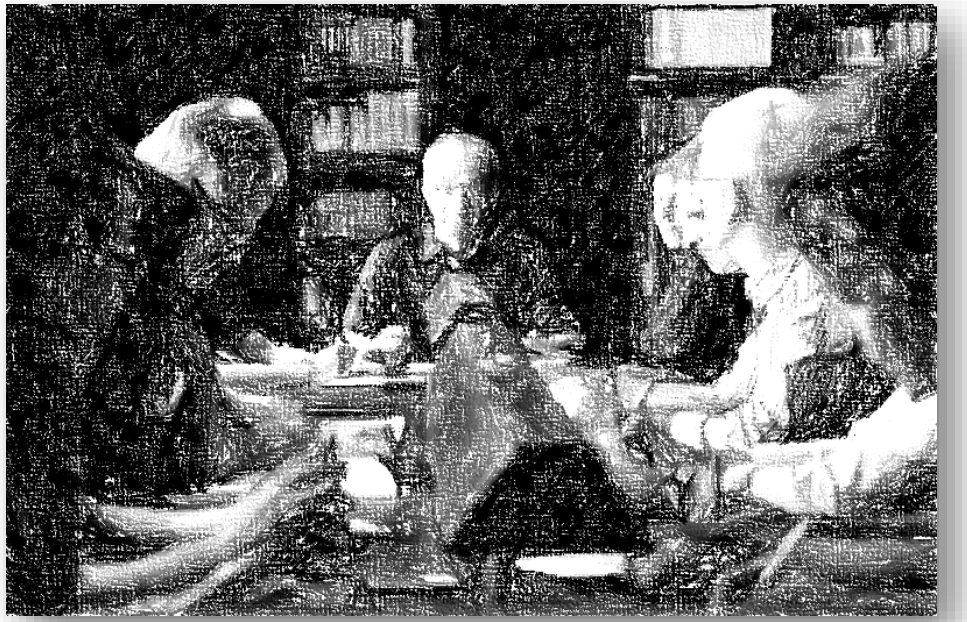
The “Committee for Ethics in Security Relevant Research” at the FLI has the following tasks:

a) Identify essential security relevant risks for human dignity, life, health, freedom, property, environment, or peaceful coexistence.

b) Discuss and assess ethical and legal aspects of security relevant research projects, when knowledge, products or technologies with DURC potential are generated.

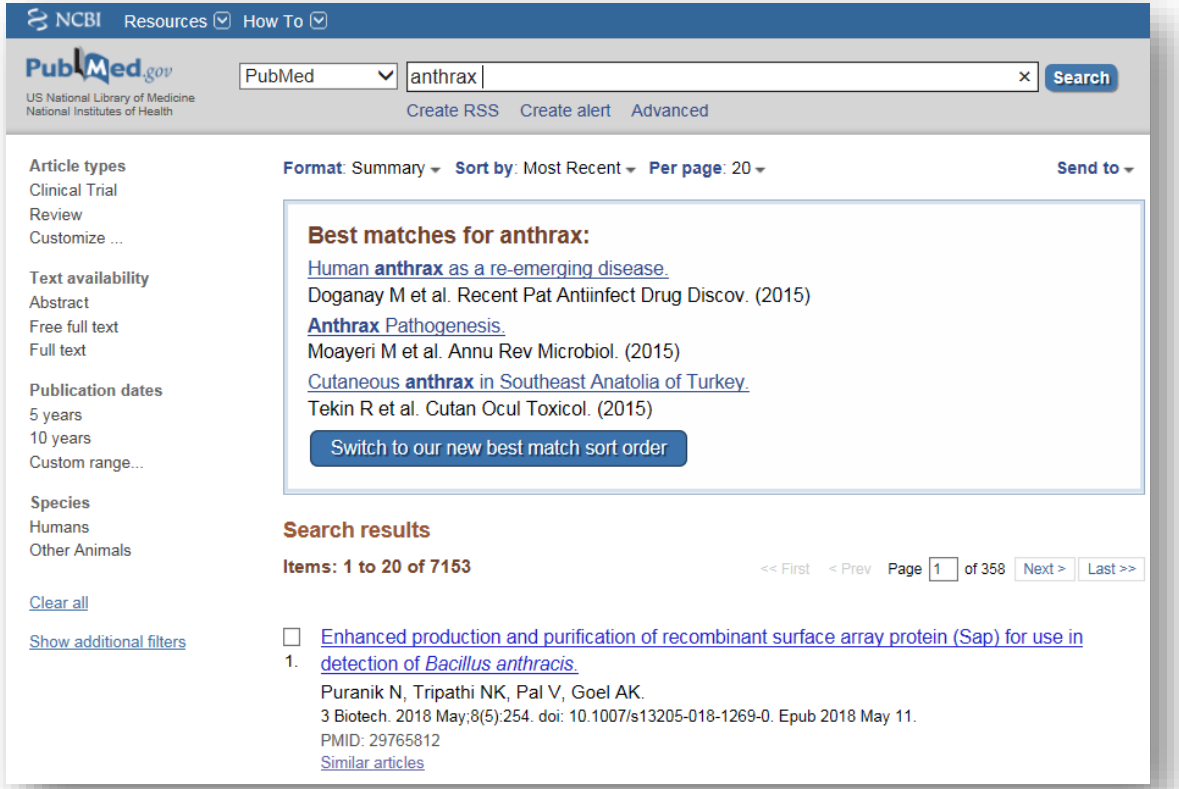
c) Increase awareness of security relevant aspects of research.

Independent of discussion by the Committee, the scientist remains fully responsible for their own research activities.



III. Freedom of scientific research, ethical responsibility, and knowledge transfer

The rapid progress of science, where a broad spectrum of easily accessible technologies and methods is available and where novel scientific insights are disseminated globally via a multitude of channels and on various levels has caused reflection and discussion on guidelines for regulation of the transfer of information, knowledge, tools, technologies, materials, and products generated by research activities. It also raises principal questions with regard to the freedom of research and its potential restriction.



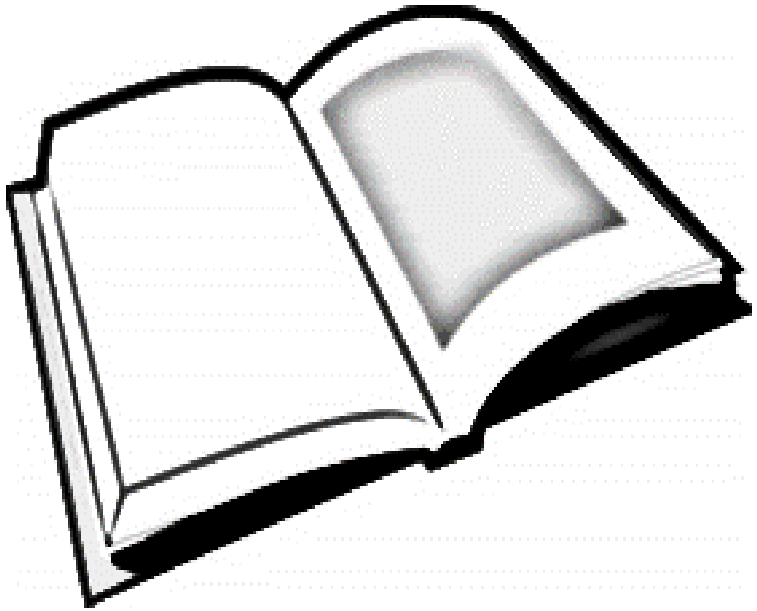
III. Freedom of scientific research, ethical responsibility, and knowledge transfer

It is evident that in these cases security interests may interfere with the interest to publish research results.

On the other hand, publication of results can also support the development of protective measures (e.g. vaccine development).

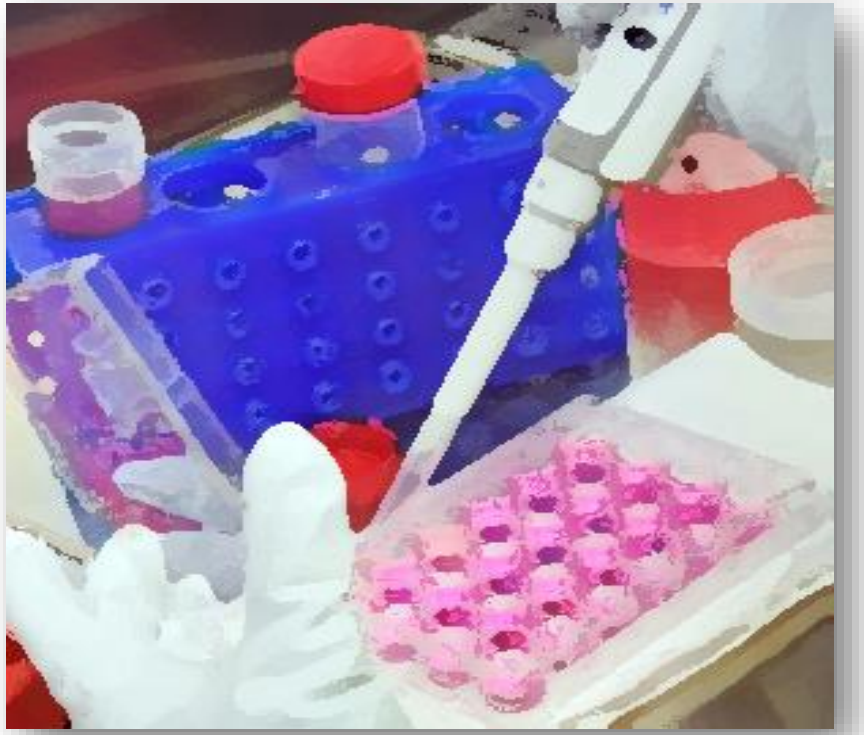
→ case scenarios I + II

Suppression of information can hamper effective protection measures against misuse by totalitarian regimes, terrorist groups, organized crime groups and lone perpetrators.



IV. Biosecurity-relevant research

The mechanisms of action of bacterial toxins, the processes of adhesion and entry, replication and spread of highly pathogenic viruses in host cells or the interaction of cellular and humoral immunity with highly virulent microorganisms are examples of pathogenesis research topics that are of great relevance for both, basic research and the development of novel diagnostics, therapeutics, and vaccines.



IV. Biosecurity-relevant research

In the USA, the following 15 pathogens (https://www.phe.gov/s3/dualuse/Pages/InstitutionalOversight.aspx) are considered as especially critical with regard to „dual use“ and experiments with these pathogens in non-attenuated form require **thorough consideration for DURC aspects**:

1. Avian influenza virus (highly pathogenic)
2. Bacillus anthracis
3. Botulinum neurotoxin
4. Burkholderia mallei
5. Burkholderia pseudomallei
6. Ebola virus
7. Foot-and-mouth disease virus
8. Francisella tularensis
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of C. botulinum
13. Variola major virus
14. Variola minor virus
15. Yersinia pestis

IV. Biosecurity-relevant research

Such biosecurity relevant research of concern includes all research activities in the field of life sciences which are likely to generate **knowledge**, **products**, or **technologies** that have the potential to be misused immediately by third parties – e.g. as weapons of mass destruction – with the aim to harm the life or health of a large number of humans (pandemic agents), animals or the environment (bio- and agroterrorism) or other important legal rights. There are various examples of past **research activities** in the field of life sciences that pose **significant considerations with regard to DURC:**

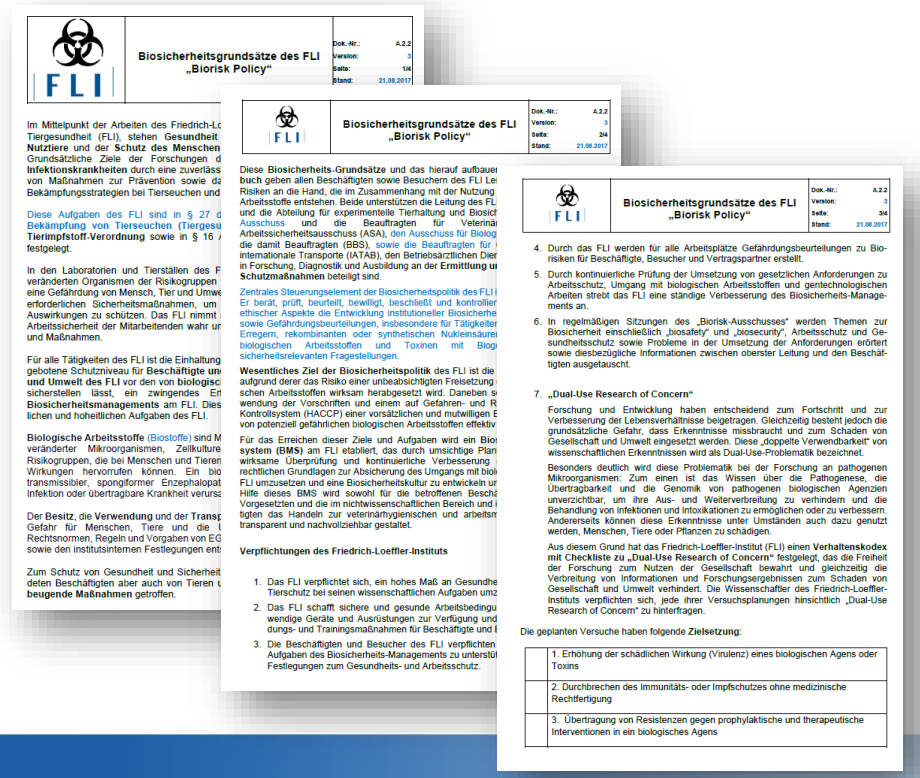
- **Aerosolization of particles using porous carrier systems (1997)**
- **Development of a „killer“ mousepox virus (2001)**
- **Chemical synthesis of a poliovirus genome (2002)**
- **Enhancement of a pathogenicity factor of vaccinia virus (2002)**
- **Reconstruction of the 1918 Spanish influenza pandemic virus (2005)**
- **Multiple antibiotic resistance of Yersinia pestis (2006)**
- **Synthesis of artificial viruses and nanorobots (2012)**
- **Alteration of the host spectrum and increase of the transmissibility of H5N1 influenza virus (2012)**

IV. Biosecurity-relevant research

Watch the video “Dual Use Research: A Dialogue”
https://www.youtube.com/watch?v=0yS1ur24j40

a) “Dual use” - Categories „Gain of function“

Useful research results and technologies can be misused. Dual-use categories could be research activities with pathogenic microorganisms with the following objectives:


Biosicherheitsgrundsätze des FLI
„Biorisk Policy“

Dok.-Nr.: A.2.2
Version: 3
Seite: 1/6
Stand: 21.08.2017

Im Mittelpunkt der Arbeiten des Friedrich-Lo
Tiergesundheit (FLI), stehen **Gesundheit**
Nutztiere und der **Schutz des Menschen**
Grundsätzliche Ziele der Forschungen d
Infektionskrankheiten durch eine zuverlässi
von Maßnahmen zur Prävention sowie da
Bekämpfungsstrategien bei Tierseuchen und

Diese Aufgaben des FLI sind in § 27 d
Bekämpfung von Tierseuchen (Tiergesu
Tierimpfstoff-Verordnung sowie in § 16 A
festgelegt.

In den Laboratorien und Tierställen des F
veränderten Organismen der Risikogruppen
eine Gefährdung von Mensch, Tier und Umwe
erforderlichen Sicherheitsmaßnahmen, um
Auswirkungen zu schützen. Das FLI nimmt
Arbeitssicherheit der Mitarbeitenden wahr ur
und Maßnahmen.

Für alle Tätigkeiten des FLI ist die Einhaltung
gebotene Schutzniveau für **Beschäftigte un**
und Umwelt des FLI vor den von biologisc
sicherstellen lässt, ein zwingendes Er
Biosicherheitsmanagements am FLI. Dies
lichen und hoheitlichen Aufgaben des FLI.

Biologische Arbeitsstoffe (Biostoffe) sind M
veränderter Mikroorganismen, Zellkulture
Risikogruppen, die bei Menschen und Tieren
Wirkungen hervorrufen können. Ein bio
transmissibler, spongiformer Enzephalopat
Infektion oder übertragbare Krankheit verurs

Der **Besitz**, die **Verwendung** und der **Transp**
Gefahr für Menschen, Tiere und die
Rechtsnormen, Regeln und Vorgaben von EG
sowie den institutsinternen Festlegungen ent

Zum Schutz von Gesundheit und Sicherheit
deten Beschäftigten aber auch von Tieren
beugende Maßnahmen getroffen.

Biosicherheitsgrundsätze des FLI
„Biorisk Policy“

Dok.-Nr.: A.2.2
Version: 3
Seite: 2/6
Stand: 21.08.2017

Diese **Biosicherheits-Grundsätze** und das hierauf aufbauen
buch geben allen Beschäftigten sowie Besuchern des FLI Le
Risiken an die Hand, die im Zusammenhang mit der Nutzung
Arbeitsstoffe entstehen. Beide unterstützen die Leitung des FL
und die Abteilung für experimentelle Tierhaltung und Biosich
Ausschuss und die Beauftragten für Veterinä
Arbeitssicherheitsausschuss (ASA), den Ausschuss für Biolog
die damit Beauftragten (BBS), sowie die Beauftragten für
internationale Transporte (IATAB), den Betriebsärztlichen Dien
in Forschung, Diagnostik und Ausbildung an der **Ermittlung u**
Schutzmaßnahmen beteiligt sind.

Zentrales Steuerungselement der Biosicherheitspolitik des FLI i
Er berät, prüft, beurteilt, bewilligt, beschließt und kontrolliert
ethischer Aspekte die Entwicklung institutioneller Biosicherhe
sowie Gefährdungsbeurteilungen, insbesondere für Tätigkeiter
Erregern, rekombinanten oder synthetischen Nukleinsäure
biologischen Arbeitsstoffen und Toxinen mit Biog
sicherheitsrelevanten Fragestellungen.

Wesentliches Ziel der Biosicherheitspolitik des FLI ist die
aufgrund derer das Risiko einer unbeabsichtigten Freisetzung
schen Arbeitsstoffen wirksam herabgesetzt wird. Daneben s
wendung der Vorschriften und einem auf Gefahren- und R
Kontrollsystem (HACCP) einer vorsätzlichen und mutwilligen E
von potenziell gefährlichen biologischen Arbeitsstoffen effektiv

Für das Erreichen dieser Ziele und Aufgaben wird ein Bior
system (BMS) am FLI etabliert, das durch umsichtige Plan
wirksame Überprüfung und kontinuierliche Verbesserung
rechtlichen Grundlagen zur Absicherung des Umgangs mit biol
FLI umzusetzen und eine Biosicherheitskultur zu entwickeln ur
Hilfe dieses BMS wird sowohl für die betroffenen Beschä
Vorgesetzten und die im nichtwissenschaftlichen Bereich und i
tigten das Handeln zur veterinärhygienischen und arbeitsm
transparent und nachvollziehbar gestaltet.

Verpflichtungen des Friedrich-Loeffler-Instituts

1. Das FLI verpflichtet sich, ein hohes Maß an Gesundhe
Tierschutz bei seinen wissenschaftlichen Aufgaben umz
2. Das FLI schafft sichere und gesunde Arbeitsbedingu
wendige Geräte und Ausrüstungen zur Verfügung und
dungs- und Trainingsmaßnahmen für Beschäftigte und
3. Die Beschäftigten und Besucher des FLI verpflichten
Aufgaben des Biosicherheits-Managements zu unterstü
Festlegungen zum Gesundheits- und Arbeitsschutz.

Biosicherheitsgrundsätze des FLI
„Biorisk Policy“

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4. Durch das FLI werden für alle Arbeitsplätze Gefährdungsbeurteilungen zu Bio-risiken für Beschäftigte, Besucher und Vertragspartner erstellt.
5. Durch kontinuierliche Prüfung der Umsetzung von gesetzlichen Anforderungen zu Arbeitsschutz, Umgang mit biologischen Arbeitsstoffen und gentechnologischen Arbeiten strebt das FLI eine ständige Verbesserung des Biosicherheits-Manage-ments an.
6. In regelmäßigen Sitzungen des „Biorisk-Ausschusses“ werden Themen zur Biosicherheit einschließlich „biosafety“ und „biosecurity“, Arbeitsschutz und Ge-sundheitsschutz sowie Probleme in der Umsetzung der Anforderungen erörtert sowie diesbezügliche Informationen zwischen oberster Leitung und den Beschäf-tigten ausgetauscht.
7. **„Dual-Use Research of Concern“**

   Forschung und Entwicklung haben entscheidend zum Fortschritt und zur Verbesserung der Lebensverhältnisse beigetragen. Gleichzeitig besteht jedoch die grundsätzliche Gefahr, dass Erkenntnisse missbraucht und zum Schaden von Gesellschaft und Umwelt eingesetzt werden. Diese „doppelte Verwendbarkeit“ von wissenschaftlichen Erkenntnissen wird als Dual-Use-Problematik bezeichnet.

   Besonders deutlich wird diese Problematik bei der Forschung an pathogenen Mikroorganismen: Zum einen ist das Wissen über die Pathogenese, die Übertragbarkeit und die Genomik von pathogenen biologischen Agenzien unverzichtbar, um ihre Aus- und Weiterverbreitung zu verhindern und die Behandlung von Infektionen und Intoxikationen zu ermöglichen oder zu verbessern. Andererseits können diese Erkenntnisse unter Umständen auch dazu genutzt werden, Menschen, Tiere oder Pflanzen zu schädigen.

   Aus diesem Grund hat das Friedrich-Loeffler-Institut (FLI) einen **Verhaltenskodex mit Checkliste zu „Dual-Use Research of Concern“** festgelegt, das die Freiheit der Forschung zum Nutzen der Gesellschaft bewahrt und gleichzeitig die Verbreitung von Informationen und Forschungsergebnissen zum Schaden von Gesellschaft und Umwelt verhindert. Die Wissenschaftler des Friedrich-Loeffler-Instituts verpflichten sich, jede ihrer Versuchsplanungen hinsichtlich „Dual-Use Research of Concern“ zu hinterfragen.

Die geplanten Versuche haben folgende **Zielsetzung**:

1. Erhöhung der schädlichen Wirkung (Virulenz) eines biologischen Agens oder Toxins
2. Durchbrechen des Immunitäts- oder Impfschutzes ohne medizinische Rechtfertigung
3. Übertragung von Resistenzen gegen prophylaktische und therapeutische Interventionen in ein biologisches Agens

Code of conduct with check list on criteria for „Dual-Use Research of Concern“

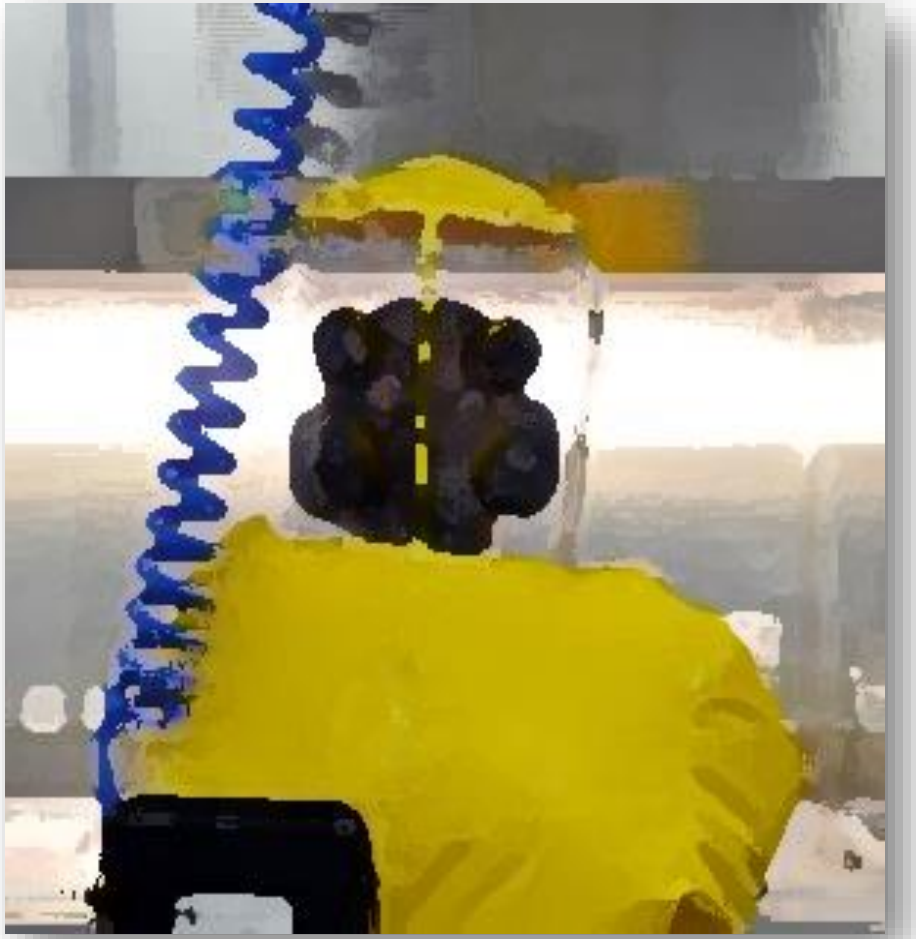
1. **Enhances the harmful effect (virulence) of a biological agent or toxin**
2. **Disrupts immunity or effectiveness of immunization without clinical justification**
3. **Confers resistances against prophylactic and therapeutic interventions to a biological agent**
4. **Increases the stability (tenacity), transmissibility (infectivity) or the ability to disseminate a biological agent or toxin („weapons-grade quality“)**
5. **Alters the host range or tropism of a biological agent or toxin**
6. **Enhances the susceptibility of a host population**
7. **Generates novel pathogenic agents or toxins or reconstitutes eradicated or extinct biological agents (synthetic genomes)**
8. **Facilitates the ability to bypass detection methods**

(source: Biosafety and biosecurity principles of the FLI, „Biorisk Policy“)

a) “Dual use” - Categories „Gain of function“

DURC is usually associated with an experimental setup in which the biological properties of a pathogen are altered. Thus, e.g. the ability to replicate, the transmissibility or the host range of critical pathogens are modified experimentally. Among other things, these changes could lead to an increased pathogenicity or to an altered host tropism of a pathogen.

Analogously, this also applies in particular to experiments with other naturally occurring high-risk viruses of risk groups 3 and 4, such as smallpox, Ebola and Lassa viruses, especially if effective prevention or treatment is not possible.



a) “Dual use” - Categories „Gain of function“

Gain of Function (GOF) generally refers to experiments in which an organism is equipped artificially (e.g. through genetic engineering) with a new function or property. Of particular concern are GOF experiments that result in the artificial enhancement of a pathogen beyond its naturally occurring wildtype character. (Accordingly, "GOF" should always indicate precisely what is meant, for example "GOF experiments in HPAI viruses").

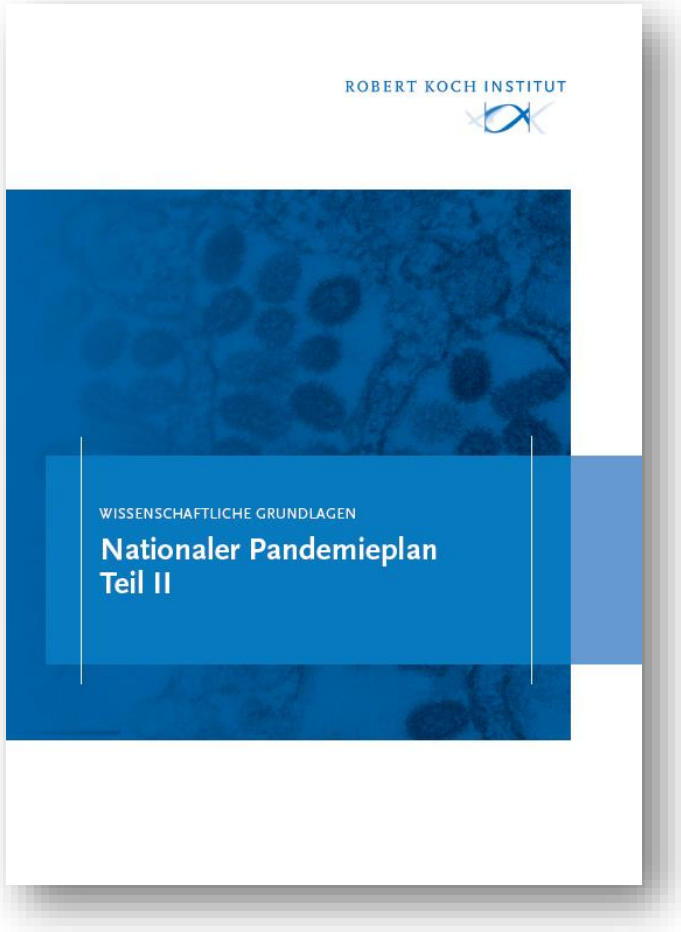
These experiments on HPAIV H5N1 were discussed intensively with regard to the problem of „GOF“ (→ case scenario I):

1. Herfst,Fouchier et al.(2012). Airborne transmission of influenza A/H5N1 virus Between ferrets. Science, 336(6088), 1534-1541.
2. Imai, Kawaoka et al. (2012) Experimental adaptation of an influenza H5 HA confers respiratory droplet transmission to a reassortant H5 HA/H1N1 virus in ferrets. Nature 486(7403), 420-428.

a) “Dual use” - Categories „Gain of function“

Here, the scientist is particularly called upon to justify the benefits of these DURC projects, as in these cases, there is a danger that severe, perhaps incurable diseases could be spread widely (pandemic) not only by unintentional escape, but also by misuse of biological agents.

However, the omission of certain research activities can also entail significant risks, for example if a vaccine against an imminent epidemic has to be found.



Case scenario I:
Engineering Bird Flu (H5N1): vaccine or weapon

In 2012, experiments with influenza viruses were discussed. Researchers manipulated HPAIV in a targeted way to detect mutations needed to make avian influenza viruses dangerous for humans as zoonotic agents, and to find out which genome changes are necessary to facilitate human-to-human transmissibility. For this purpose, host range and transmissibility were altered deliberately, the pathogen thus "adapted" for humans in order to better understand infection and to facilitate the development of vaccines. When this information became public, fears were raised of an inadvertent escape or deliberate release of this pathogen, possibly dangerous for humans, from the safety labs.

This discussion made clear that biomedical research can represent a dilemma for evaluation by society that is not easy to solve. It also became clear that the usual reaction to control the danger by restriction and prohibition is not effective, because the actual problem is not the material whose distribution is to be prevented. It is rather the knowledge and the information (here the sequence of a viral genome) which are ethically ambivalent. The decisive factor is therefore the context in which the knowledge is used.

(DZIF/drc)

Case scenario I:
Engineering Bird Flu (H5N1): vaccine or weapon

It became obvious that with these findings and the biotechnological methods available today, the synthesis of a mutant H5N1 influenza virus is possible without much effort. This leads to the conclusion that also terrorists could get a bioweapon in their hands.

The controversy in the discussion now turned against both, the experiments and the publication of the research results. Various social groups such as scientists, politicians, ethicists and lawyers struggled to determine how these experiments should be evaluated and what consequences should be deduced from them.

The scientists' references to the importance of their research for flu prophylaxis could not refute the worries. It was considered to be almost negligent to even intend to publish these research results – this would make this essential information accessible for terrorists as a blueprint for the production of a killer virus. However, the fact that the publication of the results is a crucial step in reviewing the quality of research by the research community and better categorizing its relevance was somewhat lost in the political debates on bioterrorism. (DZIF/drc)

b) „Dual-use“ dilemma

The dual use of research results for both useful and harmful purposes constitutes the dual-use dilemma and makes it difficult in many areas to make a clear distinction between "good" and "bad" research. For instance in the case of defense science between research for defense and research for offense, and between research results for peaceful and for terrorist purposes.

Especially in knowledge-oriented basic research, results are often unpredictable and research results cannot per se be classified as "good" or "bad". The correct assessment of such research is usually difficult because of yet unknown later chains of action. Furthermore, for the scientist, society, but also for the institutional committee involved, the assessment of consequences and risks arising from the potential subsequent actions of mostly still unknown “wrong” persons or institutions are extremely challenging and usually not trivial.

b) „Dual-use“ dilemma

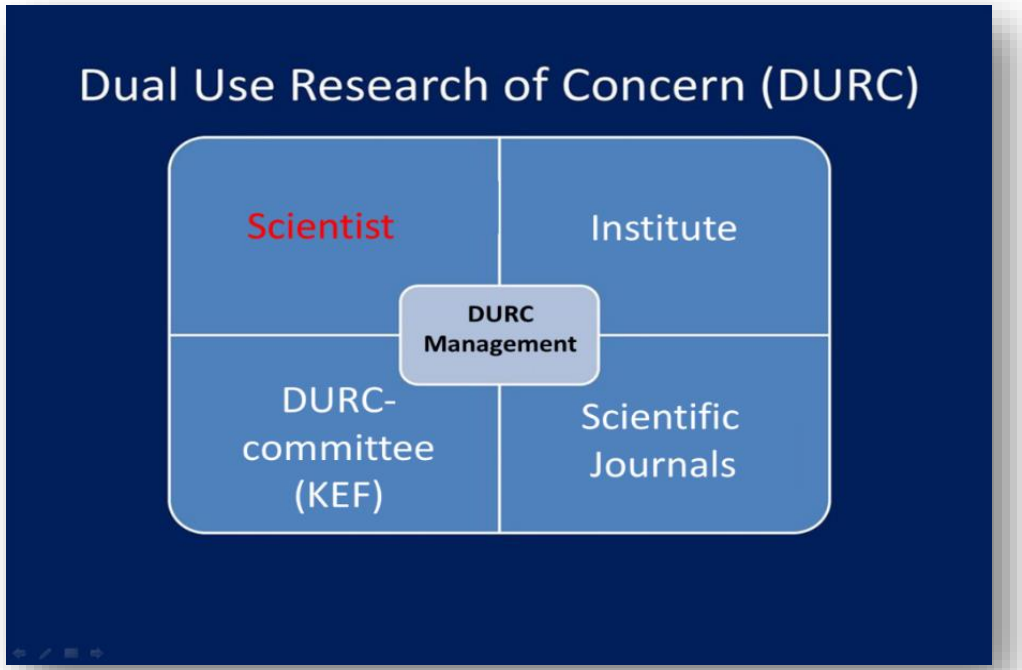
More clearly, the DURC criteria address the intended use of weapons of mass destruction because they always violate international humanitarian law.

A Bioweapon consists of a "Dirty Dozen" biological agent as a warfare agent and an operational system that allows for selective release the substance at a desired time in a desired location in a targeted manner thereby facilitating its entry into humans, animals or plants and thus increasing its infectivity or damaging effect. A well-known historical example of this is the Tartar attack on the city of Caffa in the Crimea in 1346, when corpses infected with Yersinia pestis were catapulted into the city to spread the plague among the opponents and thereby break their resistance.

Tartar attack on the city of Caffa, 1346.
Picture: University of Edinburgh

c) DURC management

Various players are required to implement a successful DURC management concept:



It is conceivable that decision processes in this DURC management are processed and displayed in the sense of a **workflow**:

1. Clarification by the leader of a research project whether one of the 15 listed biological agents is used or/and one of the 8 DURC criteria are met.

2. Institutional evaluation (expert commission, Institutional Ethical Committee) whether at least one of the eight DURC-relevant criteria is met or can arise.

3. If yes, risk-benefit analysis and, if possible, suggestions for risk reduction.

4. Documentation of this process

V. Recommendations on ethically justifiable research

a) Ethics of science

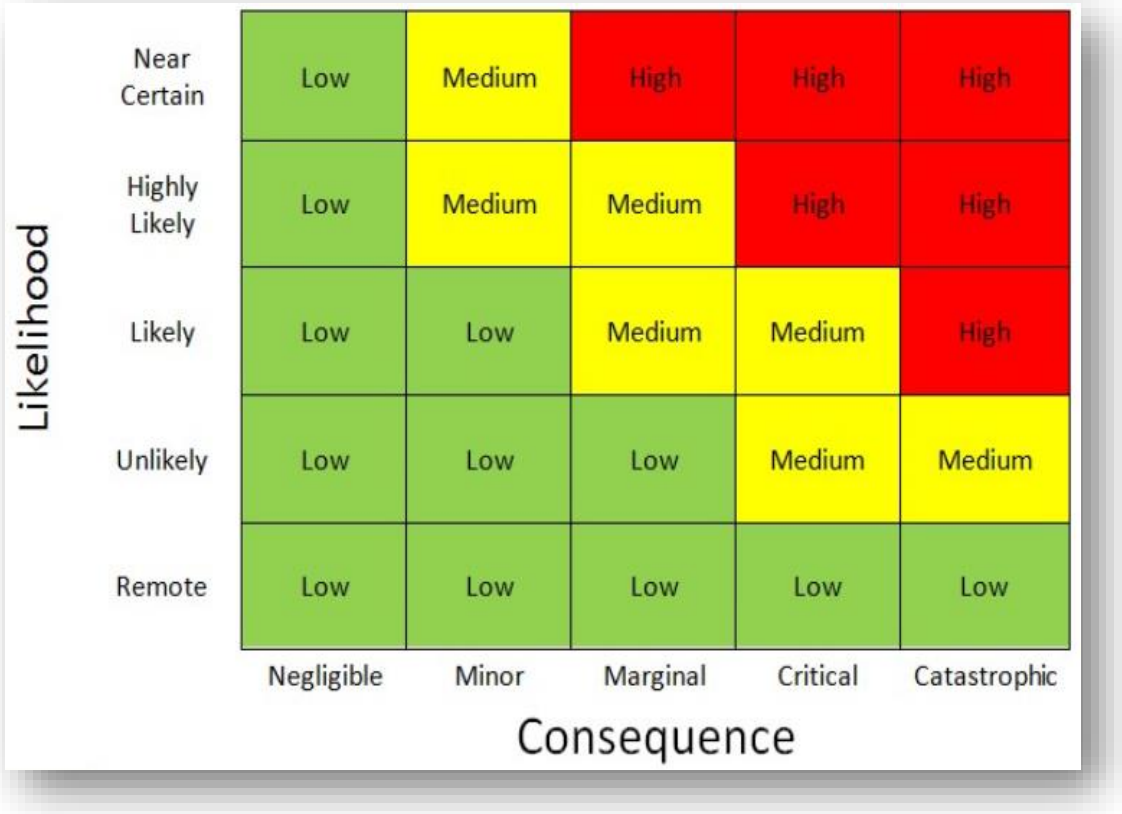
In making decisions, life scientists must not content themselves with complying with the legal foundations for "good microbiological practice", but must also observe ethical principles. In doing so, the benefits of research and its risks and dangers for human dignity, life, health, freedom, and property, the protection of the environment and other goods should be weighed against each other.

The fact that science projects have become increasingly extensive over the last few decades and are increasingly carried out in networks with numerous participating institutions involved causes an anonymization of scientific achievements and consequently also a diffusion of responsibility.

V. Recommendations on ethically justifiable research

b) Risk analysis

The researcher should analyze the possible risks of their research activities in advance. This is the prerequisite for responsible research. The consequences of, as well as the potential for use and misuse of their work by third parties, and the controllability of these risks are to be considered. At the same time, risks that could result from the omission of a research activity must also be analyzed.

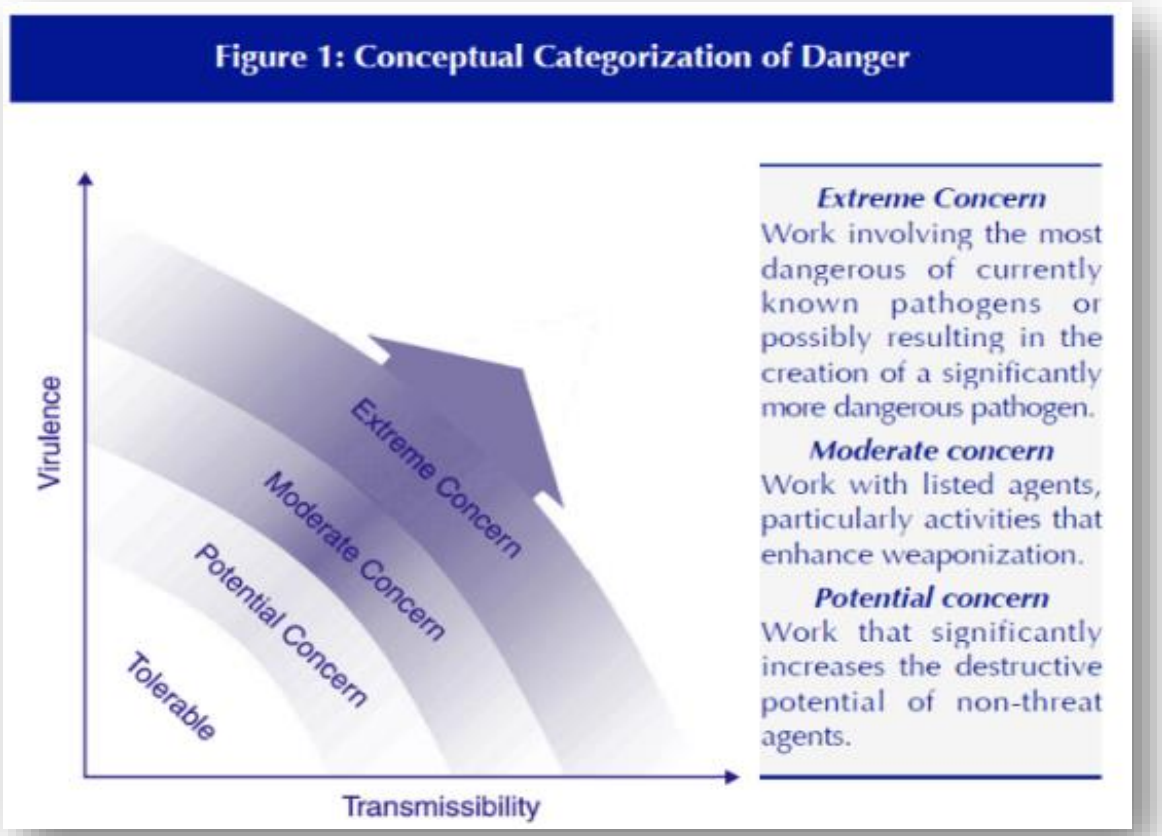


V. Recommendations on ethically justifiable research

b) Risikoanalyse

This very generalized obligation is difficult to realize: For every new research project there is at least the trivial possibility that its results could be misused by third parties at some point in the future - this abstract analysis alone therefore does not raise any dual-use concerns. Clarification is required as to where, in concrete terms, risks might be seen.

The aim of a risk analysis is to determine the risks of a technology scientifically i.e. the probability that damage might occur and the likely extent of such damage.



https://www.leopoldina.org/fileadmin/redaktion/Ueber_uns/Kooperationen/2016-04-14_DualUse_Merkel.pdf

V. Recommendations on ethically justifiable research

b) Risikoanalyse

This may result in the omission of certain research activities with an uncontrollable and disproportionate risk potential. This analysis may also lead to security measures (e.g. to prevent the release or theft of dangerous substances from laboratories) or the confidentiality of research results through physical, organizational and information technology measures (e.g. encryption of data).

V. Recommendations on ethically justifiable research

c) Minimization of risks

Researchers and the scientists involved in their projects should minimize the risks associated with the realization and use of their work as much as possible. Project leaders should address this issue in their DFG applications, and the review boards should make suggestions on how to handle the research activity applied for. Risk minimization is however explicitly necessary in view of risks to human life and health and protection of the environment.

In the case of research that is in danger of being misused, the staff members and cooperation partners must be selected carefully and under consideration of their reliability and their sense of responsibility (safety screening). In case of particular risks of dissemination of safety-related research results (for example in connection with weapons of mass destruction or export restrictions), cooperation with special counseling agencies, legal departments of research organizations or governmental security agencies (e.g. ZBS, BAFA, BSI) should be considered.

V. Recommendations on ethically justifiable research

c) Minimization of risks

Although international cooperation is a fundamental principle of successful research, in individual cases it may be advisable to restrict cooperation or to renounce partners or staff members from certain countries as a part of risk minimization efforts. Information on countries where there is a risk of misuse of certain research results can also be found in national and international regulations and lists on export restrictions.

Delivery, packaging and transport, physical security:

Security measures to prevent the release or theft of hazardous material and organizational protective measures shall be taken into account as risk minimization measures, in particular with regards to the dispatch of dual-use material (e.g. FMD virus). These should include the examination of the consignee and logistics companies authorized to handle the actual transport.

V. Recommendations on ethically justifiable research

d) Evaluation of publications

In areas of high-risk research, the possible consequences arising from publication of the results should be assessed at an early stage. This is especially true when research results could lead to specific hazards or major damage without the need for additional knowledge and without complex implementation and application procedures.

Complete omission of communication and publication of the research results is only legitimate if other measures to prevent dangers are not available.

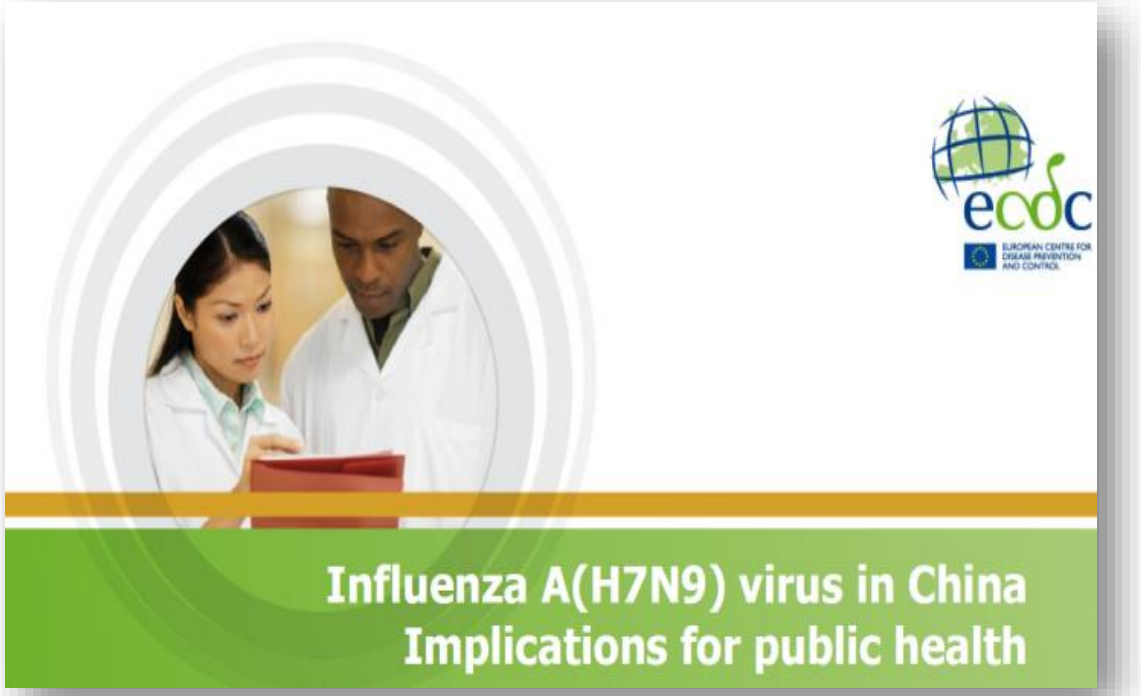
Particularly in government-funded and knowledge-based research, free exchange of information and, in particular, publication of the results are important factors for the gain of scientific knowledge and the progress of research. They also serve to facilitate transparency, reproducibility, control and thus quality assurance of the research process.

However, the dictates of transparency and communication do not exclude that the scientist minimizes certain biosafety risks of their research activities by publishing the results of their work with a time delay. In the case of research results with a high potential for misuse, the sub-results that are particularly relevant for misuse can in special cases be excluded from publication – which must be identified appropriately – or be published in an abbreviated form. In special cases, the researcher can only share individual results of their work with specific persons and thus control access to internal communication by unauthorized persons.

Case scenario II:
China jumps over its shadow: Influenza H7N9

Recent developments in China illustrate how important the access to information and the rapid flow of information are to

control outbreaks of infection. In spring 2013, the occurrence of severe infections with influenza virus H7N9 in China gave reason for major concern worldwide. It was feared that China, as in 2003 during the SARS outbreak, would apply a restrictive information policy that might delay control of the epidemic. However, the virus could be isolated rapidly from patient material and its genome could be sequenced by Chinese scientists and made accessible for influenza specialists on the internet. This openness enabled a quick reaction to the outbreak worldwide, among others by synthesis of a novel virus for vaccine production based on the published sequence. (DZIF/Drc)



VI. Biological weapons: threat, risks, and challenges

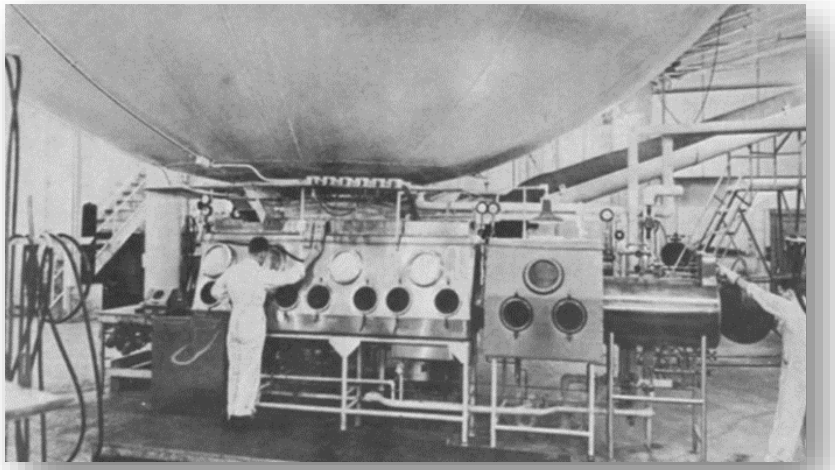
The discussion about biological weapons has been advanced by terrorist activities since September 11, 2001. The threat scenarios defined by risk analyses combine real findings about terrorism with the potential risks of natural disease outbreaks and possibilities for misuse of novel scientific and technological achievements. Inherent risks of basic research in the field of life sciences have expanded the spectrum of “dual use” for weapons purposes. In this context synthetic biology is an area that is a focus of international observation. Further, the risk of misuse of novel developments is rather seen as likely to be the result of state-sponsored activities, rather than of individuals. Responsible action by scientists and researchers therefore plays a key role in risk minimization. Codes of conduct are the means of choice to take on this responsibility.

On the Western Front 1917: German soldiers and a mule with gas masks. (© picture-alliance/akg)

VI. Biological weapons: threat, risks, and challenges

The Federal Foreign Office makes an important contribution to global defense against biological hazards with the German Partnership Program for Biological Safety and Health Security. According to the principle of dual use, biological substances or pathogens can be used by government and non-government groups alike for peaceful as well as for terrorist purposes.

The objectives of the program are, in particular, to reduce the risk of a release of biological agents (biosafety/biosecurity), to establish an early detection system for unusual outbreaks (surveillance) and to identify and characterize highly pathogenic biological pathogens in the environment. In addition, awareness of the partner countries of possible dangers is to be improved (awareness) and the implementation and reaction capacities of the national partner institutions are to be strengthened (capacity development).



“Project Whitecoat” - The Adventist Contribution to Biowarfare

Beck, WMM, 54. Jhrg. (3/2010; S. 74-78)
Strehle et al., WMM, 58. Jhrg. (2/2014; S. 42-46)

VI. Biological weapons: threat, risks, and challenges

The Biological Weapons Convention (BWC) prohibits the development, production, storage and transfer of biological weapons. The Convention does not directly prohibit the use of biological weapons, but refers to the Geneva Protocol of 1925, which makes this prohibition binding under international law. The first paragraph of Article I is the so-called General Purpose Criterion of the BTWC, which prohibits any use of biological agents for non-peaceful purposes. At the same time, any use of these agents for "preventive, protective or other peaceful purposes" is permitted. The important factor is the intention of use. As a result, there is no regulation of research by the BTWC.

https://www.giz.de/de/downloads/Deutsches_Biosicherheitsprogramm.pdf