



# Biosecurity — Freedom and Responsibility of Research

OPINION



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# 1 INTRODUCTION

## 1.1 Grounds for the Opinion

In 2012, a group of researchers in the USA and another in the Netherlands produced mutated variants of the avian influenza virus H5N1<sup>1</sup> that, in contrast to the wild type, could be transmitted between mammals (ferrets) through airborne transfer.<sup>2</sup> To date, H5N1 infection has rarely occurred in humans, and then only following close physical contact with infected poultry or contaminated surroundings.<sup>3</sup> However, where infection occurs the results are frequently fatal. The aim of the research projects was to identify mutations that render the virus more easily transmissible between humans and therefore perhaps more dangerous for humans, with a view to achieving a better state of preparedness for such changes that might occur in nature.

The studies provoked a general debate as to whether experiments designed to make a pathogen more dangerous should be encouraged at all, whether it is permissible to conduct them and publish their findings and whether it may be appropriate to place limitations on them to prevent the unintentional release of pathogens from laboratories as well as misuse, for example by bioterrorists.<sup>4</sup> Both manuscripts were examined by the US National Science Advisory Board for Biosecurity (NSABB) prior to publication. The NSABB initially recommended withholding important methods and data contained in the manuscripts from publication for security reasons and

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1 The avian influenza virus belongs to the influenza A set of viruses. The designation influenza A/H5N1 refers to the specific variations of the proteins haemagglutinin (HA) and neuraminidase (NA) that contribute significantly to the infectivity of the virus.

2 Cf. Herfst et al. 2012; also Imai et al. 2012.

3 Cf. World Health Organization 2013a.

4 For a description of the studies, the debate and the differences of opinion to which it led, see Fauci/Collins 2012.

to prevent misuse. This recommendation in turn was the initiator of public discussions, mainly in the USA and European states, that addressed fundamental questions concerning freedom of research and possible justifications for restricting it. Following a period of consultation, the World Health Organization (WHO) reached a position, whilst expressing misgivings, in favour of complete publication,<sup>5</sup> and the NSABB changed its original recommendation, finally agreeing to publication of the manuscripts in revised form<sup>6</sup>.

Nevertheless, these developments raised questions involving appropriate rules for the funding, monitoring and publication of dual use research of concern,<sup>7</sup> and set international discussion processes in motion.<sup>8</sup> For instance, from January 2012 until January 2013, influenza researchers suspended research that could make avian influenza more dangerous, declaring a voluntary moratorium in order to discuss the way to proceed.<sup>9</sup> In the USA, the research that has now resumed has become subject to new regulations on biosecurity (cf. Section 8.1.1).<sup>10</sup> A conference organized by the WHO in 2013 on the question of how to deal with dual use research of concern concluded, amongst other things, that there was a need for continuing deliberation on the matter.<sup>11</sup>

In Europe, scientific associations and virologists approached the President of the EU Commission and the Commissioners responsible for research, health, justice and

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5 Cf. World Health Organization 2012a; cf. National Science Advisory Board for Biosecurity 2012. The WHO conference attracted a degree of criticism as being an assembly biased towards the areas of public health and influenza research, without a representative number of biosecurity experts. Some observers regarded it therefore to be a foregone conclusion that the main results of the meeting provided, on the whole, support for the scientists in their desire to pursue the H5N1 experiments further. Cf. Kelle 2012.

6 American Association for the Advancement of Science et al. 2012, 10.

7 Cf. Kelle 2012. Cf. also Nature Publishing Group 2013 and Maher 2012.

8 Cf. for example Royal Society 2012a; or also Matchett/Mazza/Kendall 2013.

9 Cf. Fouchier et al. 2012.

10 For a detailed treatment of the questions surrounding research on influenza viruses that remain the subject of debate, and how it is being discussed especially in the USA, see Matchett/Mazza/Kendall 2013.

11 Cf. World Health Organization 2013b.

consumer protection in December 2013 and called for an international conference to be held with the aim of establishing a scientific foundation for the political and legal decision-makers in the EU and its member states with respect to such experiments, and developing better means of estimating the associated risks and benefits of such research.<sup>12</sup>

Prompted by the current discussion, and in view of the complexity of the legal, ethical and political questions raised by biosecurity-relevant research, the German Federal Government commissioned the German Ethics Council to draft an Opinion on the subject of biosecurity and freedom of research. The main area of the Council's remit covered the questions as to whether the legal framework and codes of conduct in the sciences and in the private sector that are currently in place in the German context constitute suitable and sufficient normative instruments, and whether they provide an adequate basis for dealing with research funding applications. The German Ethics Council has made use of this assignment to subject the area of biosecurity-relevant research to a systematic scientific, ethical and legal analysis and issue recommendations for future dealings with such research and its funding.

## 1.2 Fundamental terms

*Biosecurity* refers to the systematic protection of humans, animals, plants and the environment from hazards that may arise in connection with *biological agents*.<sup>13</sup> In the following text, the term biological agents will be used to refer to microorganisms<sup>14</sup>,

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12 Cf. letter of the European Society for Virology of 16 October 2013 (available online at: [http://www.eusv.eu/pdf/ESV%20letter%20on%20Gain%20of%20function\\_GOF\\_research%20in%20Virology.pdf](http://www.eusv.eu/pdf/ESV%20letter%20on%20Gain%20of%20function_GOF_research%20in%20Virology.pdf) [2014-04-01]) as well as the response from the Foundation for Vaccine Research of 18 December 2013 (available online at: [http://www.nature.com/polopoly\\_fs/7.14586!/file/vaccine%20foundation%20letter.pdf](http://www.nature.com/polopoly_fs/7.14586!/file/vaccine%20foundation%20letter.pdf) [2014-04-01]) to the EU Commission.

13 Cf. also Meyerson/Reaser 2002.

14 Microorganisms include "all cellular or non-cellular microbiological entities that have the capacity to reproduce or pass on genetic material", such as

toxins and other biological substances that are capable of damaging vital physiological functions.<sup>15</sup> Therefore the field of *microbiology* is one of the main areas of relevance from the point of view of biosecurity. As the science of microorganisms, it includes their genetic engineering, the artificial production of their components by means of genetic engineering, synthetic biology and the study of the toxins produced by them.

In German, the term *Biosicherheit* is used in two senses: In some cases it corresponds with the English-language term *biosafety* and refers to the protection of human life or health, the environment or other important legal interests against unintentional harm caused by working with microorganisms and toxins, for instance through their accidental release from a laboratory.<sup>16</sup> Such risks and hazards are already reduced by means of legally binding safety regulations that prescribe various measures, for example ones covering laboratory safety and occupational safety. However, *Biosicherheit* is also used where the English term *biosecurity* applies: for matters concerning the protection of humans, animals, the environment and other goods against the misuse of biological agents to cause

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bacteria, algae, fungi, protozoa and viruses. This definition corresponds to that laid down in Section 2, Para. 2 of the *Biostoffverordnung (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit biologischen Arbeitsstoffen, BioStoffV)* (Ordinance on Security and Health Protection in Activities Involving Biological Agents) of 15 July 2013 (Federal Law Gazette I p. 2514), specifically Subsection 5.3.2.

- 15 Whereas biological agents and toxins are dealt with separately in the Biological Weapons Convention, current usage of the term biological agent generally encompasses both potentially harmful microorganisms as well as the toxins produced by them as well as other hazardous substances related to biological weapons. The term *biological agent* covers more than the term *biological substance* as defined in the BioStoffV (see fn. 14 and Subsection 5.3.2), in that the BioStoffV does not include bioregulators in particular. Bioregulators are not explicitly mentioned in the lists of potential biological and chemical weapons, but are regarded as potential weapons in the context of the Biological and Chemical Weapons Conventions, see Subsection 5.2.1.
- 16 World Health Organization 2004, 47: “‘Laboratory Biosafety’ is the term used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release”.

harm, as in acts of terrorism.<sup>17</sup> In this connection, the use of biological agents as *bioweapons* is of particular relevance. The risks involved include the misuse of information about micro-organisms, for instance the misuse of plans and methods to reconstruct harmful, naturally occurring or artificially manufactured biological agents. As information is immaterial and can be disseminated very easily by digital means, questions about biosecurity risks arise not only during the execution of research and the publication of results, but also in the areas of information management, data protection and scientific cooperation. Here, they must be addressed in the early planning stages.

In the following treatment, the terms *biosafety* and *biosecurity* are used in accordance with the above definitions. In cases where the distinction between the terms *biosafety* and *biosecurity* is not relevant for the aspects or measures being treated, the term *biosecurity* is used as the more general term.<sup>18</sup> The two terms refer to distinct, but closely interconnected areas of concern: For instance, biosafety measures intended to prevent accidents can indirectly help to reduce biosecurity hazards, for example on account of the access controls that are put in place or the limitation of research projects to a limited number of high-security laboratories.<sup>19</sup> Conversely, measures designed to reduce biosecurity risks may also have an effect in the area of biosafety, for instance when risky research projects have to be shelved or restrictions are placed on the publication, perhaps

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17 World Health Organization 2004, 47: “‘Laboratory Biosecurity’ refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins”; cf. also World Health Organization 2006, iv.

18 For more information on the higher-order term *biosurety*, cf. Uhlenhaut/Burger/Schaade 2013; Carr et al. 2004, 8; for more information on the higher-order term *biorisk*, cf. World Health Organization 2006, iii.

19 At the international level, the term *laboratory biosecurity* is also used, cf. World Health Organization 2006, vii: “The protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release”.

in part, of security-relevant findings, which cannot then be taken into account when planning measures for biosafety.

The field of biosecurity is mainly characterized by the aspect that research results gained in connection with biological agents and intended to increase the fund of scientific knowledge can also be used for purposes other than the original, intended and valid aims. Insofar as such results (information, materials and new technologies) have the potential to be used both for beneficial as well as for harmful purposes, the work involved is designated as *dual use research* or biosecurity-relevant research.<sup>20</sup> For the range of dual-use research that has significant potential to give rise to knowledge, products or technologies whose misuse could cause harm to large numbers of persons, the environment or to other important legal interests, the term *Dual Use Research of Concern*, or DURC, has gained international customary usage.<sup>21</sup> In accordance with the internationally recognized definition issued by the NSABB, DURC includes work in the life sciences<sup>22</sup> that can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to cause damage to public health and safety, the environment or to other important

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20 Cf. for example National Science Advisory Board for Biosecurity 2007, ii; cf. also World Health Organization 2010, vii: "Knowledge and technologies generated by legitimate life sciences research that may be appropriate for illegitimate intentions and applications." In contrast, single use refers to possible uses that are exclusively or nearly exclusively confined to military application of technologies. Cf. Joyner 2009a, XV.

21 Cf. National Science Advisory Board for Biosecurity 2007, 17: "Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or material." For seminal treatments, see the so-called Fink Report of the National Research Council from 2004 and World Health Organization 2013b.

22 Life sciences as defined on the German-language UNESCO website: "The life sciences comprise biochemistry, bioinformatics, biology, biomedicine, biophysics, biotechnology and genetic engineering, food science, food technology, medicine, medical technology, pharmaceuticals and pharmacology, environmental management and environmental technology." [Translated from the German original.] Available on the Internet: <http://www.unesco.de/lebenswissenschaften.html> [2014-04-01].

legal interests.<sup>23</sup> It is estimated that less than ten DURC projects are conducted annually in Germany.<sup>24</sup>

It is a feature of such dual use projects of concern that the objects of research — biological agents — have in principle the potential to be employed as weapons of mass destruction. In some cases this also includes the potential to spread throughout the world through infection, thereby threatening the lives of or damaging the health of a large number of people, or causing harm to the environment or other important legal interests, even when they are only released locally. The technical term for a disease that spreads across states or continents is *pandemic*.<sup>25</sup>

As early as 2004, the US American Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology suggested considering DURC from two different points of view<sup>26</sup>: by the determination of a group of biological agents with special potential for misuse, as well as by the classification of research projects. In accordance with this, biosecurity-relevance giving cause for concern was accorded to seven types of experiments: work that (i) renders vaccines

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23 Cf. National Science Advisory Board for Biosecurity 2007, 17.

24 Estimate extrapolated from the result of the examination process carried out in the USA by the National Institutes of Health on the basis of the DURC Policy of 2012. The process identified ten projects that were classified as DURC. As the USA invests greater amounts in research than any other country, it may be assumed that fewer DURC projects are carried out in Germany. Cf. Gottron/Shea 2013, 14; Battelle Memorial Institute 2013.

25 Specifically, a pandemic refers to the dissemination of a contagious disease without restriction, and generally from one state to another or one continent to another. However, the World Health Organization has only defined the term 'pandemic' in detail in connection with the development of a multi-stage plan for estimating the risk of such an event on an outbreak of influenza. The WHO considers that there is a "substantial risk of a pandemic" (Phase 5) in situations where the disease has been transmitted to at least two states. The highest stage (Phase 6 – pandemic) has been reached where there is protracted human-to-human transmission of a new influenza virus to another of the six regions that have been specified by the WHO. The severity of the influenza is not used as a criterion to define the beginning of a pandemic, as at that stage there is insufficient data available. Also, the severity may vary from region to region or country to country, and also in the course of time. However, the severity does play a role in the decisions to be taken regarding measures that are appropriate to the situation.

26 See National Research Council 2004.

ineffective; (ii) confers resistance to therapeutically useful antibiotics or antiviral agents; (iii) enhances the virulence of a pathogen or render a nonpathogen virulent; (iv) increase transmissibility of a pathogen; (v) alters the host range of pathogens; (vi) enables the evasion of diagnostic/detection modalities; (vii) enables the weaponization of a biological agent or toxin. Section 11 and Appendix I.2 contain a recommendation of the German Ethics Council for the further development of this categorization of DURC.

The experiments on avian influenza viruses mentioned at the beginning and below (Section 1.3) have provoked a controversial discussion of risks and benefits, mainly regarding such research which aims deliberately to increase the pathogenic effects of a microorganism through strengthening its pathogenic characteristics, through increasing its transmissibility and contagiousness (infectivity) or through adapting it to new hosts (host specificity). The controversy focusses especially on cases where the research enhances a microorganism's potential to cause a pandemic, i.e. to be disseminated across borders or continents and thereby threaten the lives and health of large numbers of people even if it is only released locally.<sup>27</sup>

Within the controversial discussion on the artificial enhancement of influenza viruses, such experiments are often referred to as '*gain of function*' or GOF experiments, which represents a considerable abbreviation of the true significance of the term.<sup>28</sup> This type of DURC requires a special level of justification in respect of its benefits, because there is a danger

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27 Cf. Lackie 2012, Gain-of-function mutation; Fauci 2012; Herfst et al. 2012; Imai et al. 2012. See also the letter of the Foundation for Vaccine Research of 18 December 2013 to the European Commission: "'Gain of function' research, more properly defined as research to increase the pathogenicity, transmissibility, or alter the host range of highly pathogenic microbes with pandemic potential, including [...]"; available at: [http://www.nature.com/polopoly\\_fs/7.145861/file/vaccine%20ofoundation%20letter.pdf](http://www.nature.com/polopoly_fs/7.145861/file/vaccine%20ofoundation%20letter.pdf) [2014-04-01].

28 Some GOF experiments are not dangerous, for instance where new, harmless microorganisms are provided with innocuous new characteristics that cannot cause damage. In the following treatment, the term GOF is used only in the specific context of biosecurity-relevant experiments.



of severe, transnational harm to populations both as a result of unintentional release of agents as well release with malicious intent.<sup>29</sup> The same applies to other naturally occurring and highly dangerous pathogens such as smallpox, Ebola and Lassa viruses, especially where effective prevention or treatment are not possible.

Regarding the question of biosecurity, it is also of significance that, in addition to the field of microbiology, knowledge and developments proceeding from other scientific fields may be used to increase the harmful potential of biological agents considerably (cf. Section 2). It is not uncommon that only when such knowledge is made available do certain means of manipulation or efficient release and dissemination of microorganisms and biologically hazardous substances become feasible.<sup>30</sup> Generally, a biological weapon intended to cause mass destruction consists of a given biological agent together with a deployment system, through the use of which the agent can be delivered at a place and time of choice, and which improves the capacity of the agent to affect humans, animals or plants, i.e. increases its infectivity and harmful effects. The effectiveness of a biological weapon is often based on its being released in such a specific way. Agents and their deployment mechanisms can be qualitatively differentiated according to their effectiveness and the extent to which their deployment can be controlled. The decisive factor is the capacity of the agent to spread together

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29 In Germany, work on such microorganisms is assigned the highest biosafety security level 4 in accordance with the GenTSV (Ordinance on Safety and Security in Genetic Engineering). (Recommendation of the *Zentrale Kommission für die Biologische Sicherheit* (Central Committee on Biological Safety, ZKBS) of March 2013 for the categorization of genetic engineering work on highly pathogenic avian influenza A viruses (HPAIV) with the potential for efficient airborne transmission between mammals) and the revision of the ZKBS recommendation on risk assessment of the new type of avian influenza A virus H7N9 as donor or recipient organism for genetic engineering work in accordance with Section 5, Para. 1 GenTSV of September 2013.

30 For instance: transfer of aerosols (Mukunda/Oye/Mohr 2009; Miller/Selgelid 2008, 11, 25). For other areas: Cf. World Health Organization 2010; World Health Organization 2013b, 2.

with the dissemination instrument.<sup>31</sup> Therefore the question as to whether research on biological agents must be considered to be DURC can only be answered by applying knowledge from a range of different scientific fields.

The following section contains a brief overview of biosecurity-relevant areas of research and current bioterrorism threats, as well as of actual use of biological weapons in the past.

### 1.3 Historical background

In principle, the use of biological weapons in wartime and in terrorist attacks does not represent a completely novel category. However, the development of genetic engineering and techniques for disseminating microorganisms has increased the potential for using biological agents as highly efficient and increasingly controllable weapons. Such developments have sharpened awareness for biosecurity-relevant research.

Infectious diseases and their targeted dissemination were already being used as means to conduct war even before mankind knew that such diseases are caused by microorganisms. A documented example of this can be seen in the attack of the Tartars on the city of Caffa (now called Feodosia in Crimea) in 1346. They catapulted the bodies of plague victims into the city so as to cause plague to spread amongst their opponents and break their resistance.<sup>32</sup>

When microbiology became established as a science towards the end of the 19th century, the causes of several

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31 Cf. also Art. I Section 2 Biological Weapons Convention of 10 April 1972 on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (BWC), in force since 26 March 1975 (Federal Law Gazette 1983 II p. 132; 1015 UNTS 163): “[...] Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict [...]”. Further details in Section 5.2.1 and Appendix II.1.1.

32 Cf. Wheelis 1999a.

important bacterial infections quickly became clear, and targeted measures were adopted to prevent epidemics as well as methods for diagnosing and treating infectious diseases. At the same time, the potential for using such knowledge in warfare increased, as is evidenced by the specific development and deployment of infectious microorganisms as weapons in the First World War.<sup>33</sup> Examples of this are the attacks by the Germans and the French against horses and other domestic animals, but not against humans, using the bacteria that cause anthrax (*Bacillus anthracis*) and glanders (*Burkholderia mallei*).<sup>34</sup> Several states developed biological weapons further between the two world wars. Only Japan actually used them; this was against China by way of deployment testing during the Second World War.<sup>35</sup> The use of biological agents for non-peaceful aims has been banned since the Geneva Protocol of 1925, and since the Biological Weapons Convention (BWC) of 1972 also their manufacture, storage, acquisition or retention (cf. Section 5.2.1).

Towards the end of the 20th century and at the beginning of the 21st century, terrorists and other criminals used, in addition to conventional weapons and methods, lethal toxins and microorganisms to cause harm to other humans. For instance, followers of the Bhagwan Shri-Rajneesh-Sect released the bacterium *Salmonella enterica* serotype *typhimurium*, which causes food poisoning resulting from an intestinal inflammation, in the salad bars of various restaurants in Oregon.<sup>36</sup> 751 people fell ill as a result of these attacks.

Between 1990 and 1993 the Japanese Aum Shinrikiyo sect tried several times to deploy various biological weapons.<sup>37</sup> The attacks were unsuccessful, although the sect had recourse to considerable funds, good laboratory equipment and scientific

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33 Cf. McLaughlin/Nixdorff 2009.

34 Cf. Wheelis 1999b.

35 Cf. Harris 1999.

36 Cf. Carus 2000.

37 Cf. Kaplan 2000.

and technological expertise. This was provided by a team of young scientists headed by a microbiologist with knowledge of molecular biology, as well as a physicist.<sup>38</sup> For instance, anthrax bacteria were distributed from the roof of a building in Tokyo over a period of four days using a spray device. Apparently, the attack had no effect because the pathogenicity of the bacteria was too weak. Attempts to deploy botulinum toxin also failed because, as it appears, the scientists were unable to produce a toxin of sufficient potency. After these failures, the sect switched to using chemical weapons, and in 1995 its members released the nerve agent sarin in a number of underground trains in Tokyo. This caused the death of twelve people and injured over one thousand. These attacks had the effect of raising public awareness regarding the threat of terrorist use of biological and chemical weapons.

This situation gained added significance in 2001 when terrorist attacks were mounted using anthrax shortly after the September 11 attacks. Five people died as a result of the anthrax attacks and another six contracted infections by inhalation. These attacks caused public anxiety not only in the USA, and resulted in the adoption of security measures of considerable magnitude both by governments and by enterprises.

Today, developments in the fields of molecular biology and genetic engineering allow for more and more targeted and precise description of the mechanisms of pathogenic processes caused by infectious microorganisms. However, the progress being made in these areas also gives rise to concern that completely new, genetically modified agents could be manufactured that are better suited to terrorist attacks<sup>39</sup>, albeit this has not been the case to date.

In this connection, not only the intentional misuse of pathogenic biological agents as weapons is of relevance from the biosecurity point of view, but also, as already indicated above,

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38 Cf. Smithson/Levy 2000.

39 Cf. Wade 1980; Budiansky 1982.

the targeted modification or restoration of dangerous biological agents for research purposes, as these agents can also be used directly to wage war or for terrorist attacks. A number of examples of such research that has fuelled the biosecurity debate in recent years are given below. The modification of avian influenza viruses mentioned in Section 1.1 is particularly topical. However, various experiments had already been carried out in the previous years that provoked public and scientific discussion on security issues.

***Example 1: Development of a 'killer' mousepox virus (2001)***

With the aim of trying to suppress a rodent plague, Australian researchers attempted to prevent gestation in mice by means of a vaccine in 2001.<sup>40</sup> To this end, they used a genetically engineered mousepox virus as a vaccine vector; the mice were immune to the mousepox virus. The researchers added a gene to the virus that corresponds to a protein that is present on the surface of mouse oocytes in order to trigger an antibody response in the mice against their oocytes, causing the latter to be destroyed. In addition, the virus was equipped with a gene for production of the signalling molecule interleukin (IL)-4 that boosts the production of antibodies against the oocytes in the inoculated mice, which was to promote the destruction of the oocytes further.

Although the original virus is not dangerous for these mice, to the surprise of the researchers the inoculated mice died of an infection from the genetically modified virus. The reason for this was found to be that IL-4 not only increased the production of antibodies against the oocytes, but also suppressed another part of the immune system that is needed in order to combat the virus infection.<sup>41</sup> Although it is not possible for a mousepox virus infection to be transmitted to humans, there is concern that the human smallpox virus could be

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40 Cf. Jackson et al. 2001.

41 Cf. Nowak 2001.

correspondingly modified so as to extend its effectiveness in causing fatalities.

***Example 2: Increasing the pathogenicity factor of the vaccinia virus (2002)***

The vaccinia virus that is used as a vaccine against smallpox generally does not cause infection in humans with a functioning immune system. In contrast, the smallpox virus *Variola major* is highly virulent for humans. One factor that determines the virulence of the smallpox virus is thought to be the *smallpox inhibitor of complement enzymes* (SPICE). This can deactivate various components of the complement system that constitutes an important part of the immune system, leading to the functional deactivation of the entire complement system. Vaccinia viruses have a similar protein (*vaccinia virus complement control protein* or VCP), but this is far less effective in deactivating the complement system.

In an attempt to demonstrate the significance of SPICE as a virulence factor, in 2002 researchers modified the VCP gene in such a way that it contained exactly the same nucleotide sequence as the SPICE gene.<sup>42</sup> The protein was then produced recombinantly in a cell culture with the aid of this genetic structure, and it proved then to be more effective than VCP as a deactivator of the complement system. Although ‘only’ a recombinantly manufactured SPICE protein was used and the vaccinia virus itself was not equipped with the recombinant SPICE gene, which probably would have converted this virus to a more dangerous virus, these experiments showed that the pathogenicity of the vaccinia virus can be increased by means of relatively small interventions.

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42 Cf. Rosengard et al. 2002.

**Example 3: Reconstruction of the ‘Spanish flu’ influenza virus of 1918 (2005)**

One virus manipulation gave great cause for concern and gained prominence in 2005: It involved the reconstruction of the virus that caused the ‘Spanish flu’ pandemic of 1918. The pandemic lasted from 1918 to 1920 and is estimated to have killed up to 50 million people.<sup>43</sup> Researchers from the USA wanted to reconstruct the highly virulent virus strain in order to find an explanation for its high degree of pathogenicity. They hoped that gaining a better understanding of the pathogenicity mechanisms would allow them to develop suitable or improved prophylactic substances and therapeutic agents. The reconstruction of the 1918 virus was achieved by providing a relatively harmless influenza virus of another kind with the complete coded sequences of all eight viral gene segments of the 1918 virus strain.<sup>44</sup> The biosecurity issue related to this work is that, in addition to the potential medical benefits it could provide, it represented a construction plan for the production of a microorganism that is highly dangerous for humans. In the meantime, more gene sequences for dangerous agents have been published: The gene sequence of the smallpox virus has been publicly available since 2010, and that of the organism that causes plague, *Yersinia pestis*, since 2011.

**Example 4: Current DURC-relevant gain-of-function experiments on highly pathogenic viruses**

Since the expiry of the research moratorium mentioned above that was instigated on account of the controversy surrounding the H5N1 avian influenza virus experiments, work has commenced on further experiments involving highly pathogenic influenza viruses that are designed to increase their transmissibility.<sup>45</sup> For instance, experiments have been proposed to

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43 Cf. Johnson/Mueller 2002.

44 Cf. Tumpey et al. 2005.

45 Cf. Butler 2013a; Zhang et al. 2013.

increase the transmissibility of the new type of avian influenza virus H7N9.<sup>46</sup> It is considered that H7N9, too, may be transmissible from human to human, although this has not been observed to date.<sup>47</sup> Studies on other dangerous viruses have already been carried out and published.<sup>48</sup>

Scientists also disagree on the questions of appropriate, responsible dealings with the risks of misuse and accidents that may arise in connection with research to increase the transmissibility of dangerous influenza viruses.<sup>49</sup> Differences of opinion remain regarding benefits and risks involved with this work. Some researchers maintain that such research is already sufficiently safeguarded with respect to both unintentional release of viruses as well as their misuse as long as the existing bio-safety rules are adhered to. Further, they perceive significant benefits in this research that may arise through being better able to assess the pandemic potential of natural influenza viruses and in the expectation of gathering important knowledge that can be used in the development of vaccines.<sup>50</sup>

Other researchers argue that no concrete benefits can be expected from these experiments, because it is not possible to forecast the pandemic potential of an influenza virus on the basis of the mutation profiles determined by such experiments.<sup>51</sup> In addition, they claim that in a large number of studies scientists have so far failed to furnish evidence for any other benefits arising from the experiments.<sup>52</sup> Nevertheless, mankind is exposed to the danger of a pandemic either through the unintentional release or the misuse of the viruses. The critics regard the experiments as being especially dangerous on account of

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46 Cf. Fouchier et al. 2013.

47 There are reports of over one hundred cases of human infection, but these have apparently been caused by direct contact with poultry meat, and not through airborne transmission. Cf. Qi et al. 2013; Butler 2013b; Zhu et al. 2013.

48 Cf. Bieringer et al. 2013.

49 Cf. Wain-Hobson 2013.

50 Cf. Fouchier et al. 2013; Jaffe/Patterson/Lurie 2013.

51 Cf. Morens/Taubenberger/Fauci 2013. See also Wain-Hobson 2013.

52 Cf. Morens/Taubenberger/Fauci 2009.



the fact that even individual examples of these modified viruses, whether intentionally or unintentionally released, have the potential to spread and thereby have a global effect. In view of the fact that, to date, no adequate risk/benefit analysis has been carried out regarding such experiments with avian influenza viruses, they warn against continuing them until the scientific community has had time to exchange views on their hazards and beneficial potential and on how to proceed further.<sup>53</sup>

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53 See Wain-Hobson 2013. See also Nature Publishing Group 2013.

## **2 BIOSECURITY-RELEVANT FIELDS OF RESEARCH**

The current discussion on biosecurity in the life sciences revolves mainly around the fields of infection biology, bioinformatics, genome research, systems biology, nanotechnology, neurosciences, synthetic biology, do-it-yourself biology (or DIY biology) and targeted delivery technologies. These fields have developed most rapidly in recent years, and are of considerable relevance in respect of the biosecurity problem.

### **2.1 Infection biology**

Although most microorganisms are harmless, some can cause infectious diseases and are therefore referred to as infectious pathogens.<sup>54</sup> Research on such pathogenic microorganisms is at the centre of many current considerations concerning biosecurity, including the GOF experiments with avian influenza viruses currently under discussion. The infection paths of bacteria and viruses are extremely varied. However, most infections begin on the mucous membranes. This is one reason why dissemination via aerosols (particles suspended in air) that can be ingested via the mucous membranes of the respiratory passages represents the most favoured path for deploying biological weapons (cf. Section 2.9). Intensive research in the area of infectious pathogens is being undertaken to clarify the mechanisms of pathogenic action using the methods of modern molecular biology. In order to combat infectious diseases effectively, knowledge of the mechanisms of the processes leading to disease is essential. Research carried out over the last three decades has made it increasingly clear that many different factors play a role in determining the pathogenicity of

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54 Cf. Hacker/Heesemann 2000.

an agent. To date, no system has been understood in its full complexity. For instance, it may be that the production of a toxin is decisive for the pathogenic effect of a microorganism, but that the toxin can only take effect when other complex and less well defined processes also function, such as the capacity of the microorganism to dock onto host cells, to penetrate cells or to reproduce there and cause an infection.<sup>55</sup>

The pathogenicity of a microorganism can only be defined in terms of its interaction with the host. In order to be infectious, the microorganism must circumvent the host's immune system. Microorganisms have developed a wide range of methods for evading host immune systems<sup>56</sup>, and the molecular processes behind such strategies are the subject of intensive research.

Shortly after genetic engineering became established, it was already being used for the purpose of investigating the pathogenic methods of an agent. To this end, genetic engineering methods were employed to transfer genetic material from pathogenic agents to less harmful microorganisms in order to demonstrate that certain genes regulate certain pathogenic characteristics. For example, researchers introduced genetic material from a pathogenic *Shigella flexneri* bacterium into a harmless *Escherichia coli* strain. Analysis of the consequences of this gene transfer showed that certain parts of the genetic material from *S. flexneri* are responsible for the invasive nature of the pathogen, whereas other parts are required to produce the full degree of virulence.<sup>57</sup> Generally, this kind of experiment is carried out in order to show that a certain gene is responsible for regulating a certain characteristic, because inserting this gene into a manipulated organism causes that organism to take on (gain) that characteristic. However, dangerous pathogens can come into existence in this way, especially when additional

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55 Cf. Cotter/DiRita 2000.

56 Cf. Rajsbaum/Garcia-Sastre 2013; Baxt/Garza-Mayers/Goldberg 2013.

57 Cf. Sansonetti et al. 1983.

virulence factors are transferred to microorganisms that are already pathogenic.<sup>58</sup>

The most recent developments in the life sciences have given rise to new methods for discovering the mechanisms of pathogenicity. Developments in bioinformatics and genome research, including fast and cheap sequencing methods (cf. Sections 2.2 and 2.3) allow researchers to investigate pathogenicity factors through comparative functional genome analyses and to understand the evolution of virulence factors in pathogenic microorganisms. Systems-biological studies shed new light on the mechanics of the interactions between the host and the pathogen.<sup>59</sup> New fields of research such as the microbiome project<sup>60</sup> and the virome project<sup>61</sup> have been established on the basis of these studies. The term *human microbiome* refers to the entire community of microorganisms residing in or on the body, and *human virome* refers to the viral component of the microbiome. These projects aim to increase our understanding of the interactions between host and microorganisms and their role in respect of health and illness. Here, the primary methods used come from systems biology and bioinformatics (cf. Sections 2.2 and 2.4).

There are grounds for hope that progress in infection biology will give rise to new forms of therapy for combating infectious diseases.

## 2.2 Bioinformatics

Bioinformatics is concerned mainly with the storage and retrieval of data that is gathered in genome research by sequencing, and also with the analysis, processing and interconnecting

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58 Cf. the research designed to increase the transmissibility of H5N1 and other avian influenza viruses in Section 1 above.

59 Cf. Chua/Stinear/Howden 2013.

60 See Relman 2012.

61 See Wylie/Weinstock/Storch 2013 and Lecuit/Eloit 2013.

of this data. Also, such data is used for the targeted design of genes, genetic switching circuits and whole microorganism genomes. Bioinformatics is also used specifically in the design of therapeutic agents. In many cases, the development of new drugs is not possible without the use of complex bioinformatic modelling and computing procedures.<sup>62</sup> Bioinformatics also represents a vehicle for disseminating, exchanging and combining scientific knowledge.

From the biosecurity point of view, the accessibility of bioinformatic data can itself represent a problem. In the long term, the spread of technologies and the diffusion of scientific knowledge into areas that are outside the scope of the established security and control mechanisms in scientific research establishments can develop into a significant biosecurity problem. The same bioinformatic and computational procedures that allow relevant information to be extracted from large amounts of data with a view to designing microorganisms and drugs for humane use are equally suited for the design of microorganisms and other bioactive agents for harmful purposes.

## 2.3 Genome research

The genome encompasses the entire genetic information of a given cell. The purpose of genetic analysis is to describe the genetic structure of a microorganism or other organism.<sup>63</sup> In particular, it determines the number and microscopic structure of the chromosomes (cytogenetic analysis) and the detailed molecular structure (sequence) of the DNA and genetic products (RNA, proteins). Functional studies shed light on the biological roles played by the genes and genetic products that have been identified through the sequence analysis procedure.

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62 Cf. Yao/Evans/Rzhetsky 2009.

63 In this connection, see also *Deutscher Ethikrat* 2013, 14.

The costs of such analyses have dropped sharply thanks to progress made in developing sequencing techniques. Currently, a complete human genome can be sequenced for a few thousand US dollars.<sup>64</sup> The next generation techniques have the potential to make the analysis of whole genomes, genome fragments, genetic products and their interactions a matter of rapid and inexpensive, widely available routine.<sup>65</sup> This trend to lower costs and higher performance in sequencing and genome analysis techniques, together with new synthesis procedures, allows for genetic manipulation of microorganisms to an extent that was hitherto inconceivable. Examples of this can be seen in the complete reconstruction of the Spanish flu virus of 1918 (cf. Sections 1.3 and 3.1) as well as the chemical synthesis of the fully functional genome of a single-celled bacterium (cf. Section 2.7). As such manipulations could also be carried out with both peaceful and non-peaceful intentions, these techniques have biosecurity relevance.

## 2.4 Systems biology

Systems biology is the science whose purpose is to explain, with the aid of bioinformatics, how complex physiological systems interact with each other and function as a whole. This is done by integrating all available functional information on these biological systems into a computer aided modelling process.<sup>66</sup> Cell processes and vital biological processes in the organism as a whole are described on the basis of mathematical models. The resulting simulations allow for simplified forecasts to be made. Work of this kind greatly increases our fund of knowledge and ability to set up hypotheses, and these in turn lead to new approaches for understanding vital functions.

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64 Cf. <http://www.genome.gov/sequencingcosts> [2013-10-10].

65 Cf. Shendure/Ji 2008.

66 Cf. Thiel 2006.

One of the main aims of systems biology consists in improving our understanding of pathological processes and their therapeutic correction. For instance, a systems biological approach is used to investigate the immensely complicated immune system by means of models.<sup>67</sup> This involves especially the interactions that take place with pathogenic microorganisms.<sup>68</sup>

A popular goal currently being pursued in systems biology is to clarify how regulatory networks of transcription factors<sup>69</sup> work, i.e. of molecules that regulate the expression of genes into messenger RNA (gene transcription). A better understanding of these networks could lead to new methods of switching genetic functions on and off. It is possible to do this by means of RNA interference (RNAi), a technique in which the activity of a gene is suppressed by blocking the messenger RNA.<sup>70</sup> Systems biological approaches are also being used for the analysis of protein activities and interactivity within a cell.<sup>71</sup> So-called *proteome profiling* is used specifically in order to find new molecular points of attack for drugs.<sup>72</sup> The aim in all these cases is to influence pathological processes by therapeutic means.

Systems biology represents an especially good example of the difficulties involved in addressing biosecurity aspects in view of the technological developments taking place in the life sciences. Physiological systems such as the nervous, endocrine or immune systems do not function as isolated subsystems, but interact closely with one another. The way these systems function is regulated to a great extent by the effects of biochemical substances (bioregulators such as, amongst other things, hormones, neurotransmitters and cytokines) produced by the body itself.<sup>73</sup> These bioregulators play a key

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67 Cf. Germain et al. 2011.

68 Cf. Aderem et al. 2011.

69 Cf. Ledford 2009.

70 Cf. Boudreau/Rodriguez-Lebron/Davidson 2011.

71 Cf. Shimizu/Toh 2009.

72 Cf. Rix/Superti-Furga 2009.

73 Cf. National Research Council 2006.

role in many essential physiological functions such as respiration, cardiac activity, body temperature, consciousness and immune reactions. The normal functions of interacting physiological systems are extremely susceptible to manipulation by these bioregulators.

Manipulative interference with a subsystem through a bioregulator can have profound effects on the other subsystems and therefore on the organism as a whole. For instance, the immune messenger substance (cytokine) interleukin (IL)-1 promotes inflammation and can damage the nervous system.<sup>74</sup> IL-1 is produced by immune cells following interaction with pathogenic microorganisms. This cytokine normally enhances the activity of other immune cells. However, if this reaction is very strong, the cytokine can reach the brain via the bloodstream, where it triggers a reaction at a particular place (the hypothalamus) that is referred to as sickness behaviour. The symptoms are, amongst other things, fever, stupor and apathy. An affected person feels unwell and is more or less incapable of functioning usefully. There is already experimental evidence to show that interleukin-1 can effectively be deployed in aerosol form, so its use as a biological weapon is at least conceivable.<sup>75</sup>

## 2.5 Nanotechnology

The term nanotechnology covers a large number of techniques for investigating, manufacturing and using structures and materials at the molecular level in an order of magnitude below 100 nanometres. At this level of magnitude, known substances can display new properties. On account of their small size, nanoparticles can enter tissue much more readily than larger particles. They can be furnished with specific physico-chemical

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74 Cf. Kelle/Nixdorff/Dando 2006.

75 Cf. U.S. Army Medical Research Institute of Infectious Diseases 1987, 19; see also Rosenberg/Burck 1990, 308.



characteristics that allow them to be assimilated via the nasal mucous membranes and the respiratory passages. If designed appropriately, they can penetrate cell envelopes or overcome the blood-brain barrier.<sup>76</sup> This opens up new medical perspectives, but these are accompanied by new hazards and risks. New types of carrier systems for drugs are being developed on the basis of nanoscale materials. Such systems can transport active agents with great precision to the location within the organism concerned where they can work most effectively.<sup>77</sup> These developments are highly relevant in respect of deploying biological agents as weapons, as these, too, can be inserted into nanoparticles and transported to a given target ('targeted delivery', cf. Section 2.9).

## 2.6 Neurosciences

Some neuroscientific research is also of relevance from the biosecurity point of view on account of its potential to provide ways of influencing the way pain is processed and perceived, our emotional and cognitively controlled behaviour, attentiveness, cycles of sleeping and waking, mental agility, body temperature regulation and other physical regulation mechanisms. In the context of weapons of mass destruction, pharmacological agents such as neurotransmitters, hormones, cytokines and neuropeptides of the nervous system are of particular significance.<sup>78</sup>

Botulinum toxin represents an example of such a pharmacological agent. The toxin takes effect by suppressing the transmission of information from nerve cells to the muscles. The neurotransmitter acetylcholine is then not released into the synaptic cleft, so that it cannot have any effect on the muscle.

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<sup>76</sup> Cf. *ibid.*

<sup>77</sup> Cf. Andrade et al. 2013.

<sup>78</sup> Cf. Dando 2011.

Botulinum toxin is effective in extremely small doses. It is used as a medicine in the treatment of neuromuscular diseases such as dystonia, and also in the cosmetic market. Cases of unintentional poisoning usually occur through foodstuffs such as putrid meat or fish. Terrorists could disseminate botulinum toxin by airborne means or through deliberate contamination of food, for instance.<sup>79</sup>

Opioids are substances that have pain reducing, anaesthetic or euphoriant effects that are induced via the body's opioid receptors. Aerosols containing opioids can have the effect of making humans incapable of taking action. Derivatives of fentanyl, a member of the opioid group of substances, are thought to have been used by security forces as a response to the terrorist attack on the Dubrovka Theatre in Moscow in 2002. Fentanyl is an extremely potent analgesic that takes effect very quickly and for a short period.<sup>80</sup>

Oxytocin is known to have regulative effects on reproductive and social behaviour. For instance, intranasally administered oxytocin reduces the extent to which the amygdala is activated when a subject observes anxiety-inducing facial images.<sup>81</sup> The amygdala is of central importance in the brain for

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79 Cf. Arnon et al. 2001.

80 It is a synthetic opioid, and therefore may be more appropriately categorized as a chemical weapon. However, especially in the field of neurobiology, the demarcation line between biological and chemical weapons is unclear. In this respect, see also Royal Society 2012b, 44 f.: "Incapacitating chemical agents have been referred to as incapacitating biochemical agents by some commentators to reflect the increasing confluence of chemistry and biology in this area. Though certain characteristics of biological weapons (such as incubation period and contagiousness) may distinguish them from chemical weapons, sharp distinctions become more problematic when considering agents such as toxins (toxic chemicals derived from living organisms) and bioregulators (chemicals that regulate biological processes). Chemical and biological weapons are therefore often understood as lying on part of a biochemical threat spectrum, ranging from classical chemical agents (nerve, blood, blister agents) to biological agents (bacteria, viruses, rickettsia), with mid-spectrum agents being covered by both the CWC and the BWC. Conceivable incapacitating chemical agents typically fall within this category of mid-spectrum agents and may therefore be governed by both the CWC and the BWC".

81 Cf. Baumgartner et al. 2008.

processing emotions such as anxiety and aggressiveness, but also ones associated with sexual behaviour. In this connection, the use of nanotechnology for the application and dissemination of psychopharmaceuticals across the blood-brain barrier could gain relevance. For example, it may be possible to produce nanoparticles containing ligands that dock onto nerve cell receptors<sup>82</sup> and thereby influence neuronal functions.

## 2.7 Synthetic biology

The field of research known as synthetic biology has come into existence with contributions from a range of disciplines such as genetic engineering, genome research, engineering sciences, informatics and biology. At this stage, however, no universally accepted definition for synthetic biology has been put forward. Some very disparate areas of work fall under the umbrella term synthetic biology, including the synthesis of extensive DNA sections, the biotechnical assembly of biological systems from modules that can be reliably reproduced using techniques based on those of classical engineering, attempts to manufacture artificial cells entirely through synthesis and research on alternative biochemical systems on the basis of artificial molecules.

### *DNA synthesis*

One of the starting points for synthetic biology was the synthesis of individual genes up to an entire genome, and introduction of these into living cells. In 2010, researchers succeeded in chemically synthesizing the entire genome, consisting of a million base pairs of a single-celled bacterium. This synthetic, whole genome (derived from the genome of the bacterium *Mycoplasma mycoides*) was introduced into a bacterium of another mycoplasma species. This produced a functional bacterium with the synthetic genome and the ability to produce progeny

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82 Cf. Dhuria/Hanson/Frey 2010.

that also contained copies of the synthetic genome.<sup>83</sup> Although it cannot be said that life had been ‘synthesized’ in this way, the work does indeed represent a milestone in the synthesis of genomes and the manipulation of microorganisms.

More than 20 companies throughout the world are engaged in the chemical synthesis of DNA. They are service providers for research institutes and industrial research bodies. The techniques of chemical synthesis can also be used to manufacture genes that carry pathogenic or toxic characteristics of bacteria or viruses and can be deployed in biological weapons. Thus copies of the genome of a highly pathogenic virus could be produced and supplied.

In addition to this, synthetic biological methods could, in theory, also be implemented to produce new, modified genes and genomes in a targeted manner in order to manufacture microorganisms otherwise unknown in nature that have biological weapons capability.

### ***Modular biology inspired by classical engineering***

Synthetic biology is advancing towards a point at which it will be possible to partition the structure of complex biological systems into individual components, and then modify these components in specific ways.<sup>84</sup> An example of this can be seen in work in which the bacterium *Escherichia coli* is supplied with a genetic circuit that enables it to produce a pre-product of the substance artemisinin, which is used as an anti-malaria drug.<sup>85</sup> The aim is to reduce such switching circuit components to certain desired functions by means of standardization, so that it becomes relatively easy to use them in a variety of biological systems. Thus one of the goals of synthetic biology is to develop and use standard components (so-called *BioBricks*) that make it easier to construct genetic switching circuits.<sup>86</sup> As a result of

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83 Cf. Gibson et al. 2010.

84 Cf. Andrianantoandro et al. 2006.

85 Cf. Martin et al. 2003.

86 Cf. Gothelf 2012.

this, synthetic biology will lead to what is referred to as *de-skilling*; in other words it will make it possible for relatively inexperienced researchers to achieve complex manipulation of microorganisms by using standard components.<sup>87</sup> The de-skilling process is being promoted by means of the International Genetically Engineered Machine (iGEM) competition<sup>88</sup> held each year at the Massachusetts Institute of Technology. Teams of students from universities throughout the world compete with their synthetic biology projects. In some cases, the participating teams develop *BioBricks* and use them in their projects.

### ***Artificial cells***

Another approach that is pursued within the purview of synthetic biology concerns the assembly of molecules to form artificial cells (*protocells*) according to the 'bottom-up' principle. This technique involves the inclusion of genetic material together with biosynthetic reaction components in lipid vesicles.<sup>89</sup> The intention is to construct artificial cells that synthesize RNA, DNA and also protein molecules so that they can reproduce themselves. The intermediate aims of protocell research are to gain a better understanding of life and to establish the minimum conditions under which life is possible. In addition, however, it is also of huge commercial significance, especially regarding the generation of simple, but efficient bioreactors. These experiments have biosecurity relevance, because they include the possibility of designing completely new, artificial cells with unusual capabilities. It is, for instance, conceivable that completely artificial cells can be furnished with characteristics that include concealed hazards which only become apparent with time. Even though current research projects are still far removed from the point at which complex artificial cells can be constructed, some experts expect that the first

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87 Cf. Tucker 2011.

88 See: <http://igem.org> [2014-04-01]; <http://biobricks.org> [2014-04-01].

89 Cf. Bedau et al. 2009.

autonomously reproducing protocells will be produced in laboratories within the next five to ten years.<sup>90</sup> It is also assumed that protocells will be produced within the next 20 years that are able to survive in an open environment.<sup>91</sup>

### *Alternative biochemistry*

Another field of activity within synthetic biology has to do with the production of biological systems using non-natural biochemical substances (xenobiology).<sup>92</sup> Here, attempts are being made to insert molecular building blocks that do not occur naturally in nature into information-bearing molecules (DNA, proteins) with a view to modifying the functions of these molecules. One such example is the production of non-natural nucleotide bases for insertion into DNA.<sup>93</sup> The relevance for biosecurity is given here through the possibility of specific modification of proteins and nucleic acids so as to influence their behaviour as bioregulators.

## **2.8 Do-it-yourself biology and biohacking**

*Do-it-yourself* biology or DIY biology is a movement that was started up by a group of laymen in 2008 in the USA, and has remained especially active there up to the present. One aim of the DIY biologists, who sometimes call themselves biohackers, is to promote so-called *open-access biology*, or to help ‘democratize’ biology and thereby encourage innovativeness.<sup>94</sup> This

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90 Cf. *ibid.*

91 Cf. *ibid.*

92 Cf. Schmidt 2010.

93 Cf. Hirao/Kimoto/Yamashige 2012.

94 Cf. Tucker 2011, 75. See also Bennett et al. 2009: “The good news is that open access biology, to the extent that it works, may help actualize the long-promised biotechnical future: growth of green industry, production of cheaper drugs, development of new biofuels and the like. The bad news, however, is that making biological engineering easier and available to many more players also makes it less predictable, raising the specter of unknown dangers”.

type of research is clearly of relevance from a biosecurity point of view, as the large number of unregulated participants means that the results cannot readily be forecast, and the range of unknown dangers increases.<sup>95</sup>

Some experts are therefore concerned about an unregulated ‘amateur tinkering’ with technologies that are associated with risks.<sup>96</sup> On the other hand, other observers maintain that the current capabilities of the DIY movement are overrated, while its communal sense of responsibility is underrated. It is indeed the case that members of the DIY biology community are taking a proactive stance regarding concerns about the question of guaranteeing biosafety and biosecurity. Thus the DIYbio.org group inaugurated the ‘Ask a Biosafety Expert’ web portal in 2013. The portal can be used to post questions about biosafety and biosecurity that are then answered by experts.<sup>97</sup>

These days, it is possible for practically anyone to purchase genetic engineering material (cloning kits) as well as technological equipment such as *Polymerase Chain Reaction* (PCR) thermocyclers, centrifuges, 3D printers etc. at affordable prices. However, it is doubtful whether an individual (including a potential terrorist) can always gain the necessary expertise, and especially the so-called ‘tacit knowledge’ (i.e. hands-on knowledge that is conveyed through publishing) needed in order to be able to use such technology successfully.<sup>98</sup> Added to this is the high degree of risk for their own health wherever amateurs may have to do with illegally obtained, active pathogenic agents outside high-security laboratories.

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95 Cf. Bennett et al. 2009. See also *Gen-ethisches Netzwerk* 2013.

96 Cf. Kuiken 2013.

97 Cf. *ibid.*

98 Cf. Tucker 2011, 78.

## 2.9 Targeted delivery technologies

One precondition for the use of agents effectively for harmful purposes is that they be successfully deployed. Experts regard this as the most difficult and the decisive step in the implementation of such terrorist intentions.<sup>99</sup> As early as 2006, the significance of the progress being made in the field of 'targeted delivery' technologies for the successful deployment of biological substances for either therapeutic purposes or for terrorist attacks, was being emphasized at an international level.<sup>100</sup> Two types of deployment are particularly relevant here: deployment through the use of aerosols and deployment via viral vectors. Since 2006, considerable progress has been made in these areas.<sup>101</sup>

Deployment by aerosols has attracted a great deal of interest in recent years as a means of effective administration of drugs. However, it is also the method of choice for large-scale dissemination of biological agents as weapons.<sup>102</sup> Improvements in the use of aerosols can mainly be attributed to nanotechnological methods. Inhalable nanoparticles have been developed that have a defined size, form and surface charge. This means that bioactive agents coupled to these nanomaterials can be much more readily absorbed through the nasal mucous membranes and the respiratory passages, and across the blood-brain barrier.<sup>103</sup> In addition, methods have been developed that protect delicate substances or microorganisms against harmful environmental influences.<sup>104</sup> Widely advanced is the development of an insulin dose in the form of a powder that has the ideal particle size and constitution for targeted

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99 Cf. Kuhn 2007.

100 Cf. United Nations 2006; cf. also National Research Council 2006.

101 Cf. Nixdorff 2010.

102 See: [http://www.globalsecurity.org/wmd/intro/bio\\_delivery.htm](http://www.globalsecurity.org/wmd/intro/bio_delivery.htm) [2014-04-01]; see also in this context: U.S. Department of Defense 1998.

103 Cf. Suri/Fenniri/Singh 2007.

104 Cf. Mahajan/Gattani 2009; Van der Walle/Sharma/Ravi Kumar 2009.



administration deep within the lungs. This is the location at which it can be most effectively assimilated.<sup>105</sup>

Progress in molecular biology, immunology and tumour genetics has led to the design and development of new kinds of viral vectors for genetic therapies and for use in vaccine, cancer and immune therapies. These viruses are furnished with a certain gene that codes a bioactive protein. After a host has been infected with the virus, the gene is activated so that the bioactive substance can be synthesized and take effect within the host's body.

Recently, significant improvements have been made in the targeted transmission and activation of the genes.<sup>106</sup> The development of the lethal mousepox virus described earlier has shown that a viral vector can transmit a bioregulator very effectively (cf. Section 1.3).

Viral vectors for therapeutic use are generally administered by injection. This is, of course, impractical for the purpose of disseminating biological weapons. However, some studies have shown that viral vectors for therapeutic use can also be successfully administered by means of aerosols.<sup>107</sup> Although the inhalation of therapeutic drugs is not directly comparable with the use of biological weapons, these studies demonstrate that, in principle, viral vectors can be transmitted successfully using aerosols.

Artificial viruses, or non-viral vectors, are also being developed as vectors. These entities usually consist of molecules such as DNA or other bioactive substances that are enclosed in specially designed nanocapsules. The nanocapsules are constructed in such a way that, ideally, they only recognize the diseased cells, are then taken up into these cells and release their freight, a drug, within the cell. Examples of developments in

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<sup>105</sup> Cf. Guntur/Dhand 2007.

<sup>106</sup> Cf. Liu/Galanis/Kirn 2007; Griesenbach/Alton 2009; Schambach/Baum 2008.

<sup>107</sup> Cf. Medina et al. 2003.

this direction are the so-called *nanorobots*.<sup>108</sup> Nanorobots can interact directly with body cells on account of their small size. They can be constructed to consist of a framework of DNA or proteins that can carry biologically active freight and be furnished with chemical structures that dock onto specific cell surface structures and then release their freight. Nanorobots can also be produced so as to deliver their freight only after having been absorbed onto and taken up into a cell.

Artificial viruses are being developed primarily to circumvent the negative aspects and risks associated with the use of natural viruses as vectors. These include, in particular, safety and manufacturing difficulties, undesirable immune reactions, limited capacity for targeting as well as limited capacity for taking on freight. However, there is a problem in connection with artificial viruses, namely that at the present stage of development their capacity to transmit genes is less than that of natural viruses.<sup>109</sup> Nevertheless, there is considerable interest in continuing the development of these vectors. This may also bring with it a great potential for misuse, as the vectors could equally well be used to release toxins or bioregulators that have negative effects on physiological processes in host organisms.

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108 Cf. Douglas/Bachelet/Church 2012; Elbaz/Willner 2012; Lenaghan et al. 2013.

109 Cf. Douglas 2008.

### 3 ASSESSMENT OF THE RISKS

Regarding the degree of threat presented by biosecurity-relevant research, the following general appraisal may be made from the scientific point of view: The new developments in the life sciences, and especially the more complex technologies, suggest that, if at all, threats to public security are more likely to arise through their misuse in the medium to long term than in the short term. Concern is nonetheless already being expressed that terrorists or states could avail themselves of the new biotechnologies more or less immediately for the purpose of producing biological weapons.<sup>110</sup> However, at least in cases where the researcher himself or herself is not also the perpetrator,<sup>111</sup> the difficulties, the threat to the (mis-)user's own health<sup>112</sup> and the amount of time needed in practice to carry out biotechnological processes often tend to be underestimated.<sup>113</sup> Empirical studies have shown that "As biotechnology moves from the scientific bench to a more applied setting, it follows a well-established historical pattern of slow and incremental change and diffusion consistent with other major technologies."<sup>114</sup>

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110 As early as 2003, the CIA reached this conclusion: "Advances in biotechnology, coupled with the difficulty in detecting nefarious biological activity, have the potential to create a much more dangerous biological warfare (BW) threat. The Panel noted: The effects of some of these engineered biological agents could be worse than any disease known to man" (Central Intelligence Agency 2003).

111 The possibility of researchers themselves becoming perpetrators was adequately demonstrated by the anthrax attacks that followed the 9-11 attacks on the World Trade Centre. Amongst others, the Max Planck Society's code of conduct entitled '*Hinweise und Regeln der Max-Planck-Gesellschaft zum verantwortlichen Umgang mit Forschungsfreiheit und Forschungsrisiken*' (Max Planck Society Guidelines and Rules on a Responsible Approach to Freedom of Research and Research Risks) includes allusions to the possibility of deliberate misconduct by scientists.

112 However, this will not have a restrictive effect on perpetrators who are willing to sacrifice their own lives, albeit such a willingness may only rarely be encountered in connection with highly pathogenic agents.

113 Cf. Vogel 2008.

114 Cf. *ibid.*, 50.

In practice, it is not easy to successfully implement complex biotechnological methods. This requires expertise acquired over many years, specially equipped laboratories and production facilities, as well as considerable funding. Therefore technically elaborate processes are more likely to be implemented by researchers or other persons who enjoy the support of large institutions and can look back on many years of practical experience. The present opinion of experts, backed up by the few well documented terrorist attacks involving biological weapons that have occurred so far, is that terrorists who are not themselves conducting corresponding research will tend to fall back on naturally occurring agents and traditional biological or chemical weapons.<sup>115</sup>

Also, stricter access rules in some states, especially the USA, have made it more difficult to obtain dangerous agents without legitimate proof of identity both of persons and institutions.<sup>116</sup> This could make it harder for terrorists to acquire dangerous agents. It is therefore not surprising that, because of the difficulty in obtaining the agents subject to research, international health and security experts currently assess the danger of misuse of research results or research objects, i.e. in particular modified viruses or bacteria, as being of an intermediate order of magnitude.<sup>117</sup> Perpetrators who do not have specialist knowledge would probably decide on using natural agents rather than trying to modify dangerous agents by genetic means. The use of sophisticated technologies, by bioterrorists or any other perpetrators is highly dependent on the required expertise including tacit knowledge, i.e. long-term,

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115 See in this connection Section 1.3 (the attacks of the Bhagwan Shri Rajneesh sect in 1984 in the USA, of the Aum Shinrikiyo sect in 1995 in Japan and the 2001 anthrax attacks in the USA).

116 Cf. U.S. Department of Health and Human Services/U.S. Department of Agriculture 2005. In addition, see also Rohde et al. 2013.

117 Results obtained from the 'Threat and Risk Assessment of Biological Agents' project as part of the Global Health Security Initiative involving international health and security experts (verbal communication from Christian Herzog, Robert Koch Institute).

practical experience on the part of those concerned, as well as on the current state of the de-skilling trend.

This does not, of course, exclude the possibility of experts using their knowledge for terrorist aims, nor of terrorists secretly obtaining the required knowledge in the relevant fields and techniques over long periods of time. It is extremely difficult to forecast when the de-skilling process and the general availability of knowledge will have reached a point at which the risk hazard becomes significantly greater.

The Global Health Security Initiative's 'Threat and Risk Assessment of Biological Agents' project, conducted under the aegis of the Robert Koch Institute, has developed an internationally agreed methodology for assessing naturally occurring biological agents. With the aid of health and security experts, an attempt was made to categorize agents regarding their relevance for bioterrorism. The categories take account not only of the pathogenic characteristics of each agent, but also in each case the technical and social aspects, the availability of agents, how easy it is to obtain them, how they can be prepared and disseminated, as well as the likely success of countermeasures if an attack were to be perpetrated.<sup>118</sup>

A comparable assessment of dual use research is more difficult, as relevant factors such as the hazard potential of an agent are parameters that are connected with the research activities themselves; they are subject to modification, and the research results as well as the way they may influence other hazard-relevant factors are very difficult to forecast. In addition to this and as already mentioned, the various technological fields are interconnected, so the hazard potential of individual techniques cannot be assessed in isolation, rather the research project as a whole must be analysed.

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118 Available on the Internet: <http://www.ghsi.ca/english/index.asp> [2014-04-01].

### 3.1 Exemplary scenarios and criteria for hazard assessment

The likelihood of dangers arising from bioterrorist action can to a certain extent be estimated with the aid of projected scenarios. The main criteria for assessing the probability of misuse actually occurring are:

- » Availability of the agent: Degree of difficulty involved in obtaining and, as the case may be, producing these agents in significant quantities<sup>119</sup>;
- » Therapy options: Availability of effective vaccines, antibiotics, antiviral therapeutic agents, antisera;
- » Availability of the technology: Complexity of a technology versus the de-skilling process;
- » Availability of the expertise: Availability of specialist knowledge (scientific/technical as well as tacit knowledge);
- » Characteristics of a suitable facility: Laboratory equipment, laboratory security level;
- » Availability of funds for infrastructure and the organization's personnel.

Other factors necessary for a risk assessment comprise the quantitative and qualitative extent of the potential damage, the role played by international aspects and the social and political context of the research.<sup>120</sup>

The following passage contains three scenarios in which some of the technologies described above are used. The scenarios are presented only for the purpose of illustrating the interrelationships that need to be taken into account in risk analysis on the basis of the risk assessment criteria already mentioned.

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<sup>119</sup> These are only the main criteria. However, they need not apply in each case: For instance, with viruses that can be transmitted from human to human, the production of large quantities may not be essential.

<sup>120</sup> Cf. Tucker 2012, 79 f.

### *Scenario 1: Fabrication of a polio virus using a chemically synthesized genome*

When the genome of the polio virus was chemically synthesized in 2002, this represented the first instance of the generation of the complete, synthetic genome of a microorganism.<sup>121</sup> The polio virus is a simple virus with a relatively small genome, and is therefore relatively easy to synthesize. The chemically synthesized polio virus genome was not autonomously active, but it could be transformed into infectious particles in a cellular extract containing the necessary biological components. Therefore the decisive step was not the chemical synthesis of the genome, but its transformation into infectious particles.<sup>122</sup>

It transpired that, for this step, the participating researchers did not exactly follow established protocols, and were successful only by using their intuitive skill resulting from many years of experience.<sup>123</sup> At one point, such tacit knowledge was of particular importance, namely when it came to preparing an extract of mammalian cells that was needed for the creation of a functioning virus on the basis of the artificial genome. Here, the researchers had to take into account subtle aspects of the experimental process. If other researchers would try to repeat the experiment without this tacit knowledge, they would not be successful.

The virus itself is present in culture stocks in those laboratories in which it is the subject of research, and all employees who work with the agents have access to it. Polio viruses probably also exist in institutions that archive collections of microorganisms. Whenever a sample is requested, the institution concerned is obliged to check whether the order has been placed by a *bona fide* scientist who has a legitimate reason for doing the work.<sup>124</sup> In any case, work with viruses of this degree of complexity requires many years of relevant experience,

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121 Cf. Cello/Paul/Wimmer 2002.

122 Cf. Ouagrham-Gormley/Vogel 2010.

123 Cf. Vogel 2008.

124 Cf. Rohde et al. 2013.

and especially specific expertise in dealing with and cultivating polio viruses, as well as a suitably equipped laboratory. This would include having an effective vaccine that protects laboratory staff from being infected.

To date, the polio virus has not appeared in the list of bio-agents suitable for use as biological weapons, because the majority of people throughout the world have been immunised against polio.<sup>125</sup> However, the reappearance of the polio virus in the Syrian civil war in 2013 has shown how quickly an apparently no-longer dangerous virus can revert to becoming a threat for part of the population of a given country and — on account of refugee movements — beyond.<sup>126</sup> Where, in addition, only certain sections of a population in a given state are sufficiently protected through vaccination or have access to medical care<sup>127</sup>, naturally occurring agents can also be deployed with effect against those who are not protected.

### *Scenario 2: Reconstruction of the ‘Spanish flu’ influenza virus of 1918*

The synthesis of a more complex virus and its transformation into infectious particles represents an even greater challenge than the production of an artificial polio virus. One such goal has already been mentioned above, namely the reconstruction, in 2005, of the influenza A virus that caused the Spanish flu pandemic of 1918.<sup>128</sup> The influenza A virus has a genome that is divided into eight different segments, and it is much larger than that of the polio virus. Also, the influenza virus contains many proteins that are required for, amongst other things, the replication of the genome. Nevertheless, the researchers succeeded in synthesizing all eight coded segments of the 1918

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125 Cello/Paul/Wimmer 2002.

126 The Robert Koch Institute has issued a warning that there is a risk of polio viruses being introduced into Germany on account of the movements of refugees from Syria (*Robert Koch-Institut* 2013a, 481).

127 Cf. <http://sz.de/1.1813905> [2014-01-14].

128 Cf. Tumpey et al. 2005.



Spanish Flu influenza virus genome. A relatively harmless influenza A virus was furnished with these segments, and this made it as highly pathogenic as the 1918 virus.

There were no cultured stocks of the 1918 influenza virus available. Therefore the information that was needed on the RNA sequences of the eight coded segments of this virus had first to be obtained through the examination of several histological lung samples preserved in formalin, as well as lung samples from a victim whose body was preserved in permafrost in Alaska. The reconstruction of the virus was achieved on the basis of cooperation between scientists from three prestigious institutions in the USA — the Armed Forces Institute of Pathology, the Centers for Disease Control and Prevention and the Mount Sinai School of Medicine.<sup>129</sup>

These experiments were designed, amongst other things, to develop an effective vaccine, and also to verify whether existing influenza virus vaccines would have a protective effect against infection with the reconstructed virus. To date, however, no vaccine against the 1918 Spanish Flu influenza virus has been found.

In order for it to be deployed as an active agent in a biological weapon context — perhaps in large quantities — special knowledge about disseminating viruses by means of aerosols to achieve the desired effects would be necessary. These are aspects that would have to be clarified in the course of lengthy experiments, because for most viruses the information is not available and such research has not yet been carried out. However, an influenza virus that can be transmitted from human to human might cause a pandemic even if at first only a few people are infected. Therefore it is conceivable that a terrorist, working in a team that is doing research on influenza viruses, could infect him- or herself and thereby cause worldwide dissemination of the virus. However, this mode of dissemination would not be as efficient as the targeted deployment of a

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129 Cf. *ibid.*

large quantity of the agent, and its results would be even less predictable.

***Scenario 3: Rendering a microorganism resistant to antibiotics or antiviral therapeutic drugs***

In comparison with the first two scenarios, the transfer of immunity against antibiotics to bacteria by genetic manipulation is technically less demanding. Also, the required level of expertise — including tacit knowledge — is comparatively easy to obtain. Even the task of cultivating the bacteria so that enough are available for a terrorist attack would generally not represent an insurmountable obstacle.<sup>130</sup> Introduction of antibiotic resistance into microorganisms is a common genetic engineering technique that is practised routinely in laboratories. The difficulty in this scenario consists in disseminating the agent in order to affect a sufficiently large number of persons. For this, special knowledge specific to each microorganism is required.

The infections caused by multiresistant germs in hospitals are extremely difficult to treat, and this shows clearly what the consequences can be when a microorganism acquires immunity to a range of antibiotics.<sup>131</sup>

However, the introduction of resistance against antiviral drugs by means of genetic engineering represents a greater challenge. The main reason for this is to be found in the fact that both the cultivation of viruses as well as the actual genetic engineering work involved in introducing resistance against antiviral drugs is technically more difficult than that required to make bacteria resistant to antibiotics.<sup>132</sup>

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130 Cf. Madigan et al. 2010; Watson et al. 1992.

131 Cf. de Kraker et al. 2011; Giamarellou/Poulakou 2009.

132 Cf. Moss 1985.

## 3.2 Conclusions

The scenarios described above illustrate clearly the difficulties involved in assessing whether terrorists may be able to implement the latest developments in the life sciences successfully for the purpose of producing novel types of biological agents and deploying them as weapons, and they also highlight the need to differentiate between the various agents and areas of research. The appraisal depends on many factors that each plays a role either individually or in combination with others. As a general rule, we can assume that the more complicated the technology required, the less high is the likelihood that it currently presents a terrorism risk. In this respect, specialist and tacit knowledge, and also the current state of the de-skilling process, all play important roles, whereby the latter is particularly difficult to assess. As the practical handling of these complex technologies becomes easier, while implementation of the corresponding security measures often lags behind the technological steps, it may prove to be important for the protection of the public and the environment to work out practicable measures, including preventive measures, in the various DURC domains as soon as possible.

Even in cases where research appears not to represent a particularly high risk at present, certain preventive protection and ancillary measures are called for, depending on the possible consequences. For however unlikely it may be that a certain kind of attack, deliberately perpetrated by terrorists or others, will actually occur and threaten the lives of or damage the health of a large number of people or cause harm to the environment or other important legal interests, if harmful agents are once released in an uncontrolled way the results may be catastrophic, possibly even affecting the whole world (as in the case of influenza viruses).

This applies especially where highly pathogenic microorganisms are specifically modified in research establishments (e.g. in respect of their pathogenicity or host specificity) in such

a way that exceptional dangers may arise for humans and the environment if they are misused or accidentally disseminated.

## 4 ETHICAL QUESTIONS SURROUNDING BIOSECURITY-RELEVANT RESEARCH

The possibility of misuse of biological research findings represents an ethical dilemma, as promising and beneficial aspects remain inextricably linked with threatening factors that give cause for serious concern.<sup>133</sup> Not only individual researchers, but also the organizations for which they work, the funding bodies involved and in many cases a state or states are equally confronted by this dilemma.

The essential scientific problem of dual use potential has not only arisen in recent times. It has become acutely relevant in discussions of scientific answerability since scientists began to collaborate in work on weapons of mass destruction, especially nuclear and chemical weapons. However, the new level of awareness surrounding the issue of biosecurity in general and DURC in particular raises some fundamental questions: To what extent must the life sciences research community itself take on responsibility for possible misuse of its research and the results of such research? How may it be possible to ensure that scientific research is conducted responsibly? What options are there that will help to identify biosecurity relevance in individual research projects and in the development of new fields of research and allow for measures to be adopted with a view to preventing misuse? To what extent can research establishments oblige scientists to adopt certain risk strategies? And to what extent can a society or a state put legislation in place that requires all researchers to pursue a risk strategy?

These questions must be appraised from the ethical, legal and societal points of view, and the results of such appraisal can then be made concrete in the form of binding codes of conduct within the scientific community as well as national and international laws designed to reduce the risk of misuse.

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<sup>133</sup> Cf. Bezuidenhout/Rappert 2012, 5.

Recommendations for legal and other regulations require appraisal of the underlying moral orientations and their ethical validation. In the area of biosecurity, this concerns fundamental ethical considerations such as freedom and safety, chance and risk, the question as to what constitutes appropriate risk containment, and first and foremost the issue of the relationship between science and society.

Especially in recent decades, the continuing growth of our fund of knowledge in the life sciences has dramatically widened the scope of their application, bringing with it a gamut of specific possibilities and risks. One effect of this development, which will be discussed in more detail in the following passages, has been to expand a traditionally intra-scientific ethos to one that encompasses the notion of science's fundamental responsibility towards society as a whole. In the life sciences in particular, it is often difficult to draw a clear distinction between the acquisition of knowledge and its technical application (cf. Section 4.1).

In forming a judgement on the risks pertaining to DURC, ethical reflection can begin with the instruments that have already been established for biosafety risk assessment (cf. Section 4.2). However, the risk scenarios that apply to biosafety on the one hand and biosecurity on the other hand overlap only to a certain extent. In the area of biosecurity, uncertainties remain that cannot, at present, be dealt with using classical risk assessment instruments, or at least not to a sufficient extent. Therefore Section 4.3 is devoted to ethical questions of risk containment and possible ways of implementing it in the context of biosecurity. Finally, principles governing responsible dealings with problems of biosecurity are presented that favour the precautionary principle through inclusion of certain risk assessment elements (cf. Section 4.4).

## 4.1 The scientific ethos and scientific answerability

### 4.1.1 Advancement of scientific knowledge and technical implementation in the life sciences

The current problems of biosecurity arise mainly in the area of research, but also in the implementation of research findings, and this primarily in the field of synthetic biology.<sup>134</sup> Correspondingly, international discussion revolves mainly around questions that are already to be found in the context of traditional research ethics (e.g. balancing research restrictions and prevention of publication against freedom of research). The discussion is founded on a specific, internal scientific ethos that has developed in the course of centuries and is accepted by a great majority of the scientific community.<sup>135</sup> Proceeding from the list of attributes compiled by Robert K. Merton<sup>136</sup>, this includes especially:

- » the pursuit of generalizability through orientation towards standards of argumentation (universalism),
- » the universal right to participate in scientific knowledge, hence public access to scientific knowledge (communalism),
- » the preparedness on the part of the scientist to subordinate private interests in selecting projects and processes for gaining knowledge (disinterestedness),
- » recognition of the fact that scientific convictions are subject to error, together with the preparedness to respond to demands to justify personally held claims concerning validity (organized scepticism).

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134 Cf. Engelhard 2011.

135 Cf. Gethmann 1996; Lenk/Maring 1998; Nida-Rümelin 2005, 834 ff.

136 Cf. Merton 1959.

These central elements of a scientific ethos based on self-obligation have formed the basis for the confidence that the public has placed in scientists and the sciences since the beginning of the modern era.<sup>137</sup> This ethos remained uncodified for a long period of time.

Especially in the natural sciences, there has been a move towards 'Big Science'<sup>138</sup> since the Second World War. This means that research in the natural sciences increasingly takes place less on the basis of individual effort than through teamwork and in larger projects, often on an international scale. These developments have exacerbated the tendency for scientific work to become anonymized, and this in turn has diminished the individual sense of responsibility. Thus the traditional, internal scientific ethos, nourished mainly by interaction and communication within small groups and governed by instruments of direct control, has lost much of its formative character. In recognition of this development, initial steps were taken in the form of codes of conduct some time ago, and this was followed in due course by their being rendered legally binding. Thus in 1998, the *Deutsche Forschungsgemeinschaft* (German Research Foundation) presented a memorandum containing recommendations to secure the principles of good scientific practice. In accordance with this, institutes of higher education and other research establishments must comply with the 'Rules of Good Scientific Practice' when applying for funding from the Foundation.<sup>139</sup> Universities and research establishments indicated their acquiescence by establishing their own binding codes of conduct.

This process reflects the experience of those living in modern industrial societies that their lives are significantly

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137 Cf. Gethmann 1996; Weingart 1998.

138 See De Solla Price 1963.

139 Cf. [http://www.dfg.de/foerderung/grundlagen\\_rahmenbedingungen/gwp](http://www.dfg.de/foerderung/grundlagen_rahmenbedingungen/gwp) [2014-04-01]. These rules have been revised several times, the latest revision being made in 2013.



influenced by the phenomenon of ‘scientification’.<sup>140</sup> To an ever greater extent, however, the sciences bring forth applications and bring about practical consequences that cannot be seen only in terms of progress, but may also have negative effects on society as a whole. As a result of this, the sciences are increasingly understood as being not merely self-contained processes that take place within a scientific community, but rather as being an integral component of general societal interrelationships. Science is being assessed not merely on the basis of the quantity of knowledge that is amassed<sup>141</sup> or whether something is technically feasible, but according to more general societal parameters. Thus science and research are also subject to society’s critical appraisal. Accordingly, the ethical appraisal of science must concern itself not only with the practical consequences of knowledge, but also with the effects of the research process and its findings on society as a whole.<sup>142</sup> This brings its focus to bear on questions of scientific responsibility in the social context, and the tangible results are ethical codes of conduct that define what may be considered to be responsible research (cf. Section 7).

Questions of responsibility in research are closely connected with its experimental activities. This applies especially where humans, but also animals, are the subjects of research, where research is done on biological agents and where experiments are carried out in the field, e.g. where genetically modified organisms are released into the environment. Questions of responsibility in handling scientific knowledge have been debated intensively since scientists were involved in the production and use of chemical weapons in the First World War

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140 Phenomenological and pragmatic approaches in scientific philosophy have, especially, been addressing these issues since the nineteen-thirties. Cf. Husserl 1962; Dewey 1938. Since the Second World War, scientific philosophy has subjected them to comprehensive processes of philosophical reflection; cf. Habermas 1968; Janich/Mittelstraß/Kambartel 1974.

141 To this extent, science’s internal normative self-regulation is not to be seen as running contrary to scientific freedom. Compare the extensive investigation of scientific freedom to be found in Wilholt 2012.

142 Cf. Gethmann 1996.

and in the construction of the atomic bomb.<sup>143</sup> These discussions have made it clear that the traditionally perceived divide between the accumulation of scientific knowledge on the one hand and its technical application on the other cannot be maintained.

#### 4.1.2 The normative self-regulation of modern science

The new understanding of science that has been developing since the beginning of the modern era is characterized by two forms of differentiation.<sup>144</sup> On the one hand, a modification in the style of knowledge gathering is evident that can be summarized in terms of the trend 'from contemplation to intervention': Contemplation of natural processes is increasingly being complemented by intervention in these processes. On the other hand, the forms of productive and practical knowledge are changing in that they are being seen in relationship with one another. Knowledge is the key to instrumental benefit in terms of practical goals. Neither of these distinctions is new, but the relationship between them is.

##### *From the contemplation of nature to intervention in nature*

According to antique and medieval thought, knowledge can only be gained through a contemplative, i.e. exclusively reflective approach to nature.<sup>145</sup> Thus up until the late Middle Ages

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<sup>143</sup> Cf. also Lenk 1991, 7 ff.

<sup>144</sup> Of the founding fathers of modern science, Francis Bacon presented this explicitly in his work *Novum Organon*, published in 1620, so that we now speak of the Baconian method; cf. Schäfer 1993. The well-known statement on 'wisdom as power' represents the culminative expression of all that has been said on the difference between the scientific understanding of antiquity and the Middle Ages and that of the modern era, which latter remains the home of scientific endeavour to this day. Cf. Gethmann 2005.

<sup>145</sup> Plato supplied a pithy explanation for this. Knowledge can only be of the general and immutable, but the world around us is particular and changeable; therefore we can only achieve knowledge through contemplation of the general. (Plato employs this proposition implicitly and consistently

practically no attempt was made to establish a systematic link between knowledge as such and productive control over nature, i.e. what we often refer to as technology. Modern science, in contrast, its own roots reaching back to the late Middle Ages, is persuaded that causal or conditional relationships in natural processes can only be discovered through intervening in them.<sup>146</sup> The paradigm that characterizes this transformation in the acquisition of knowledge is the experiment, the investigation that takes place in a laboratory fashioned by man.<sup>147</sup> Only when knowledge becomes the result of interventions in natural processes is an alliance between knowledge and the art of engineering possible. Not until the middle of nineteenth century did a broadly based link emerge between modern science and its large-scale technological application. This had considerable effects on society, for applicable knowledge of this kind has implications of power.

Modern science's interventionist mode of knowledge acquisition and its practical implications lead directly to those problem areas that regularly give rise to tension between the realm of science and society in general. Where 'power' is mentioned, thoughts on control cannot be far away. Thus one may regard the problems that arise in connection with 'knowledge as power' as being problems concerning the control of power. Where knowledge breeds power, the question must be raised as how this power is to be controlled and, as necessary, constrained, how science may exercise its power appropriately and who shall exercise authority over that knowledge.<sup>148</sup> For power goes hand in hand with responsibility.

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in his main epistemological and metaphysical dialogues. Cf., for example, Plato, *Menon* 80d–86e; Plato, *Parmenides* 128c–135b).

146 Cf. Mittelstraß 1970.

147 For a treatment of the experiment as the connective element between 'normal' life and science, cf. Tetens 1987; Janich 1997; (on biology in particular) cf. e.g. Gutmann 2005.

148 Francis Bacon himself was no champion of scientific freedom, but rather assumed an ideal in the form of the systematic organization of all knowledge, a planned regulation of discoveries and inventions with a view to easing and improving man's lot. Cf. in this connection Dewey 2010, 224.

### *Productive and practical knowledge*

A further distinction is to be made between technological, i.e. productive knowledge and practical knowledge (that concerns interpersonal relationships). Here, too, the relationship between these two types of knowledge has undergone change. Aristotle defines productive knowledge to be that whose purpose lies without the knowledge-acquiring agent, for instance in connection with the manufacture of an article, whereas the purpose of practical knowledge resides within the agent himself or herself.<sup>149</sup> We need the latter in order to counsel others, to organize a society by legislative means or to practise medicine, for instance.<sup>150</sup>

Whereas productive knowledge secures and improves man's sway over the nature that surrounds him, practical knowledge has to do with the problems of orientation inherent in human coexistence.<sup>151</sup>

### *Transformation of the life sciences*

Both transformations can also be observed in developments taking place in modern biology, and especially in the areas of molecular biology and genetics. Modern biology regards the realm of the living from the point of view of potential intervention. This implies a productive paradigm of action.

The knowledge gained through the life sciences is, on the one hand, to be attributed to the domain of productive

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149 Aristotle, *Eth. Nic.* VI 5 etc.

150 As one of the most significant philosophical interpreters of this modern understanding of science, Bacon combines these two aspects in a curious way. That which is poetical, i.e. technological, natural scientific knowledge gained through intervention in natural processes, serves a practical end that resides within the knowledge-acquiring agent. In somewhat generalized form, it serves to liberate man from natural and social constraints (cf. Schäfer 1993 on the 'Baconian method'). For a criticism of the defence of the instrumental benefits of scientific findings, see Willholt 2012, 152, 154, where he points out the catalogue of damage that has resulted from scientific discoveries.

151 Therefore Mittelstraß translates the Greek terms for productive and practical knowledge into 'knowledge of disposal' ('*Verfügungswissen*') and 'knowledge of orientation' ('*Orientierungswissen*'), see Mittelstraß 1992.

knowledge (as exemplified in the developments in plant and animal breeding that allow targeted modification through genetic engineering). On the other hand it opens up paths of action that can substantially alter people's social interactions. Therefore the ethical foundation for an assessment of productive knowledge in the life sciences is now grounded in the domain of practical knowledge. The ethics of the life sciences is not merely a decorative adjunct to research, but determines the essential questions of legitimacy in research.

### **4.1.3 Individual entitlement and societal obligation to carry out research**

In the course of the nineteenth century, research in the life sciences led to the discovery, by means of suitable experiments, of microorganisms (bacteria, and then also viruses) which are capable of invading living organisms and propagating themselves and identified them as the causal agents of well-known human, animal and plant diseases. This knowledge soon proved very beneficial, opening up the way towards the implementation of hygienic measures to prevent the spread of diseases like cholera through bacterial infection. Since these beginnings, research on especially highly pathogenic or toxic bacteria and viruses with the aim of analysing their structure and disease pathways has become an important part of life science research. In parallel, our knowledge of diagnostics, therapies and preventive and proactive measures to combat disease increased, and current research efforts ensure that progress in this field continues.

Life sciences research has long since focused on microorganisms that have the capacity to cause severe harm to or kill humans, animals or plants. This also involves putting suitable security measures in place to protect laboratory staff and prevent the release of harmful microorganisms into the environment. These measures have also kept pace with scientific

progress and practical experience and are subject to continuing improvement. In the nineteen seventies, technical and other organizational safety procedures for laboratories were standardized through the establishment of four risk classes for microorganisms. These were initially laid down in the form of guidelines, and later confirmed by means of legislation and ordinances.

This development in the area of laboratory safety illustrates how work involving harmful or potentially harmful biological agents can only be justified if both the scientific community and society shoulder their respective responsibilities. What is at stake is not the question of permitting research as such, but the establishment of a framework of requirements and conditions, designed to protect humans and the environment, within which the research may be carried out. The state has the obligation to guarantee freedom of research and to promote such research as benefits society. This includes increasing our fund of knowledge and technologies that provide protection for humans and the environment against known hazards and risks. Biological research represents an essential part of our efforts to prevent and treat disease. However, all expectations of using research to increase our knowledge and open up chances must be balanced against the possible risks.

## **4.2 Ethical appraisal of the risks of life sciences research as a necessary basis for responsible action**

As has already been stated, technological applications in the field of biotechnology are of increasing relevance in the life sciences. Biotechnology has advanced to become a high-tech discipline, as has nanotechnology. Characteristic of high-tech is its dependency on a great deal of scientific research that is itself dependent on technological developments. The temporal and spatial separation between scientific research and

technological development is steadily diminishing.<sup>152</sup> Thus high-tech combines science and technology in a particularly marked fashion. As these technological aspects impinge both on the generation of knowledge as well as on its application in life sciences research, questions of scientific ethics and of technological ethics are on convergent courses. In this respect, risk assessment as a basis for responsible decision-making takes on a central role.

As the determination of harmful characteristics of biological agents and their risk potential regarding dissemination scenarios is of paramount importance for both biosafety as well as biosecurity, the immediate requirement is to establish what instruments are available to this end and how to determine their scope. The key terms in this context are ‘risk’ and ‘chance’, and correspondingly ‘likelihood’ and ‘harm’.

#### **4.2.1 Uncertainty and inequality as elements of modern technology and science**

In view of the way the accretion of knowledge in the life sciences and technological application mutually influence each other, ethical questions surrounding modern technology are becoming directly relevant for life science research. The modern attitude to research and technology is formed by two aspects of ethical relevance:

*On the one hand* it recognizes that in many cases a given means of achieving a given goal can only provide a certain degree of probability that the goal will, in fact, be achieved. For many imponderable factors may take effect between the outset of a project and its conclusion. Also, technological activity may result in consequences that could not be foreseen. Such consequences affect people’s individual well-being, their social and institutional links and the environment.

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<sup>152</sup> Cf. Li 2011, 3–5.

*On the other hand* current research and technology are also characterized by the fact that those who have to shoulder the burdens involved in their application are, frequently enough, not the ones who can benefit from them.

In summary: In both cases, modern technological practice and modern attitudes towards it are determined by the issue of having to act within a context of uncertainty and inequality. This is distinctive both of biotechnology as well as of genetic engineering. Whereas in earlier days the cultivation of plants and breeding of animals was aimed straightforwardly towards the achievement of concrete improvements in characteristics that would benefit mankind, modern attitudes to the practice of biotechnology are as moulded by uncertainty regarding the consequences as is the case with other areas of technology more usually associated with that of engineering. These uncertainties are centred mainly around the consequences of releasing genetically modified organisms in view of the extremely complex interaction of a given biological system with other ones, with nature and the environment.

Thus *uncertainty* and *inequality* represent salient features of modern research and technology that give rise to *specific* moral problems. For instance, the question arises as to whether a risk may be taken by an individual where a goal cannot be achieved with certainty (individual risk) or indeed transferred to others (transferred risk)<sup>153</sup>, or whether one may expose people to risks which they have not freely chosen to accept, and where they cannot or may not benefit from achievement of that goal.

#### 4.2.2 The ethical scope of risk assessments

The *concept of risk* represents a proven instrument that can be used to perceive and describe hazardous circumstances,

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<sup>153</sup> For a treatment of this issue, see Nida-Rümelin/Schulenburg/Rath 2012, 30 ff.



appraise them on this basis and then address them in the most appropriate way possible.<sup>154</sup> The terms danger and risk may be differentiated as follows: 'Danger' refers to a perceived situation, whereas 'risk' is a function of the potential damage that may occur and the likelihood of a given event taking place. Thus 'risk' may be expressed in numerical terms. In some cases, discrepancies arise between the perception of danger on the part of members of the public, 'scientific experts' and other actors such as involved companies.

There is a need in principle for modern, technically versed societies to progress from the primary perception of danger to a more general and socially binding assessment of risk, so that they are able to formulate strategies of safety and security on this basis.<sup>155</sup> This requirement is an ethical requirement. It can be fulfilled through public debate, generally on the basis of concrete experience such as that gathered in the assessment of biotechnological projects involving risk, in which the content of security policies is aired. This must include room for the expression of public unease. For such anxiety is often indicative of a communication deficit concerning biotechnological developments — or there is indeed genuine cause for concern. Therefore it is important to include representatives of civil society, for differing interests and degrees of involvement can lead to very disparate assessment of the benefits and risks of research. Through discussion involving the scientific

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154 The terms danger and risk may be differentiated as follows: 'Danger' refers to a situation (natural or social) that confronts a person and corresponds to that person's situative perception. 'Risk', on the other hand, arises as a result of human action (or inaction) and is a (numerical) function of the potential damage that may occur and the likelihood of a given event taking place. A danger may give rise to a risk under circumstances in which people recognize an existing threat but undertake nothing to allay it. The distinction given here between 'danger' and 'risk' is aligned with that suggested by Luhmann (1991, esp. 30 f.), whereby Luhmann uses the term 'decision' throughout instead of 'action'. As a consequence of this, Luhmann directs his attention more towards positive action and less towards failure to act. (For a critical treatment of the term 'decision', see also fn. 159).

155 This also includes the degree to which dangers and risks can be insured. Cf. Dewey 2010, 223 and Appendix II.4.

community and other members of society including the general public, differences can be aired and, perhaps, resolved.

However, in the context of biosecurity, the factors to be taken into account go beyond the risks involved in essentially opportunity-oriented technological applications (that can, in principle, be subjected to risk-chance assessment). They include in particular damage that may be caused through malicious action, e.g. on the part of bioterrorists. This shows clearly where the limits of conventional risk assessment are to be found.

### *The limitations of the concept of risk*

Any instrument used for rational orientation is subject to inherent limitations that are determined by the scope of the criteria. In the case of the term 'risk' mentioned above, expressed as the numerical product of the damage and the likelihood of an event occurring<sup>156</sup>, these limitations are predefined on the basis of the requirements of distributability and comparability. The limitations are determined through the weighting of the parameters, i.e. their numerical expression both in respect of the probability of occurrence as well as of the ensuing damage. Specifically in the case of bioterrorist acts, the likelihood of their being perpetrated cannot be expressed numerically because so few have, to date, taken place. On the other hand, it is often possible to quantify the damage that may be expected to occur when an agent is misused.<sup>157</sup>

Beyond this, conventional risk-chance assessment procedures are generally subject to pragmatic limitations. The assessment of an action involving risk does not include any implied degree of acceptability or inacceptability. For instance, both from the individual as well as the collective points of view normative boundaries can, in principle, be drawn for the

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<sup>156</sup> Cf. fn. 154.

<sup>157</sup> For instance, the damage that will occur if a certain modified influenza virus is released can be quantified.

acceptability of potential damage ('deontological demarcation'<sup>158</sup>). However, for the purpose of expressing such boundaries, a formal and explicit concept of risk as laid down above (at the beginning of Section 4.2.2) is required.

***Risk comparison: the principle of pragmatic coherence***

In the interests of reaching rational decisions, a society that wishes to set up binding instruments for dealing with risks should not avoid the issue of weighing up options for action against each other by comparing risks. Risk comparisons serve, essentially, to clarify questions of the *acceptability* of the consequences of an action that affects a person (including oneself).<sup>159</sup> In such rational treatment of risks, it is important to distinguish between their acceptance and their acceptability.

What is meant by risk acceptance is the actual preparedness — which in an ideal case can be described in empirical, social-scientific terms — of an individual or a group of individuals to undertake or accept an action that may have hazardous consequences, or not to undertake it as the case may be. Notwithstanding this, no guarantee exists that actual preparedness to accept risks on the part of individuals and collectives will be free from inconsistency or is indeed compatible with established standards of rationality. For the ethical appraisal of risks it is therefore essential to define the term *acceptability* to complement the actual degree of acceptance. Thus standards and norms are needed and they are to be implemented

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158 Nida-Rümelin/Schulenburg/Rath 2012, 135 ff., 161 ff. and 179 ff. The inclusion of the standard decision theory in the risk-chance assessment suggests that the risk-chance assessment necessarily presupposes a consequentialist type of ethics. However, this is by no means the case. On the contrary, benefit-ethical and obligation-ethical points of view can both be integrated. Rescher 1983 and Gethmann 1993 provide examples of such approaches.

159 The attribute 'involving risk' refers here to actions and not to decisions, as in Luhmann 1991. Even if one adopts the Cartesian formula that external action is a manifestation of an inner decision, then it is precisely *not* the decision that involves risk, but its implementation or failure to do so, i.e. the action. Decisions, on the other hand, are not subject to moral or legal jurisdiction any more than desires or intentions, etc. For anybody can wish for anything, without having any a priori claim to that wish being fulfilled.

with critical judgement. The question as to whether a given risk can be or should be accepted by an individual or a group should then be contingent on these standards and norms being fulfilled.

Hypothetical precepts for action<sup>160</sup> in respect of the acceptability of risks can be justified insofar as the principle of *pragmatic coherence*<sup>161</sup> is acknowledged. This principle states that: If you are prepared to accept a risk in respect of an action, then — assuming that you are behaving rationally and the benefit is of the same magnitude — you should also be prepared, in principle, to accept a risk in respect of another action of the same risk type where that risk is less or at most of the same magnitude. This principle does, however, assume that every person strives to achieve coherence in his or her actions. It applies both to individuals as well as — and here the consequences are especially far-reaching — to society. Even if one grants that neither individual actions nor political decisions always follow the principle as a matter of course (because other issues may overrule it), it is not easy to find anything that is ethically implausible in the principle itself.

The true scope of application of the principle of pragmatic coherence is to be found in the appraisal of actions in which

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160 However, the idea that it may be possible to formulate *categorical* imperatives for risk acceptance proves to be too ambitious, because — in order to avoid a naturalistic fallacy — normative premises would necessarily have to be applied. In contrast, though, it is possible to formulate *hypothetical* imperatives. Such hypothetical imperatives suffice, in almost all contexts of action, to achieve orientation for taking action; and this also applies to DURC. Generally, formulating such hypothetical precepts for action is possible quite straightforwardly, and that is what is constantly being done in everyday life, technology and science.

161 First formulated by Gethmann, 1993. Also appealing to Immanuel Kant, Charles Fried suggested a similar principle: “[...] that all persons may impose risk of death upon each other for the ends and to the extent that all other persons may do so” (Fried 1970, 185). The difference lies in the fact that Fried assumes the model of a ‘fully conscious decision for taking action’ (and therefore either limits the principle’s scope of validity to ‘rational’ persons, or must establish another principle, namely one of rationality), whereas the principle of pragmatic consistency is valid for the generalizability of the ‘normal case’, i.e. the actions that are *de facto* morally habitual, but usually not subjected to discussion (‘revealed preferences’).

risk-chance assessment is possible either directly or at least in analogy. This scope is, admittedly, limited: firstly, where the protection against dangers and risks is involved that may not be countenanced under any circumstances, and secondly where estimation of the likelihood of an event occurring is so uncertain that no comparison can be made. In view of these aspects, the principle of pragmatic coherence must be augmented, especially where biosecurity is involved.

However, the principle must also be observed regarding *precautionary* measures in respect of damage scenarios that are taken into consideration in connection with biosecurity where prevention, corrective action (e.g. therapy) and compensation for bioterrorist attacks are involved<sup>162</sup>. For instance, when decisions on preventive measures are taken, the approximate likelihood of an event occurring is taken into account as well. Also, when damage has occurred, remedial measures are to be assessed in such a way as to include the potential for damage that they themselves may cause. Finally, compensatory measures must also be classified according to risk-chance aspects pertaining to actual damage that has occurred (e.g. compensation for damage following statutory vaccination programmes as preventive measures against a pandemic).

### **4.2.3 On the ethical reconstruction of the term security**

Using the principle of pragmatic coherence as a basis, a contribution may also be made towards defining the term ‘security’. By way of preparing the ground, we should first reject the — frequently encountered — usage that implies that security may

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<sup>162</sup> The principle is of service in assessing individual options for action both retrospectively and also in advance (comparison of options). Thus it is not to be understood in the sense that new risks are added to existing ones (risk aggregation). For an exhaustive treatment of possible misunderstandings, cf. Gethmann 1993, 46 ff.

be equated to actual absence of malfunction or accident. For a course of action may indeed be free of malfunctions and accidents, but nevertheless subject to high risk. Conversely, a high degree of sensitivity to detect errors in a technical system can lower the risk of incalculable damage. For instance, if a technical facility is judged to be 'safe', this generally simply means that it fulfils a certain prescribed criteriology of safety. When seen in this way, security — or, in this case more appropriately: safety — is also a normative term. This is characterized by the fact that the circumstances to which it relates are ordered comparatively. This formulation includes the possibility that the classification of a technical plant is not merely a binary matter of 'safe/not safe', but rather of degree ('to a certain extent safe'). This approach is reflected in the categorization of the technical safety requirements for laboratories into four classes: S 1 to S 4.<sup>163</sup>

Therefore the ranking of relevance should begin with an investigation of the criteria for deciding whether one thing may be regarded as being safer or more secure than another. If one assumes that such a condition prevails where that thing carries less risk, then the definition of the term 'risk' that has already been presented — the numerically expressible connection between the potential damage and the likelihood of an event occurring — represents the starting point for rendering the term 'security' more precise.<sup>164</sup>

The following *three postulates* would appear suitable and sufficient for a limited application of the principle of pragmatic coherence in questions of biosecurity, in order to define the term 'security' and therefore delineate what is meant by the rational handling of risks. In accordance with this, an option for action can be regarded as being 'safer or more secure than

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163 *Biostoffverordnung (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit biologischen Arbeitsstoffen, BioStoffV)* (Ordinance on Security and Health Protection in Activities Involving Biological Agents) of 15 July 2013 (Federal Law Gazette I p. 2514). Cf. Section 5.2.

164 For the following, cf. Gethmann 2001.

another' if it satisfies the following criteria (a) to (c) (assuming that the scope of the consequences of that action are limited):

**(a) Predictability postulate**

“Where alternative courses of action present themselves, choose those for which the consequences can best be predicted.”

The capacity to foresee the consequences of an action (be it one of commission or omission) presupposes a certain level of knowledge. One needs to know the causality attributes, or at least the conditional circumstances that pertain between the courses of action. Knowledge of such causality and conditions is only available and possible where normal experience or science can reconstruct causal relationships or conditional patterns. Thus the predictability postulate immediately leads to the requirement to conduct research in order to establish the consequences of actions. Risk minimization requires scientific research. To require minimization of risk and at the same time hinder research on the consequences of courses of action is contradictory.

**(b) Controllability postulate**

“Where alternative courses of action with predictable consequences are available, choose those whose problematic consequences can best be contained.”

The controllability postulate implies the requirement to use technology to contain risks that are themselves the result of technological or research applications. Technology or research that cannot be controlled by technological means cannot be classified as being morally sound.

**(c) Reversibility postulate**

“Where alternative courses of action with predictable and controllable consequences are available, choose those whose consequences can best be reversed.”

This principle reflects that discretion that is often used intuitively in everyday contexts: Even when courses of action

appear to be controllable, an element of uncertainty should be assumed, so that reversible courses of action are preferable to ones that cannot be reversed, or only reversed to a lesser extent.

In accordance with the treatment above, the understanding of 'security' expressed through the postulates (a) to (c) entails the necessity always to articulate the element of comparativity that resides in the criteria for security. For the task of 'making something safer' is one that can never be brought to a conclusion: There is no such thing as an absolutely safe state. Therefore the term 'security' refers to an iterative process, one that has no alternative in today's society.

The constant and continuous monitoring of technological development and application must include not only the control of technological processes, but, in deference to the principle of common welfare, the social implications as well.

### **4.3 Dealing with uncertainty — the precautionary principle**

Risk-chance assessments, risk-risk comparisons carried out using the appropriate instruments and safety standards that are laid down in consequence of them are all essentially dependent on the availability of information about event probabilities and damage scenarios. However, such information is not always available, for instance at the cutting edge of research and innovation.

When a course of action is subject to uncertainty, it must be borne in mind that there is no third option beyond the possibility of action or refraining from action. In such cases, those concerned are more or less fated to choose between action or inaction. In such cases, it is not per se preferable to choose not to implement a course of action only because there is uncertainty



regarding the likelihood of certain consequences.<sup>165</sup> Failure to act can be associated with just as much uncertainty concerning the consequences as the corresponding course of action. No statistically reliable information exists for biosecurity-relevant research concerning the likelihood of negative, biosecurity-relevant events occurring (e.g. bioterrorist attacks), nor for possible negative consequences that may result from failure to undertake such research (e.g. into the treatment or prevention of some serious infectious disease).

In view of such uncertainties, ethical reflection on taking action under risky circumstances has led to various approaches aimed at formulating criteria for justified recommendations for action.<sup>166</sup> However, the following analysis shows that with the exception of the precautionary principle (when it is appropriately interpreted), the approaches are, in view of the challenges to be overcome in the realm of biosecurity, unsuitable or at best only of limited suitability as instruments for risk assessment.

### *The Laplace criterion*

Probably the oldest criterion can be attributed to the physicist Laplace.<sup>167</sup> It simply assumes that where information on the likelihood of possible events occurring is missing, then their probability is uniform, as is the case when a die is thrown.

However, this does not apply to events such as terrorist misuse of biological agents or research results, because their probability practically cannot be quantified. Therefore the Laplace criterion cannot usefully be implemented.<sup>168</sup>

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165 An obligation to refrain from research can, however, be justified in cases where it lays the foundation for some catastrophic consequence, or there is a risk of this happening. Cf. below in this section.

166 For an overview of these, see Nida-Rümelin/Rath/Schulenburg 2012, 93 ff.; Rath 2011, 51 ff.

167 Nida-Rümelin/Rath/Schulenburg 2012, 101 ff.

168 Cf. criticism supplied by Nida-Rümelin/Rath/Schulenburg 2012, 101.

### *The maximin criterion*

The so-called maximin criterion<sup>169</sup> that has been formulated by a number of authors requires that in cases where uncertainty exists regarding the consequences of actions, the least damaging option should be selected rather than the most beneficial. In certain cases of uncertainty where actions can have catastrophic effects there is even a moral obligation to refrain from action. Therefore approaches based on the maximin criterion frequently lead to courses of action characterized by risk aversion. Where consequences may otherwise be catastrophic, this is also justifiable. However, the criterion is open to the criticism that it often leads to paradoxical results, for instance in cases where two courses of action have roughly similar potential for harm, but the potential benefits are very disparate.<sup>170</sup> Where biosecurity is concerned, the problem is compounded by the paucity of information regarding the likelihood of events taking place.<sup>171</sup>

### *The minimax criterion*

The minimax criterion<sup>172</sup> attempts to counter the criticism directed against the maximin criterion by requiring the minimization of the maximum relative loss that results from selecting a given course of action in preference to others. To this end, first of all an alternative option is laid down for each event that promises to produce greater benefits. Then, for each possible event, the difference of each other option is calculated compared with the respective greatest benefit value. To put it rather loosely, the point behind the criterion is to find that course of action that may be expected to give rise to the least regret. Again, in the context of biosecurity the assumed parallelization

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169 Cf. Wald 1950. The criterion has been reimplemented both by Hans Jonas as well as by John Rawls (Jonas 1979, 70 ff.; Rawls 1979, 174 ff.).

170 For criticism of individual aspects, cf. Kern/Nida-Rümelin 1994; Nida-Rümelin/Rath/Schulenburg 2012, 95 ff.

171 For the biosecurity context, the modification of the maximin criterion suggested by Leonid Hurwicz (see Hurwicz 1951) does not alter the result.

172 Cf. Savage 1951.

of the degree of regret with the difference between the benefit values is normatively questionable, because regret over losses of human life or health cannot be quantified in the same way as financial losses.<sup>173</sup>

### *The precautionary principle*

The precautionary principle states that, under certain circumstances, (massively) restrictive measures may be justified where a given technology or some course of action threatens to cause serious and irreversible damage to humans or the environment, even if no reliable scientific risk analysis is available.<sup>174</sup>

In contrast to the other approaches mentioned, the precautionary principle has been adopted as an initial principle of legal policy.<sup>175</sup> Thus it has, especially, become part of national and international environmental legislation. Today, however, the precautionary principle also represents an internationally established ethical decision-making criterion in cases of scientific uncertainty.<sup>176</sup>

Although the precautionary principle exists in a variety of versions, the pronouncedly risk-averse version mentioned above has been given special attention with reference to the ‘principle of responsibility’ advocated by Hans Jonas amongst others. The precautionary principle takes particular account of the vulnerability of nature, the environment and mankind in the face of the modern scale of man’s technological — and irreversible — interventions. It also implies a discrepancy between man’s technical capabilities and his moral competence.<sup>177</sup> Hans Jonas summarized the ethical content of the precautionary principle thus: Act in such a way that you do not endanger the continuing existence of mankind, avoid the greatest damage

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173 Cf. description and criticism supplied by Nida-Rümelin/Rath/Schulenburg 2012, 102.

174 Cf. Bachmann 2007, 1.

175 See also Rath 2008, 114 ff.; Nida-Rümelin/Rath/Schulenburg 2012, 105 ff.

176 Cf. Nida-Rümelin/Rath/Schulenburg 2012, 107.

177 Cf. Jonas 1979, 28.

that one can imagine and do not try to weigh that up against any benefits.<sup>178</sup> This principle means that, in the context of biosecurity, research and the application of its findings should not be restricted only when unequivocal scientific proof of harm being caused by them has been supplied. However, it remains a matter of debate as to when exactly the precautionary principle requires that certain high-risk activities be refrained from. Two different versions have been formulated: the *strong* version and the *weak* version:

The strong version of the precautionary principle reverses the burden of proof: A risk-intensive action should be refrained from and also prohibited until such time as proof can be furnished that a certain level of societal security is guaranteed. One problem inherent in this variant consists in that reversing the burden of proof may lead to large-scale restriction relating to research and innovative technology, although no proof of their potential for harm has been furnished.

Advocates of the weak version of the precautionary principle seek to avoid overrestrictive prohibition in cases of uncertainty. They base their arguments on the premise that, where uncertainty prevails, preventive measures should indeed be undertaken if high-risk activities threaten to have serious negative consequences for highly valued goods such as human life or the environment, but beyond this no obligation to refrain from undertaking that activity can be derived from these circumstances per se.<sup>179</sup>

### ***Risk provisioning requirement***

Using the weak version of the precautionary principle, it is also possible to transform its static formulation into a procedural

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178 Cf. Jonas 1979, 76 ff., 86 ff., passim; cf. also Jonas 1985, 67 etc.

179 Compare also the text of Principle 15 of the Rio Declaration: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (United Nations 1992).

rule for risk provisioning. Such a risk provisioning requirement can be operationalized on the basis of the following four postulates:

**(a) Burden of argument**

In accordance with the basic rule of modern philosophy: “In case of doubt, freedom to act is better than restriction of freedom,” the state may not put (prohibitory) restrictions in place merely on the basis of uncertainty due to lack of information, but only where there are good grounds for the assumption that a technology or product is potentially harmful. However, a lack of scientific proof for the harmful potential cannot per se justify not implementing state-regulated measures with a view to minimizing risk. If, therefore, plausible grounds exist for the assumption that severe damage may be caused, this may justify reasonable restrictions of the radius of action with a view to minimizing risks.

**(b) Responsibility to conduct research**

The principle of circumspect provisioning for risk also includes societal and state responsibility to conduct appropriate research. Correspondingly, scientific resources must be deployed in order to reduce the level of uncertainty through finding out more about possible risks and the likelihood of their becoming reality so as to be able to carry out careful risk analyses using the information that accrues. The aim of such risk analyses is to provide a scientific basis for assessing technological risks in terms of the probability of damage occurring and its extent. Also, ancillary research should be undertaken as early as possible in newly developing areas of science, and this should include ethical considerations. This is to provide a basis for weighing up risks against chances in order to determine what needs to be done in terms of putting preventive measures into place.

### **(c) Risk provisioning**

As indicated above, a technology should not be prohibited solely because no scientific proof of its harmlessness has been supplied. Nevertheless, both the state and the scientific community have obligations to provide against risks. This can entail measures designed to reduce risks, and in certain cases even justify prohibiting research. The risk provisioning postulate also includes the necessity to monitor and review research.<sup>180</sup>

### **(d) Public dialogue**

In addition to the internal process of risk assessment within the scientific community, where uncertainty prevails, there is also a need to ensure that the discussion becomes part of a public dialogue to establish a social framework for responsible dealings with new areas of research and innovation.

There are various reasons why the public should be included in decisions of scientific policy.<sup>181</sup> One of these is that such a process balances out the views of the experts, that tend to be biased in favour of technical aspects, through everyday, practical considerations.<sup>182</sup> Participation promotes transparency in matters of conflicts of values and areas of consensus and dissension, helps to establish models for the constitution of norms through ethical discourse and increases the degree of information available to and accepted by those (potentially) affected in a wider sense.<sup>183</sup> Participation of this nature can mean that those affected contribute to the information pool, take part in the processes of assessment and themselves profit from their results that are then publicly accessible.<sup>184</sup>

When members of the public take part in the information process, emotional, pragmatic and especially cultural appraisals can be given more room. Aspects of this sort can be brought

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180 Cf. Bachmann 2007.

181 Cf. Nanz/Fritsche 2012.

182 Cf. Renn 1999 and 2003.

183 Cf. Skorupinski/Ott 2000.

184 Cf. Schicktanz 2006.

out into the open in the course of discussion, and if the need arises they can be subjected to further scrutiny so that they can more readily be integrated into the academic and scientific debate.<sup>185</sup> These processes are not results orientated (in the sense of filling in knowledge gaps or negotiating agreements), but rather have the nature of reflective discussion.<sup>186</sup> Thus public participation fulfils the function of complementing the discussions that will already be taking place amongst experts and various social groups.

#### **4.4 Dealing responsibly with biosecurity risks in the life sciences — the ethical dilemma of Dual Use Research of Concern**

The question of laboratory security has always been a necessary adjunct to the development of the life sciences in their modern form. Measures taken are designed to protect scientists and other laboratory personnel and prevent the unintentional dissemination of microorganisms and spread of disease via infection of staff. Initially, therefore, instruments of risk assessment are implemented with the aim of achieving biosafety. The person mainly responsible for implementing the necessary laboratory safety measures is the researcher. This applies even more stringently in cases where dangerous microorganisms are being handled in the laboratory that have the potential to cause an epidemic if released into the environment.

Questions of biosecurity, on the other hand, refer to the malicious use of biological agents by third parties or researchers themselves and to the malicious use of research results such as publications on the manufacture or modification of certain dangerous biological agents. In the main, the questions revolve around Dual Use Research of Concern (DURC), in other words

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185 Cf. *ibid.*

186 Cf. Renn 1999, 126 f.; cf. also Schicktanz 2006.

work that can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to cause damage to public health and safety, the environment or to other important legal interests (cf. Section 1.2).

In contrast to the biosafety situation, there are additional challenges involved in risk appraisal and risk provisioning in matters of biosecurity. Here, the hazard potential of a biological agent cannot solely be derived from knowledge of its toxic or pathogenic characteristics. The critical point is its suitability as a bioweapon, which is essentially determined by its ease of handling and how well it can be disseminated. On a different level, the threat of terrorism generally is highly dependent on national and international structures and developments.

As strategies that are based exclusively on risks being determined in terms of damage potential multiplied by probability of occurrence are not sufficient, adequate biosecurity precautions, especially in the area of DURC, must be achieved through the development of suitable instruments and techniques, the establishment of areas of responsibility and the identification of persons responsible. These instruments and techniques should, as indicated above (cf. Section 4.3), be based on the precautionary principle, because other principles suggested for risk appraisal do not suffice.

The situation can arise in a DURC scenario that a researcher finds himself or herself on the horns of a dilemma, between the desire to achieve certain research goals and the desire to avoid risks that can arise from misuse of the results. The precept of risk provisioning does not resolve this dilemma, but requires that these competing requirements be weighed up against each other with a view to preserving the greatest possible number of normative aspects within the complex of freedom to research and necessity to avoid risk. On account of the extraordinary risk potential of DURC and the imponderables involved in weighing up the various factors, the process of justifying a given course of action is beyond the capacity of an individual researcher. The collective threat requires



broadly-based consideration and legitimization of courses of action.

It is a basic prerequisite for a DURC-specific precautionary strategy that DURC-relevant problems should be examined in all phases of the scientific knowledge-gathering process (project design, project execution, dissemination of results). And prior to this, it must be clear what types of research project (i.e. what areas, what aims and what methods, cf. Section 1.2) and agents involve a specially high potential for misuse and therefore give rise to a particularly high degree of concern.

On this basis, the next step is to investigate the extent to which risk assessment instruments that are already in place for biosafety purposes can usefully be extended to cover the area of biosecurity, taking the precautionary principle into account. One important aspect of this includes the aim of improving the quality of information for biosecurity-specific risk assessment. *On the one hand*, the ancillary determination of possible risk scenarios involving misuse of research results by terror groups or states conducting biological weapons research is a matter of prime importance. *On the other hand*, a structural and procedural framework can be established to help those involved in the risk assessment and risk-chance appraisal in their efforts to deal responsibly with the challenges presented by DURC.

The question as to what constitutes 'appropriate' handling of biosecurity risks in research needs to be addressed by the scientific community generally, specifically by individual life scientists, by the state, by security experts and indeed by society as a whole. A suitable answer can only be found on the basis of cooperation between all the persons and bodies concerned in the search for the best risk provisioning strategy, i.e. one that takes account of all the various interests and clarifies the apportionment of responsibility (cf. Section 10).

## 5 LEGAL FRAMEWORKS FOR DUAL USE RESEARCH IN GERMANY

The legal frameworks for Dual use research in the life sciences in Germany consists of instruments at a number of different levels. These include national constitutional law, international law, European law and also various branches of sub-constitutional law already existing.

### 5.1 Constitutional premises

#### 5.1.1 Academic freedom

Article 5, Para. 3 of the Basic Law for the Federal Republic of Germany protects the process of autonomous scientific enquiry without reservation, i.e. the freedom to research is not limited by any express restrictions. In the interests of securing pluralism in science and innovative freedom, the Federal Constitutional Court has formulated a broad interpretation of the term ‘science’. It includes “everything that can be regarded in its content and form as being a serious, planned attempt to establish truth”.<sup>187</sup> This constitutional guarantee covers both university as well as non-university research, including so-called industrial research<sup>188</sup>. In certain cases, the broad umbrella of protection spread over scientific freedom is somewhat limited in that only the responsible use of this freedom is regarded as being worthy of protection.<sup>189</sup> However, such a functionalization of the exercise of freedom runs contradictory to the open-ended evolution and autonomy that is the purpose of the constitutional guarantee. The fact that in the course of exercising

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<sup>187</sup> Thus the Federal Constitutional Court decisions 35, 79 (113); most authors agree with this. [Translators’ rendering of the German original.]

<sup>188</sup> The last point is subject to debate. In this connection, see Teetzmann 2014, 43.

<sup>189</sup> Cf. Dickert 1991, 402 ff.; also Teetzmann 2014, 40.

this freedom third party rights may be affected does not in itself imply that the scientist no longer enjoys the protection provided by the first sentence of Article 5, Para. 3 of the Basic Law.<sup>190</sup> Conflicting interests and positions must first be shown to be justified and then stand up for themselves in the subsequent process of weighing up the different rights.

The guarantee of scientific freedom is of significance not only as a defence against State interventions, but also because it obliges the State to establish a supporting framework and undertake flanking measures to secure that freedom.<sup>191</sup> It devolves upon the State to ensure that scientific endeavour can be pursued independently and within a functioning framework.

As modern science takes place in a complex of cooperative activities between the State, scientific organizations and society, its regulation is correspondingly complex as well. The State must fulfil a double function as a 'mediator' charged with setting boundaries and at the same time as an enabling facilitator.<sup>192</sup> By regulating science, the State can take recourse to various forms of self-governance based on specific expert knowledge. Setting internal scientific standards in this way, for instance by means of codes of conduct, helps on the one hand to secure open attitudes to innovation and flexibility, and on the other hand to promote acceptance through participation and mediation of interests. Equally, there are the dangers of in-transparent/unclear accountability, selective articulation of interests and control instruments proving to be deficient.<sup>193</sup> The question as to whether, and if so to what extent, the State's restraint in terms of biosecurity legislation can be countenanced, or whether it needs to limit scientific freedom (for instance by means of notification or permission requirements, research or publication restrictions) for the sake of preventing harm or

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190 Cf. also Federal Constitutional Court decision 128, 1 (40).

191 Individual points are disputed, cf. Fehling in: Dolzer/Vogel/Graßhof 2011, Art. 5 Para. 3 Basic Law, recitals 23 to 50.

192 See especially Trute 1994.

193 For a more detailed treatment, see Höfling 2008, 45 ff.

risk provisioning, can only be decided upon on a sector-by-sector basis, thus in this case for biosecurity-relevant research. The aspects that need to be dealt with here include those legal interests that suffer disadvantage on account of biosecurity research activity, the (ir-)reversibility of consequences of actions, the risk potential and the likelihood of damage occurring, but also the extent of possible benefits.<sup>194</sup>

### 5.1.2 Restrictions on biosecurity-relevant research

As biosecurity-relevant research can entail risk for individual and collective protected goods, the State has a fundamental constitutional duty to protect the integrity of those legal interests that are affected. Such obligations arise on the one hand through the guarantees of fundamental rights contained in the Basic Law, which implies the need to protect as well as to defend.<sup>195</sup> In the context of biosecurity legislation, the Basic Law specifically provides for the protection of ‘life’ and ‘physical integrity’, by which both the health of the individual as well as of the population as a whole are meant. On the other hand, there are other constitutional provisions that commission the State to provide for protection. Thus Article 20a of the Basic Law requires the State to protect the natural foundations of life and animals, amongst other things as part of “its responsibility towards future generations”. This provision can also require risk precaution measures.<sup>196</sup> The requirement to secure peace as expressed in Article 26, Para. 1 of the Basic Law is structurally comparable to a great extent.<sup>197</sup>

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194 See also Würtenberger/Tanneberger 2014.

195 See here only Federal Constitutional Court decisions 39, 1; 46, 160; 49, 89; 79, 174; 88, 203.

196 See Federal Constitutional Court decision 128, 1 (37).

197 Also, Article 1, Para. 2 of the Basic Law may be invoked, in which the German people acknowledge their commitment to peace in the world. Cf. Federal Constitutional Court decision 47, 327 (382).

Primarily, it devolves upon the legislature to enforce these — constitutional — duties to protect. As the Federal Constitutional Court has pointed out on several occasions, in realizing the duties to protect already mentioned, the legislature possess a broad discretion and a broad scope for evaluation and enactment measures.<sup>198</sup> At least, the State must provide for a certain minimum of effective protection. At the same time, it must take account of possible encroachment that such an intervention may cause on the fundamental right of those who represent the source of that danger. This constellation of ‘protection through intervention’ gives rise to a complex structure of fair balance.

The legislators’ tasks of appraisal, evaluation and enactment are made more specific on the basis of structural elements. For the problems examined in this Opinion, the following aspects are of significance:

1. The State’s duty to protect is activated where individual or collective goods suffer (private) harm or are endangered. In order to justify restriction of the unreserved freedom of science, such goods must be protected by the constitution as well. This is manifestly the case for the constitutional goods contained in the first sentence of Article 2, Para. 2 of the Basic Law, but it also applies to the protection of the environment and animals and to securing peace.
2. The duty to protect is activated in the case of any action that oversteps a certain level of relevance. This means that not only actual disturbances or dangers (in a police law sense) are relevant, but under certain circumstances prior risks as well. Here, it is necessary to perform a relational assessment (amongst other things) of the likelihood of an event occurring and the degree of damage that may ensue

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<sup>198</sup> See for instance Federal Constitutional Court decisions 77, 170 (214); 79, 174 (202); 85, 191 (212).

in order to address the question as to whether a danger or risk level has been reached that activates the duty to protect.

3. The State has a broad discretion in choosing the instrument to be used for providing protection. Theoretically, the possible instruments range from an appeal to professional standards such as codes of conduct to notification and permission obligations to prohibition of publications and research. One view is that such restriction of publication does not fall within the scope of the prohibition of prior censorship as laid down in the third sentence of Article 5, Para. 1 of the Basic Law.<sup>199</sup>
4. A decision to use a specific means of intervention or a specific programme of protection is taken on the basis of assessment criteria such as the intensity and degree of the encroachment on the good to be protected, the immediacy or probability of the encroachment, the possibility or impossibility of ancillary risk management and so forth. On the other hand, it is bounded by the degree of encroachment on scientific freedom. The clear duty to take action is given where, for instance, there are grounds for assuming that there is a specific danger of the use of biological weapons. In contrast, and in certain circumstances, a general risk of misuse without a sufficiently specific danger to life or limb can be limited according to circumstances by simple procedural and organizational regulations, too.

The complexity of the process of balancing of interests is intensified in cases where the State's intervention to protect life and limb runs counter to the scientific freedom to conduct research aimed to secure public health.

5. However, the parliamentary prerogative that ensues from the constitutional principles of democracy and the rule

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<sup>199</sup> Article 5, Para. 1, Sentence 3 refers, as systematic exegesis reveals, exclusively to the freedom of communication as laid down in Article 5, Para. 1 of the Basic Law. For another opinion, see Fehling in: Dolzer/Vogel/Graßhof 2011, Art. 5, Para. 3 of the Basic Law recitals 713 with further references; Teetzmann 2014, 95 f.

of law (*Rechtsstaatsprinzip*) is also of decisive importance. This means that in fundamental normative areas, especially where the exercise of fundamental rights is concerned, but generally in all questions of substantial significance for the society as a whole (insofar as these are in any way possible to be regulated by the State) essential decisions are to be taken by the parliamentary legislators.<sup>200</sup> The parliamentary legislators' obligation to take action and to set standards concerns not only the question as to whether legislation is to be enacted altogether, but also its scope and specific degree.<sup>201</sup> This does not mean that the Parliament has the only competence to regulate<sup>202</sup>, but — insofar as the requirement to regulation is not disputed — a regulation with *sufficient certainty* is necessary, so as to ensure enough flexibility for the administration or the government's political capacity to act is guaranteed where it is appropriate and necessary.<sup>203</sup> However, it remains a matter of debate as to when this sufficient certainty, in a given situation and in different regulative areas, has been achieved. This is particularly the case where new knowledge is being generated and external expertise is called in by the administration regarding the implementation of legislation.<sup>204</sup> Here, it may generally be stated that, in normative relevant areas where it is not possible or appropriate to formulate an exact conditional programme in a legislative framework, the parliamentary legislator must at least lay down procedural rules within the realm of the parliamentary prerogative that determine for

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200 Federal Constitutional Court decisions 49, 89 (126 f.); 61, 260 (275); 80, 124 (132); 101, 1 (34). In this connection and with reference to the following, see further treatment in Vöneky 2010, 214 ff.

201 Federal Constitutional Court decision 101, 1 (34).

202 Cf. also Seiler 2000, 87.

203 Cf. Ossenbühl 2007, Para. 101 recital 61.

204 For a general treatment of the deparliamentization debate, cf. Puhl 2005, Para. 48. Cf. also Voßkuhle 2005, Para. 43 recital 51. General treatment of committee composition and questions of legitimacy, contributions in Sommermann 2001; general treatment of non-ministerial scope e.g. Schmidt 2007, 175 ff.

calling in external expertise and serve to order the interests concerned. Thus a formal law must determine procedure and organization<sup>205</sup> and ensure that the decision-making bodies concerned are constituted in accordance with the task — in other words, in a generally balanced and competent manner.<sup>206</sup>

## 5.2 International Law and European Law: premises and influences

The constitutional framework sketched above is amplified and influenced by norms of international law and the law of the European Union (cf. Appendix II).

### 5.2.1 Specifically biosecurity-relevant international agreements

The Biological and Chemical Weapons Conventions<sup>207, 208</sup> have been ratified by Germany and are therefore binding for Germany. The Biological Weapons Convention of 1972 prohibits the development, manufacture, storage, purchase or retention of certain microbiological or other biological agents and toxins as well as weapons, equipment and deployment devices intended for the use of these agents and toxins, and therefore deals with, amongst other things, biosecurity-relevant research. By way of implementing this Convention, it is forbidden in Germany

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205 Cf. also Voßkuhle 2005, Para. 43 recital 66.

206 Cf. Dreier 2006, Art. 20 recital 122; Voßkuhle 2005, recitals 68 ff. and 72.

207 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (Biological Weapons Convention) of 10 April 1972, in force since 26 March 1975 (Federal Law Gazette 1983 II p. 132; 1015 UNTS 163).

208 Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (Chemical Weapons Convention) of 13 January 1993, in force since 29 April 1997 (Federal Law Gazette 1994 II p. 806; 1974 UNTS 45).



and for German citizens to develop, manufacture, store or purchase any biological agents for non-peaceful purposes, and this includes research projects. However, at the same time the Convention allows research on such agents for the preventive, protective or 'other peaceful purposes'. The Convention specifically includes preventive and protective purposes (such as prevention of disease) under 'peaceful purposes'. For the area of biosecurity-relevant research under discussion here (which is characterized by the fact that its purpose is not to produce biological weapons), the decisive question is what types and quantities of biological agents may be or may not be justified by peaceful purposes. However, international law provides no answer to it, because the Convention does not contain any definition.<sup>209</sup> After the decision was taken during the Conference of the Parties in 2002 to elaborate recommendations for strengthening the Biological Weapons Convention by 2006, and this also includes the recommendation to discuss the development of codes of conduct for scientists<sup>210</sup>, a variety of different efforts have been undertaken towards developing biosecurity-related codes of conduct at both the international level and the national level.<sup>211</sup> It was also agreed during the Conference of the Parties in 2006 to continue the international discussions on this complex of subjects within the structures of the Convention.<sup>212</sup> However, this has not produced any results to date. By the next Conference of the Parties in 2016, the States are to

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209 For more details of the scope, cf. Appendix II.1.1.

210 Cf. United Nations 2002, recital 18 No. v: "At its eighth plenary meeting on 14 November 2002, the Conference decided, by consensus, as follows: (a) To hold three annual meetings of the States Parties of one week duration each year commencing in 2003 until the Sixth Review Conference, to be held not later than the end of 2006, to discuss, and promote common understanding and effective action on: [...] v. the content, promulgation, and adoption of codes of conduct for scientists".

211 Cf. Section 7.

212 Cf. United Nations 2006, Part III, recital 7 a No. iv: "Oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention".

have handled the questions concerning the new scientific and technical developments within the scope of the Convention.<sup>213</sup> This is to include the identification of possible means of control. As early as 1986, the Meeting of the States determined that the Convention indisputably covers all naturally or artificially created or altered microbiological or other biological agents and toxins as well as their components, irrespective of their origin, means of manufacture or the question as to whether they cause harm to humans, animals or plants.<sup>214</sup> The contracting States have identified various challenges concerning potential misuse.<sup>215</sup> Further, progress in the area of targeted delivery technologies was considered by the contracting States to be of special significance regarding the danger of biological substances being released, including by means of terrorist acts.<sup>216</sup> Also, cooperation and assistance as laid down in Article X<sup>217</sup> is to be dealt with thoroughly<sup>218</sup>: Today, infectious diseases are regarded as global health problems, so that all States profit where disease control is strengthened on the international level.<sup>219</sup> In this respect, cooperation and the potential for misuse generate a conflict that is to be resolved by means of active measures being undertaken by the contracting States.<sup>220</sup> In view of the increasing convergence of biological weapons technology and chemical weapons technology<sup>221</sup>, questions concerning biosecurity-relevant research fall also within the scope of the Chemical Weapons Convention.<sup>222</sup> Article II defines relevant

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213 Cf. United Nations 2011a.

214 Cf. United Nations 2006: “[...] the Convention is comprehensive in its scope and that all naturally or artificially created or altered microbial and other biological agents and toxins, as well as their components, regardless of their origin and method of production and whether they affect humans, animals or plants, [...], are unequivocally covered by Article I.”

215 Cf. United Nations 2012: recitals 7 and 9; Nixdorff 2010.

216 Cf. Nixdorff 2010.

217 Cf. United Nations 2011a.

218 Cf. Millett 2011.

219 Cf. Zacher 1999, 266 ff.

220 Cf. United Nations 1986, recital 51.

221 Cf. Section 1.

222 Cf. also Trapp 2013, 175 ff.

terms such as ‘chemical weapon’, ‘toxic chemical’, or aims that are not prohibited under the Convention. Also, an appendix contains an exact list of chemicals, and there are detailed rules for implementation and verification as well as ones for the protection of confidential information. Each contracting State submits to a far-reaching enforcement mechanism. Therefore it is not surprising that the German law that implements the Chemical Weapons Convention contains rules for inspection and security checks that go considerably further than is the case where the Biological Weapons Convention is implemented and where no verification regime exists. Furthermore, discussion is taking place under the auspices of the Chemical Weapons Convention (as demonstrated during the Third Review Conference in 2013) as to how the verification system can be adapted to reflect developments in science and technology.<sup>223</sup> This especially affects the area in which biological weapons and chemical weapons are on a converging course. The Convention on Biological Diversity<sup>224</sup> contains explicit research-related regulations of access to genetic resources and to the technologies associated with them. However, extensive restrictions for reasons of security are possible, so the obligations to cooperate do not limit the options of the State Parties to restrict research on account of the danger of misuse. However, no legislation to implement the obligations has been enacted in Germany.<sup>225</sup> The Cartagena Protocol on Biosafety, concluded by the signatories of the Convention on Biological Diversity, aims — in accordance with the precautionary principle laid down in the Rio Declaration on Environment and Development<sup>226</sup> — to secure an appropriate level of protection in the use of genetically modified organisms (GMOs) produced by modern biotechnological means, placing special

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223 Cf. Organisation for the Prohibition of Chemical Weapons 2013, 15, 9.71.

224 Convention on Biological Diversity of 5 June 1992, in force since 29 December 1993 (Federal Law Gazette 1993 II p. 1742; 1760 UNTS 79).

225 Cf. Teetzmann 2014, 135.

226 Cf. United Nations 1992.

emphasis on transboundary movements (Article 1). From the biosecurity point of view, the following regulations are significant: Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States (Article 17). Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol (Article 25)<sup>227</sup>. A State that fails to adopt suitable domestic measures is obliged to dispose of the living modified organism in question by repatriation or destruction, as appropriate. In addition, information is to be made available to the Biosafety Clearing-House concerning such cases.<sup>228</sup>

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227 The reference in Article 25 to the domestic measures shows that the Protocol expressly does not prescribe a uniform standard for distinguishing between legal and illegal movements; cf. Mackenzie et al. 2003, 159 f.

228 The Protocol has been implemented in the Regulation (EC) No: 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (Legal Gazette L 287/1 of 5 November 2003), the Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (Federal Law Gazette L 260/13 of 30 September 2008), last modified through the Commission Implementing Decision 2013/218/EU of 6 May 2013 (Legal Gazette L 130/26 of 15 May 2013), and in the two German statutory instruments on the transport of dangerous goods: *Verordnung über die Beförderung gefährlicher Güter mit Seeschiffen* (GGVSee) (Ordinance on the transport of dangerous goods with sea-going ships) in the version as published on 16 March 2014 (Federal Law Gazette 2014 I p. 301) and the *Verordnung über die innerstaatliche und grenzüberschreitende Beförderung gefährlicher Güter auf der Straße, mit Eisenbahnen und auf Binnengewässern* (GGVSEB) (Ordinance on the domestic and transboundary transport of dangerous goods by road, railway and on inland waterways) in the version as published on 22 January 2013 (Federal Law Gazette 2013 I p. 110).

The WHO's Pandemic Influenza Preparedness (PIP) Framework on the sharing of influenza viruses is a recommendation on safety regulations to provide for the exchange of virus samples, genetic datasets and comparable (research) materials.<sup>229</sup> The rules are primarily aimed at ensuring rapid and systematic exchange of H5N1 and other influenza viruses between reference laboratories, as well as covering access to vaccines and other benefits of research (1.5; 2). The goal is to take precautions against pandemics. This is based on the obligation to pass on biological material obtained from H5N1 cases with approval for further transfer in accordance with the Standard Material Transfer Agreement that is laid down in the appendix (5.1.1, 5.1.2). Genetic sequencing data is to be shared between the dispatching laboratory and other WHO laboratories (5.2.1). In addition, a system regulating access to the benefits of pandemic precautionary measures is to be established, consisting of the assessment of the pandemic risk, access to vaccination viruses, diagnostic kits, reference samples, capacity building in influenza research and monitoring, storage of antiviral drugs and vaccines, simplified access to vaccines for developing countries, a graded pricing system for vaccines, technology transfer and financing mechanisms (6).

### **5.2.2 Guarantees of the Charter of Fundamental Rights of the European Union, regional and universal human rights treaties**

The international human rights treaties and the guarantees of the Charter of Fundamental Rights of the European Union do not extend the protection for scientific freedom beyond the Basic Law; rather, they allow for more comprehensive restrictions. Article 13 of the Charter does, like the German Basic Law, guarantee scientific freedom, but not unlimited. The

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<sup>229</sup> World Health Organization 2011.

European Convention on Human Rights and the International Covenant on Civil and Political Rights do not expressly protect scientific freedom, but only indirectly, i.e. in a weaker way than the Basic Law, by way of freedom of expression, freedom of thought and freedom of conscience. Intervention can be justified where is deemed necessary for national security, territorial integrity or public safety, maintaining order, prevention of criminal acts, protection of health or prevention of dissemination of confidential information on the protection of public security, health or fundamental rights and freedoms.<sup>230</sup> Interventions regarding scientific publications that are protected through freedom of expression<sup>231</sup> are also allowed insofar as these are covered by legislation. The Charter of Fundamental Rights of the European Union and international human rights treaties also contain far-reaching duties to protect in respect of life, bodily integrity and health<sup>232</sup>. Protective measures dealing

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230 Thus, expressly, the far-reaching Article 10 Para. 2 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) of 4 November 1950, in force since 15 December 1953 (Federal Law Gazette 1952 II p. 686; ECTS No. 5), in the version published on 22 October 2010 (Federal Law Gazette 2010 II p. 1198; ECTS No. 194): “The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.”

231 Cf. European Court of Human Rights, *Sorguç/Turkey*, 21 January 2010 – 17089/03 (recitals 35 f.); European Court of Human Rights, *Lombardy/Italy*, 20 October 2009 – 39128/05 (recital 30); Teetzmann 2014, 106.

232 Cf. Art. 2 and 3 of the European Charter of Fundamental Rights, signed on 12 December 2007, in force since 1 December 2009 (Legal Gazette C 326/391 of 26 October 2012); Art. 2 Para. 1 Sentence 1 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) of 4 November 1950, in force since 15 December 1953 (Federal Law Gazette 1952 II p. 686; ECTS No. 5), in the version published on 22 October 2010 (Federal Law Gazette II p. 1198; ECTS No. 194); Art. 6 Para. 1 Sentence 2 of the International Covenant on Civil and Political Rights of 16 December 1966, in force since 23 March 1976 (Federal Law Gazette 1973 II p. 1534; 999 UNTS 971); expressly Art. 12 Para. 1 of the International Covenant on Economic, Social and Cultural Rights of 9 December 1969, in force since 3 January 1976 (Federal Law Gazette 1973 II p. 1570; 999 UNTS 3).

with research of concern must therefore not remain ineffective insofar as life is at risk. However, the choice of means remains at the discretion of the member States.<sup>233</sup> In addition, Article 37 of the Charter guarantees a high level of protection of the environment. Furthermore, peace is recognized as being one of the aims of the Union and thus as an objective of common interest (Article 3, Para. 1 Treaty on European Union).

### 5.2.3 Liability according to international law

According to the law of state responsibility, the consequence of a breach of an obligation under international law is the obligation to make restitution, which means to re-establish the situation that existed before and to compensate for the damage. This applies where a norm laid down in international law is infringed. Particularly relevant in this respect are the Biological and Chemical Weapons Conventions, the Cartagena Protocol on Biosafety and obligations arising from human rights treaties. In addition to this, States have the duty to take precautions to avoid risks of serious transboundary incidents causing harm to or threatening the lives of citizens and the environment of other States on account of the effects of activities taking place on their own territories. In respect of research carried out by private actors, however, a State will only be liable as far as the research took place under the supervision or control of that State, or the State had the duty to prevent such private persons from undertaking such actions. A State is liable especially in cases where it has not taken sufficient care to prevent transboundary damage.

In addition to the liability of States under customary international law, the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol

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233 Cf. European Court of Human Rights, *Budayeva and others/Russia*, 20 March 2008 – 15339/02 and others (recitals 134 f.).

on Biosafety (which is not yet in force) specifies that persons having control over genetically modified living organisms are also liable. The Protocol includes the possibility of exemptions from and limits of liability in cases of *force majeure*, acts of war or civil unrest and other similar cases. However, in accordance with the object and purpose of the Protocol such exemptions do not apply to cases of misuse, e.g. by means of acts of terrorism.

### **5.3 Directly applicable European Union law and the sub-constitutional legal situation in Germany**

Activities connected with life science research in Germany are subject to a large number of specific laws and regulations. These are mainly focussed on the area of biosafety standards. The following detailed examination of the legal situation in Germany illustrates the extent to which biosecurity risks are already covered by these safety standards, and whether the mechanisms already take account of possible misuse of research and results in the life sciences.<sup>234</sup>

#### **5.3.1 Export controls according to the EC Dual Use Regulation**

The EC Dual Use Regulation<sup>235</sup>, as a Regulation of the European Union, represents directly binding law for the EU member States. The subject regulated is the export of dual-use items.

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<sup>234</sup> See the more detailed exposition of the legal situation in Appendix II.

<sup>235</sup> Council Regulation (EC) 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items of 5 May 2009 (Legal Gazette L 134/1 of 29 May 2009), last modified through Regulation (EU) 388/2012 of the European Parliament and of the Council of 19 April 2012 (Legal Gazette L 129/12 of 16 May 2012).



The export of such items to a non-EU State requires approval. The Regulation covers items for both civil and military purposes. Irrespective of this, however, all items are subject to permission that are listed in Appendix I, including biological material such as, for instance, avian influenza viruses.

Permission for export is issued by means of a two-stage system: Firstly, the permission requirement is to be confirmed on the basis of the Annex to the Regulation. Then a decision is reached as to whether approval is to be granted. The term 'dual-use items' that is relevant for permissions also includes 'technology', i.e. 'specific technological knowledge' that is contained in technical documentation. Correspondingly, publications may also be subject to the system of control. However, basic research and generally accessible information or information required for patent applications in the technical item descriptions of the Annex is generally exempted. In addition, the permission decision takes account of tangible indications, i.e. a definite potential for danger, that export items may be misused. Thus a general potential for misuse, that is a characteristic of the biosecurity context, is not in itself sufficient to justify withholding permission. The EC Dual Use Regulation only covers questions of export. The emergence of risks in the research process itself and research-related biosecurity risks are not covered by export law.

The problems involved in the export control legislation for publications can be illustrated in the case of the publication of the research results produced by Fouchier on H5N1<sup>236</sup> in the journal *Science* (i.e. in a journal of a 'foreign' country). A Dutch court ruled that the publication required approval on account of the export control legislation. In contrast, publication in a local Dutch journal would not have been subject to approval according to export control legislation. In addition to this, in cases involving the export of a technology the question as to whether, in a specific instance, the requirement to obtain

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236 Fouchier 2012.

approval may not apply because the research is of a basic nature or the information involved is freely available, the export control authorities may be faced with difficult decisions. The Dutch court to whom Fouchier appealed was of the opinion that the studies had a ‘practical goal’, namely to clarify how to produce a virus that can be transmitted by airborne means. Thus they were not to be classified as basic research, a decision that elicited protest from both Fouchier and other virus researchers. And even though the method had previously been described in specialist literature, in the case in question new results had been produced, so that the information involved could not be regarded as being freely available and therefore exempt under the Regulation.<sup>237</sup>

In addition to the EC Dual Use Regulation, the Foreign Trade and Payment Act<sup>238</sup> (*Außenwirtschaftsgesetz*, AWG) and the Foreign Trade and Payments Ordinance<sup>239</sup> (*Außenwirtschaftsverordnung*, AWV) are relevant items of German export control law. They apply exclusively to export controls in respect of military goods.

### 5.3.2 National special laws

#### *Infectious diseases protection laws*

The Act on the Prevention and Control of Infectious Diseases in Man<sup>240</sup> (*Infektionsschutzgesetz*, IfSG) serves especially to prevent and combat infectious diseases in humans. Protection against infectious diseases in animals and plants

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237 Decision of 20 September 2013 of the District Court of the North Holland Region of the Netherlands (Rechtbank Noord-Holland HAA 13/792).

238 German Foreign Trade Act of 6 June 2013 (Federal Law Gazette I p. 1482).

239 Foreign Trade and Payments Ordinance of 2 August 2013 (Federal Law Gazette I p. 2865), modified by Article 1 of the Ordinance of 25 March 2014 (Federal Gazette AT of 31 March 2014 V1).

240 Infectious Diseases Protection Act (*Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen*, IfSG) of 20 July 2000 (Federal Law Gazette I p. 1045), modified by Article 4, Para. 21 of the Act of 7 August 2013 (Federal Law Gazette I p. 3154).

is regulated separately by means of the Epizootic Diseases Act (*Tierseuchengesetz*, TierSG) and the Plant Protection Act (*Pflanzenschutzgesetz*, PflSchG) (see below). Environmental protection as such is not included in these laws.

The IfSG regulates measures aimed to provide protection against transmissible diseases as well as ones to recognize and avoid them and prevent their dissemination. The authorizations for measures and intervention laid down in the IfSG all assume that there is a definite expectation of danger. Therefore relevant measures concerning, especially, dual-use research projects, cannot be adopted merely on the basis of some abstract risk, but only when a concrete threshold of danger has been crossed. Notwithstanding this, if the potential damage is particularly grave, a relatively small likelihood of an event occurring can suffice.<sup>241</sup> Nevertheless, the usual hypothetical dual use situation, i.e. the possibility that the research item could be misused by terrorists, is not in itself sufficient.

Even so, some of the provisions of the IfSG do at least indirectly promote biosecurity: One such is the permission and notification requirement for anyone working with pathogens, except where this takes place under the supervision of a person who is already authorized. Furthermore, approval is also required where pathogens are passed on to others. The question as to whether approval is granted depends on the individual capabilities of the applicant. Approval may be withheld if the applicant does not have the necessary expertise or displays a lack of reliability in carrying out the work. Infringements of the approval and supply regulations are subject to penalties. However, no mechanism exists by which an applicant is to be examined specifically in respect of biosecurity-relevant factors.

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241 BVerwGE 142, 205 (216).

### ***Biostoffverordnung (Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents)***

The Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents (*Biostoffverordnung*, BioStoffV)<sup>242</sup> serves to protect employees dealing with biological agents. The Ordinance also covers genetically modified biological agents for cases in which the Genetic Engineering Act does not contain equivalent or more stringent regulations. Biological agents in this sense are certain parasites and microorganisms such as bacteria, fungi and viruses that can cause infections in or have sensitizing or toxic effects on humans. They are divided into four risk groups according to the health risks that they involve. Work may only be done on them in laboratories that fulfil the requirements of the respective protective categories (S 1 to S 4). Prior to and during work on biological agents, employers are required to carry out regular hazard assessments. As may be necessary in the light of the results, the measures laid down in the Ordinance for the protection of both employees *and* other persons who may be exposed to danger are to be modified. However, there are no provisions covering an obligation to assess biosecurity-related risks as part of the hazard assessment. The BioStoffV requires that, prior to initial activities that fall into the protective categories 3 and 4, an official permission must be obtained. In addition, before work corresponding to protective categories 2 to 4 commences, the employer must lay down the measures that are to be carried out in cases of operational malfunctions or accidents in order to minimize their effects on the safety and health of employees and other persons. However, this does not refer to the risk of misuse. According to the BioStoffV, access to dangerous agents of the risk groups 3 and 4 is to be restricted to authorized, competent and reliable employees. Also, access controls must be put in place. In

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<sup>242</sup> *Biostoffverordnung (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit biologischen Arbeitsstoffen*, BioStoffV) (Ordinance on Security and Health Protection in Activities Involving Biological Agents) of 15 July 2013 (Federal Law Gazette I p. 2514).

addition to this, all employers operating in a laboratory that deals with biological agents must report any accident or operational malfunction that could lead to a health hazard for the employees to the responsible local authority. However, there is no nationwide, uniform reporting system in place. It is also not clear to what extent the misuse of biological agents constitutes an operational malfunction that must be reported. There is no reporting system that covers actual or suspected misuse or a definite danger of misuse that may have become apparent. The BioStoffV is an ordinance for employee protection that qualifies the general German Occupational Safety and Health Act (*Arbeitsschutzgesetz*)<sup>243</sup>. The object and purpose of the BioStoffV is the protection of the employees of the respective facility. However, third parties outside the facility whose physical integrity or life could be threatened by misuse of the biological agents are indirectly protected as well on account of the protective measures contained in the Ordinance, insofar as they may be put at risk on account of the use of biological agents by employees.

### ***Genetic engineering law***

The purpose of the Genetic Engineering Act (*Gentechnikgesetz*, GenTG)<sup>244</sup> are very wide-ranging and include the environment and material goods in addition to the protection of human health. The object is to provide protection against harmful effects of *genetic engineering work* and the handling of genetically modified products. The aim is to achieve safer 'classical' genetic engineering, and not the general enhancement of biosafety. Prior to the commencement of and during

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243 *Arbeitsschutzgesetz (Gesetz über die Durchführung von Maßnahmen des Arbeitsschutzes zur Verbesserung der Sicherheit und des Gesundheitsschutzes der Beschäftigten bei der Arbeit, ArbSchG)* (German Occupational Safety Act) of 7 August 1996 (Federal Law Gazette I p. 1246), last modified through Art. 8 of the Act of 19 October 2013 (Federal Law Gazette I p. 3836).

244 *Gentechnikgesetz (Gesetz zur Regelung der Gentechnik, GenTG)* (Genetic Engineering Act) in the version published on 16 December 1993 (Federal Law Gazette I p. 2066), modified through Art. 4 Para. 14 of the Act of 7 August 2013 (Federal Law Gazette I p. 3154).

genetic engineering work a risk assessment is to be carried out and as required safety measures are to be modified. Legislation on genetic engineering work divides it into four safety classes. Genetic engineering work in the safety classes 3 and 4 requires approval. Genetic engineering work in the safety classes 1 and 2 requires application, registration or giving notice to the responsible authority. As part of the approval process, the opinion of the Central Committee on Biological Safety (*Zentrale Kommission für die Biologische Sicherheit, ZKBS*) must be obtained. This body also carries out the risk assessment and the classification of the genetic engineering work. The main focus of the Committee's assessment is on biosafety risks. It has no remit to assess possible dual-use risks that may arise from genetic engineering work.

The release of genetically modified organisms (GMOs) is also subject to permission. The improper, biosecurity-relevant release of GMOs, particularly release without permission, is illegal according to the Genetic Engineering Act.

Permission for the operation of a genetic engineering plant or a genetic engineering laboratory may only be given where no circumstances are present that give rise to concern about the reliability of the operator and the persons responsible for the supervision and inspection of the plant. The reliability check does contain references to the risk of misuse or biosecurity-relevant risks, but the approval authority is under no obligation to pursue investigations. The operator of a genetic engineering plant and persons who release GMOs must appoint biosafety officers and task them with carrying out ongoing safety checks of the plant equipment, operation and release locations. The tasks of the officer relate to questions of biosafety; however, the surveillance also indirectly promotes protection against misuse of the GMOs and therefore also the enhancement of biosecurity.

### ***Epizootic Diseases Act and Plant Protection Act***

Amongst other things, the Epizootic Diseases Act<sup>245</sup> (*Tierseuchengesetz*, TierSG) regulates requirements for permission and notification for activities, including research, that have to do with pathogens that afflict animals on a large (epizootic) scale. However, research that is not connected with the scientific investigation or control of epizootics is not covered by the TierSG.

The Plant Protection Act<sup>246</sup> also regulates measures to prevent the dissemination of injurious organisms, thereby also including dangers (for humans) arising from their malicious release. However, these preventive measures for the protection of humans have mainly to do with the handling of plant protection products. Biosecurity risks that may arise on account of research projects are not object of the Act.

### ***Security clearance law***

The Security Clearance Act<sup>247</sup> (*Sicherheitsüberprüfungsgesetz*, SÜG) and legislation at federal state (i.e. *Länder*-)level provide for the screening of vital facilities with a view to mitigating dangers that can arise in security-sensitive areas. Through security screening of persons who are to be entrusted with security-sensitive work, negative effects in the area concerned such as the ‘misappropriation’ of the facility itself or any security-relevant items to be found within it, for instance through a

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245 *Tierseuchengesetz* (TierSG) (Epizootic Diseases Act) in the version published on 22 June 2004 (Federal Law Gazette I p. 1260, 3588), last modified through Art. 4 Para. 88 of the Act of 7 August 2013 (Federal Law Gazette I p. 3154). This Act will cease to be effective on 1 May 2014; it will be replaced by the *Tiergesundheitsgesetz* (*Gesetz zur Vorbeugung vor und Bekämpfung von Tierseuchen*, TierGesG) (Animal Health Act) of 22 May 2013 (Federal Law Gazette I p. 1324).

246 *Pflanzenschutzgesetz* (*Gesetz zum Schutz der Kulturpflanzen*, PflSchG) (Plant Protection Act) of 6 February 2012 (Federal Law Gazette I p. 148, 1281), last modified through Art. 4 Para. 87 of the Act of 7 August 2013 (Federal Law Gazette I p. 3154).

247 *Sicherheitsüberprüfungsgesetz* (*Gesetz über die Voraussetzungen und das Verfahren von Sicherheitsüberprüfungen des Bundes*, SÜG) (Security Screening Act) of 20 April 1994 (Federal Law Gazette I p. 867), last modified through Art. 4 of the Act of 7 December 2011 (Federal Law Gazette I p. 2576).

terrorist attack from within, are to be avoided or rendered less damaging. However, the security screening of such persons is of varying degrees of intensity. Thus at federal level, for instance, ‘extended security clearance’ is carried out in vital facilities, whereas at Länder-level ‘standard screening’ regularly suffices<sup>248</sup>. Specific statutory ordinances are enacted that lay down which facilities are to be covered by the security clearance regulations. At federal level and in some federal states certain (research) facilities are included that work with highly toxic substances or highly pathogenic microorganisms on a large scale. It transpires, however, that their categorization by means of ordinance to determine the scope of security checks is generally too inflexible to meet requirements in cases such as a single research experiment that may spontaneously and unexpectedly present a risk of misuse.

#### ***Transport of hazardous substances law***

Legislation on the transport of hazardous substances, especially the Transport of Hazardous Substances Act<sup>249</sup> (*Gefahrgutbeförderungsgesetz*, GGBefG) and the statutory instruments enacted on the basis of that Act, also covers toxins and substances liable to cause infection. However, the measures involved mainly cover biosafety aspects, and in this respect safety risks resulting from the *conveyance* of toxins and infectious substances.

#### ***Regulations on liability***

Within the scope of national law, liability for damage resulting from the handling of biological substances is regulated by means of the general law of tort and the hazard liability provisions contained in genetic engineering legislation.

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<sup>248</sup> In such screening no identity check is carried out and no check of the last place of residence is carried out.

<sup>249</sup> *Gefahrgutbeförderungsgesetz (Gesetz über die Beförderung gefährlicher Güter, GGBefG)* (Transport of Hazardous Substances Act) in the version published on 7 July 2009 (Federal Law Gazette I p. 1774, 3975), modified through Art. 2 Para. 148 of the Act of 7 August 2013 (Federal Law Gazette I p. 3154).



Section 823, Para. 1 of the German Civil Code provides for redress for culpable injury. In principle, biosecurity-related damage can be covered by this. Prerequisites, however, are at least negligence on the part of the responsible person and a sufficient degree of attributability. This means that liability may be attributed for such damage that may occur in the light of experience, i.e. not beyond all probability. Duties of care that may justify the accusation of negligence may arise on the basis of legal norms. Likewise, codes of conduct in research can imply standards of care that can be relevant for questions of liability. Attributability can definitely be ruled out in cases where the damage is caused by third parties. For this reason, biosecurity damages are excluded from the liability of the laboratory operators according to Section 823, Para. 1 of the German Civil Code in most cases.

The strict liability that applies to genetically modified organisms according to Section 32, Para. 1 of the Genetic Engineering Act covers more cases. Here, culpability is not a necessary condition; in other words, as far as the strict liability in genetic engineering legislation is concerned the performance of all duties of care and compliance with safety/security requirements are not relevant. The scope of liability is intended to encompass the risks of genetic engineering in a comprehensive manner. The essential point is that the damage must be a consequence of characteristics of an organism that can be attributed to genetic engineering activities. The person undertaking such activities remains liable to provide compensation even when the actions of a third party has also contributed to the damage. The restriction of the causality to circumstances in which attributability can be proven, as laid down in Section 823, Para. 1 of the German Civil Code, is generally not commensurate with the comprehensive protective purpose contained in the strict liability provisions of the Genetic Engineering Act. The only circumstances in which this may be questionable are those in which misuse is perpetrated by third parties. If organisms for which the plant operator has been

responsible are misused, the operator is not liable for that misuse if those organisms have been passed on in accordance with the applicable protection regulations (and hence some other operator is liable). If the organisms have simply disappeared, the operator remains liable. Damage caused is not attributed to the organism giving rise to liability in cases where the misuse is in connection with an organism that has been reconstructed, for instance on the basis of its construction plan having been published.

Liability according to the Genetic Engineering Act is limited to 85 million euros. The insurability of risk that this limitation is intended to provide is to be supplemented, according to the Act, by means of a mandatory coverage requirement. However, no such statutory instrument has yet been enacted to date. In view of the impossibility of assessing the risks, insurance cover is generally refused by insurance companies.

## **5.4 Conclusions**

Biosecurity-related research is covered by a large number of different legal rules, whereby these are mainly expressed in terms of biosafety standards. However, there is no coherent regulatory system in the life sciences that aims directly at minimizing and preventing misuse of research and of the results of research. This is true of national legislation, European legislation and international law:

Foreign trade and export control legislation is concerned with questions of export, and not with risks that arise within the research process itself. The security clearance laws are designed to address dangers arising from possible adverse acts against security-sensitive facilities that threaten the lives and health of the public and threaten other legal interests. The security screening is not directed specifically towards biosecurity risks, but it does include them implicitly. The Act on the Prevention and Control of Infectious Diseases in Man regulates

the issues of protecting persons against contagious diseases, detecting them, avoiding them and their dissemination, but it does not include environmental risks. It also serves to deal with concrete dangers, and therefore usually does not cover biosecurity-relevant issues. Regarding research, the Epizootic Diseases Act only contains regulations that affect scientific research on or the control of epizootics. Plant protection legislation, on the other hand, does cover measures to prevent the dissemination of injurious organisms, and thereby includes hazards resulting from the malicious release of such organisms, but in this latter respect it does not include the protection of humans.

Genetic engineering legislation aims to protect both the population and the whole environment, but it only regulates how to deal with genetic engineering work. The strict liability applies only to damage that results from a genetically modified organism. The Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents (BioStoffV) regulates dealings with biological agents, but is limited to their usage by employees or an operator without employees. The Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents and genetic engineering legislation are focused on minimizing biosafety dangers or risks in work involving dangerous biological agents. What is missing, however, as is the case with the Act on the Prevention and Control of Infectious Diseases in Man, is explicit reference to the risk of misuse in the dual use research context. A feature common to both areas is the assignment of the biological agents used in research to one of four risk classes that determine the requirements in respect of laboratory safety. In genetic engineering legislation, a given project is assigned to one of the four risk classes. Here, not only the biological agent itself, but also its modified characteristics and the vector involved (usually a virus) are included in the risk assessment. Also, genetic engineering research projects are subject to the obligations to perform risk assessment and minimize risk both prior to commencement

of research as well as during project execution. Here too, however, there are no provisions covering an obligation to assess biosecurity-related risks that go beyond questions of biosafety. Therefore the basic question arises concerning an extension of biosafety-related assessment and permission procedures to include biosecurity-related procedures. As is already the case with biosafety-related regulations, requirements could be tailored to the risk potential of a given project.

Some biosafety measures already take account of biosecurity aspects indirectly. Especially those safety measures involving access restrictions and access control to the laboratories, requirements concerning the qualifications and responsibility of the employees, accompanying evaluation and documentation of a research project, the generation of lists of the biological materials used, as well as the documentation of material transfer and material dispatch and the tasks of a biological safety officer, already serve to reduce the danger of misuse and can be adopted for use in the biosecurity context.

The Biological and Chemical Weapons Conventions provide only for general rules from which no concrete requirements for dual-use research can be derived. To date, no supplementary international agreements have been negotiated. In addition to this, not even in the area of biosafety do binding, uniform international or European safety standards exist. Although the classification of biological agents and their handling into four safety categories is now agreed in principle internationally, the actual assignments to the categories vary from State to State throughout the world, and even within the European Union. Also, there is no internationally binding obligation to notify when laboratories of safety category 3 or 4 commence operation, nor when biosecurity-related or biosafety-related incidents occur within them.

Neither on a global level nor within the European Union does legislation exist that specifically addresses biosecurity-relevant research.

## 6 RESEARCH FUNDING

### 6.1 Basic principles and limitations of research funding in Germany

In democratic societies, research funding represents a decisive instrument to enable research to be carried out, especially in areas of special relevance to society as a whole. It has a constitutional foundation in the basic right to scientific freedom, which not only entails the right to defend that freedom, but also a framework of responsibility on the part of the State. Where research funds are distributed, the principle of equality as laid down in Article 3, Para. 1 of the Basic Law must be observed.

Article 74, Para. 1, No. 13 of the Basic Law extends concurrent legislative power for “the promotion of research” to the Federation. Nevertheless, despite the major significance of research funding in terms of achieving research freedom, Germany has not yet enacted corresponding legislation. Article 91 lit. b of the Basic Law lays down cooperative responsibility for the promotion of research to be shared by the Federation and the federal states.

Support for research is divided into institutional funding and project-oriented funding. The funding of non-university research institutions and the bodies responsible for them (the Max Planck Society, the Helmholtz Association, the Leibniz Association and the Fraunhofer Society) is supplied by the Federation and that federal state in which the respective body has its headquarters. The funding of the German Research Foundation as a Germany-wide funding organization that is administered by the scientific community itself comes from the Federation and the federal states. State funding for research programmes and projects has greatly increased since the nineteen-eighties. It is augmented by funding supplied by the federal states. In contrast to the EU, in which the

Framework Programme for Research & Innovation is legally binding<sup>250</sup>, funding programmes are decided upon by the ministries concerned or by the Federal Cabinet.

Risk research represents an important component in the areas of protection against dangers and prevention of risks. This has long been the case in efforts to prevent and control outbreaks of epidemics. For instance, from 1999 until 2011, the Federal Government has provided around 122.3 million euros for research into highly pathogenic organisms (S3 and S 4 agents).<sup>251</sup>

Between 2007 and 2012, 13 million euros were approved for funding of research projects in connection with highly pathogenic agents as part of the Federal Ministry for Education and Research's programme '*Schutz vor Gefahrstoffen, Epidemien und Pandemien*' (Protection against Hazardous Substances, Epidemics and Pandemics), itself part of the 'Research for Civil Security' programme. The main emphasis was on the development of detection methods for highly pathogenic agents.

## 6.2 Direction of research funding in the EU

The European Union manages its research funding through the instruments of the Research Framework Programmes.<sup>252</sup> Since the inception of the Fifth Research Framework Programme, the observance of the 'fundamental principles of

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<sup>250</sup> Cf. Section 6.2.

<sup>251</sup> Five ministries were involved in distributing the funds: The Federal Ministry for Education and Research with 51.88 million euros, the Federal Ministry of Health with 30.27 million euros, the Federal Ministry for Food and Agriculture with 28.03 million euros, the Federal Ministry of Defence with 10.05 million euros and the Federal Ministry of the Interior with 2.2 million euros (cf. German Bundestag 2012).

<sup>252</sup> Cf. in this connection also the European Group on Ethics in Science and New Technologies 1998, 2000 and 2008; as well as the Group of Advisers on the Ethical Implications of Biotechnology 1997.

ethics'<sup>253</sup> is required in research projects. This is also of significance for biosecurity-relevant research:

The new 'Horizon 2020' Framework Programme for Research & Innovation<sup>254</sup> that will start in 2014 with a funding volume of around 86 billion euros (Article 6) also requires that research and innovation activities within its scope take account of 'basic ethical principles' in addition to applicable legislation. This includes in particular the Charter of Fundamental Rights and the European Convention on Human Rights (Article 19 Horizon 2020). In this norm, the ethical underpinnings of research are closely connected with fundamental aspects of human rights. The Framework Programme for Research & Innovation places special emphasis not only on the principle of proportionality and the individual's right to physical integrity, but also on "the need to ensure high levels of human health protection." (Art. 19, Para. 1, Horizon 2020). However, the statements of the European Group on Ethics in Science and New Technologies (EGE) are only, as before, to be "taken into account" (recital 24).

Also, the boundaries of research support, including prohibitions of such support, are specified exactly: They comprise three areas<sup>255</sup>; these are, however, areas which are not relevant for biosecurity-relevant research.

The possibility that various regulations of the member States could be of relevance in research funding can be inferred from the provision on research on human stem cells: These

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253 Article 6 (1) of the Decision No. 1982/2006/EC concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007–2013) of 18 December 2006 (Legal Gazette L 412/1 of 30 December 2006) (no longer in force).

254 Cf. Regulation 1291/2013/EU establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014–2020) and repealing Decision No. 1982/2006/EC of 11 December 2013 (Legal Gazette L 347/104 of 20 December 2013).

255 They are: human cloning for reproductive purposes, modification of the genetic heritage of human beings and research activities intended to create human embryos solely for the purpose of research (Art. 19 Para. 3, Horizon 2020).

may, in principle, be financed, but not “for research activities that are prohibited in all the Member States” (Art. 19, Para. 4). Also, no EU funding shall be available in any member State for an activity that is forbidden in that State (Art. 19, Para. 4). These basic aspects of funding may also be of decisive significance for questions of biosecurity-relevant research funding where activities are already forbidden in individual member States or such prohibitions arise.

To this day, there are very few provisions that specifically address biosecurity aspects. The Commission’s recommendation for the current Horizon 2020 Framework Programme for Research expressly includes the restriction to civilian application.

As part of Horizon 2020’s second focal point, an integrated approach to key technologies is advocated that includes biotechnology and nanotechnology (Part II 1. Horizon 2020). This also connects up with the measures designed to provide for appropriate inclusion of small and medium sized businesses in Horizon 2020 and promote public-private partnerships (Articles 18 and 19). Biotechnology (such as synthetic biology) is named as being a “future innovation driver” (Part II 1.4.3.). Concerning nanotechnology, “tools for risk assessment and management” are to be provided (Part II 1.2.3.) and for biotechnology, questions of “management aspects of the overall and specific risks” in deployment are to be included (Part II, 1.4.1).

From 2014 onwards, another core area for research funding “is to improve the lifelong health and well-being of all” (Part III, 1.1.) in the context of societal challenges. This includes making preparations for “emerging epidemics” and “the threat of increasing anti-microbial resistance” (Part III, 1.1.). However, these provisions do not contain restrictions on the funding of biosecurity-relevant research.

Regarding the objective “to foster secure European societies” (Part III, 6.1., Horizon 2020), there is reference not only to an increasing sense of insecurity amongst the citizens (also



on account of terrorism-related threats), but also expressly to building “resilient, inclusive [...] societies in Europe”, and to bridging the research and innovation gap in Europe (Part III, 6.3.1). Further aims are the engagement of citizens in research and innovation and increasing “Europe’s resilience to crises and disasters” (Part III, 6.3.2. and 3.). This also includes building up EU capabilities in dealing with natural disasters and disasters caused by human intervention, amongst other things through risk management for various hazard types (Part IV, 3.3.).

However, the EU issued information for researchers that included specific mention of dual use as being a problem as part of the previous, 7th Framework Programme for Research and Technology.<sup>256</sup> According to this, it is expected of researchers who apply for funding that their approach include awareness of the dual use problem, a strategy for dealing with biosecurity risks, the involvement of external experts in risk management and a strategy for the dissemination, communication and use of the research results.<sup>257</sup> Also, the result of a discussion entitled ‘A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research’ and an information leaflet containing requirements for applicants are available to researchers on the website of the 7th Framework Programme.<sup>258</sup> What is expected of them is an awareness of risks, the adoption of appropriate measures in dealing with dangerous materials, an appropriate strategy for informed consent and concomitant confidentiality, the inclusion of an advisory body for reducing risk and a dissemination and information strategy for research results that is to be

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256 Cf. European Commission 2013, 18 f.

257 Cf. *ibid.*, 19.

258 Cf. on the internet: [http://cordis.europa.eu/fp7/ethics\\_en.html](http://cordis.europa.eu/fp7/ethics_en.html) [2014-04-01]; [http://ec.europa.eu/research/participants/data/ref/fp7/89797/improper-use\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/fp7/89797/improper-use_en.pdf) [2014-04-01]; <ftp://ftp.cordis.europa.eu/pub/fp7/docs/dual-use.doc> [2014-04-01].

managed by this body.<sup>259</sup> Within the scope of the 7th Framework Programme, 396.9 million euros have been distributed by the European Union since 2007 for funding projects connected with research on highly pathogenic agents.

To date, the EGE has not drafted an opinion specifically devoted to biosecurity-relevant research.<sup>260</sup> However, the opinion on synthetic biology<sup>261</sup> drafted in 2009 also addresses biosecurity issues, and amongst other things it demands that the Biological Weapons Convention be extended to include restrictions on or the prohibition of research in the field of synthetic biology:

“New tools may be derived from synthetic biology for the military sector such as biomaterials or bioweapons. Ethical analysis must assess the goal of security in relation to transparency. In addition, the EGE recommends control mechanisms such as licensing and registering of tools in order to prevent terrorist uses of synthetic biology. The Group also recommends that the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction should incorporate provisions on the limitation or prohibition of research in synthetic biology.”<sup>262</sup>

Also, the EGE recommends to the Commission the drawing up of a code of conduct in research concerning synthetic microorganisms to “assure that synthetic biology organisms are manufactured in a way that they cannot autonomously survive

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<sup>259</sup> Dual use is not mentioned in the European Commission's guidelines for the development of communication strategies (European Commission 2012).

<sup>260</sup> Cf., however, the lecture given by Anna Lönnroth on 'Ethical, Safety and Security Considerations around Funding of Gain-of-Function Research in Infectious Diseases' on 19 February 2013 in Brussels during the 24th Meeting of the European Group on Ethics in Science and new Technologies.

<sup>261</sup> Cf. European Group on Ethics in Science and New Technologies 2010.

<sup>262</sup> Ibid., 80, Recommendation No. 9. Summary available on the internet: [http://ec.europa.eu/bepa/european-group-ethics/docs/press\\_release\\_opinion\\_25\\_en.pdf](http://ec.europa.eu/bepa/european-group-ethics/docs/press_release_opinion_25_en.pdf) [2014-04-01].

if accidental release into the environment would take place” (Recommendation No. 3).<sup>263</sup>

In the current 8th Framework Programme, Horizon 2020, reference is only made to the European Charter for Researchers and the Code of Conduct for Employing Researchers, containing general precepts of research freedom and research boundaries. However, it is emphasized specifically that these two codes of conduct are of a voluntary nature. As such, they have no relevance for decisions concerning research funding.<sup>264</sup>

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<sup>263</sup> Ibid., 77.

<sup>264</sup> European Commission 2005, Annex 1; see here also for more details on research freedom and its limitations, also on the dissemination of results and on accountability, including in respect of society as a whole.

## 7 CODES OF CONDUCT IN GERMANY — INSTRUMENTS OF SELF-RESPONSIBILITY

Since the Second World War, recommendations have been developed concerning commitments on the part of scientists and engineers that are reminiscent of the Hippocratic Oath in medicine.<sup>265</sup> On an international level, the UNESCO issued a recommendation on the situation of scientific researchers as early as 1974 in which it emphasized the ‘ethical aspects’ of scientific research.<sup>266</sup> Furthermore, codes for the responsible conduct of research have come into existence since the nineteen-eighties that have been drawn up by scientific associations themselves with the purpose of committing their members to conduct research in a responsible manner.<sup>267</sup> At present, specific international and national guidelines and codes of conduct exist for the life sciences and biosecurity-relevant research.<sup>268</sup> The codes of conduct that have been drawn up in Germany by the German Research Foundation (2008), the Max Planck Society (2010) and the Leibniz Association (2012) are described in more detail below. In addition, codes of conduct are analysed that have relevance for companies in Germany.

For the purposes of this Opinion, the term ‘code of conduct for research’ is taken to refer to standards designed to require researchers to conduct research in an ethically justified, responsible manner. In some cases, these codes of conduct also recommend that a commission be established with the remit to provide advice as to what constitutes an ethically responsible research project. Several codes of conduct establish internal standards with a view to preventing scientific misconduct and

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265 German translation issued by Lenk 1991, 398 ff.

266 *Ibid.*, 381 ff.

267 Cf., for instance, the code of conduct of the British Computer Society (1984/85); code of ethical conduct of the American Sociological Association (1989), issued by Lenk 1991, 388 ff.

268 Cf. especially World Health Organization 2010, 31. For an overview of other codes of conduct, see *ibid.*, Annex 8, 58 ff.

at the same time ensuring that the propagation of knowledge — or even truth itself — be secured as the goal of scientific endeavour. As the fulfilment of these standards represents a necessary condition for responsible scientific research, these codes of conduct can, from an ethical point of view, also be regarded as an *internal ethos* of scientific activity.<sup>269</sup>

However, some of the codes of conduct in the area of biosecurity-relevant research go beyond this: For instance, research shall be committed to furthering human welfare and protecting the environment. In the context of their research projects, scientists should undertake efforts to minimize as far as possible risks that threaten human dignity, liberty, property and the environment. Thus the purpose of these codes of conduct in the field of biosecurity-relevant activities is the definition of standards for scientific responsibility towards society: Behavioural norms are to be laid down for scientists that no longer only serve science directly, but also society as a whole. For this reason, they are occasionally referred as ‘*external to science*’.

It should be borne in mind here the distinction between ‘external to science’ and ‘internal to science’ is problematic, because scientific decisions are often influenced by external values, especially where the selection of the goal of the research is concerned; besides science is part of society and as such it cannot escape its responsibilities towards society (cf. Section 4.1).

Codes of conduct for responsible research undoubtedly have a *de facto* binding character. Beyond this, they can also indirectly be of legal relevance, for instance in connection with employment law or the liability of a researcher. Whether they contain directly binding legal standards for researchers has yet to be analysed.

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269 Cf. Vöneky 2012, 68 ff.

## 7.1 Codes of conduct laid down by scientific organizations in Germany

To begin with, the codes of conduct of the German Research Foundation (*Deutsche Forschungsgemeinschaft*, DFG), the Max Planck Society (*Max-Planck-Gesellschaft*, MPG) and the Leibniz Association (*Leibniz-Gemeinschaft*)<sup>270</sup> will be presented and compared. These associations are all public sector bodies<sup>271</sup> with differing functions and purposes.

According to Article 1 of its Statute, the German Research Foundation aims especially to provide financial and immaterial support for research projects. Therefore its purpose is to foster research. The DFG's code of conduct addresses all scientists.<sup>272</sup> As the code is to influence scientists' 'conduct', it covers more than just decision-making on funding and supplies fundamental recommendations for the specific field of research with highly pathogenic microorganisms and toxins.

In contrast, the Max Planck Society (MPG) is a research association comprising 82 research institutes from Germany and elsewhere. The institutes cover a variety of different scientific fields. In addition, the MPG undertakes a funding function and cooperates with other research facilities and researchers. The MPG code of conduct is addressed to all those who work in MPG institutes or are supported by its funding. This includes scientific members, research group leaders, external scientific members, scientific staff, PhD students, guest scientists and also non-scientific staff.<sup>273</sup> The purpose of this code of conduct is the prevention of misuse of research and the prevention of risks of research by the persons concerned. It also applies to persons who are not working directly for an MPG institute, for

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270 Regarding codes of conduct for private companies, see Section 7.3 below.

271 As it constitutes an internal instruction for employees and is therefore legally binding for them, the '*Hausverfügung: Dual-Use-Potenzial in der Forschung*' (In-house Instruction: Dual-Use potential in research) issued by the Robert Koch Institute will not be discussed (*Robert Koch-Institut* 2013b).

272 Cf. *Deutsche Forschungsgemeinschaft* 1951.

273 Cf. *Max-Planck-Gesellschaft* 2010, II.A.2.

instance when they are engaged as reviewers to evaluate other researchers' projects.<sup>274</sup> In contrast to the DFG code, the MPG code is not specially designed to address the possible misuse of microorganisms and toxins. Instead, it contains general provisions relating to the danger of research misuse.

Finally, in its capacity as a registered scientific association, the Leibniz Association addresses its biosecurity-specific code of conduct to its member institutions such as the Leibniz Institutes or Academies.<sup>275</sup>

### **7.1.1 German Research Foundation: 'Code of conduct: Working with highly pathogenic microorganisms and toxins' (2008/2013)**

On 25 April 2008, the Executive Committee of the DFG<sup>276</sup> published its 'Code of Conduct: Working with Highly Pathogenic Microorganisms and Toxins'.<sup>277</sup> On 13 March 2013, this was updated by the DFG's Senate Commission on Genetic Research.<sup>278</sup>

The introduction to this code of conduct mentions a consensus that public safety is to be considered of highest priority; at the same time, however, "we must also consider the benefits to human health that can be achieved through research with pathogenic organisms, as well as freedom of research and freedom of publication". In the DFG's view, it is necessary for research to be carried out on pathogenic microorganisms and toxins, and this research should be restricted only as much as is necessary. The DFG regards this as being the only way towards

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274 Cf. *Max-Planck-Gesellschaft* 2010, II.D.1. Para. 3. Cf. also *ibid.* II.A.2.: MPG researchers are required to observe the code for activities beyond the scope of the society as well, such as consulting work, where they carry joint responsibility for commercial enterprises or in connection with journals.

275 For further details, see Teetzmann 2014, 163.

276 The DFG is a registered association, and its members are mainly state institutes of higher education or other state research facilities.

277 *Deutsche Forschungsgemeinschaft* 2008.

278 *Deutsche Forschungsgemeinschaft* 2013.

developing strategies for controlling dangerous pathogens and protecting the public against infectious diseases. At the same time, the DFG calls for responsible handling of such work, and expects scientists to appraise their experiments as early as the planning stage and before work commences in respect of possible dual-use relevance. Further, the results of such an appraisal, covering both the experiments as such as well as any planned publications, should be documented in the laboratory journals.

The DFG is also of the opinion that “researchers must be allowed to continue to publish data relating to highly pathogenic microorganisms and toxins in peer-reviewed journals”. The DFG considers prohibition of publications of sensitive research results to be an unsuitable instrument for minimizing the danger of misuse, declaring the publication of results to be an essential prerequisite for scientific self-evaluation, as “only known dangers can be countered”. It expressly declares that it will continue to fund such research.

The code of conduct lays down that project leaders should already take account of existing or possible dual-use relevance when applying for funds. The reviewers are requested to appraise the information provided by the applicant and issue a recommendation to the review boards. In a second step, the review boards are tasked with carrying out a careful examination of proposals having dual-use relevance. Where necessary this should be done after prior examination by an ad hoc working group. Where appropriate, suggestions should then be made regarding the way the work should be performed. As required, the responsible Senate Commission and/or the Senate itself can be involved in the process.

The DFG also emphasizes the need to continue funding academic exchange and the sharing of data, materials and methods in relation to research on pathogenic microorganisms and toxins (within the limits set by national and international laws and guidelines).

The DFG also recommends Universities and non-university institutions to hold regular seminars and other events for



students, doctoral researchers and postdoctoral researchers in connection with work on highly pathogenic microorganisms and toxins, as well as using the annual briefings required by the Genetic Engineering Act to raise awareness amongst researchers for dual use challenges.

In one broadly formulated recommendation, the DFG advocates “the continued development of best practice in connection with highly pathogenic microorganisms and toxins”. Finally, it recommends that results be shared with other organisations within Germany and abroad (e.g. the Medical Research Council (MRC), the Wellcome Trust in the UK, and the American Society for Microbiology (ASM)).

As the DFG expressly states in its code of conduct that it intends to continue to fund research involving highly pathogenic microorganisms and toxins, the recommendations essentially only contain — beyond the affirmation of funding — procedural suggestions regarding the assessment of dual use relevant research. Only the review boards are in a position to make concrete suggestions “as to how the proposed work should be carried out”, where appropriate in consultation with the responsible Senate Commission or the Senate.

No further material criteria for the assessment of work in the area in question are prescribed either for the experts directly commissioned, or for the review boards. According to the code of conduct, even experiments designed to increase the ‘bioweapon capability’ of biological agents or toxins could still be funded using public money (DFG Code of Conduct, Recommendation Nos. 1, 4). The same applies to experiments designed to increase the transmissibility of pathogens or to disclose the ineffectiveness of vaccines (DFG Code of Conduct, Recommendation Nos. 1, 4). This means that the gain-of-function experiments described in Section 1 (in which avian influenza viruses were to be modified in such a way that they become transmissible by air or from human to human) would, in principle, be open to funding, except insofar as the review boards may decide otherwise on a case-by-case basis.

### 7.1.2 Max Planck Society: “Guidelines and Rules on a responsible approach to freedom of research and research risks” (2010)

On 19 March 2010, the Senate of the Max Planck Society issued its ‘Guidelines and Rules on a responsible approach to freedom of research and research risks’. These rules represent a comprehensive code of conduct for dealing with dual-use problems arising in basic research in all sections of the MPG. They are not exclusively aimed at biosecurity-relevant research. The MPG rules have been adopted by the University of Kiel.<sup>279</sup>

In contrast to the DFG code of conduct, the legal limits of research are expressly mentioned prior to the ethical limits, and emphasis is laid on the fact that the legal provisions have higher priority.<sup>280</sup> Also, the relationship between the rules of the code of conduct and other codes is clarified. Other rules apply ancillary to the MPG rules in order to ensure good scientific practice, and they may be supplemented by more specific codes such as that of the DFG, as long as these do not conflict.<sup>281</sup> No researcher of the MPG may “limit himself or herself to compliance with legal requirements, but [...] must also observe ethical principles”.

The material guiding principle of the code of conduct underlines that research in the MPG, notwithstanding the complexities surrounding its benefits and risks, should be committed to welfare of mankind and the protection of the environment.<sup>282</sup> The code lays down the following “principles of ethically responsible research”: The responsibility to conduct risk analyses and to minimize risks; the responsibility to take care in publication; the responsibility to document and

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279 University of Kiel, *Grundsätze der ‚Forschungsfreiheit und Forschungsrisiken‘*. Available online: <http://www.uni-kiel.de/gf-praesidium/de/recht/interne-richtlinien/forschungsfreiheit-und-forschungsrisiken.pdf> [2014-04-01].

280 Cf. *Max-Planck-Gesellschaft* 2010, II.A.3.; II.B. Concerning compliance with legal requirements, cf. *ibid.* II.D.2.

281 Cf. *Max-Planck-Gesellschaft* 2010, II.A.2.

282 Cf. *Max-Planck-Gesellschaft* 2010, I.A.

communicate risks; the responsibility to carry out training and education.<sup>283</sup>

According to these rules, each researcher has a primary duty to recognize possible risks and to take account of their consequences and potential use and misuse of the research work, as well as considering means of keeping its implementation under control. Attention should also be paid to the context in which the research is carried out as well as to the identity of the persons who commission work or with whom the researcher may cooperate. In certain cases restrictions should be placed on international cooperation.

The second principle regarding risk minimization concerns each researcher's obligation, shared with all others involved, to ensure that threats arising from the execution and implementation of the work to human dignity, life, health, liberty and property as well as the environment are minimized as far as possible. This requirement applies throughout the duration of a research project. In cases where there is a risk of research being misused, co-workers and cooperation partners are to be selected with care. Research applications addressed to the Max Planck Society and other funding bodies are to include references to such risks and measures designed to minimize them.

The third principle governs how to deal with publication: Where risk-laden research is to be carried out, the possible consequences of a publication must be subjected to an evaluation as well. Of decisive importance here is the question as to whether research results may lead to specific hazards or large-scale damages directly, i.e. without any prior complex implementation or application processes. The recommendation is to limit, modify or delay the publication of results in order to minimize risks. As a last resort — in specific cases and perhaps for a limited period of time — communication and publication shall not be carried out at all.

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<sup>283</sup> Cf. *Max-Planck-Gesellschaft* 2010, II.C.1 ff.

The code also contains provisions for documentation: Where research gives rise to risks for constitutionally protected goods, scientists shall provide documentation of such risks — together with an evaluation of the potential benefits — and the measures that have been adopted to minimize them.

The code also covers internal communication regarding risks: In cases of actual or possible legal infringements, the code requires of the scientists involved that, firstly, the responsible colleague, and as required the head of the research department, the executive director of the institute concerned and in special cases the Directorate of the Max Planck Society be informed.

In contrast to the DFG code of conduct, the MPG code expressly lays down the following fourth principle: As ultima ratio, research that is irresponsible shall not be carried out, and it also specifies the criteria for deciding on this.<sup>284</sup> It may be appropriate not to undertake research in cases where the risk evaluation shows that “where risk potential is disproportionate or cannot be restricted”. Here, the MPG rules require the responsible researcher to carry out an “ethical evaluation of the remaining risks” after the definition of possible protective measures may be assisted by considering the question of whether, on balance, the potential damages outweigh the potential benefits of the research. The degree of possible damage as well as the likelihood of it occurring should be taken into account, and also whether the results that the research may yield could be directly used for harmful purposes and whether implementation of the results can be kept under control. High-risk research may be acceptable where third parties carry out research that may be subject to actual or possible misuse or where safety standards are not observed, and the purpose of the justifiable research is to counter such dangers or minimize resulting damages.

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<sup>284</sup> Cf. *Max-Planck-Gesellschaft* 2010, II.C.5.

In cases of doubt, the ethics commission whose inauguration is laid down in the code of conduct itself can be consulted.<sup>285</sup> The code sets out in detail the circumstances under which an appeal to the ethics commission may be made, the commission's tasks, its interdisciplinary constitution and its voting procedures. Any scientist engaged in a project, the President of the MPG, any scientific member and also any external cooperation partner may approach the ethics commission.<sup>286</sup> The ethics commission is to provide advice in matters concerning the implementation of ethical principles, mediate in serious differences of opinion between researchers, and it can also issue recommendations for carrying out research projects. In the performance of these duties, the commission has recourse to a far-reaching authority to supply information, clarify and interrogate.<sup>287</sup> Should the commission entertain doubts as to whether a project complies with the MPG rules, the responsible researcher is to be informed, and to be heard without delay by the commission. The researcher is also to be informed as quickly as possible about the commission's conclusive recommendation and the grounds on which it is based. The scope of the commission's competences and the rights of the researchers in this procedure indicate that there is the aim of an effective implementation of the code of conduct.

### **7.1.3 Leibniz Association: Code of Conduct for Biosecurity for Facilities dealing with Biological Resources (2012)**

On 30 November 2012, the Executive Board of the Leibniz Association issued its 'Code of Conduct for Biosecurity for Facilities in dealing with Biological Resources'. With this,

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<sup>285</sup> Cf. *Max-Planck-Gesellschaft* 2010, II.D.1. Para. 4, II.D.3.

<sup>286</sup> Cf. *Max-Planck-Gesellschaft* 2010, II.D.3. Para. 4.

<sup>287</sup> Cf. *Max-Planck-Gesellschaft* 2010, II.D.3. Para. 6.

the Leibniz Association and its biodiversity research network adopted the Code of Conduct on Biosecurity for Biological Resource Centres<sup>288</sup> issued by the European Consortium of Microbial Resources Centres. Express mention is made of its function as a supplement to legislative requirements, and also to the fact that the requirements of the Biological Weapons Convention are regarded as setting the decisive, internationally valid standards that define the boundaries of justifiable research in biosecurity-relevant areas. The aim of this code is to raise levels of awareness in the member organizations with a view to preventing the misuse of research in the life sciences: The intention is to prevent facilities in which work on microbiological resources is carried out from contributing, directly or indirectly, to the misuse of biological agents.<sup>289</sup> However, the code does not aim to influence research activities or restrict the range of biological resources that are used.<sup>290</sup> The code requires that those Leibniz Association member bodies that have to do with microbiological resources, store them or pass them on acknowledge and observe the code.<sup>291</sup> The code is to apply not only to Leibniz Association members, but “all those engaged in the life sciences”, including relevant associations.

The code lays down specific basic rules for seven areas: These concern biorisk management, basic and advanced training, the reporting of misuse, the maintenance of confidentiality for internal and external communication, research and the transfer of knowledge, access controls and supply of materials, packaging and transport. This code also requires that dual-use aspects be evaluated both before research projects are applied for and during their execution, and that reliable and appropriate risk appraisal be carried out.<sup>292</sup> Risks that may result from

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288 Available on the Internet: [http://www.embarc.eu/EMbaRC\\_CoC\\_Biosecurity\\_final.pdf](http://www.embarc.eu/EMbaRC_CoC_Biosecurity_final.pdf) [2014-04-01].

289 Cf. *Leibniz-Gemeinschaft* 2012, II. Goal.

290 Cf. *Leibniz-Gemeinschaft* 2012, I. Preamble.

291 Cf. *Leibniz-Gemeinschaft* 2012, II. Goal.

292 Cf. *Leibniz-Gemeinschaft* 2012, III. Code of Conduct, 1, 5.

the publication of results are to be minimized. Biosecurity aspects must also be taken into consideration where knowledge is passed on to others. Measures are to be undertaken to secure potential dual-use material, including physical measures and access controls. Checks are to be carried out to ensure that recipients of potential dual-use materials have the required authorization, and only authorized logistics companies are to be entrusted with the transport of such material. Biorisk management is to be integrated into the organization as a whole and subjected to review. Areas of responsibility are to be defined that ensure the implementation of legal requirements and cover communication with staff and any third parties involved. The code also provides for the protection of whistleblowers: Misuse or suspected misuse should be reported as a matter of course; any observation of misuse of biological material, associated information or technologies or suspicion relating to such misuse is to be reported to competent persons or commissions, and through this no disadvantage is to be suffered by the person submitting the report. Specific attention is to be paid to the dual-use dilemma and existing regulatory measures in basic and advanced training processes. The code requires that regular courses be given to this end.

#### **7.1.4 Central aspects of the codes of conduct in comparison**

##### *The scientist's freedom and responsibility*

While confirming that work on highly pathogenic microorganisms and toxins is in principle worthy of funding, the DFG code of 2013 mentions the possibility that such research may be open to misuse. In this, the DFG follows the criteria that have been developed in the USA to ensure that dual use research of concern (DURC), especially, be subjected to special evaluation. However, despite emphasising public safety as being of utmost priority, the code contains few concrete statements on

dealings with DURC dangers. There are no recommendations for risk assessment criteria, nor for risk-benefit analyses. The area of risk prevention is only mentioned briefly (No. 3 DFG Code). Research in this area shall be restricted as little as possible. Thus the possibility of withholding funding in certain cases — even when the research may be supported in principle — is not expressly mentioned, with a tendency for it rather not to be realized.

The 2010 MPG code of conduct does not contain any statements on dealing with specific biological agents, but in its more general provisions concerning the prevention of research misuse it goes considerably further. Although it emphasizes the significance of research and freedom to carry out research for human health, prosperity and security as well as the environment, it also refers to the responsibility of scientists to observe the boundaries placed not only by legal norms, but also by broader ethical principles. In contrast to the DFG code of conduct, the MPG rules contain a catalogue of measures with different intensity. As a last resort, this includes not undertaking irresponsible research and not publishing results. It also provides a mechanism for ensuring compliance, in particular through the inauguration of an ethics commission that is to provide advice on implementing the rules and issues recommendations for research projects.

The Leibniz Association code of conduct concentrates on concrete recommendations for dealing with biological resources. It stresses that the code should contribute towards raising awareness of a basic 'ethical understanding' with a view to prevent misuse in the life sciences. However, the code expressly states only general obligations to take account of dual-use aspects, to carry out risk assessment, to minimize risks and to report cases of misuse.



*Measures for ensuring responsible practice in biosecurity-relevant areas of research*

*Risk assessment:* The need for risk assessment is included in all three codes of conduct. The DFG assigns this task to the scientists, consulting experts and especially to the review boards. The latter are to be involved, as required, with the convocation of an ad-hoc working group and consultation with the responsible Senate Commission or the Senate itself. The MPG code of conduct requires researchers or their superiors to conduct a risk assessment; the consequences and possible implementation scenarios and potential for misuse as well as ways of controlling the latter are to be taken into consideration. According to the code of conduct, it may prove necessary to conduct enquiries regarding the context of a research project, the identity of the person commissioning the work and any cooperation partners who may be involved. In specific cases, the consequence of such a process (i.e. the responsible decision of a researcher or his/her superior) and of the recommendation of the MPG ethics commission may be not to undertake certain experiments where the risk potential is disproportionate and cannot be limited. The Leibniz Association considers that biorisk management should be integrated into the organization as a whole. Areas of responsibility are to be laid down in consultation with staff and any third parties involved.

*Risk minimization:* The DFG considers that DURC is necessary, and it only mentions general measures for minimizing the risks involved. Scientists should evaluate their experiments regarding possible dual-use relevance as early as the planning stage and before work commences, and to document such an evaluation.<sup>293</sup> In addition, project managers should draw attention to this aspect when applying for funding. Review boards should then make recommendations as to how the work being applied for should be carried out. However, such experiments should be restricted as little as possible. The code also generally

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293 Newly adopted in the 2013 version of the DFG Code of Conduct.

advocates developing the process of best practice in dealings with highly pathogenic microorganisms and toxins further. In its treatment of the risks for human life and health and the protection of the environment, the MPG code of conduct expressly lays down the need to minimize risks. These measures are to be evaluated and implemented before a research project begins and while it is being executed. In individual cases, this may have the consequence that it may be necessary that research is not to be undertaken, or international cooperation is to be restricted, or results are not to be published. The code of conduct of the Leibniz Association only mentions risk minimization in connection with the publication of results, and with a view to preventing their misuse.

*Access control; restriction of cooperation:* According to the code of conduct of the Leibniz Association, the maintenance of security and access controls for staff and visitors are to be set up in accordance with the results of the risk assessment. The MPG code of conduct also mentions the possibility of restricting international cooperation in order to minimize risks.

*Supply, packaging and transport; physical security:* The MPG code of conduct makes specific reference to security measures against the release or theft of dangerous material and measures of an organizational nature with a view to minimizing risks. Going beyond this, the Leibniz Association code of conduct includes the provisions that recipients of dual-use material shipments should be screened, only authorized logistics companies be commissioned to transport such shipments and that all rules regarding export controls be observed.

*Responsible persons:* In the MPG code of conduct, responsibility for observing ethical principles in research is expressly assigned to the scientists in charge of the project in question. This also devolves upon senior staff as part of their supervisory tasks, as well as the MPG itself within the scope of its authority to issue instructions.

*Ethics commission:* Only the MPG code of conduct lays down provisions for the inauguration of an ethics commission

tasked with giving advice concerning the implementation of the rules. The advice of such an ethics commission can be sought by any person involved in a project, by the President of the MPG and (where evidence of a legitimate interest is furnished) by any member of staff or doctoral student of the MPG, and even by external cooperation partners, in order to establish whether a planned or current project is in accordance with the MPG rules. Provision is also made for the ethics commission to hear the responsible researcher, and for that person to be informed of the commission's final recommendation.

*Securement of internal and external communication:* The Leibniz Association specially mentions the need to prevent unauthorized access to internal and external email communication, postal and telephonic communication and research data concerning dual use research. The MPG code of conduct, too, requires extended security measures such as ones designed to make computing facilities more secure. The requirement to provide for transparency is not regarded as running counter to such security measures and access controls.

*Provision of information to staff:* All three organizations consider the provision of information to and the training of staff in matters of biosecurity and DURC to be essential. The DFG expects best practices to be subjected to continuing development through exchange with other national and international scientific bodies.

*Communication and publication:* The DFG mentions the need to publish in scientific journals, for international cooperation and for scientific exchange in its code of conduct. The MPG does acknowledge the importance of transparency and communication, but also stresses that risks in connection with dual use relevant research need to be minimized regarding human dignity, life, health, freedom and property and also concerning the protection of the environment — as necessary by scientists to modify their communications and publications. In extreme cases, such communication and publishing should not be undertaken at all. The Leibniz Association's code

of conduct makes general reference to the facts that the duty to minimize risks also extends to publications and that biosecurity aspects should be borne in mind when knowledge is transferred, and also that unauthorized access to internal communication “is to be prevented”.

*Documentation of illegal acts or misuse:* The codes of conduct of both the MPG and the Leibniz Association require that illegal acts or misuse be documented.

## **7.2 Codes of conduct in research and freedom of research**

### **7.2.1 Constitutional aspects of the codes of conduct issued by scientific organizations**

The codes of conduct of the scientific organizations that have been examined here represent examples of self-regulative setting of standards. The purpose is to influence the actions of the respective addressees. The ‘quality’ of these regulative effects must be judged in terms of whether the codes of conduct contain rules of law in a strict sense, as well. However, private legal entities such as these three scientific organizations do not have the authority to issue laws. It is possible for private legal entities to be furnished with such authority, but this is not the case here.

Going beyond this, a clarification is necessary as to whether issuing codes of conduct in research may be regarded as an administrative act. If this is the case, it is necessary to examine whether certain provisions in the codes of conduct limit the scientific freedom and have to be analysed in the context of the duty not to interfere with this right.<sup>294</sup> In determining the

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<sup>294</sup> Should this question be answered in the affirmative, this would in turn give rise to a considerable difficulty: the absence of a law as a legal foundation that is required by the constitution.

extent to which a scientific organization can be regarded as being an organ of the State, various factors play a role, such as the type of the inaugural act, the type of organization, the way statutory influence on policy and decision-making is laid down, the degree of supervision and the degree of financial control.<sup>295</sup> It is also possible that an organization is only considered to be bound in certain areas by human rights, whilst in others it is itself protected by fundamental rights such as scientific freedom. The question as to whether the self-regulatory mechanisms in scientific research as exemplified in the codes of conduct under appraisal here are to be classified as administrative acts that has to be in conformity with fundamental rights is a matter of debate. However, even if one denies it this does not mean that codes of conduct in research have no relevance at all from the point of view of fundamental rights. In any case the State is obliged — on the basis of its duty to protect researchers affected by the codes of conduct and in the fulfilment of its basic responsibility according to general law — to ensure that such non-state regulations do not constitute an inappropriate interference in the exercise of free scientific enquiry.<sup>296</sup> Where codes of conduct in research are adopted by public legal entities such as universities, this has to be analysed as a different case.<sup>297</sup> The fundamental question arises here, and indeed extends to the entire scope of all research, as to whether and to what extent the need for an act of parliament, derived from the rule of law and the principle of democracy, may call for a legally based structure and statutory framework (*Grundordnung*) of this area (see Section 6 on research funding).<sup>298</sup>

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295 Federal Constitutional Court decision 128, 226 (244 f.).

296 Cf. Wilms (will be published soon), 153 ff.; Teetzmann 2014.

297 The University of Kiel provides an example of this. Available on the Internet: <http://www.uni-kiel.de/gf-praesidium/de/recht/interne-richtlinien/forschungsfreiheit-und-forschungsrisiken.pdf> [2014-04-01].

298 Cf. only Mager 2009, Para. 166 recital 50.

## 7.2.2 The form and degree of bindingness of codes of conduct in research

Whereas the DFG and the Leibniz Association specifically name their recommendations ‘code of conduct’, and refer directly to the area of biosecurity, the MPG calls it more general guidelines and rules for research. The rules issued by the Max Planck Society are intended to support those working under its auspices in that they provide an ‘ethical guideline’. As part of the self-regulation process,<sup>299</sup> it is to help prevent misuse of research, avoid risks and provide for a procedural framework. They are therefore not referred to as directly binding legal norms of the Max Planck Society, but as ‘ethical guidelines’, and expressly differentiated from statutory norms, and especially from legal regulations.<sup>300</sup> Thus they can also be regarded in a broad sense as being a code of conduct, like those of the DFG and Leibniz Association, and specifically as a code for the responsible conduct of research (cf. Section 7.1) forming part of the self-regulation process. The codes of conduct do, however, indirectly attain legal relevance in the context of the enforcement measures of employment law. In addition to this, it is to be assumed that they have indirect legal effects on the basis of the principles of tort and criminal law. From the criminal law point of view, for instance, personal negligence can be based on failure to observe risk minimization measures laid down in a code of conduct, although this has to be decided on an case-by-case basis. If duties of care that are laid down in a code of conduct are not observed, this will usually constitute negligence in terms of legal liability.

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299 Cf. *Max-Planck-Gesellschaft* 2010, B.

300 Cf. *ibid.*

## 7.3 Codes of conduct of private sector organisations

There are three codes of conduct that deal with biosecurity-relevant research in private sector organisation based in Germany: One of them, essentially based on the DFG code of conduct, is a position paper on the topic of biosecurity issued by the *Biotechnologie-Industrie-Organisation Deutschland* (German Biotechnological Industry Organization) in 2008. The other two are codes of conduct issued by associations from the sectors of genetic synthesis and synthetic biology in 2009: the *Harmonized Screening Protocol* of the International Gene Synthesis Consortium and the *Code of Conduct for Best Practices in Gene Synthesis* of the International Association Synthetic Biology.

### 7.3.1 BIO Deutschland: Position Paper (2008)

The *Biotechnologie-Industrie-Organisation Deutschland* (BIO Deutschland), currently with 300 member companies, is a registered sector association. In its position paper of 10 December 2008 it expressly committed itself to the DFG 'Code of conduct for working with highly pathogenic microorganisms and toxins' that was published in 2008.<sup>301</sup> There are no essential differences in the content of the two papers. The BIO Deutschland paper merely differs where the DFG code of conduct refers directly to its own role or committees.

Therefore, just as the DFG code of conduct, the BIO Deutschland position paper on biosecurity-relevant research advocates, in principle, research and research funding in this field, the publication of research findings in peer-reviewed journals and the promotion of international cooperation and exchange of information, materials and methods (subject to

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<sup>301</sup> Cf. *Biotechnologie-Industrie-Organisation Deutschland* 2008.

compliance with national and international legislation and regulations).<sup>302</sup>

The position paper does not contain any definite instructions or restrictions governing researchers' activities or decision-making in the member companies. It therefore is not limiting biosecurity-relevant research to the benefit of any given goods to be protected such as life of the population or public health.

### 7.3.2 Voluntary commitments in the genetic synthesis industry

#### *International Gene Synthesis Consortium: Harmonized Screening Protocol (2009)*

To date, seven companies specializing in the synthetic manufacture of DNA have joined the International Gene Synthesis Consortium (IGSC).<sup>303</sup>

In 2009, the IGSC issued a *Harmonized Screening Protocol*<sup>304</sup>. It contains regulations for 'Gene Customer Screening' and 'Gene Sequence Screening' regarding biosecurity risks and the documentation of such screening. The protocol lays down how the genes that are to be synthesized are to be matched with database records on biosecurity-relevant pathogens. The protocol contains the express aim of building up a comprehensive database of all potentially dangerous sequences. According to information provided by the company responsible for implementing the protocol, Life Technologies, this database was commissioned in November 2011, and since then it has been continuously extended.<sup>305</sup> The protocol also requires that

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302 Cf. *ibid.*, 2. to 5.

303 Available on the Internet: <http://www.genesynthesisconsortium.org/members.php> [2014-04-01].

304 Cf. International Gene Synthesis Consortium 2009.

305 Oral communication by André Rusch during the 'WHO Informal Consultation on Dual Use Research of Concern' from 26 to 28 February 2013 in Geneva.



customers be verified against various lists of sanctioned persons. It specifies that products should only be dispatched to reliable end customers or to intermediate traders who screen their own customers. Biosecurity-relevant sequences are only to be dispatched to such customers who are in a position to fulfil all legal requirements relating to these agents and can prove that they are conducting legitimate research.<sup>306</sup>

Information on the screening results, the sequence concerned, the transport vector used and the customer data must be kept for eight years.<sup>307</sup> In addition, special emphasis is laid on cooperation and the exchange of information with national and local security and intelligence agencies, and that all IGSC companies are committed to observing all applicable laws and regulations, including provisions laid down by the WHO.<sup>308</sup> The IGSC companies intend to cooperate in future in order to integrate further recommendations by public authorities, scientists and civic bodies into their work.

***International Association Synthetic Biology: Code of Conduct for Best Practices in Gene Synthesis (2009)***

Eight companies, mainly from Germany, as well as some private persons belong to the International Association Synthetic Biology (IASB) based in Heidelberg. In 2009, the IASB issued a code of conduct<sup>309</sup> that is similar in many aspects to the IGSC screening protocol. The current signatories of the code of conduct comprise six German companies and two Chinese companies. The code of conduct contains instructions for ensuring a safe and responsible handling of the chemical synthesis of genetic sequences for commercial or non-commercial purposes with a view to preventing their intentional misuse. This is especially necessary prior to the fulfilment of customer orders.

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306 Cf. International Gene Synthesis Consortium 2009, 2.

307 Cf. *ibid.*, 3.

308 Cf. *ibid.*, 5.

309 Cf. International Association Synthetic Biology 2009.

*Risk evaluation:* Sequences of genes to be chemically synthesized are to be compared with database records of genetic sequences to establish any similarities with genes that display pathogenic or toxic characteristics. In addition, tests are to be carried out to establish whether these genetic sequences match any biological agent that could be used as a biological weapon and is listed amongst the biological agents contained in the appendix associated with currently valid biological weapons export control legislation.

*Risk management:* The identity of the customer is to be checked. For certain characteristic sequences, further appropriate enquiries are to be carried out (No. 8). Should there be definite grounds for suspecting that illegal activities are involved, the authorities are to be informed (No. 5).

*Data retention:* The companies also commit themselves to retaining records and statistics relating to biosecurity-relevant enquiries for a period of eight years (No. 4).

### **Outlook**

In the USA and in Germany the export of chemically produced genetic sequences is subject to legal provisions where these sequences can be matched with the pathogenic or toxic characteristics of a biological agent that has the potential for the use as a biological weapon. In Germany, the relevant legal instrument is the Council Regulation (EC) 428/2009 of 5 May 2009 (EC Dual-Use Regulation). Here, the codes of conduct serve mainly to provide for prior clarification as to whether a sequence is subject to export control legislation, in which case a process of application involving the security authorities is to be implemented. As in specific cases genetic sequences may be synthesized in research facilities, the IASB code also specifically addresses the non-commercial sector.

IASB and the IGSC try in drafting these codes of conduct to contribute towards a global consensus on standards for responsible creation and export of synthetic genetic sequences. Currently, the number of Chinese companies in this market

is on the increase. To date, two of them have signed the IASB code of conduct. Both companies are undertaking considerable efforts to promote it, for instance with joint events that were held in Heidelberg, Shanghai and Hong Kong in 2012 and 2013. These events were also supported by British security authorities and the FBI.

## 7.4 Conclusion

Notwithstanding the fact that the codes of conduct in research mentioned above serve the justified purpose of closing gaps that exist in the legal regulation of biosecurity relevant research, they are insufficient, whether taken individually or together.

There are several reasons for this: First of all it is decisive that none of these codes of conduct apply to all researchers and other staff in German research institutions. They all address only to a limited group of researchers; even *de facto* all of them can only be binding for a limited circle of researchers and other staff in research institutions. For instance, biosecurity relevant research conducted at universities that do not receive DFG funding and do not cooperate with the MPG are not covered by these codes. Projects that are funded by Federal Ministries are not included within the scope of any of these codes of conduct. To date, there is no Germany-wide code of conduct relating to biosecurity that applies to all researchers and other staff working on DURC. In 2013, the DFG and the Leopoldina set up a working group to draft a code of conduct covering security-relevant research. However, it remains to be seen to what extent this code of conduct will specifically address biosecurity relevant research, and whether it will apply throughout Germany.

The second reason that the existing codes of conducts are insufficient is due to the fact that their provisions are, on the whole, far too general and unspecific: With the exception of

the MPG code of conduct, there are few provisions determining responsible research in the field of DURC, especially in the life sciences (risk assessment, risk minimization, refraining from research and publication). This also applies to the aspect of research funding by the DFG and the codes of conduct for corresponding biosecurity-relevant research in the private sector.

Thirdly, the existing codes also fail to regulate the field of DURC sufficiently because the standards that are laid down are not backed by an institutional system of support, again with the exception of the MPG code of conduct in which the establishment of an ethics commission is expressly provided for. It is also not clear how standards, insofar as standards are formulated at all, are to be implemented in practice and, as required, enforced, and how such enforcement may be monitored. This problem is exacerbated by the lack of clear provisions for DURC-specific training measures for researchers that would help to translate the content of the codes into daily practice.

Finally, the existing codes of conduct do not suffice because they have not been drafted in a process involving all relevant stakeholders, especially the respective scientific organizations including universities and scientific funding bodies.

# 8 SELECTED EXAMPLES ILLUSTRATING HOW BIOSECURITY-RELEVANT RESEARCH IS HANDLED IN OTHER COUNTRIES

## 8.1 USA

### 8.1.1 Overview and historical development

Since the terrorist attacks of 11 September 2001 (cf. Section 1.3), questions of biosecurity have become much more significant in the USA than was previously the case.<sup>310</sup> Biosecurity is now seen as being a problem of national urgency. In terms of legislation, this resulted in the enactment of the Patriot Act in 2001 and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, shortly after the attacks took place.<sup>311</sup> In particular, this new awareness of the potential for misuse of research in the life sciences led to two commissions of enquiry of the National Academies (the Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, also referred to as the Fink Committee, and the Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, also referred to as the Lemon-Relman Committee), as well as to the establishment of the National Science Advisory Board for Biosecurity (NSABB), addressing questions as to how to avert the misuse of knowledge gained in the life sciences. The Fink Committee published its report in 2004 and presented it upon request to Congress. The report identified the restricted area within the more general field of dual-use research which the NSABB later labelled Dual Use Research of Concern (DURC). According to the NSABB,

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<sup>310</sup> Cf. Miller/Engelberg/Broad 2002.

<sup>311</sup> Cf. the overview in Matchett/Mazza/Kendall 2013, 51 ff.

DURC is “research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, or material.”<sup>312</sup>

In contrast to broader dual-use questions in the life sciences, the need for regulation of DURC was identified. Furthermore, the Fink Committee recommended more thorough education and training for scientists in the field of dual use, and that the work of biosafety commissions should be broadened to cover biosecurity as well. Decisions on the publication of biosecurity-relevant research results should be made by the scientists themselves.

The report drafted by the Lemon-Relman Committee in 2006 makes special mention of the dangers associated with bioregulators.<sup>313</sup>

In 2005, the National Science Advisory Board for Biosecurity (NSABB), which functions in the capacity of a central scientific commission, was founded at the instigation of the United States Government, as had been recommended in the Fink Report. The task of the NSABB is to address issues related to biosecurity and dual use research at the request of the United States Government. In individual cases, research projects may be submitted to the Board for appraisal.

In 2007, the NSABB presented its paper ‘Proposed Framework for the Oversight of Dual Use Life Science: Strategies for Minimizing the Potential Misuse of Research Information’.<sup>314</sup> The paper identifies the need for a governmental framework for responsible handling of biosecurity questions. However, this recommendation was not immediately implemented.

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<sup>312</sup> See National Science Advisory Board for Biosecurity 2007.

<sup>313</sup> Cf. National Research Council 2006. According to it, the military or terrorist use of bioregulators is comparable with that of toxins. The misuse of bioregulators can considerably increase the threat represented by biological weapons, so that bioregulators are to be regarded as potential biological weapons (United Nations 1991).

<sup>314</sup> See National Science Advisory Board for Biosecurity 2007.

In 2010, the Presidential Commission for the Study of Bioethical Issues also issued recommendations on questions of biosecurity in its report on synthetic biology. This includes a recommendation to the government to undertake periodic appraisals of security and safety risks arising from synthetic biology (Recommendation 12: Periodic Assessment of Security and Safety Risks).<sup>315</sup> However, on account of possible disadvantages that this may entail for researchers in the United States, the Bioethics Commission is critical of unilateral restrictions on transfer of data and material for reasons of security. Should the government become aware of significant deficits in the 'management' of concerns relating to security, the Commission recommends that all researchers should be required to report on their activities, including the so-called 'do-it-yourself biology' community. In addition, it suggests that revision of export controls may be appropriate insofar as this does not disproportionately curtail the exchange of material and information within the scientific community (Recommendation 13: Oversight Controls).<sup>316</sup>

In March 2012, new government guidelines came into force (Policy for Oversight of Life Sciences Dual Use Research of Concern).<sup>317</sup> These represent a framework to enable those research funding bodies and research facilities that receive Federal funding to carry out the assigned task of determining whether federally funded research projects are to be classified as DURC or not. The basis for such a classification is provided by the seven categories of research projects, which were defined in the 2007 NSABB report<sup>318</sup> as DURC and have since been revised and supplemented by a list of 15 weaponizable biological agents.

In February 2013, and as a response to the controversy surrounding research on H5N1 and H7N9 viruses, the U.S.

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315 Cf. Presidential Commission for the Study of Bioethical Issues 2010, 13 ff.

316 Cf. *ibid.*, 14 ff.

317 Cf. U.S. Department of Health and Human Services 2012.

318 See National Science Advisory Board for Biosecurity 2007.

Department of Health and Human Services issued concrete guidelines on funding for research in which highly pathogenic H5N1-type avian influenza viruses are produced that can be transmitted between mammals over the respiratory route.<sup>319</sup> The examination should take the following criteria into account:

1. The virus anticipated to be generated could be produced through a natural evolutionary process.
2. The research addresses a scientific question with high significance to public health.
3. There are no feasible alternative methods to address the same scientific question in a manner that poses less risk than does the proposed approach.
4. Biosafety risks to laboratory workers and the public can be sufficiently mitigated and managed.
5. Biosecurity risks can be sufficiently mitigated and managed.
6. The research information is anticipated to be broadly shared in order to realize its potential benefits to global health.
7. The research will be supported through funding mechanisms that facilitate appropriate oversight of the conduct and communication of the research.

Also, the National Institutes of Health (NIH) initiated an appraisal of current research within its area of responsibility. According to this, 381 funded research projects and 404 internal research projects are dealing with biological agents that are covered by the new guidelines. However, the NIH only classified ten of the funded projects as DURC. Seven of these DURC projects are devoted to influenza viruses, while the others deal with pathogens that cause anthrax, plague and botulism respectively.<sup>320</sup>

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319 Cf. U.S. Department of Health and Human Services 2013a.

320 Cf. Gottron/Shea 2013.



For the implementation of the new guidelines, the United States Government presented, also in February 2013, a ‘Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern’<sup>321</sup> that lays down the procedural steps required:

1. Clarification by the research project supervisor as to whether one of the 15 named biological agents is being used.
2. Institutional examination (generally by an expert commission in the research facility/university) as to whether the research would produce one of the seven DURC-relevant effects or whether one of these effects could result from the research; if yes, then an assessment of benefits and risks is to be carried out, if appropriate, with recommendations for risk minimization.
3. Documentation of this process and forwarding to the funding federal agency, if appropriate to the NIH.

These regulations also include US-financed research projects that are being carried out beyond the borders of the USA. Research that is not funded by federal agencies should be subjected to these regulations on a voluntary basis.

In August 2013, the U.S. Department of Health and Human Services announced a monitoring system for H7N9-GOF experiments that supplements the guidelines for funding H5N1 studies.<sup>322</sup>

## 8.1.2 Codes of conduct in the USA

In the NSABB report entitled ‘Proposed Framework for the Oversight of Dual Use Life Science: Strategies for Minimizing the Potential Misuse of Research Information’<sup>323</sup>, the scientists

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321 Cf. U.S. Department of Health and Human Services 2013b.

322 Cf. Jaffe/Patterson/Lurie 2013.

323 See National Science Advisory Board for Biosecurity 2007.

themselves are accorded a key role in recognizing the dual-use potential of the life sciences and in making efforts to minimize the risk of possible misuse of research results. The report does not represent a fully developed code of conduct, but rather a set of recommendations for developing such a code ('Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences').<sup>324</sup> It defines the responsibility of each scientist working in the life sciences as follows: The scientists should:

1. assess their own research efforts for dual use potential;
2. seek to remain informed concerning dual use research;
3. train others to identify dual use research of concern, manage it appropriately, and communicate it responsibly;
4. serve as role models of responsible behaviour;
5. be alert to potential misuse of research.<sup>325</sup>

The considerations were intended to encourage scientific organizations and establishments to develop their own codes of conduct on this basis. This is seen to be beneficial in acquainting scientists and laboratory staff with the responsibilities that they personally bear.

In the selected sample, the number of codes of conduct that included aspects of dual use and biosecurity in scientific associations increased from five to fourteen between 2005 and 2010.<sup>326</sup> In 2010, the NSABB presented its report 'Enhancing Responsible Science: Considerations for the Development and Dissemination of Codes of Conduct for Dual Use Research'<sup>327</sup> containing a 'Code of Conduct Toolkit' to aid drafting a code of conduct in research that takes account of the social responsibilities of scientists.

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324 See *ibid.*, Appendix 4, 51 f.

325 Cf. *ibid.*, 57.

326 National Science Advisory Board for Biosecurity 2010, 13 ff.

327 See National Science Advisory Board for Biosecurity 2010.

In 2010, the Department of Health and Human Services issued voluntary guidelines for trading with chemical genetic sequences that are based on codes of conduct from the bio-synthesis sector with cooperation from state agencies.<sup>328</sup> The manufacturers of chemical genetic sequences are called on to abide by two important specifications: They should know who the recipients of their products are. They should also know whether their synthesized DNA contains “sequences that give cause for concern”.

## 8.2 The Netherlands

The Netherlands and Italy<sup>329</sup> are the only states that have pursued the task of elaborating a national code of conduct for questions of biosecurity in life science research. In 2005, the Royal Netherlands Academy of Arts and Sciences (KNAW) inaugurated a ‘Biosecurity Working Group’ at the instigation of the Ministry of Science and Culture. In June 2007, the group presented ‘A Code of Conduct for Biosecurity’<sup>330</sup> that addresses researchers and laboratory staff, research establishments and research funding bodies. It is based on the ‘IAP Statement on Biosecurity’<sup>331</sup> issued by the InterAcademy Panel in 2005.

In drafting this code, it was considered to be of particular importance to seek an exchange with persons actively involved in this field of research and with other representatives of the sciences, business and politics: “Raising awareness is the most important objective of a code of conduct on biosecurity”<sup>332</sup>. In the KNAW’s view, the process of drafting the code has raised

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328 U.S. Department of Health and Human Services 2010.

329 Cf. National Committee for Biosafety, Biotechnologies and Life Sciences 2010.

330 Cf. Royal Netherlands Academy of Arts and Sciences 2008.

331 See InterAcademy Panel 2005.

332 Royal Netherlands Academy of Arts and Sciences 2008, 26.

levels of awareness and sensitivity within the scientific community, but also in society as a whole.

The Dutch code of conduct defines basic principles, identifies target groups and formulates rules of conduct in respect of:

- >> Raising awareness on questions of biosecurity;
- >> Research and publication policy;
- >> Accountability and oversight;
- >> Internal and external communication;
- >> Accessibility;
- >> Shipment and transport.

Public research funding bodies agreed that all life science funding applications must take account of the KNAW code of conduct in research.<sup>333</sup>

The first progress report<sup>334</sup> contains the recommendation to develop the code of conduct further, amongst other things by coordinating publishing information and educational materials (including a website with current information), continuation of the dialogue with relevant partners in government and society, referring to experts who can advise on the publication of results of potential dual-use life sciences research and conducting periodic evaluations on the awareness and compliance with the code. However, biosecurity codes of conduct have not yet been adopted by universities. The main reason for this is that a number of universities have already adopted the 'The Netherlands Code of Conduct for Scientific Practice' that was commissioned by the Association of Universities in the Netherlands in 2004.<sup>335</sup>

In 2008, a biosecurity network was set up in the Netherlands that includes various ministries, health organizations, communities, research establishments and emergency

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333 Cf. *Rathenau Instituut* 2011, 2.

334 Cf. Van der Bruggen 2011.

335 Cf. Schuurbijs/Osseweijer/Kinderlerer 2009.

services. The National Coordinator for Counter-Terrorism and Security represents the hub of the network. One result of the work carried out by the network has been the publication of the 'Biosecurity Self-Scan Toolkit' online.<sup>336</sup>

As the H5N1 research project headed by Ron Fouchier at the University of Rotterdam was funded by the NIH in the United States, no Dutch research funding bodies were involved.<sup>337</sup> However, the Dutch Government required Fouchier and the Erasmus Medical Center Rotterdam to obtain an export licence in accordance with the EU Dual-Use Regulation to confirm the legitimacy of publication of the results of the GOF experiments with H5N1 on ferrets in a foreign journal (see Section 1), because the Appendix to the Regulation that specifies goods that require approval includes avian influenza viruses and associated technical information. Although the researchers were of a different opinion, the export licence for the publication in the journal *Science* was applied for and granted in April 2012. However, in December 2012 the authorising agency revoked the approval. In their appeal against the obligation to obtain approval, Fouchier and his institute maintained that the aim of the ferret study was to extend the basic fund of knowledge concerning the transmissibility of influenza viruses, so that it constitutes basic research. Further, the method used to produce mutant varieties of the virus had already been described. As such, it amounts to generally available information and is therefore, in accordance with the Regulation, not subject to approval. However, the adjudicating court<sup>338</sup> rejected the claim in September 2013 on the following grounds: It is not the province of the researcher to decide whether his studies constitute basic research or applied research; his studies had

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336 Available on the Internet: <http://www.biosecuritytoolkit.com> [2014-04-01].

337 It has not yet been exhaustively clarified whether the code of conduct applies to Ron Fouchier's experiments on account of the indirect funding contributions made by Dutch bodies.

338 Decision of 20 September 2013 of the District Court of the North Holland Region of the Netherlands (Rechtbank Noord-Holland HAA 13/792).

a “practical goal”, and therefore did not constitute basic research; even though the method had already been described in the literature, in the concrete case in question completely new results had been obtained, so that the exemption grounds of information being generally available did not apply.

This decision has been vehemently criticized in research circles. On 16 October 2013, the European Society for Virology, also representing the European Society for Clinical Virology, appealed to the President of the EU Commission and the Commissioners responsible for research, health, justice and consumer protection. The main thrust of the criticism is based on concern that a department of the Dutch Ministry of Trade should make decisions as to whether and where a scientific publication may or may not appear. The critics demand an open discussion of the Dutch court’s decision at an “appropriate” institutional level. For in their view the issue goes beyond Fouchier’s virological research, with implications for the freedom to conduct research, scientific ethics, the significance of free exchange of research findings and the management of security-relevant information.

### *The Dutch risk management system*

In view of the controversy surrounding Fouchier’s experiments, the Royal Netherlands Academy of Arts and Sciences (KNAW) was commissioned by the Dutch State Secretary for Education, Culture and Science to conduct an evaluation of the experience gathered in connection with the biosecurity code of conduct<sup>339</sup> and advise the government on matters of dual-use research. In particular, the Academy was to address the following questions:

- >> How should dual-use research be assessed?
- >> Who should assess dual-use research?

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339 Cf. Royal Netherlands Academy of Arts and Sciences 2013.

The Biosecurity Committee that was then set up by the Academy carried out an investigation of the experience gained in connection with the biosecurity code of conduct. The Committee established<sup>340</sup> that the code of conduct had only reached a certain portion of the target group: Experienced scientists were more aware of it than doctoral students. Although the code of conduct did raise a certain degree of awareness of dual-use issues, the Commission concluded that this was not a sufficient basis for a biosecurity policy. The Fouchier case provides a useful example here. Fouchier himself was a member of the committee that drafted the biosecurity code of conduct.<sup>341</sup> Nevertheless, this appears not to have led to consequences concerning his decision about conducting and publishing the results of the H5N1 research project.

The Biosecurity Committee<sup>342</sup> recommended setting up a central 'Biosecurity Advisory Committee for Research in the Life Sciences' to assess the management of dual-use research. This Advisory Committee is to have a consultative function; it should be open to all stakeholders, and be independent and transparent. It should consist of a core group of at least five, at most seven members, who are to be supported by ad-hoc experts from specific areas. It should be affiliated to the Netherlands *Gezondheidsraad* (Health Council). The Biosecurity Committee recommends using an 'assessment framework' to establish whether a given research project constitutes DURC that involves the following aspects:

- >> the biological agent that is being studied,
- >> the nature of the research,
- >> the social and political context of the research.

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340 Cf. *ibid.*, 11 f.

341 Cf. *ibid.*, 33.

342 Cf. *ibid.*, 48 f.: 'Conclusions and Recommendations'.

As such, the criteria differ from those used to assess DURC in the risk management system of the United States. The US system simply refers to a list of 15 internally defined 'select agent' and a list of seven internally defined experiments. Thus decisions are made on the basis of a fixed matrix of agents and methods. The persons concerned in the Netherlands criticize this system because agents and activities that are not on the lists will not be taken into account, and context-relevant social and political factors will not be considered. These include, for instance, the question as to the degree of development of a given technology, the extent of possible harm, whether the danger is acute and possible repercussions that a project may have on an international scale. However, a precondition for the feasibility of assessments that take account of all these aspects is that those conducting them be well informed about the biological and context-relevant dual-use implications. That is the reason why the report does not contain assessment criteria consisting of specific lists, but simply the three assessment categories listed above.

The KNAW Biosecurity Commission also established in its report that the primary responsibility for assessing the dual-use relevance of a project lies with the researcher himself or herself, or with the institutions in which researchers are employed. It did not expound on this aspect in detail. If a project is deemed to be DURC, advice is to be sought from the Biosecurity Advisory Committee for Research in the Life Sciences. The Committee is empowered to issue one of the following recommendations: the research may (a) be carried out without extra conditions being imposed, (b) be carried out if a number of conditions are met or (c) should not be carried out or the findings should not be published (in full).



## 8.3 United Kingdom

In 2002, the British Foreign Office presented the Green Paper ‘Strengthening the Biological and Toxin Weapons Convention: Countering the Threat from Biological Weapons’<sup>343</sup> to Parliament. As one of eleven measures to be considered, the Paper emphasized the need to develop codes of conduct for academic and professional bodies:

“Codes of Conduct for Professional Bodies: such codes would be developed by academic and professional bodies to lay out standards for work relevant to the prohibitions of the Convention. Such codes could include, inter alia, a statement that scientists will use their knowledge and skill for the advancement of human, animal and plant welfare and will not conduct any activities directed toward the use of microorganisms or toxins or other biological agents for hostile purposes or in armed conflict.”<sup>344</sup>

In 2004, the Royal Society presented a paper entitled ‘The Roles of Codes of Conduct in Preventing the Misuse of Scientific Research’<sup>345</sup>, containing considerations on the functions and basic content of a code of conduct. As research funding bodies, the Wellcome Trust, the Medical Research Council and the Biotechnology and Biological Sciences Research Council jointly developed funding guidelines on the subject of biosecurity, and in 2005 they presented a joint declaration on funding practice.<sup>346</sup> In the future, funding applications must contain reference to any possible misuse of the research results. Clear rules are laid down for decision-making committees. Considerations of questions of misuse constitute part of the guidelines for good scientific practice.

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343 See U.K. Foreign and Commonwealth Office 2002.

344 *Ibid.*, 16.

345 See Royal Society 2005.

346 Biotechnology and Biological Science Research Council/Medical Research Council/Wellcome Trust 2005.

## 8.4 Conclusions

In all three states, a process of exchange between political bodies and scientific organizations has taken place with a view to establishing codes of conduct for DURC and linking these with the appraisal of biosecurity issues as part of research funding procedures. Aspects of self-regulation of research establishments as well as state regulation are both of relevance here. Despite these efforts, however, no specifically biosecurity-related codes of conduct have been laid down at the university and research establishment levels. On the other hand, general codes of scientific or research ethics have been introduced in universities, especially in the Netherlands, but also in the United Kingdom and, sporadically, in the United States.

## 9 THE NEED FOR BASIC, ADVANCED AND CONTINUING EDUCATION IN THE AREA OF BIOSECURITY

Prevention of the misuse of research findings is generally contingent on a marked, high level of awareness and knowledge in matters of biosecurity. This is especially true in terms of identifying DURC and then seeking responsible ways of dealing with it. Many biosecurity experts regard education of life scientists in the area of biosecurity to be one of the most effective means of preventing misuse.<sup>347</sup> Several surveys and investigations have revealed that there is a need for further development in this regard. They have shown that the majority of life scientists do not devote a great deal of active consideration to questions of biosecurity, mainly because they have little awareness of possible dual-use implications of their work.<sup>348</sup> The results of a survey taken during 130 teaching seminars held in 15 countries, showed that only a few of the participants had taken account of possible biosecurity risks in their work prior to the seminars. Equally few were aware of current developments in dual-use research or were well acquainted with the Biological Weapons Convention.<sup>349</sup> A survey of German universities offering courses of study in the life sciences revealed that only one of 22 responding institutions offered its students a module that deals specifically with the biosecurity aspects of life science research.<sup>350</sup>

Life scientists can only carry out effective risk assessment of their work when they understand what the risks are and have an awareness of the hazards that they entail. Codes of conduct, too, can only serve their purpose fully when scientists are so

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347 Cf. Rappert/Chevier/Dando 2006; Carlson/Frankel 2011; United Nations 2011b.

348 National Research Council 2010; Mancini/Revill 2008.

349 Cf. Rappert 2011.

350 Cf. Hoppe 2011.

well informed about dual-use issues that they have gained awareness and understanding of the risks involved and have therefore developed an interest in the codes and a desire to abide by them:

“It is not enough simply to put such Codes in place. Without effective measures to educate scientists about the existence and importance of such Codes, attitude and awareness will remain largely unchanged”.<sup>351</sup>

It is also clear to the states parties of the Biological Weapons Convention that there is a general lack of awareness for dual-use issues, and they have been promoting “awareness-raising education” since 2005.<sup>352</sup> This has led to some notice being taken by the scientific community and the public at large. Nevertheless, their efforts to establish a sustainable strategy of awareness-raising have not yet made satisfactory progress. In view of this, several Biological Weapons Convention states parties have made a clear statement on the issue:

“The frequent lack of awareness of aspects related to biosecurity and the obligations of the Convention amongst life scientists has to be addressed more urgently, strategically, and comprehensively”.<sup>353</sup>

The deficits in the implementation of “awareness-raising education” are attributed to, amongst other things, frequently overloaded curricula, but especially to a lack of resources for the development of teaching units concerning biosecurity and lack of expertise amongst teaching staff.<sup>354</sup> In recent years, online teaching modules have been developed in order to fill the information gaps concerning dual-use aspects of the life sciences and their relevance for the Biological Weapons

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351 Cf. United Nations 2005a, 34; See also United Nations 2005b.

352 Cf. United Nations 2005a.

353 Cf. United Nations 2011b, 4.

354 Cf. Minehata/Shinomiya 2010.

Convention.<sup>355</sup> These modules have been devised in such a way that they can be readily incorporated into existing curricula, and so that both students and their teachers, who are themselves no experts in that field, can learn together in an effective, active learning process.<sup>356</sup> One of these programmes is directed specifically at teaching staff ('train the trainer').<sup>357</sup> Thus learning modules already exist, and they can be tailored to fit a range of study courses such as bachelor, masters or PhD curricula. However, further steps must be taken to achieve their implementation in the German educational and scientific frameworks.

Over the past decade, Germany has introduced the bachelor/masters system in universities as part of the Bologna Process. ASIIN, the German accreditation agency for programmes of study in this area, recommends, amongst other things, training modules in biosafety/biosecurity as being essential components in the education of bioscientists.<sup>358</sup> The members of the German *Konferenz Biologischer Fachbereiche* (Conference for Biological Faculties) and the German *Verband Biologie, Biowissenschaften und Biomedizin* (Association for Life Sciences) adopted this recommendation in a declaration issued in 2010.<sup>359</sup> In this, all biological faculties are called upon to ensure that aspects of biosecurity and biosafety become mandatory modules in bachelor and masters curricula.

There is also a need to take action in the area of graduate studies, which in accordance with the spirit of the Bologna Process "also aim to achieve specialized scientific competence,

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355 See University of Bradford 'Dual-Use Bioethics. Educational Module Resource', available online at: <http://www.brad.ac.uk/bioethics/educationalmoduleresource> [2014-04-01]; Federation of American Scientists: 'Biosecurity Education Portal', available online at: <http://www.fas.org/programs/ssp/bio/educationportal.html> [2014-04-01].

356 Cf. Novosiolova/Mancini/Dando 2013.

357 See University of Bradford, 'Train the Trainer', available online at: <http://www.brad.ac.uk/bioethics/TraintheTrainer/30CreditBiosecurityModule> [2014-04-01].

358 Cf. ASIIN 2011, 5.

359 *Erklärung zur biologischen Sicherheit*. Available online: [http://www.vbio.de/informationen/wissenschaft\\_gesellschaft/thema\\_biosicherheit](http://www.vbio.de/informationen/wissenschaft_gesellschaft/thema_biosicherheit) [2014-04-01].

a scientific world view in a comprehensive sense and highly developed capacities for scientific reflection and scientific communication”.<sup>360</sup> The introduction of a teaching module on the topics of dual use and biosecurity into graduate studies would help to achieve this goal.

In addition to this, it would be advisable to develop and implement relevant training and advanced training programmes for life scientists in the area of biosecurity. Biosecurity issues also need to be given greater coverage in the training and advanced training of biological safety officers and biosecurity officers.

In view of the present state of development, rapid implementation of such recommendations in individual educational and research institutions will require active engagement and support from state sources.

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<sup>360</sup> Hegselmann 2013a, Para. 5, 8.; see condensed version of the contribution: Hegselmann 2013b.

## 10 NORMATIVE CONCLUSIONS

### 10.1 Normative principles for the assessment of biosecurity-relevant research

It is clear from the scientific, ethical and legal aspects that have been presented above that the topics of biosafety and biosecurity, though related, need to be carefully differentiated from each other, each area having its own empirical and theoretical scope and specific normative aspects requiring evaluation. On the whole, biosafety has to do with the prevention of unintentional harm to humans and the environment that may arise through insufficient protective measures or negligence, for instance. The area of biosafety is already covered by a far-ranging canon of internal scientific standards and legal provisions based on previous experience and general principles of risk assessment, and these are already part of daily practice. With regards to biosafety, risk assessment of relevant research can be carried out with some degree of precision, because both of the factors that determine the risk, namely the degree of probable damage and the likelihood of it occurring, can be estimated in principle on the basis of practical experience and simulation, allowing instruments of risk comparison to be implemented.

In contrast, such instruments for risk assessment and comparison cannot be applied with the same degree of reliability with regards to biosecurity. Biosecurity has to do with scenarios in which harm to humans, the environment or other legal interests is caused intentionally. It is true that the degree of damage likely to arise through misuse of life science research can often also be estimated reliably, because it makes no difference whether biological agents are released because of a researcher's carelessness or by bioterrorists intent on causing harm. However, the likelihood of such an event occurring through malicious intent is practically impossible to judge.

This is because such acts are either irrational, so a probability estimate cannot be reliably grounded in previous experience or profiling techniques, or they are carried out with a degree of forethought that also obviates any benefits of past knowledge. Also, whether an act is completely irrational or at least rational to the extent of being carefully planned, there is — at present — only a very small pool of experience on which to draw with a view to estimating probabilities of future events. As, on the other hand, the possibility of bioterrorist attacks and other types of detriment to humans and the environment that result from malicious misuse of life science research and research results cannot be excluded, the precautionary principle must play a major role in the normative evaluation of such cases.

Nevertheless, questions of biosecurity and biosafety do converge at least in those cases where a bioterrorist may choose to or have to use laboratory facilities to prepare or carry out an attack. Intentions may also play a role in biosafety contexts, for instance where established security regulations are consciously evaded through a researcher's neglect (e.g. in not fulfilling documentation requirements) or through attempts to gain advantage (e.g. failing to perform certain test steps or theft of materials). Normal laboratory security measures designed to counter such behaviour, such as access controls, may under certain circumstances provide a considerable degree of protection against similar acts planned by bioterrorists. Therefore certain biosafety risk assessments and the consequences drawn from them may also be applicable where biosecurity measures are needed. This is especially likely in high-security laboratories. Similarly, considerations of biosafety cannot completely ignore the possibility of irrational acts or intentional sabotage. Thus the scope of biosafety and the scope of biosecurity overlap, because biosecurity measures are to some extent based on the same risk assessment scenarios that apply to biosafety measures. Where there is no overlap, however, the respective normative consequences are derived from different principles of appraisal.



Specifically, the maintenance of biosecurity both inside, but especially outside the laboratory context is subject to a great deal of uncertainty that cannot be resolved satisfactorily by means of the instrument of risk assessment. For instance, there is no way of establishing a reliable statistical basis for estimating the probability of a dangerous microorganism being manufactured for use in a terrorist act in a low-security laboratory or simply in a garage. Therefore it is not sufficient to attempt to address actual dangers. Rather, there is a need to make access to biological agents or research results by unauthorized persons a priori difficult. From the point of view of normative assessment of such scenarios, the precautionary principle must be used for want of any more suitable starting points. The principle could be used to justify prohibitions, albeit such prohibitions could themselves give rise to problematic consequences.

## **10.2 The justification of risk management measures for the sake of biosecurity**

Both biosafety regulations and biosecurity regulations serve first and foremost to reduce risks. As already mentioned, the many biosafety regulations already in place are associated with risk assessments according to generally accepted rules, and risks can be compared on the basis of other risks that are already known and regulated. Thus risk assessment, in combination with the principle of pragmatic coherence (cf. Section 4.2.2), represents a highly plausible *modus operandi*, and can be used as an instrument for the normative justification of research activities.

In contrast, considerable doubt must be entertained as to the capacity of regulations in matters of biosecurity to exercise the same persuasive potential. As a precondition for applying the precautionary principle, the question must be resolved as to what conceivable degree of damage can justify making

restrictions or prohibitions binding, where the likelihood of damage occurring cannot be estimated. There are, at present, no concrete, generally accepted ethical and legal criteria that can be used to underpin such a clarification (except where the circumstances are extreme). In addition to this, the fact that the precautionary principle exists in both a weak form and a strong form is indicative of the possibility that measures for managing risk may be subject to fundamentally diverging opinions as to whether they are justifiable.

Even though the probability of a terrorist attack taking place is practically non-quantifiable in the context of biosecurity, its assessment can be approached by determining factors such as the terrorists' capacity to obtain knowledge, data and materials, to access laboratories (which cannot be completely excluded), to obtain practical training in laboratories and to avail themselves of laboratory infrastructures. According to the weak version of the precautionary principle, precautionary measures can then be geared to these factors, leading for instance to the restriction of certain research projects to specific high-security laboratories, special scrutiny of and checks on those working there, checks on and possible prohibition of material transfer, control and monitoring of research work and the control and possible prohibition of publication. One risk minimization measure that is oriented to the strong variant of the precautionary principle is that of desisting from or prohibiting extremely risky research.

Opinions diverge regarding the two versions of the precautionary principle, especially how commensurable such measures are with regard to freedom to conduct research. One objection against restrictive measures based on the precautionary principle raises ethical concerns based on the scientist's commitment to the pursuit of truth and the accretion of knowledge. In view of this, restrictions on scientific freedom can only then be justified where they serve to protect important legal interests against significant and sufficiently real dangers. According to this approach, and even though the misuse

of certain DURC results can produce catastrophic results, any biosecurity regulation would be based only on low probability events with uncertain risk potentials. In this case, biosecurity regulation would be aimed at the prevention not of concrete, but rather abstract dangers that do not justify such far-reaching interventions into scientific freedom, or only do so to a very limited extent.

Whilst accepting the premise that restriction of the freedom to do research may only be justified with regard to the preservation of constitutionally protected goods, the opposite view maintains that this is precisely the case here: Biosecurity regulation addresses the real, and therefore sufficiently concrete threat of bioterrorist attacks that put such constitutionally protected goods (life and health of a multitude of humans and animals; the environment; peace) at risk.

One argument that may be levelled against the strong version of the precautionary principle in particular is that abstaining from research or restricting it may itself increase certain risks. This course of action may result in deficits in knowledge and technologies that curtail the development of suitable provisions to guard against risks such as techniques for identifying biosecurity emergencies quickly or that unnecessarily restrict the range of effective decontamination and therapeutic options. The other side holds that such disadvantageous restriction would only occur where it can be certain that the research projects in question would indeed increase the range of response options. Especially in the field of basic research, such an outcome can hardly be predicted or planned for.

In sum, no arguments are available that disqualify the precautionary principle — at least in its weak form — as a normative yardstick for maintaining biosecurity. On the contrary, and in association with the duty of the state to protect its citizens, good grounds can be found that justify a wide range of precautionary and defensive biosecurity measures based on the precautionary principle, up to and including restriction or prohibition of research. Equally, however, the heterogeneity of

research scenarios and the divergency of opinions regarding the potential danger and the justification of precautionary and defensive biosecurity measures means that any such measures must be determined on the basis of transparent and rational criteria. Also, the decision-making process must be underpinned by an institutional framework.

## 10.3 Ensuring the transparency of assessment processes

A transparent and effective assessment process for questions of biosecurity requires that the following preconditions be met: Stakeholders must be identified and involved in the process, the interests to be weighed and the relevant assessment criteria must be determined, justifiable risk provisioning measures must be laid down, and suitable instruments must be developed for their implementation.

### 10.3.1 Stakeholders

The whole field of biosafety and biosecurity together is characterized by the involvement of a range of different stakeholders with various but interconnected areas of responsibility.

The *individual scientist* plays a central role here. He or she bears responsibility for the research being conducted, and as an expression of epistemic rationality this responsibility extends not only to the scientific community and upholding good scientific practice, but also covers the issues of ensuring safety and minimizing risks. Therefore the scientist's responsibility is linked to society as a whole.

The *scientific community* as a whole can be regarded as another stakeholder. This community is represented by a wide variety of organizations, and where these are affected by issues of biosecurity, they have the task of codifying the scientists'

responsibility towards society in the form of professional standards such as codes of conduct, and of ensuring their observance.

Research funding bodies represent a third group whose position is on the interface between science and society. Public funding bodies, especially, have the joint tasks of promoting research in the interests of society and the sciences on the one hand, and, on the other hand, containing dangers and risks that arise through research activities and withholding funding from certain types of research as required.

Finally, *society* itself is a stakeholder, for instance in that it is dependent on research to achieve and maintain certain standards of living and to provide for future generations. At the same time, it is also a societal task to ensure that the state fulfils its duty to protect individuals and populations from harm that may result from biosecurity-relevant research.

### 10.3.2 Balancing of interests and criteria

Modern science is subject to both internal obligations and controls as well as those imposed externally by society at large, and these may diverge in their aims and expressions. This can be especially true of risk assessment in respect of research projects. From a researcher's point of view, certain security measures based on scientific criteria may appear sufficient to ensure 'safe' research (in laboratories, for instance), whereas society as a whole may see a need to impose considerably more far-reaching requirements with regard to the containment and controllability of risks associated with research and their possible consequences. It is not appropriate simply to brush off such differences by claiming that lay persons' lack of knowledge renders them less able to form competent judgements. This argument is in any case irrelevant where it is not possible to carry out risk assessment according to tried and tested procedures, as is the case in many biosecurity-related areas. On

the contrary, in such cases risk assessment must be extended to the process of discourse in which all the stakeholders can voice their various claims, interests and opinions.

In the main, this involves freedom to conduct research on the one hand and the protection of life and physical integrity, the environment and other important legal interests on the other. The former may be impaired by restricting its range of action; the latter imperilled by risk-laden research. Hazards may arise either on account of the goal of a research project (e.g. the production of modified biological agents), or through the way it is carried out, so that both aspects must be subjected to appraisal regarding their individual potential for misuse. Other factors to be included in any assessment are the likelihood that new knowledge will be gained and whether other benefits may result, e.g. for human life and health.

In some types of biosecurity-relevant research, the hazard potential is especially great. Such 'Dual Use Research of Concern' (DURC) involves work that can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to threaten public health and safety, the environment or other important legal interests.<sup>361</sup> To date, only very few research projects fall into this category. According to a current NIH survey, ten research projects in the USA are considered to constitute DURC. It may therefore be assumed that less than ten such projects are being conducted in Germany at present.<sup>362</sup> Where DURC is involved, the state is under obligation to undertake special risk mitigation measures. This includes determination of the scope of research that must be subject to regulation, particularly with regard to the biological agents that, according to current knowledge,

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<sup>361</sup> Cf. National Science Advisory Board for Biosecurity 2007, 17.

<sup>362</sup> Estimate extrapolated from the result of the examination process carried out in the USA by the National Institutes of Health on the basis of the DURC Policy of 2012. As the USA invests greater amounts in research than any other country, it may be assumed that fewer DURC projects are carried out in Germany. Cf. Gotttron/Shea 2013, 14; Battelle Memorial Institute 2012.

represent an especially high risk for humans and the environment. The process of determination must also identify those types of research that can increase the potential of such biological agents to cause harm. On this basis, decisions affecting DURC can be justified using the precautionary principle.

However, the process of reaching decisions remains a matter of controversy. There is agreement that this process needs to be sufficiently well anchored in legislation. There is also a consensus that special attention must be paid to DURC projects whose aim is to strengthen the virulence of a micro-organism with respect to its pathogenic effects on humans or animals to the extent that its dissemination outside the laboratory has the potential to cause a serious epidemic amongst humans. However, opinions differ as to how legislation should be formulated so that for this kind of DURC project with its particularly high potential for causing harm, the presumption of inadmissibility can be justified.

Those who are in favour of regulating the presumption of inadmissibility for certain projects assume that democratic principles, the rule of law and the state's obligation to protect the life and health of the population will be better served by going beyond case-by-case considerations and devising an abstract and general legal provision that prohibits such research because of its special risks. Exceptions to such prohibition must then only be made on the basis of a probable, distinctive, concrete and preponderant benefit concerning the aversion of danger for life and human health.

Those who are not in favour of such a form of regulation consider a case-by-case, criterion-based appraisal for all DURC projects to be the better mode of decision-making rather than a statutory reversal of the burden of proof as described above. This view is grounded in an appreciation of scientific freedom and the potential benefit of science for society. Notwithstanding other legal requirements, approval for a research project should then only be withheld where the risks remain indefensible compared to the chances associated with the research

aims. A risk is to be deemed indefensible particularly in cases where it represents a disproportionately large threat to public health or the environment. Considering the small number of DURC projects altogether and the fact that the objects of such research (biological agents) have a per se capacity to be used as weapons of mass destruction, proponents of this view see little merit in a further differentiation of legal provisions so as to highlight certain individual agents or types of DURC.

### 10.3.3 Averting danger and risk mitigation

There are a number of possible ways of effecting the responsibilities of the stakeholders already mentioned (i.e. the scientists, the scientific organizations, the funding bodies, but also society as a whole and state authorities) on the basis of the precautionary principle and the legislators' obligation to protect the public with the aim of lessening the dangers associated with the misuse of research.

*Raising scientists' awareness:* An important precondition for averting biosecurity-related dangers consists in raising levels of awareness amongst scientists and laboratory staff concerning the hazards and risks involved, and their associated responsibilities towards the scientific community and society. In current life science research, scientists' responsibilities in the general area of biosecurity focus mainly on the DURC issue.

*The scientific community's self-commitment:* The counterpart to raising awareness in individual scientists for averting biosecurity-related dangers and providing risk mitigation measures can be found in the collective responsibility of the scientific community that is especially visible regarding its various instruments of self-commitment. Such self-commitment must be anchored in highly binding agreements within the scientific community.

*Making interdisciplinary expertise available:* Assessing the risks involved in DURC is complex, and therefore those who



have to carry out such assessment and then make decisions need to be able to avail themselves of interdisciplinary expertise so that they can take account of context-dependent factors<sup>363</sup> (Cf. Section 3.1).

*Conditions on which research funding is contingent:* Research funding itself can be an instrument of internal and external risk mitigation, in that it is made contingent on the fulfilment of certain conditions or withheld altogether. Life science research projects are generally dependent on funding by public or private bodies. It is to be assumed that biosecurity-specific risk management will be in their own interests. In principle, withholding funds for certain research projects does not constitute a restriction of freedom to conduct research and therefore need not be weighed against the principle of scientific freedom. However, the principle of equality of treatment needs to be upheld.

*Measures with a legal foundation:* In consideration of the possible consequences of DURC for society, its admissibility can be made contingent on an obligation to register research projects or on obtaining official approval (possibly with varying formulation of the burden of proof) or on the fulfilment of specified requirements; additionally, restrictions may be placed on its scope. Where such measures are taken into consideration, thought should also be given to the possibility that increased bureaucratic overheads may hinder legitimate research.

*Documentation:* It goes without saying that wherever biosecurity-relevant research is carried out, all stages of its implementation and the results that are produced must be available

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<sup>363</sup> These factors include:

- those that have to do with the likelihood of misuse being perpetrated (availability of the agent, level of development of the technology, availability of the technology, availability of expertise, features of the establishment, availability of therapeutic options);
- the quantitative and qualitative degree of potential harm;
- the social and political context of the research;
- the role that international aspects may play.

for scrutiny by authorized third parties. Therefore requirements relating to documentation of such research must take special account of the need for accountability and openness for review by third parties.

*Monitoring the research:* Monitoring of research projects and their results by external experts can help to maintain an up-to-date overview of the hazard potential and risks involved, with the option to put appropriate measures in place.

*Placing restrictions on the scope of research projects:* Restriction of research by law or on the basis of legal provisions represents a weighty means of reducing risks, whether the restriction involves only specific measures to contain the risks or prohibition of an entire project. Therefore prohibition must be well grounded, because scientists' freedom to conduct research may only be restricted to a reasonable extent.

*Placing restrictions on the publication of research findings:* Especially where DURC is concerned, there are grounds for assuming that restrictions on the publication of certain research results as well as abstaining from publication either voluntarily or as the result of a ban may help to avert danger. Should such a restriction take place on the basis of a prohibition, special grounds would have to be supplied, based on an appropriate risk analysis.

*Funding of research on biosecurity:* In order to ensure that new developments in the life sciences are treated in a responsible manner, systematic research must be carried out in the field of biosecurity itself. Consequently, funding for biosecurity-related risk research and associated topics should be increased.

#### **10.3.4 Risk management instruments**

The measures described in Section 10.3.3 for averting biosecurity-related hazards can be implemented by means of the following instruments. These instruments can be used cumulatively and in parallel.

*Curricula in initial and advanced training courses and continuing education:* The increasing significance of biosecurity means that levels of awareness amongst life scientists need to be raised during their university training, and amongst laboratory staff during their vocational training. As an initial step, these groups should be acquainted more thoroughly and consistently with biosecurity problems than has been the case hitherto. This entails appropriate modification of the curricula to include biosecurity topics. In addition to this, scientists and laboratory staff working on biosecurity-relevant research could be required to attend regular courses on suitable topics, and encouraged to take advantage of appropriate opportunities to extend their personal training. These measures could help to make all those engaged in the life sciences more aware of specifically biosecurity-related issues as well as biosafety issues.

*Code of conduct in research:* The scientific community can be bound to self-commitment in maintaining biosecurity by means of an internal code of conduct that applies to scientists and laboratory staff working in the relevant disciplines. It should be adopted by all applicable public and private research establishments in Germany and revised as required. Such a code of conduct should contain specific mention of the scientific ethos and the scientist's responsibility towards society with reference to matters of biosecurity. The code should also define what are to be considered as appropriate research goals and methods, as well as the safety and security standards that must be upheld in connection with biosecurity. Even if such a code of conduct in research does not have the status of a statutory instrument, in practical terms it can be very effective. Its principles and guidelines set visible standards that demarcate responsible research, and they have considerable normative and binding effects. Thus failure to abide by such a code of conduct can be construed to be ethically indefensible or irresponsible.<sup>364</sup> However, to have such a binding effect, certain

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<sup>364</sup> See in this connection Vöneky 2012.

aspects must be taken into consideration when the material standards of a code of conduct are elaborated and laid down. In addition to its moral potency, a code of conduct can become indirectly legally binding by its being connected to contracts subject to employment law.

An argument could be raised against such a code of conduct as follows: In a sociological context, it is far more common in modern societies to replace, *de facto*, moral accusations (e.g. “Your behaviour is reprehensible!”) by references to current law (e.g. “Your behaviour is illegal!”).<sup>365</sup> Such recourse to current law can be seen as being conducive to a greater degree of liberty and to have a pacifying effect.<sup>366</sup> The latter could become less effective if a tendency develops towards an ‘ethicization’ of the law that is applicable to science, and as a result the need arises to adapt research projects so that they comply with guidelines that lack legal status, and in that sense to subject them to ‘ethical’ evaluation. Counter to this, it may be argued that opening up the legal framework for non-legal standards of responsibility — or supplementing it through them — does not run contrary to the spirit of the German legal system, designed as it is to provide a framework of justice in the widest sense, as long as such ethical standards and their function as normative instruments can be validated from the procedural point of view with regard to their content. However, the objection does highlight that such a standard of responsibility for biosecurity must take account of constitutional principles such as, in particular, fundamental rights and human rights, of how they may be weighed against each other, but also of the need to achieve exactness in regulation. These fundamental rights and human rights include not only scientific freedom, but also the protection of an individual’s life and physical integrity. If a code of conduct for biosecurity-related research requires research to be conducted responsibly, it must also lay down in

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<sup>365</sup> Cf. Van den Daele/Müller-Salomon 1990, 43.

<sup>366</sup> Cf. Luhmann 1978, 8 ff.; cf. also Luhmann 1993, 124 ff.

sufficient clarity what constitutes responsible research, or what the fundamental ethical principles of responsible conduct may be for a researcher.

In order to ensure uniformity in standards of responsibility from a normative point of view, a code of conduct for biosecurity-related research must apply uniformly throughout Germany. As biosecurity is also a transnational issue, efforts should be undertaken to achieve international consensus on responsible dealings with biosecurity-related research.

*Approval authority:* One option for supervising and controlling biosecurity-relevant research consists in conferring decision-making authority to a federal agency that would then be competent to issue approval for DURC projects following consultation with a committee of scientific experts. Conferring this task to a federal agency would provide for the possibility of having decisions appraised by a competent court. Another possibility would be to confer the function of an approval authority to the DURC Commission (see below).

In accordance with the measures considered to be necessary, the approval authority could issue approval contingent on various requirements that allow intervention in research to be tailored as required. Such requirements could be, for instance, special forms of documentation, external monitoring, restriction or prohibition of publication of research findings, or even restriction of the research itself. As a last resort, approval could be withheld if a research project is deemed to have an indefensibly high hazard potential. A framework in which intervention can be tiered in this way has the advantage that the rights of researchers to conduct their work freely and the right of society to enjoy protection can be balanced in the most appropriate way.

*Consultative body:* Instead of an approval authority, a body with a merely consultative function could be considered. The respective body would then be called in to form an appraisal prior to DURC being initiated in either the public or the private sectors. This approach would be comparable with the

situation in medical research on humans where, beyond statutory regulations, doctors have the obligation based on their professional responsibility to obtain the advice of an ethics commission recognized in public law before commencing research on humans. The consultative tasks could be assumed by the commission of scientific experts (DURC Commission) described below.

*Commission of scientific experts:* The interdisciplinary expertise that the appraisal of DURC requires could be focussed by the establishment of a DURC Commission for Germany that would be tasked with assessing DURC projects concerning their acceptability in terms of their potential benefits and the possible risk of their being misused. It is manifest that, in order to be able to carry out this task, the DURC Commission should include life science and (bio)security experts as well as biosecurity expertise from civil society. In keeping with the precepts derived from the democratic and legal principles of Basic Law, the work of such a Commission must be underpinned by a legal framework that clarifies the scope of what constitutes relevant research, the number of members and how they are to be selected, the need for it to have multidisciplinary character, its modus operandi and the kind of findings that it is to deliver.

In addition to the appraisal of DURC projects and, as appropriate, supplying responsible approval authorities with an opinion, the DURC Commission could undertake a number of other tasks for which its expertise would be relevant. These could include consultative support for researchers in the planning phases of DURC projects or during their execution, e.g. with respect to specific results or consequences, the provision of advice to the sciences, politics and the general public on DURC-related developments, the investigation of DURC-related incidents and developments (reported, for instance, by whistleblowers), regular reporting on current biosecurity-relevant developments in the life sciences, cooperation and exchange of information with comparable institutions in other

countries and at an international level, and evaluation of the quality of its own work.

Finally, as a further step consideration should be given to the establishment of a similar DURC Commission at EU level with a view to covering aspects of transboundary research cooperation in the life sciences and ensuring a degree of consistency in internationally applicable evaluation standards.

*DURC officer:* For individual researchers, the task of keeping up to date with scientific findings and developments in society connected with the rapidly evolving area of biosecurity represents a major challenge. It may not be possible for them to do this in such depth that they remain as well informed as their own projects require. To meet this need, a DURC officer could be appointed in each establishment where biosecurity-relevant research is carried out. The DURC officer would provide advice in the planning stages and implementation of research projects, and either monitor the documentation or carry out the documentation that is required. The DURC officer's job profile could be modelled on those of the biological safety officers whose appointment is laid down in the Genetic Engineering Act.

## 11 SUMMARY AND RECOMMENDATIONS

Research results obtained in the life sciences can be used not only for the benefit of individuals and society as a whole, but also misused with intent to cause harm. In 2012, two studies in which the transferability of avian influenza viruses between mammals was artificially increased through experiment caused worldwide concern regarding the possibility of misusing research findings. They proved to be the initiator of an ongoing international debate about how to deal with life sciences research that is open to misuse.

In English usage, a distinction is made between protecting against hazards that arise unintentionally and measures to prevent misuse. In the former case, the term used is *biosafety*; in the second case it is *biosecurity*. Another term, *Dual Use Research of Concern*, abbreviated to DURC, has established itself in international usage to refer to research work which, if misused, may endanger public health or national security. Such biosecurity-relevant research includes work that can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to cause damage to public health and safety, the environment or to other important legal interests. The subject matter of the research, also referred to as *biological agents*, consist of micro-organisms, toxins and other biological substances that can cause damage to essential physiological functions.

In the sense intended here, biological agents have the potential, at least in principle, to be used as weapons of mass destruction, and in some cases they could spread throughout the world by means of infection, even if they are only released locally. However, it is often difficult to assess the degree of risk involved, as this is dependent not only on the specific characteristics of the biological agents themselves, but on many other context-dependent factors. For instance, the question as to whether a biological agent can be put to use as a biological



weapon may depend on how easy it is to handle, how readily it can be disseminated, what degree of expertise is required to effect this and how likely it is that terrorists will be able to dispose of such expertise. On a quite different level, the threat of terrorism generally is highly dependent on national and international structures and developments. One aspect is, however, clear: Irrespective of all laboratory security standards, it is not possible to exclude misuse categorically.

In view of these fundamentally incalculable aspects, ethical analysis reveals that a risk-containing strategy that may be applied to questions of biosafety, i.e. one that is based on the characteristics of a biological agent, the assumption of its unintentional release and the type of measures adopted to prevent this, and then defines the risk as a function of the agent's damage potential combined with the likelihood of its being released, will not suffice when applied to DURC. Within the scope of DURC, the complexity is compounded by the dilemma that in biosecurity-related contexts, both research and abstaining from research can have disadvantageous consequences for mankind. In addition to this, not only are the current and future risks involved in such research often difficult to assess, but the fundamentally open-ended nature of research dictates that the same applies to possible benefits. This is especially true where the straightforward aim of increasing our fund of knowledge is interwoven with the goals of protecting life or improving the health of the population.

In view of this, ethical analysis leads to the conclusion that scientific responsibility in the area of biosecurity is mainly to be governed by the precautionary principle. This is to find expression in the development of a risk containment strategy that includes all relevant interest groups and which aims, in each case, for an appropriate and balanced consideration of the relevant context-dependent factors.

An appraisal of the current legal situation reveals that dual use research in the life sciences is covered by a large number of different legal stipulations, but that these are mainly expressed

in terms of biosafety standards. On the other hand, there is no coherent regulatory system in the life sciences that aims directly at minimizing and preventing misuse of research and the results of research. This is true of national legislation, European legislation and international law.

Therefore the question arises as to whether existing gaps in legal and other regulatory systems concerning DURC could be closed by establishing a national biosecurity code of conduct for responsible research that, firstly, sensitize researchers and other persons involved in biosecurity-relevant fields to possible misuse, and in practical terms exercise a desirable influence on their behaviour. In Germany, for example, codes of conduct that are relevant to this area have been drawn up by the German Research Foundation, the Max Planck Society and the Leibniz Association.

However, in order to ensure that a national biosecurity code of conduct for responsible research may have a more beneficial effect in encouraging those involved to take on personal responsibility, there is a need for one that covers all persons and institutions participating in relevant research in Germany (instead of only some), that more clearly formulates the material stipulations for responsible action and, thirdly, whose institutional adoption and implementation is guaranteed. In this connection, it should be borne in mind that the process of elaborating such a code, with the involvement of all concerned, can in itself have a beneficial effect. In addition, a sustainable heightening of awareness concerning biosecurity issues is generally considered to be contingent upon such content being integrated more thoroughly in the basic, further and ancillary training of all persons involved in the life sciences.

Nevertheless, on consideration of past experience both in Germany as well as in various other states that were appraised, measures designed to heighten awareness and codes of conduct are not in themselves sufficient. This is also confirmed by most biosecurity experts. In order to provide a suitable strategy

for dealing with biosecurity risks that is properly grounded in the precautionary principle, the German Ethics Council considers it to be necessary to complement measures designed to promote people's own sense of responsibility by legislative ones. Such measures should allow for the implementation of a transparent process for the assessment of research projects lying within the scope of DURC.

In the recommendations that follow, the first aim of the German Ethics Council is to motivate researchers to become aware of and engage in debate on biosecurity issues. The Ethics Council considers that the researchers must themselves be capable of estimating the potential for risks and misuse to which their specific area of research is subject. For this reason, the recommendations begin with the individual researchers and the scientific community. In addition, recommendations are formulated for research funding bodies, for legislators and for international initiatives.

The German Ethics Council recommends:

### **1. Raising the level of awareness for questions of biosecurity in the scientific community**

In view of the potential for misuse of dual use research in the life sciences, there is a need to increase the degree of awareness amongst members of the scientific community for these issues and to promote an underlying culture of responsibility.

- a) To this end, we recommend including questions of biosecurity in undergraduate and graduate curricula, as well as those of training programmes for ancillary staff in the relevant branches of science. The *Kultusministerkonferenz* (Standing Conference of the Ministers of Education and Cultural Affairs of the Länder in the Federal Republic of Germany) and the *Konferenz Biologischer Fachbereiche* (Conference for Biological Faculties), the responsible central accreditation agency and the authorities responsible for vocational training curricula should adopt measures to give questions of biosecurity more prominence in curricula.

- b) The responsible state authorities should provide funding for the development of suitable biosecurity-related learning material for training and further training schemes. This material should include references to the available biosecurity-related international training and educational schemes for life scientists and laboratory personnel.
- c) Persons involved in dual use research in the life sciences should engage in regular further training in this area. The institutions concerned should provide such training and ensure that staff members avail themselves of it.
- d) Public discourse between the scientific community and the general public should take place with a view to ensuring that questions of biosecurity are aired to an appropriate degree.

## **2. Elaboration of a national biosecurity code of conduct for responsible research that defines what constitutes a responsible manner of dealing with biosecurity questions.**

Institutes of higher education, research institutes and specialist scientific associations should establish a national biosecurity code of conduct for responsible research for Germany by means of a common, open and transparent process. As an aid to this process, the organizations concerned should also be able to avail themselves of the expertise that can be provided by the Robert Koch Institute and government security agencies.

The code should supply benchmarks for responsible dealings with biosecurity-related questions that cover areas beyond the scope of legal and otherwise binding obligations.

The code should be expressly adopted by all relevant public and private research facilities throughout Germany, and it should be elaborated in more detail as the need arises.

In order to achieve a sound balance between freedom to research (and the concomitant freedom to publish) on the one hand, and the need to protect high-value goods, especially life and the health of people and the environment, on the other hand, the code should contain the following normative

principles and benchmarks that form a framework for all activities associated with DURC:

- a) By means of suitable educational processes, persons involved in biosecurity-relevant research should acquire the competence to identify any dual-use potential that their research may carry within it, as well as to assess the accompanying risks and danger of misuse. Institutes of higher education and other research facilities should provide appropriate courses to allow for the acquisition of such expertise.
- b) Researchers should examine their research programmes to assess whether they are biosecurity-relevant. In particular, they should establish whether such research programmes fall within the scope of DURC and whether the special requirements that apply to this area (see Recommendations 4.2 and 4.3) need to be fulfilled. The results of these examinations are to be documented.
- c) Researchers should also assess research programmes to establish whether they may entail risks that are comparable to those specifically applying to DURC, even though they may not have been identified as such to date. Here, too, the DURC Commission should be informed.
- d) In planning and executing biosecurity-relevant research, the following measures should be adopted with a view to minimizing the risks:
  - (i) As a first step, the aims and risks of the planned research should be identified.
  - (ii) Research programmes should be examined in order to establish whether the research targets that are to be achieved could also be achieved by other means that carry less risk.
  - (iii) Research programmes should be examined in order to establish the extent to which, in the event of problems arising, means of dealing with such problems exist or are themselves the subject of concomitant research.
  - (iv) Research programmes should be examined in order to establish whether the benefits are sufficient to justify

taking the risks involved. Here, it is of particular importance to examine whether the research programme involved carries an unreasonably high risk for protected goods such as life and the health of people and the environment. Should such an examination reveal that the risk is not justifiable, then the research programme should not be pursued.

Some members of the Ethics Council are, in addition, of the opinion that the potential damage can be presumed to outweigh the potential benefits in the case of research programmes in which the virulence of a micro-organism in respect of its pathogenic effects for humans or animals would be strengthened to such an extent, or such strengthening is to be anticipated, that its dissemination outside the laboratory is likely to produce a serious epidemic amongst humans. Such programmes should not be carried out unless a direct, concrete and preponderant benefit in terms of diminishing hazards for human life and health is probable.

- (v) During the course of the programme, a concomitant biosecurity monitoring programme should be carried out with a view to providing for regular risk assessment and risk minimization.
- e) The results of biosecurity-relevant research are, in principle, to be published. However, researchers should consider whether the research results may open up avenues of misuse to such an extent that passing them on or publishing them should, exceptionally, be restricted or not done at all. This also applies to entering into and carrying out research cooperation programmes. Further, researchers acting in the capacity of reviewers or editors as part of the scientific process should also observe the principles listed above.
- f) Researchers should also investigate whether the special requirements applying to DURC (see Recommendations 4.2 and 4.3) need to be fulfilled before publishing their research findings.

### 3. Research funding

- a) Public or private funding bodies in Germany that operate in the field of life sciences should ensure that DURC projects only receive funding if the scientist entrusted with project management has agreed to comply with the German biosecurity code of conduct for responsible research.
- b) DURC projects should not be funded if the DURC Commission has passed a negative vote (see Recommendation 4.3). Requirements as laid down by the DURC Commission should be included in the funding notice.
- c) In the context of risk containment, society in general has a legitimate interest in establishing a fund of knowledge concerning responsible handling of new developments in the life sciences. Therefore the public funding bodies should increasingly support relevant risk research and ancillary research on biosecurity-related questions.

### 4. Recommendations for legislation

Legally binding regulations on DURC should include:

- » the legal definition of DURC (Recommendation 4.1);
- » the obligation to consult the DURC Commission prior to commencement of DURC (Recommendation 4.2);
- » the appointment of a DURC Commission (Recommendation 4.3);
- » the establishment of a procedure for evaluating the DURC consultation procedure (Recommendation 4.4);
- » the extension of the remit of biosafety officers to include the field of DURC.

Various members of the German Ethics Council recommend supplementing the DURC consultation procedure with an approval procedure to be conducted by a Federal authority such as the Robert Koch Institute. This could be modelled on the approval procedure laid down in the *Gentechnikgesetz* (Genetic Engineering Act), with the inclusion of the *Zentrale Kommission für die Biologische Sicherheit* (Central Committee on Biological Safety).

#### **4.1. Legal definition of the field of Dual Use Research of Concern (DURC)**

The legal definition of dual use research of concern should encompass work in the field of the life sciences that can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to cause damage to public health and safety or essential natural resources. Detailed regulations should be laid down in the form of a statutory ordinance. Such an ordinance should, in particular, cover the groups of research programmes listed below. It should also stipulate that the DURC Commission is to draw up a list of particularly dangerous biological agents that are involved in such research programmes. The list is to be kept up to date in accordance with the currently available scope of knowledge.<sup>367</sup> This includes:

- » work intended to enhance the harmful consequences of listed agents;
- » work intended to enhance the susceptibility of a host population to listed agents;
- » work intended to induce or increase the resistance of listed agents against therapeutic or prophylactic antimicrobial or antiviral substances;
- » work intended to increase the transmissibility and infectious potential of listed agents;
- » work intended to alter the host range of listed agents;
- » work intended to increase the stability of listed agents;
- » work intended to render detection of listed agents more difficult;
- » work intended to reduce the effectiveness of medical countermeasures such as vaccinations and therapeutic and prophylactic substances with respect of listed agents;

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<sup>367</sup> The German Ethics Council has not decided on a specific list for the recommendations.



- >> work intended to increase the ability to deliver and disseminate listed agents or to enable their weaponization by any other means;
- >> work intended to generate completely new, especially dangerous biological agents or to reconstitute highly dangerous biological agents that have already been eliminated (through eradication, control or extinction).

#### **4.2. Consultation prior to and in the course of carrying out DURC**

Researchers should be legally obliged to consult the DURC Commission (see Recommendation 4.3) before conducting DURC (see Recommendation 4.1) in either public or private contexts.

Further, the following should be made the subject of legal stipulations:

- a) The researcher's obligation, in cases where potentially biosecurity-relevant research is involved, to examine whether a given research programme lies within the scope of DURC and is therefore contingent on the DURC Commission having been consulted. The results of such an examination are to be documented by the researcher;
- b) The researcher's obligations to provide information to and to document proceedings for submission to the DURC Commission concerning the execution and the results of DURC;
- c) Concomitant monitoring of DURC by the responsible DURC officer.

#### **4.3. Inauguration of a central DURC Commission**

For areas considered to constitute DURC (see Recommendation 4.1), an interdisciplinary commission should be set up on the basis of appropriate legislation. The commission should include life sciences and security experts as well as biosecurity expertise from civil society. The legislation concerned should provide the framework for determining the number of commission members, who they should be and how they should

be selected, and the nature of resolutions to be passed by the commission. The commission should be affiliated to an institution that already exists, such as the Robert Koch Institute, and work in close cooperation with the Central Committee on Biological Safety.

Remit of the DURC Commission:

a) Assessment of DURC-relevant programmes (consultation procedure)

The DURC Commission provides consultation regarding research programmes submitted to it and passes a vote.

(i) Issuing of recommendations concerning the execution of DURC: The consultation is to pursue in particular the question as to whether the benefits are sufficient to justify taking any risks involved. Here, it is of particular importance to examine whether the research programme involved carries an unreasonably high risk for protected goods such as life and the health of people and the environment. Should such an examination reveal that the risk is not justifiable, then a negative vote should be passed.

Some members of the Ethics Council are, in addition, of the opinion that a negative vote should be passed for all research programmes in which the virulence of a micro-organism in respect of its pathogenic effects for humans or animals is to be strengthened to such an extent, or such strengthening is to be anticipated, that its dissemination outside the laboratory is likely to produce a serious epidemic amongst humans. The only exceptions to this are cases in which a direct, concrete and preponderant benefit in terms of diminishing hazards for human life and health is probable.

(ii) Issuing of recommendations on measures for reducing risks, and thereby also on the question as to whether alternatives exist through which the research targets can be reached with less risk;

- (iii) Issuing of recommendations concerning concomitant monitoring of DURC;
- (iv) Issuing of recommendations concerning planned research cooperations involving DURC;
- (v) Provision of advice concerning the transmission or publication of DURC findings.

The commission's work includes, in addition, the following tasks:

- b) Provision of advice to individual researchers;
- c) Subsequent evaluation of completed DURC;
- d) Registration, documentation and as required examination of information concerning events and development giving cause for concern within the scope of DURC ('whistleblower' events);
- e) Drafting of regular reports on current biosecurity-related developments in the life sciences for the purpose of informing the scientific and political communities and the general public;
- f) Annual reports on the DURC Commission's own work, giving particular emphasis to the consultation procedure;
- g) Cooperation and exchange of information with comparable institutions from other countries and on an international level.

#### **4.4. Evaluation of the DURC consultation procedure**

On the basis of the DURC Commission's annual reports and an additional evaluation commissioned by the Federal Government, the Federal Government will present a report to the Bundestag every four years. The main content of this report should be an opinion as to whether the procedures governing DURC to date have performed effectively. The report should also cover the question as to whether further regulation in the form of an approval process is required.

## 5. International initiatives

- a) In view of the risk of misuse of knowledge and results gained from biological research, scientists and scientific organizations should embark on an international process of reflection on the possible benefits and the risks of DURC. The aim of such reflection should be to reach scientific consensus on what constitutes responsible research in this area. This includes efforts to develop biosecurity codes of conduct for responsible research at EU level and at a global level.
- b) The Federal Republic of Germany should advocate a worldwide, uniform and as far as possible binding definition and classification of DURC under international law. This includes setting up unified laboratory safety classifications for biosecurity-relevant research.
- c) The Federal Government should advocate the conclusion of an agreement under international law, taking into account the interests of threshold and developing countries, that defines the fundamental principles and limitations of responsible dual-use research in the life sciences in harmony with the Universal Declaration of Human Rights. To this end, the elaboration of a corresponding international soft-law declaration on the part of the WHO or UNESCO by way of an initial step should be given express support.
- d) The Federal Republic of Germany should advocate that the European Union only promote DURC within the context of current and future EU Framework Programmes where the preconditions for responsible research as specified above are fulfilled. For the purpose of examining applications, the establishment of a DURC Commission at EU level according to the model proposed here for a German DURC Commission should be considered. In addition to this, the Federal Government should advocate that unified legislation and standards be established for DURC in all member states.

# APPENDIX I. EXAMPLES OF FACTORS INVOLVED IN THE ASSESSMENT OF DURC

## I.1 Examples of DURC-relevant microorganisms and toxins

The following comparison of several lists of microorganisms of risk classes 3 and 4 as well as toxins that are relevant in connection with biological weapons technology has been collated from three sources:

1. List of biological weapons from the German War Weapons Control Act (as of 2013).
2. Rolling Text of a Protocol to the Biological Weapons Convention from 2001.
3. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern von 2013.

These lists of DURC-relevant microorganisms and toxins are not exhaustive.

Other biological agents that are not microorganisms and not toxins (bioregulators, cf. Section 2.4), can be DURC-relevant. To date, however, they have not been included in the lists of agents.

Designation of the microorganisms in the table: (No.) = Risk group; (#) = only animal-pathogenic; all the others are human-pathogenic or human-pathogenic and animal-pathogenic; (\*) = microorganisms and toxins that are not included in the list of U.S. Select Agents.

From the German War Weapons Control Act <sup>368</sup>	From the Biological Weapons Convention Draft Protocol <sup>369</sup>	From the U.S. Oversight Policy <sup>370</sup>
Microorganisms		
Monkeypox virus (3)	Monkeypox virus (3)	
Pseudorabies (3)		
	African horse sickness virus (3, #)	
African swine pest virus (4+, #)	African swine pest virus (4+, #)	
Bacillus anthracis (3)	Bacillus anthracis (3)	Bacillus anthracis (3)
Blue tongue virus (3, #)	Blue tongue virus (3, #)	
Brucella abortus (3)		
Brucella melitensis (3)	Brucella melitensis (3)	
Brucella suis (3)	Brucella suis (3)	
Burkholderia mallei (3)	Burkholderia mallei (3)	Burkholderia mallei (3)
Burkholderia pseudomallei (3)	Burkholderia pseudomallei (3)	Burkholderia pseudomallei (3)
Chikungunya virus (3, *)		
Clostridium botulinum (toxigenic strains)		Clostridium botulinum (toxigenic strains)
Coxiella burnetii (3)	Coxiella burnetii (3)	
Dengue fever virus (3, *)		
Eastern equine encephalitis virus (3)	Eastern equine encephalitis virus (3)	
Ebola virus (4)	Ebola virus (4)	Ebola virus (4)
Francisella tularensis (3)	Francisella tularensis (3)	Francisella tularensis (3)
Yellow fever virus (3, *)	Yellow fever virus (3, *)	
Crimean-Congo hemorrhagic fever virus (4)	Crimean-Congo hemorrhagic fever virus (4)	
Hantavirus (3, *)	Hantavirus (3, *)	
Influenza-A viruses (HPAIV) (3+) Subtype H5 or H7 (4)		Influenza-A viruses (HPAIV) (3+) Subtype H5 or H7 (4)
		Influenza-A virus (reconstructed 1918 strain) (3)
Japan-B encephalitis virus (3, *)		
Junin virus (4)	Junin virus (4)	
Lassa fever virus (4)	Lassa fever virus (4)	
Lyssavirus (rabies virus) (3)		
Machupo virus (4)	Machupo virus (4)	
Marburg virus (4)	Marburg virus (4)	Marburg virus (4)
Foot and mouth disease virus (4, #)	Foot and mouth disease virus (4, #)	Foot and mouth disease virus (4, #)
Newcastle disease virus (3, #)	Newcastle disease virus (3, #)	
Rickettsia prowazekii (3)	Rickettsia prowazekii (3)	
Rickettsia rickettsii (3, *)	Rickettsia rickettsii (3, *)	
Rift Valley fever virus (3, *)	Rift Valley fever virus (3, *)	
Rinderpest virus (4, #)	Rinderpest virus (4, #)	Rinderpest virus (4, #)
Salmonella typhi (3, *)		
Shigella dysenteriae (3, *)		

From the German War Weapons Control Act <sup>368</sup>	From the Biological Weapons Convention Draft Protocol <sup>369</sup>	From the U.S. Oversight Policy <sup>370</sup>
Variola-major virus (smallpox virus) (4)	Variola-major virus (smallpox virus) (4)	Variola-major virus (smallpox virus) (4)
		Variola-minor virus (alastrim) (4)
Venezuelan equine encephalitis virus (3)	Venezuelan equine encephalitis virus (3)	
Vesicular stomatitis virus (3, *)		
Russian spring-summer encephalitis virus (3)	Russian spring-summer encephalitis virus (3)	
Western equine encephalitis virus (3)	Western equine encephalitis virus (3)	
Whitepox virus (4, *)		
Yersinia pestis (3)	Yersinia pestis (3)	Yersinia pestis (3)
Tick-borne encephalitis virus (3, *)		
Toxins		
	Abrin toxins	
	Anatoxins (*)	
Botulinum neurotoxins	Botulinum neurotoxins	Botulinum neurotoxins
	Bungarotoxins (*)	
	Ciguatoxins (*)	
Clostridium perfringens toxins	Clostridium perfringens toxins	
Conotoxin		
Microcystin (cyanoginosin) (*)		
Ricin	Ricin	
Saxitoxin	Saxitoxin	
Shiga toxin	Shiga toxin	
Staphylococcus aureus enterotoxins	Staphylococcus aureus enterotoxins	
Tetrodotoxin		
	Trichothecene toxins	
Verotoxin (*)		

368 *Gesetz über die Kontrolle von Kriegswaffen (Ausführungsgesetz zu Art. 26 Abs. 2 des Grundgesetzes, KrWaffKontrG)* (War Weapons Control Act) in the version published on 22 November 1990 (Federal Law Gazette I p. 2506), last modified through Art. 2 Para. 2 of the Act of 6 June 2013 (Federal Law Gazette I p. 1482).

369 United Nations 2001.

370 U.S. Department of Health and Human Services 2013b.

## I.2 Examples of DURC-relevant experiments

Code of Conduct of the German Research Foundation 2013 <sup>27</sup>	U.S. DURC Policy (2012) <sup>272</sup>	In-house Instruction of the Robert Koch Institute 2014 <sup>273</sup>	German Ethics Council
work intended to enhance the virulence of pathogenic microorganisms or to modify apathogenic microbes so that they become pathogenic.	enhances the harmful consequences of the agent or toxin	to enhance the virulence of microorganisms or toxins	work intended to enhance the pathogenic effects of biological agents
		to modify the absorption properties of a biological agent or its toxicokinetics in a manner that enhances their effects	
	enhances the susceptibility of a host population to the agent or toxin	to render toxins more readily assimilable  to enhance the susceptibility of host organisms	work intended to enhance the susceptibility of host organisms to biological agents
experiments to induce resistance to therapeutically effective antibiotics and antiviral substances	confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies	to enhance or induce the resistance of microorganisms to therapeutic or prophylactic antimicrobial or antiviral substances	work intended to induce or increase the resistance of biological agents against therapeutic or prophylactic antimicrobial or antiviral substances
experiments intended to enhance the transmissibility of pathogens	increases the stability, transmissibility, or the ability to disseminate the agent or toxin	to achieve the transmissibility of microorganisms or to enhance their infectivity	work intended to increase the transmissibility and infectivity of pathogenic microorganisms
experiments intended to modify the host range and the stability of pathogens	increases the stability, transmissibility, or the ability to disseminate the agent or toxin	to enhance the tenacity of microorganisms or toxins	work intended to change the host range of biological agents
	alters the host range or tropism of the agent or toxin	to modify the host tropism of a microorganisms or toxin	work intended to increase the stability of biological agents
work intended to evade diagnostic methods and detection conditions	confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies	to facilitate the evasion of diagnostic methods	work intended to evade diagnostic methods and detection methods
work that demonstrates the ineffectiveness of vaccines	disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification	to decrease immunity against microorganisms	work intended to demonstrate ways of reducing the effectiveness of medical countermeasures such as vaccinations and therapeutic and prophylactic substances



Code of Conduct of the German Research Foundation 2013 <sup>371</sup>	U.S. DURC Policy (2012) <sup>372</sup>	In-house Instruction of the Robert Koch Institute 2014 <sup>373</sup>	German Ethics Council
		to demonstrate ways of reducing the effectiveness of medical countermeasures (vaccinations and therapeutic and prophylactic substances)	
experiments to increase the 'bioweapon' characteristics of biological agents or toxins	increases the stability, transmissibility, or the ability to disseminate the agent or toxin	to enhance the dissemination potential, potential for introduction or 'bioweapon' characteristics of microorganisms or toxins	work intended to increase the potential for dissemination or introduction or enhance any other 'bioweapon' characteristics of biological agents
	generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above	to generate completely new pathogens or recreate reduced (eradicated/eliminated/controlled/extinct) pathogens	work intended to create completely new, especially dangerous biological agents or to recreate biological agents that have already been reduced (eradicated, controlled or extinct)
		Is it to be anticipated that through the publication of (literature) research or theoretical work carried out <i>in silico</i> <ul style="list-style-type: none"> <li>• third parties may be empowered to develop or optimize agents or technologies that can be implemented directly to cause harm to humans, animals or plants</li> <li>• or vulnerabilities may be demonstrated for which no countermeasures are available?</li> </ul>	
		Research that may be anticipated to have similar effects and consequences to those listed here is being carried out.	

371 Deutsche Forschungsgemeinschaft 2013.

372 U.S. Department of Health and Human Services 2012.

373 Robert Koch-Institut 2013b.

A second appendix section containing a detailed portrayal of selected legal aspects has not been translated into English.

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# GLOSSARY

<b>Aerosols</b>	Particles suspended in air
<b>Anthrax (Bacillus anthracis)</b>	Bacterial infectious disease also known as splenic fever
<b>BioBricks</b>	Standardized components of circular DNA produced in synthetic biology
<b>Bioinformatics</b>	The discipline involving biology and information technology that registers, stores, processes, evaluates and presents biological data.
<b>Biological agents</b>	Microorganisms, toxins and other biological substances that can cause harm to vital physiological functions in animals or humans
<b>Biological and Chemical Weapons Conventions</b>	International agreements on the prohibition of the development, manufacture, storage, purchase or retention of certain biological (Biological Weapons Convention) or chemical (Chemical Weapons Convention) agents and toxins as well as weapons intended for their use and means of deployment
<b>Bioreactors</b>	Containers for cultivating certain microorganisms
<b>Bioregulators</b>	Biochemical substances that regulate cellular process in multi-organ systems
<b>Biosafety</b>	The protection of humans, animals, the environment and other goods from unintentionally caused dangers arising from the handling of microorganisms and toxins, for instance through their accidental release from laboratories
<b>Biosecurity</b>	The protection of humans, animals, the environment and other goods against the misuse of biological agents to cause harm, as in acts of terrorism
<b>Bioweapons/biological weapons</b>	The targeted use of especially transmissible or highly pathogenic biological agents and toxins as weapons
<b>Botulinum toxin</b>	Bacterial metabolic product having toxic effects on the human musculature and the autonomic nervous system
<b>Code of conduct in research/code of conduct</b>	Guidelines that are not directly legally binding relating to responsible research
<b>De-skilling process</b>	Process by which the requirements in terms of expertise or practical experience in carrying out certain activities and operations is reduced by the provision of easily implemented technologies

<b>Do-it-yourself biology</b>	A movement in the community of biologists characterized by experiments being carried out outside established research establishments
<b>Dual-use research</b>	Research whose results have a potential for being used for harmful purposes
<b>Dual Use Research of Concern</b>	Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, or to other important legal interests
<b>Epidemic</b>	A temporally and locally massed outbreak of an infectious disease
<b>Gain-of-function experiments</b>	In the context of the debate on H5N1 avian influenza viruses that have been modified by researchers: Experiments in which the pathogenic effects of a microorganism are increased either directly, or by increasing its transmissibility or by adapting it to new host organisms
<b>Genome</b>	Totality of the genetic information in a cell
<b>H5N1, H7N9</b>	Also known as avian influenza viruses, H5N1 and H7N9 belong to the influenza A set of viruses. The designations influenza A/H5N1 and H7N9 refer to the specific variations of the proteins haemagglutinin (HA) and neuraminidase (NA) that contribute to the infectivity of the viruses.
<b>Influenza viruses</b>	Highly infectious RNA viruses that cause a disease of the respiratory passages (influenza) that makes it more easy for other pathogenic or toxic agents to take effect
<b>Mutation</b>	A change in the genetic information at a specific genetic location
<b>Pandemic</b>	Spread of an infectious disease that crosses national or continental boundaries
<b>Pathogenic</b>	Having the capacity to cause disease
<b>Polio virus</b>	An RNA virus belonging to the group of the enteroviruses that has no viral envelope and is transmitted faecal-orally
<b>S1 to S4 laboratories</b>	Refers to technical safety/security standards of laboratories
<b>Soft law</b>	Rules of conduct that cannot be attributed to a formal legal source and are not directly binding, but have been established by a legal entity that could, in principle establish binding law
<b>Tacit knowledge</b>	Knowledge that is gained through experience and is implicitly available
<b>Targeted delivery technologies</b>	Technologies that allow for targeted activation of certain desired effects at certain locations in the body

**Vaccinia virus**

A virus that does not occur naturally, has a very low degree of pathogenicity for humans and is used, amongst other things, for smallpox vaccination

**Whistleblower protection**

The protection of persons from repercussions that may threaten them on account of their having reported misuse or suspicion of misuse

# ABBREVIATIONS

<b>ADN</b>	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterway
<b>ADR</b>	European Agreement concerning the International Carriage of Dangerous Goods by Road
<b>ArbSchG</b>	Arbeitsschutzgesetz (German Occupational Safety Act)
<b>ASR</b>	Articles on State Responsibility
<b>AWG</b>	Außenwirtschaftsgesetz (German Foreign Trade Act)
<b>AWV</b>	Außenwirtschaftsverordnung (Foreign Trade and Payments Ordinance)
<b>BAFA</b>	Bundesamt für Wirtschaft und Ausfuhrkontrolle (Federal Office of Economics and Export Control)
<b>BAnz</b>	Bundesanzeiger (Federal Gazette)
<b>BGB</b>	Bürgerliches Gesetzbuch (German Civil Code )
<b>BGBI.</b>	Bundesgesetzblatt (Federal Law Gazette)
<b>BGHZ</b>	Entscheidungen des Bundesgerichtshofs in Zivilsachen (Decisions of the Federal Court of Justice in Civil Cases)
<b>BioStoffV</b>	Biostoffverordnung (Ordinance on Security and Health Protection in Activities involving Biological Agents)
<b>BMBF</b>	Bundesministerium für Bildung und Forschung (German Federal Ministry of Education and Research)
<b>BMELV</b>	Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (German Federal Ministry for Food and Agriculture)
<b>BMG</b>	Bundesministerium für Gesundheit (German Federal Ministry of Health)
<b>BMI</b>	Bundesministerium des Innern (German Federal Ministry of the Interior)
<b>BMVg</b>	Bundesministerium der Verteidigung (German Federal Ministry of Defence)
<b>BR-Drs.</b>	Bundesratsdrucksache (printed document of the Bundesrat (Federal Council))
<b>BT-Drs.</b>	Bundestagsdrucksache (printed document of the Bundestag (Federal Parliament))
<b>BVerfGE</b>	Entscheidungen des Bundesverfassungsgericht (Decisions of the Federal Constitutional Court)
<b>BVerwGE</b>	Entscheidungen des Bundesverwaltungsgerichts (Decisions of the German Federal Administrative Court)



<b>BWC</b>	Biological Weapons Convention
<b>CFR</b>	Code of Federal Regulations
<b>CIA</b>	Central Intelligence Agency
<b>CWC</b>	Chemical Weapons Convention
<b>DFG</b>	Deutsche Forschungsgemeinschaft (German Research Foundation)
<b>DIY</b>	'do-it-yourself'
<b>DNA</b>	Deoxyribonucleic acid
<b>DURC</b>	Dual Use Research of Concern
<b>DVBl</b>	Deutsches Verwaltungsblatt (German legal gazette for public law)
<b>EGE</b>	European Group on Ethics in Science and New Technologies
<b>EGMR</b>	Europäischer Gerichtshof für Menschenrechte (European Court of Human Rights)
<b>EMRK</b>	Europäische Menschenrechtskonvention (European Convention on Human Rights)
<b>EuGH</b>	Europäischer Gerichtshof (European Court of Justice)
<b>EUGRCh</b>	Europäische Grundrechtcharta (European Charter of Fundamental Rights)
<b>EUV</b>	Vertrag über die Europäische Union (Treaty on European Union)
<b>GenTG</b>	Gentechnikgesetz (Genetic Engineering Act)
<b>GenTSV</b>	Gentechnik-Sicherheitsverordnung (Regulations on Genetic Engineering Safety)
<b>GG</b>	Grundgesetz (German Basic Law)
<b>GGBefG</b>	Gefahrgutbeförderungsgesetz (Transport of Hazardous Substances Act)
<b>GGVSEB</b>	Gefahrgutverordnung Straße, Eisenbahn und Binnenschifffahrt (Ordinance on the domestic and transboundary transport of dangerous goods by road, railway and on inland waterways)
<b>GGVSee</b>	Gefahrgutverordnung See (Ordinance on the transport of dangerous goods with sea-going ships)
<b>GOF</b>	gain of function
<b>GVO</b>	Gentechnisch veränderter Organismus (genetically modified organism (GMO))
<b>HA</b>	haemagglutinin
<b>HPAIV</b>	Highly pathogenic avian influenza virus

<b>IAP</b>	Inter-Academy Panel
<b>IASB</b>	International Association Synthetic Biology
<b>IfSG</b>	Infektionsschutzgesetz (Infectious Diseases Protection Act)
<b>iGEM</b>	International Genetically Engineered Machine
<b>IGH</b>	Internationaler Gerichtshof (International Court of Justice)
<b>IGSC</b>	International Gene Synthesis Consortium
<b>IL</b>	interleukin
<b>IPbpR</b>	Internationaler Pakt über bürgerliche und politische Rechte (International Covenant on Civil and Political Rights)
<b>IPwskR</b>	Internationaler Pakt über wirtschaftliche, soziale und kulturelle Rechte (International Covenant on Economic, Social and Cultural Rights)
<b>ISPS code</b>	International Ship and Port Facility Security Code
<b>KNAW</b>	Koninklijke Nederlandse Akademie van Wetenschappen (Royal Netherlands Academy of Arts and Sciences)
<b>KrWaffKontrG</b>	Kriegswaffenkontrollgesetz (War Weapons Control Act)
<b>MPG</b>	Max-Planck-Gesellschaft (Max Planck Society)
<b>MRC</b>	Medical Research Council
<b>NA</b>	neuraminidase
<b>NIH</b>	National Institutes of Health
<b>NSABB</b>	National Science Advisory Board for Biosecurity
<b>PCR</b>	polymerase chain reaction
<b>PflSchG</b>	Pflanzenschutzgesetz (Plant Protection Act)
<b>RIAA</b>	Reports of International Arbitral Awards
<b>RID</b>	Regulation concerning the Carriage of Dangerous Goods by Rail
<b>RKI</b>	Robert Koch Institute
<b>RNA</b>	ribonucleic acid
<b>RNAi</b>	RNA interference
<b>SOLAS</b>	Convention for the Safety of Life at Sea
<b>SPICE</b>	Smallpox inhibitor of complement enzymes
<b>SÜFV</b>	Sicherheitsüberprüfungsfeststellungsverordnung (Security Clearance Check Identification Ordinance)
<b>SÜG</b>	Sicherheitsüberprüfungsgesetz (Security Screening Act)

<b>TierGesG</b>	Tiergesundheitsgesetz (Animal Health Act)
<b>TierSG</b>	Tierseuchengesetz (Animal Epidemic Act)
<b>UmweltHG</b>	Umwelthaftungsgesetz (Environmental Liability Act)
<b>UN</b>	United Nations
<b>UNTS</b>	United Nations Treaty Series
<b>U.S.C.</b>	United States Code
<b>VCP</b>	Vaccinia virus complement control protein
<b>WHO</b>	World Health Organization
<b>ZKBS</b>	Zentrale Kommission für die Biologische Sicherheit (Central Committee on Biological Safety)



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