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## *Biosecurity – Freedom, Responsibility, and Legitimacy of Research*

### I. Introduction

The subjects of biosecurity and the containment of biological weapons remain highly relevant and important, particularly in times with as many instabilities as today. These instabilities at the national and international level become manifest in terrorist attacks, as in Madrid 2004, London 2005, Boston 2013, Paris 2015, and Copenhagen 2015, the establishment of a terrorist regime, the so-called IS (“Islamic State”), that controls areas in the Middle East, the new confrontation with Russia due to the annexation of the Crimea and the armed conflict in Ukraine.

Science seems to be far apart from any security concerns. Science is, as long as it is aimed toward peaceful purposes, characterized by often fruitful cooperation between different researchers in different parts of the world, searching for knowledge, striving to improve the living conditions by fighting climate change, hunger, major diseases, like Ebola, and pandemics caused by an influenza virus or other agents. Many areas of science in the 21st century try to solve the major, global problems of humankind. It does not seem easy to link peaceful scientific research to the security problems of our times.

But this picture does not seem to be correct. The new, threatening instabilities of the years 2014/2015 are characterized by blurred lines: There are no clear frontiers, no limited “battlefields”, often no combatants that are recognizable, and there is no clear strategy how to restore

or maintain security. It is a new world disorder.<sup>1</sup> And it would be false to assert that terrorists have no link to our western societies and act far away in Sudan, Yemen, Afghanistan etc. from our universities and research institutes. It is striking that some of the main terrorists of the 9/11 attacks, the Boston attacks, and of the IS are or were students in western countries (Germany, U.S., and UK) before or during the time they formed part of a terrorist group.<sup>2</sup> Those terrorists did not use biological weapons or biological agents to threaten the population and the world community. But their strategy has been and still is to cause pure horror and the maximum amount of instability in the centers of western civilization.<sup>3</sup> Especially if one looks at attacks by IS during the last months – the beheading and burning of hostages, the destruction of cultural goods – there do not seem to exist any legal or moral limits.

Biological warfare and bioterrorism have some very specific characteristics that make them different from other kinds of use of weapons: Biological warfare agents are easy to hide, difficult to detect or protect against;<sup>4</sup> they will

“normally have a delayed effect due to an incubation period. The diseases caused can be highly lethal and may be contagious, consequently capable of causing incapacitation or death of thousands. Even their use in a small scale, eg by releasing a very small quantity into a water supply, could cause extensive casualties and de-

1 „Ordnungen sind unter Druck. Unordnung greift um sich.“ Cf. the German Foreign Minister *Frank-Walter Steinmeier*, „Auf der Suche nach Ordnung in der Unordnung: europäisch-asiatische Zusammenarbeit in einer unübersichtlichen Welt“, presentation at the ASEAN-Secretariat General in Jakarta, 3.11.2014, available at: [http://www.auswaertiges-amt.de/DE/Infoservice/Presse/Reden/2014/141103-BM\\_ASEAN.html](http://www.auswaertiges-amt.de/DE/Infoservice/Presse/Reden/2014/141103-BM_ASEAN.html).

2 Mohammed Atta, one of the 9/11 terrorists, the hijacker-pilot of American Airlines Flight 11, studied for many years at the Technischen Universität Hamburg-Harburg/Germany; Tamerlan Tsarnaev, one of the terrorists of the Boston Marathon Bombing, studied at the Bunker Hill Community College/Boston/U.S.; Dzhokhar Tsarnaev, the second Boston Marathon Bombing terrorist, studied at the University of Massachusetts/Dartmouth/U.S. and has been an U.S.-citizen since 2012, cf. <http://www.fbi.gov/news/updates-on-investigation-into-multiple-explosions-in-boston/updates-on-investigation-into-multiple-explosions-in-boston> and A. Ross, Der

Körper der Muslime, *Frankfurter Allgemeine Zeitung*, 4.3.2015, 3. The “Islamic State” militant known as “Jihadi John”, who has been pictured in the videos of the beheadings of Western hostages, is a British national from west London who finished his computing degree at University of Westminster/UK in 2009, cf. BBC news, 26.2.2015 available at: <http://www.bbc.com/news/uk-31637090>.

3 It is no coincidence that the major terrorist attacks of the last decades occurred in New York, Madrid, London, Boston, Paris, and Copenhagen, all of them either capital cities and/or financial and cultural metropolises.

4 D. Svarc, Biological Weapons and Warfare, in R. Wolfrum (ed.), *Max Planck Encyclopedia of Public International Law*, Vol. I, 2012, 945; A. Nouri/*Ch.F.Chyba*, Biotechnology and biosecurity, in N. Boström/M.M. Cirkovic (eds.), *Global Catastrophic Risks*, 2008, 454: “Biological weapons are distinct from other so-called weapons of mass destruction”.

struction. [...] [B]iological weapons can be used for political assassinations, in order to cause social disruption [...], economic damage [...], or environmental problems.<sup>5</sup>

Having this in mind it is not astonishing that especially the biological sciences have been for some years a focal point in regard to security concerns.<sup>6</sup> Even if there have been, so far, very few attacks of biological terrorism by non-state groups, the use of biological and other agents to intentionally kill “enemies” or damage their environment is a long-standing technique.<sup>7</sup> Without being an alarmist: It might be only a question of time until the first major act of bioterrorism takes place.<sup>8</sup>

If terrorists or other criminals use scientific findings, it is a problem of so-called *dual use*. The notion of dual

use means that terrorists or criminals can misuse findings of research to do severe harm or even to build weapons of mass destruction.<sup>9</sup> Dual use is especially worrying in the field of biological sciences as the result could be that a virus or other agent is used that spreads all over the world and causes the death or disease of individuals, animals, or the damage of the environment. Hence it is not astonishing that after special kinds of so-called gain of function (GOF)<sup>10</sup> experiments in the Netherlands and the U.S. were funded and took place,<sup>11</sup> an intense and interdisciplinary discussion started about the limits of the freedom of biological science, the responsibility of researchers and the legitimacy of rules regulating research in the field of biological sciences before the results were published. This debate has not yet ended.<sup>12</sup> On the contrary, it has been intensified,<sup>13</sup> since in this field of sci-

5 D. Svarc, Biological Weapons and Warfare, in R. Wolfrum (ed.), Max Planck Encyclopedia of Public International Law, Vol. I, 2012, 945.

6 Another important and currently hotly debated area is certain research in the field of so-called geoengineering, see for instance the two volume report: Climate Intervention: Reflecting Sunlight to Cool Earth, 2015 by the Committee on Geoengineering Climate, available at: <http://www.nap.edu/catalog/18988/climate-intervention-reflecting-sunlight-to-cool-earth>. For more examples of global catastrophic risks due to science, see N. Boström/M.M. Cirkovic (eds.), Global Catastrophic Risks, 2008. For universities, research institutions, and think tanks dealing with existential risks see Future of Humanity Institute, Oxford Martin School & Faculty of Philosophy, UK; Cambridge Centre for the Study of Existential Risk (CSER), University of Cambridge, UK and Future of Life Institute, Boston, U.S.; available at: <http://www.fhi.ox.ac.uk/>, <http://cser.org/> and <http://futureoflife.org/home>.

7 Cf. D. Svarc, Biological Weapons and Warfare, in R. Wolfrum (ed.), Max Planck Encyclopedia of Public International Law, Vol. I, 2012, 945; S. Vöneky, Die Fortgeltung des Umweltrechts in internationalen bewaffneten Konflikten, 2001, 8 et seq.

8 “There is clear evidence that some terrorist groups, such as Al Qaeda [...], considered and experimented with biological weapons”; For current concerns see The Guardian, Top-secret military warning on Ebola biological weapon terror threat, 21.2.2015, available at: <http://www.theguardian.com/uk-news/2015/feb/21/top-secret-ebola-biological-weapon-terror-warning-al-qaida-isis>.

9 For the differentiation between dual use research and dual use research of concern (DURC) see below.

10 These are such kinds of GOF-experiments in which the pathogenic effects of a microorganism are increased either directly or by increasing its transmissibility or adapting it to new host organisms.

11 For details see German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 9, available at: <http://www.ethikrat.org/files/opinion-biosecurity.pdf>.

12 For some voices from the current debate see: Reconstruction of the 1918 Influenza Virus: Unexpected Rewards from the Past (Taubenberger et al. - mBio 2012), available at: [www.ipg-journal.de/kommentar/artikel/keine-experimente-458/](http://www.ipg-journal.de/kommentar/artikel/keine-experimente-458/); Globalize the discussion (Fouchier & Osterhaus - Nature 2012); Gain-of-

function experiments on H7N9 (Fouchier et al. - Nature 2013); H5N1 virus: Transmission studies resume for avian flu (Fouchier et al. - Nature 2013); Circulating Avian Influenza Viruses Closely Related to the 1918 Virus Have Pandemic Potential (ECDC, 2014), available at: [http://ecdc.europa.eu/en/activities/sciadvicelayouts/forms/Review\\_DisbForm.aspx?List=a3216f4c-f040-4f51-9f77-a96046dbfd72&ID=765](http://ecdc.europa.eu/en/activities/sciadvicelayouts/forms/Review_DisbForm.aspx?List=a3216f4c-f040-4f51-9f77-a96046dbfd72&ID=765); COMMENTARY: The case against ‘gain-of-function’ experiments: A reply to Fouchier & Kawaoka (Lipsitch, Galvani - CIDRAP 2014), available at: <http://www.cidrap.umn.edu/news-perspective/2014/06/commentary-case-against-gain-function-experiments-reply-fouchier-kawaoka>; On the Need for a National Board To Assess Dual Use Research of Concern (Casadevall et. al - J Virol, 2014), available at: <http://jvi.asm.org/content/88/12/6535.long>; The H5N1 Moratorium Controversy and Debate (Casadevall & Shenk - mBio, 2014), available at: <http://mbio.asm.org/content/3/5/e00379-12.long>; What Science Should We Fund? Questioning New Policy on H5N1 Gain-of-Function Research (Evans - SciAm Blogs, 2013), available at: <http://blogs.scientificamerican.com/guest-blog/2013/01/15/what-science-should-we-fund-questioning-new-policy-feldfunktion-geändert-on-h5n1-gain-of-function-research/>; Keine Experimente! Das Züchten neuer Krankheitserreger ist sinnlos und gefährlich. Es muss aufhören (Lipsitch - IPG, 2014), available at: <http://www.ipg-journal.de/kommentar/artikel/keine-experimente-458/>.

13 For the current debate on biosecurity and biosafety see for instance: Das Missbrauchsrisiko in den Biowissenschaften - Biosicherheitsrelevante Forschung zwischen Freiheit, Fortschritt und Verantwortung, Freiburg 2014, available at: <http://www.jura.uni-freiburg.de/institute/ioeffr2/symposien/missbrauchsrisiko>; Cambridge Working Group, Cambridge/Boston/U.S. 2014, available at: <http://www.cambridgeworkinggroup.org/>; Meeting of the Working Group, Abrüstung und Nichtverbreitung biologischer und chemischer Waffen, Berlin 2014; BiochemSecurity2030-Project, Biological and Chemical Security in an Age of Responsible Innovation, London 2014; Side-Event Germany and Tunisia, Biosecurity and Limits of Research, UN Meeting of State Parties, Biological Weapons Convention, Geneva/CH 2014; VW Stiftung, Symposium Dual Use on Microbes: Biosafety, Biosecurity, Responsibility, Hanover 2014, available at: <http://www.volkswagenstiftung.de/dualuseresearch.html>.

ence an especially high, perhaps even existential or global catastrophic, risk<sup>14</sup> can be present if certain research is misused. It was only in October 2014 that the White House announced that the U.S. government is launching a deliberative process to assess the potential risks and benefits associated with GOF-studies and that during this period, the U.S. government will

“institute a pause on funding for any new studies that include certain gain-of-function experiments involving influenza, SARS, and MERS viruses, and encourages those currently conducting this type of work – whether federally funded or not – to voluntarily pause their research while risks and benefits are being reassessed.”<sup>15</sup>

It can be shown, discussing the topic of dual use of biological sciences means dealing with essential questions for our future: What responsibility do researchers, society, the state, and even the global community have to prevent the misuse of scientific knowledge? How should the freedom of research be determined considering the risks of misuse? How can the risks of misuse be effectively minimized without disproportionately restricting research and science?

In this article, I want to add a few nuances to the arguments and insights brought forward up to now and I will refer to the German Ethics Council’s<sup>16</sup> interdisciplinary report on biosecurity, which was released in 2014.<sup>17</sup> In the end, it can be shown that there are still large gaps that should be closed by the national and European legislator as well as by the international community. By closing these gaps these actors will meet their legal obliga-

tions to sufficiently protect human rights and to be in compliance with the precautionary principle as a normative standard that governs low probability high risk scenarios.

## II. Biosecurity and dual use research of concern (DURC)

In order to understand the notion of biosecurity one has to, first of all, differentiate between biosecurity and biosafety: Biosecurity aims to prevent the intentional misuse of research results; biosafety aims to prevent accidental release.<sup>18</sup> The latter is an area, in which risk-minimization measures, like having safe laboratories, are in practice and have been extensively enshrined in the law in Germany.<sup>19</sup> To differentiate between biosecurity and biosafety, however, does *not* mean that there is *an absolute dichotomy* between these areas. Quite to the contrary, it can be stated that means to ensure biosafety can promote more biosecurity and vice versa.

Additionally the concept of *dual use research of concern* (DURC) is important: DURC is research in the biological sciences that has significant potential to give rise to knowledge, products, or technologies, which could be directly misapplied by the researcher or a third person as weapons of mass destruction.<sup>20</sup> This concept is important, since it allows one to distinguish – by definition – from a security point of view the most dangerous experiments from other experiments that are less dangerous: As it is a principle of justice and a duty according to constitutional law that similar cases have to be treated similarly and different cases have to be treated differently, the

14 For this notion see N. Boström/M.M. Cirkovic (eds.), *Global Catastrophic Risks*, 2008; A. Nouri/Ch.F.Chyba, *Biotechnology and biosecurity*, in N. Boström/M.M. Cirkovic (eds.), *Global Catastrophic Risks*, 2008, 450 et seq.; Ch. Phoenix/M. Tredler, *Nanotechnology as global catastrophic risk*, in N. Boström/M.M. Cirkovic (eds.), *Global Catastrophic Risks*, 2008, 481 et seq.

15 Available at: <http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research> and <http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf>.

16 The German Ethics Council was established in 2007 by an act of parliament as an “independent council of experts”; Art. 1 Gesetz zur Einrichtung des Deutschen Ethikrats of 16.7.2007 (Eth-RG), *Federal Law Gazette I* 1385. The president of the German Parliament appoints the members of the German Ethics Council. The German Ethics Council shall be composed of twenty-six members specializing in scientific, medical, theological, philosophical, ethical, social, economic, and legal concerns. The German Ethics Council shall contain representatives of a variety of ethical approaches and a pluralist spectrum of opinions. The legal duties of the Council are informing the public, encouraging discussion in society, and preparing opinions as well as recommendations for political and legislative action.

17 German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014 (Fn. 11). In 2012 the Federal Ministries of Research and of Health tasked the Ethics Council with investigating, whether we in Germany are sufficiently prepared with respect to the misuse of research from the biological sciences. The final version of the report was agreed on in March 2014. The author was head of this working group of the German Ethics Council.

18 Cf. M. Böckenförde, *Biological Safety*, in R. Wolfrum (ed.), *Max Planck Encyclopedia of Public International Law*, Vol. I, 2012, 937.

19 For details see Annex II, 235 et seq. of the German version *Deutscher Ethikrat, Biosicherheit – Freiheit und Verantwortung in der Wissenschaft*, 2014 (Fn. 11).

20 For similar definitions see: National Science Advisory Board for Biosecurity, *Proposed Framework for the Oversight of Dual Use Life Sciences Research*, 2007, 17, available at: <http://fas.org/biosecurity/resource/documents/NSABB%20draft%20guidelines%20on%20dual%20use%20research.pdf>; German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, 14; WHO, *Responsible life sciences research for global health security*, 2010, definition VII.

notion and reasonable definition of DURC allows us to differentiate between groups of experiments in the life sciences that have to be treated differently.

### III. Setting the scene

#### 1. Can there be a rational assessment of biosecurity risks?

The assessment of risks in the area of biosecurity is difficult and cannot be done from a natural science or international relations perspective only. Insights of security experts have to be taken into account as well. Risk assessment has to be an interdisciplinary endeavor. Today, on the basis of natural science and security expertise, it seems plausible to differentiate between various agents and between different groups of experiments.<sup>21</sup> There is often some kind of criticism that listing agents is simplistic and leaves lacunae but a convincing alternative, a more “functional” approach, has not yet been developed.

Besides the necessity to differentiate between various agents, it can be assumed that the more complicated the technology required to create or to modify an agent is, the lower the likelihood that it will be misused by somebody. However, these are only observations at a single point in time, since a technology that is difficult to use and implement today may be easy to implement tomorrow.<sup>22</sup> This is even more true if one thinks of future developments of so called do-it-yourself biology which is done outside of research institutions and companies.

Another problem of evaluating the risks in the area of biosecurity is that nobody can quantify the risk of a terrorist attack with an agent stemming from a laboratory. In the past, there have been successful and unsuccessful attacks by non-state entities and individuals with biological agents;<sup>23</sup> most recently, the “anthrax letters” which were used after the attacks of 9/11 in 2001 in order to kill and harm people in the U.S.<sup>24</sup> Fortunately these have

been very rare cases. But even if the probability is very low, the risk does not equal zero for such an attack.

#### 2. An ethic of risk

Very rare cases whose probability of occurrence is not zero but who have (potentially) huge consequences are sometimes called “Black Swans”.<sup>25</sup> How can we rationally deal with “Black Swan” scenarios if they might have huge negative impacts? It would be irrational and not justified to strive for zero risk in regard to every action that includes risks: It is rational that we do not strive for zero risk in driving cars – which would mean to reduce the maximum speed to zero miles per hour or to prohibit driving cars – because we gain mobility, i.e. we, as individuals and societies, get a direct benefit from driving cars; and because we – or at least the drivers and users of cars – do consent to take the risks caused by driving cars. Because of these arguments (direct benefit and consent of the individuals) it is justified that a society accepts a statistically determined number of deaths caused by car accidents every year.<sup>26</sup> This is at least true if the society enacts laws and regulations that aim to minimize the risks in a proportional way.

On the other hand, it would be irrational to treat every “Black Swan” as if there is a zero risk. This obviously does not reflect reality. Hence, the decisive question is: When is it rational to strive for zero risks? From an economic (and utilitarian) perspective zero risks are hardly justifiable; this is not true, however, if the negative consequences, the damages and deaths, are huge, for instance if a dangerous virus escapes from a laboratory.<sup>27</sup> As the misuse of certain biological agents falls into the category of low probability high risk scenarios – one even could speak of an existential or catastrophic risk<sup>28</sup> – one should strive for a zero risk in regard to biosafety concerns and in regard to biosecurity concerns. This is true if an agent, for instance certain types of influenza viruses, can cause

21 Cf. German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, p. 43 et seq.

22 Cf. German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, p. 43 et seq.

23 Followers of a sect released the bacterium *Salmonella enterica* serotype typhimurium in Oregon/U.S.; 751 people fell ill; in the early 1990ies a Japanese sect tried several times to deploy various biological weapons; cf. German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, p. 19 et seq.

24 Five people died; six contracted infections by inhalation; these attacks caused significant economic damages and widespread public anxiety, cf. German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, p. 19 et seq.; A. Nouri/Ch.F.Chyba, *Biotechnology and biosecurity*, in N. Boström/M.M. Cirkovic (eds.), *Global Catastrophic Risks*, 2008, 450 et seq.

25 Cf. N.N. *Taleb*, *The Black Swan, The Impact of the Highly Improbable*, 2007, 44 et seq.

26 For the differentiation between classes of risk and the importance of consent, cf. J. Nida-Rümelin, B. Rath, J. Schulenburg, *Risikoethik*, 2012, 29 et seq. However, driving a car is not a personal risk in the strict sense, as the car driver is not entirely isolated from others who cannot be affected in any way.

27 This is certainly not astonishing and rather a no-brainer but nevertheless important to state in order to show the limits of a (false) zero risk bias very clear; see for instance R. Dobelli, *Die Kunst des klaren Denkens*, 8. ed., 2015, 110, who makes expressly the differentiation between the justified risk if a society does not prohibit to drive cars and the unjustified risk if a dangerous virus can escape from a laboratory. The latter is one of the rare cases of a justified zero risk bias.

28 J. Nida-Rümelin, B. Rath, J. Schulenburg, *Risikoethik*, 2012, 48 et seq.; similar R.A. Posner, *Catastrophe. Risk and Response*, 2004, 141; for further references see N. Boström/M.M. Cirkovic (eds.), *Global Catastrophic Risks*, 2008.



an endemic or pandemic upon intentional or unintentional release. The material and immaterial damages caused by such an endemic or pandemic can be quantified and these huge negative consequences make it rational to strive for a zero risk and irrational not to do so.

On this basis, it is possible to reinforce the so-called precautionary principle as a decisive ethical basis for decisions in the field of low probability high risk research scenarios.<sup>29</sup> As a legal principle intended to protect the environment, the precautionary principle is not only part of the law of the European Union, it is also laid down in several international treaties, as for instance the 1991 Protocol of Environmental Protection to the Antarctic Treaty<sup>30</sup> that regulates inter alia research in Antarctica and the 2000 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol);<sup>31</sup> sometimes it is argued that it is part of customary international law, already.<sup>32</sup> A widely accepted version of the legal principle states that where there are threats of serious or irreversible damage, the lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent damages.<sup>33</sup> Hence it has to be distinguished from the preventive or protective principles that provide for an obligation of States to prevent known or foreseeable harm outside their territory.<sup>34</sup>

In the field of biosecurity-relevant research this means that, since the misuse of certain research from the biological sciences could lead to severe or even catastrophic or existential damages and there is no zero risk of misuse, measures to reduce the risk have to be taken; hence, from an ethical point of view, it is not decisive that one cannot quantify the probability of misuse; however it

is decisive that one knows that the probability is not equal to zero and the negative consequences might be catastrophic.

### 3. The framework of constitutional and international law

The same result – that measures to reduce the biosecurity risks in the field of biological sciences have to be taken – can be derived from legally binding human rights. The fundamental rights of the researchers – the freedom of research – may be restricted in a proportional manner for legitimate aims. This is even true in regard to the freedom of research as it is laid down in the German Grundgesetz (GG), the German Basic Law.<sup>35</sup> Art. 5 para. 3 GG states: “Arts and sciences, research and teaching shall be free. [...]”

However it would be a misunderstanding to conclude that every limitation of the freedom of research is a violation of this right.<sup>36</sup> A violation of Art. 5 para. 3 GG is only given if there are no legitimate aims or the limitation is not necessary to reach the aim or it is disproportional in relation to the protected good.<sup>37</sup>

The protection of the life and health of human beings are legitimate aims according to the German Basic Law Art. 2 para. 2 GG<sup>38</sup> that can justify proportional limitations of the right of freedom of science.<sup>39</sup> Therefore it is – for instance – no violation of Art. 5 para. 3 GG that there is the duty to consult an interdisciplinary ethics commission before conducting research on human beings in the area of drug testing.<sup>40</sup> The duty to protect life and health of individuals includes a duty of the State organs to assess and evaluate risks even if there are low probabi-

29 J. Nida-Rümelin, B. Rath, J. Schulenburg, *Risikoethik*, 2012, 105 et seq.

30 Federal Law Gazette 1994 II, 2478. For details see S. Vöneky, S. Addison-Agyei, *Antarctica*, in R. Wolfrum (ed.), *Max Planck Encyclopedia of Public International Law*, Vol. I, 2012, 426 et seq. Parties of the Protocol are inter alia China, France, Germany, India, Russia, UK and the U.S.

31 Cartagena Protocol on Biosafety to the Convention on Biological Diversity of 29.1.2000, 39 ILM 1027, M. Böckenförde, *Biological Safety*, in R. Wolfrum (ed.), *Max Planck Encyclopedia of Public International Law*, Vol. I, 2012, 939.

32 For an overview see: M. Schröder, *Precautionary Approach/Principle*, in R. Wolfrum (ed.), *Max Planck Encyclopedia of Public International Law*, Vol. VIII, 2012, 400 et seq.

33 Similar Principle 15 of the Rio-Declaration states: “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.”

34 M. Schröder, *Precautionary Approach/Principle*, in R. Wolfrum (ed.), *Max Planck Encyclopedia of Public International Law*, Vol. VIII, 2012, 401.

35 Grundgesetz für die Bundesrepublik Deutschland (Basic Law),

23.5.1949, Federal Law Gazette 1, [http://www.gesetze-im-internet.de/englisch\\_gg/index.html](http://www.gesetze-im-internet.de/englisch_gg/index.html); see for the interpretation of the freedom of research according to the German Basic Law: M. Fehling, *Bonner Kommentar, Grundgesetz*, 2011, Art. 5 Abs. 3 para. 1 et seq. For the philosophical debate of the freedom of research see T. Wilholt, *Die Freiheit der Forschung, Begründungen und Begrenzungen*, 2012,

36 This is only the case in regard to human dignity as laid down in Art. 1 para. 1 GG: “Human dignity shall be inviolable. To respect and protect it shall be the duty of all state authority”. Therefore every limitation of human dignity is a violation; there are no ways to justify limitations of human dignity because of legitimate aims; hence torture can never be justified according to German constitutional law even if it is done in order to prevent a major terrorist attack.

37 Cf. BVerfG, 1.3.1978, 1 BvR 333/75; 1 BvR 174/75; 1 BvR 178/75; 1 BvR 191/75; BVerfGE 47, 327, 369 et seq.

38 “Every person shall have the right to life and physical integrity. [...]”

39 Cf. BVerfG, 18.2.2010, 2 BvR 2502/08 (CERN).

40 S. Vöneky, *Foundations and limits of an “ethicalization” of law*, in: F. Battaglia, N. Mukerji, J. Nida-Rümelin (eds.), *Rethinking Responsibility in Science and Technology*, 2014, 183 et seq., 197 et seq.

lity scenarios.<sup>41</sup> The same is true if there is a proportional limitation of the freedom of science in order to protect the environment (Art. 20a GG);<sup>42</sup> this is no violation of Art. 5 para. 3 GG either.

The legitimate aims according to the 1950 European Convention on Human Rights required to limit the right of freedom of expression, which entails the right of freedom of science, are even broader: Art. 10 para. 2 European Convention on Human Rights (EuCHR)<sup>43</sup> reads:

“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.*”

Therefore one can conclude, that a law that is proportional according to Art. 5 para. 3 GG cannot be a violation of the freedom of science/freedom of expression as part of the international human right treaties.

Besides it is well established that human rights oblige States not only to respect, but also to protect the fundamental rights of the individuals and the public.<sup>44</sup> Thus, the legislator is obliged by human rights to lay down rules to minimize risks for protected goods, such as the life and health of human beings. This duty exists according to the German Basic Law and for every State that is party to the 1950 European Convention on Human Rights or the 1966 International Covenant on Civil and Political Rights (ICCPR)<sup>45</sup>, like – for instance – the Netherlands, the UK, and the U.S.

Apart from human rights, the questions of biosecurity-relevant research are covered by other important rules of international law, especially the 1972 Biological Weapons Convention (BWC).<sup>46</sup> The BWC is an important treaty because it rules out any storage or use of biological weapons. But it aims to prevent research which has no peaceful purpose.<sup>47</sup> The BWC, as it stands now, is not designed to regulate or manage dual use research. In the area of research regulation it has many lacunae. Besides this, it does not contain a verification regime.<sup>48</sup>

Another international treaty, which has many lacunae in regard to biosecurity-relevant research, is the Cartagena Protocol.<sup>49</sup> The protocol aims to ensure biosafety and includes only very few rules about the illegal cross-border transfer of certain agents if they are modified li-

41 Cf. BVerfG, 18.2.2012; BvR 2502/08 (CERN); BVerfG, 8.8.1978, 2 BvL 8/77, BVerfGE 49, 89, 142 et seq.: “Will der Gesetzgeber die Möglichkeit künftiger Schäden durch die Errichtung oder den Betrieb einer Anlage oder durch ein technisches Verfahren abschätzen, ist er weitgehend auf Schlüsse aus der Beobachtung vergangener tatsächlicher Geschehnisse auf die relative Häufigkeit des Eintritts und den gleichartigen Verlauf gleichartiger Geschehnisse in der Zukunft angewiesen; fehlt eine hinreichende Erfahrungsgrundlage hierfür, muß er sich auf Schlüsse aus simulierten Verläufen beschränken. Erfahrungswissen dieser Art, selbst wenn es sich zur Form des naturwissenschaftlichen Gesetzes verdichtet hat, ist, solange menschliche Erfahrung nicht abgeschlossen ist, immer nur Annäherungswissen, das nicht volle Gewißheit vermittelt, sondern durch jede neue Erfahrung korrigierbar ist und sich insofern immer nur auf dem neuesten Stand unwiderlegten möglichen Irrtums befindet.”

42 Cf. for an interpretation of Art. 20a GG and the duties of the parliament to prevent risks BVerfG, 24.11.2010, 1 BvF 2/05, para. 118: „In legislating, the legislature must balance not only the interests affected by the use of genetic engineering on the one hand and their regulation on the other hand [...] But it must likewise comply with the duty contained in Article 20a GG also to protect natural resources out of responsibility for future generations (see BVerfGE 118, 79, 110). This duty may be imposed both in order to avert dangers and also to take precautions against risks. The environmental interests thus protected by Article 20a GG also include the preservation of biological variety and the guarantee of a

species-appropriate life for endangered animal and plant species.“

43 European Convention on Human Rights and Fundamental Freedoms, 213 UNTS 221; Federal Law Gazette 2002 II, 1055.

44 An obligation to protect, not only an obligation to respect; cf. UN Commission on Human Rights, Res. 2005/69, 20.4.2005, UN Doc. E/CN.4/2005/L.10/Add.17; General Comments No 13 § 46, HRI/GEN/1/Rewv. 7, 87.

45 999 UNTS 171; Federal Law Gazette 1973 II, 1543.

46 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (Biological Weapons Convention), Federal Law Gazette 1983 II, 132; 1015 UNTS 163.

47 Art. 1: “Each State Party to this Convention undertakes never in any circumstance to develop, produce, stockpile or otherwise acquire or retain: Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.” Cf. as well *D. Svarc*, Biological Weapons and Warfare, in R. Wolfrum (ed.), Max Planck Encyclopedia of Public International Law, Vol. I, 2012, 946.

48 *D. Svarc*, Biological Weapons and Warfare, in R. Wolfrum (ed.), Max Planck Encyclopedia of Public International Law, Vol. I, 2012, 948.

49 Fn. 31.

ving organisms (Art. 25).<sup>50</sup> But even those rules do not bind all those States, where one can find significant biosecurity-relevant research; Parties of the Protocol are – inter alia – the EU, UK, and Germany, but not the U.S..

The rules of the Cartagena Protocol are supplemented by a liability protocol, the Nagoya Protocol on Liability to the Cartagena Protocol,<sup>51</sup> which has not yet entered into force. It is striking that the Nagoya Protocol on Liability lays down liability for illegal crossborder transfer as well (Art. 3 para. 3)<sup>52</sup> and only provides exceptions from liability for situations that are equivalent to an international or non-international armed conflict (“[a]ct of war or civil unrest”) but not for terrorist activities (Art. 6). The Nagoya Protocol on Liability is ratified by Germany and the EU, and signed – inter alia – by France and UK, but not the U.S..

#### 4. Rules of European and national law

Furthermore, one has to look at the applicable legal regulations in Germany and Europe. It is beyond the scope of this paper to go into details, but in a nutshell one can state that it can be shown that the existing legal rules in Germany and in Europe that govern research in life sciences are neither sufficient nor coherent. They either encompass only limited areas of biosecurity or they target mainly special questions of biosafety, like the German Genetic Engineering Law.<sup>53</sup>

That the existing rules are far away from a coherent system of regulation for biosecurity-relevant research can be shown since, according to EU law, a publication in the area of biosecurity-relevant research only needs a permit from the export authorities if it will be published in a journal outside the EU.<sup>54</sup> Even the important area of research funding has not been regulated with respect to biosecurity risks: Within the EU Framework Programme for Research, the new Horizon 2020, there are no restrictions for funding this kind of research (Art. 19 Horizon 2020).<sup>55</sup>

In the end, one has to conclude that there are many gaps in the area of biosecurity-relevant research concerning the legal framework at the European and national level.

#### 5. Codes of conducts for responsible research

The question is whether these gaps can be filled in by codes of conduct for responsible research: These codes are issued as an instrument of “self-responsibility” or “self-governance” by research organizations, like the German Research Foundation (DFG),<sup>56</sup> Max Planck Society (MPG)<sup>57</sup> and the Leopoldina.<sup>58</sup> These codes are important in setting normative standards but they are not sufficient in effectively regulating biosecurity-relevant research.<sup>59</sup>

50 Art. 25: “Illegal Transboundary Movements 1. 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. Such movements shall be deemed illegal transboundary movements. 2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate. 3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.”

51 The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, available at: [http://bch.cbd.int/protocol/NKL\\_text.shtml](http://bch.cbd.int/protocol/NKL_text.shtml).

52 Art. 3 para. 3: “This Supplementary Protocol also applies to damage resulting from unintentional transboundary movements as referred to in Article 17 of the Protocol as well as damage resulting from illegal transboundary movements as referred to in Article 25 of the Protocol.”

53 Gentechnikgesetz (Gesetz zur Regelung der Gentechnik, GenTG), Federal Law Gazette 1993 I, 2066; Federal Law Gazette 2013 I, 3154. For details see German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 96 et seq.; C. Teetzmann, Rechtsfragen der Sicherheit in der Biologischen Forschung, in: S. Vöneky (Hrsg.), FIP 4/2014, VII et seq. 5 et seq.; available at: [http://www.jura.uni-freiburg.de/institute/ioeffr2/online-papers/FIP\\_4\\_2014\\_Rechtsfragen\\_Biosicherheit.pdf](http://www.jura.uni-freiburg.de/institute/ioeffr2/online-papers/FIP_4_2014_Rechtsfragen_Biosicherheit.pdf)

54 For the legal grounds and practical consequences see German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 96 et seq. and 149.

55 German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 110 et seq.

56 Code of Conduct: Working with highly pathogenic microorganisms and toxins (2008/2013); available at: [http://www.dfg.de/download/pdf/dfg\\_im\\_profil/reden\\_stellungnahmen/2013/130313\\_verhaltenscodex\\_dual\\_use\\_en.pdf](http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2013/130313_verhaltenscodex_dual_use_en.pdf). Cf. H.C. Wilms, Die Unverbindlichkeit der Verantwortung, 2015, 60 et seq.

57 Guidelines and Rules on a responsible approach to freedom of research and research risk (2010); available at: <https://www.mpg.de/232129/researchFreedomRisks.pdf>. The author was part of the Max Planck Working Group that drafted the code. For further discussion of the code see H.C. Wilms, Die Unverbindlichkeit der Verantwortung, 2015, 65 et seq.

58 The Leopoldina drafted, after the report of the German Ethic Council was published, a code of conduct together with the DFG and members of Max Planck Society; the code is very similar to the Max Planck Code of Conduct mentioned above: Scientific Freedom and Scientific Responsibility Recommendations for Handling Security-Relevant Research (2014); available at: [http://www.leopoldina.org/uploads/tx\\_leopublication/2014\\_06\\_DFG-Leopoldina\\_Scientific\\_Freedom\\_Responsibility\\_EN.pdf](http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf).

59 For details see S. Vöneky, Foundations and limits of an “ethicalization” of law, in: F. Battaglia, N. Mukerji, J. Nida-Rümelin (eds.), Rethinking Responsibility in Science and Technology, 2014, 199 et seq.

Why is this the case? Although the codes of conduct mentioned above often include important elements of risk minimization, the standards of the codes are “ethical” standards. Hence these codes are not directly legally binding. Their enforcement is thus unclear. Only some codes establish an ethics commission that is able to vote and consult on difficult or “unethical” cases, as for instance the Max Planck Code but not the new DFG/Leopoldina Code. Moreover these codes have a limited number of addressees since they only bind the respective members of the scientific society, but not all researchers in a State, in Europe or worldwide. Last but not least these codes of conduct can have some kind of output legitimacy but no democratic legitimacy. Output legitimacy is given if a regulation can solve a problem in an adequate way. Democratic legitimacy is given only if there is a clear link to an act of parliament.<sup>60</sup> As the codes of conducts mentioned above lack a legal basis and even the commissions that drafted the codes were not set up on a legal basis,<sup>61</sup> democratic legitimacy is not given. Codes of conducts as means of self-regulation can promote some kind of output legitimacy, if and only if they solve the problems of biosecurity; up to now, however, there is no empirical data supporting the last assumption.

To sum up: legal rules as well as codes of conduct that cover important areas of biosafety and biosecurity do exist; but until now there is no coherent system of rules and other measures that aims to prevent the risk of misuse of biosecurity-relevant research.

#### IV. Is there a way forward? Recommendations for legitimate future normative standards

As the existing legal and ethical rules and regulations show, there is no easy solution in regulating biosecurity-relevant research. Recommendations that shall improve the current situation have to focus on different levels. The most important are the following five:<sup>62</sup>

1. The first level aims to raise the level of awareness for questions of biosecurity in the scientific community.
2. The second level targets the elaboration of a national biosecurity code of conduct.
3. The third level concerns important limits in research funding.

4. The fourth level displays recommendations for legislation in Germany, especially the legal bases for a new DURC-Commission.

5. The fifth names European and international initiatives.

From this order, it however cannot be concluded that certain recommendations are more important than others; all recommendations do intertwine. Biosecurity is a problem that can neither be solved by so-called ethical self-governance and private standard setting nor on a national level.

##### 1. Raising of awareness

The idea is to promote a culture of responsibility and improve the knowledge of researchers in the life sciences with respect to biosecurity. Therefore, questions of biosecurity should be integrated into undergraduate and graduate curricula, as well as into the training and continuing education of life scientists and laboratory personnel.<sup>63</sup>

##### 2. A national biosecurity code of conduct

Secondly, the elaboration of a national biosecurity code of conduct that defines the responsible manner of dealing with problems of biosecurity can be recommended.<sup>64</sup> Although there are no empirical data, it seems *prima facie* plausible to argue that such a code of conduct, which is drafted by the main actors of the scientific community, is a useful instrument for this community to enhance and promote some kind of self-responsibility. In the code, standards that extend *beyond the legal* obligations should be established.

With respect to the normative principles that the code of conduct should include, I want to mention the following important points. Concrete obligations to minimize risks should be enshrined: Research programs should be examined in order to establish whether the benefits are sufficient to justify taking the risks involved. Besides, it is of particular importance for the researcher to examine whether the research carries unreasonably high risk for protected goods such as the health of people as well as the environment.<sup>65</sup> Should such an examination reveal that the risk is not justifiable, then the research should not be pursued. Generally, the same ap-

60 S. Vöneky, *Recht, Moral und Ethik*, 2010, 130-224.

61 For a different example see: Deutscher Corporate Governance Kodex (cf. <http://www.dcgk.de/en/home.html>). Through the declaration of conformity pursuant to § 161 Stock Corporation Act (Aktiengesetz), this code has a link to an act of parliament and hence democratic legitimacy.

62 Cf. German Ethics Council, *Biosecurity – Freedom and Respon-*

*sibility of Research*, 2014, 176 et seq.

63 Cf. German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, 179.

64 Cf. German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, 180 et seq.

65 This is a deontological element and therefore not a risk-benefit assessment, only.



plies with respect to publication and research cooperation programs.

Besides this, it has to be argued that the code of conduct should also contain a kind of additional burden of justification for certain research programs: This should be the case for those experiments for which it is *foreseeable* that the *pathogenic effect of a microorganism will be enhanced* by a scientist in such a manner that the danger of an *epidemic of a severe disease* for humans is given. This kind of GOF-experiments should generally not be undertaken, unless a direct, concrete, and overwhelming benefit for the protection of humans against dangers to life or health is probable. The reason for this special burden of justification for *certain GOF-experiments* is that these experiments – in contrast to other fields of research in the biological sciences – create *new and high* risks for public health. If no direct, concrete, and overwhelming benefit for the protection of humans against dangers to life or health is probable before research begins, it must be assumed – because the pathogenicity is increased through the action of the researcher – that the potential damage outweighs the potential benefit of the research program.<sup>66</sup> These are the cornerstones of a recommendation for a national code of conduct for biosecurity.

### 3. New limits for research funding

The third recommendation concerns the area of research funding.<sup>67</sup> With respect to the funding of dual use research of concern, it should be ensured that the scientist entrusted with project management has agreed to comply with the new code of conduct on biosecurity. Research programs that are not justifiable in the above sense, should not be funded.

However, and this is very important, whether this is the case in the special area of dual use research of concern (DURC) cannot be decided by the researcher or the funding party, but should previously be assessed by a so-

called Dual Use Research of Concern Commission, a DURC-Commission, which has to be established for this purpose. This new commission shall take *consultative votes* on DURC-relevant experiments in Germany and their votes shall decide on the research funding of DURC.<sup>68</sup>

Although the votes of commission shall only be consultative one and hence this is *not* a proposal of a permit procedure<sup>69</sup> such a consultative procedure has decisive positive side effects for the researcher: if there is a positive evaluation of an experiment by the commission the researcher can be sure that he or she is conducting an experiment that is ethically justified and lawful. In legal terms this would exempt the researcher from any liability.<sup>70</sup>

### 4. A new DURC-Commission based on an act of parliament

The DURC-Commission is an important part of the fourth recommendation. Here the recommendations for new legislation are summarized:<sup>71</sup> The legal establishment of the DURC-Commission is recommended; besides the stipulation of a *legal obligation* of researchers *to consult* the DURC-Commission before conducting DURC is recommended. The DURC-Commission must be, as biosecurity questions and biosecurity risk assessment cannot be answered by natural sciences alone, an interdisciplinary commission that should include life sciences and security experts as well as biosecurity expertise from civil society. It is essential to ensure that the proposal of a DURC-Commission is a proposal for a consultation procedure and no permit for DURC-experiments will be necessary.

The consultation by the Commission should again refer to the criteria for risk minimization mentioned above, that is whether the benefits are sufficient to justify taking the risks involved. Here as well, it is coherent to propose an additional burden of justification for DURC

66 This proposal was supported by some members of the German Ethics Council including the author; cf. German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 182.

67 Cf. German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 183.

68 Cf. German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 185 et seq.

69 Even a permit procedure including certain kinds of experiments is not uncommon according to German law; a permit procedure is for instance obligatory according to an act of parliament if a researcher wants to do experiments with human beings in a drug trial, wants to work with embryonic stem cells, or even wants to conduct research in Antarctica; cf. sect. 40-42 Gesetz über den Verkehr mit Arzneimitteln (AMG, Medicinal Products Act (The Drug Law)), 1.12.2005; Federal Law Gazette I 2005, 3394, [http://www.gesetze-im-internet.de/englisch\\_amg/index.html](http://www.gesetze-im-internet.de/englisch_amg/index.html); Gesetz

zur Sicherstellung des Embryonenschutzes im Zusammenhang mit der Einfuhr und Verwendung menschlicher embryonaler Stammzellen (StZG), 28.6.2002; BGBl. 2002 I, 2277, Federal Law Gazette 2013 I, 3154; Gesetz zur Ausführung des Umweltschutzprotokolls vom 4.10.1991 zum Antarktis-Vertrag (Umweltschutzprotokoll-Ausführungsgesetz, AUG), Federal Law Gazette 1994 I, 2593; Federal Law Gazette 2013 I, 3154.

70 Liability is an important point when discussing questions of biosecurity and biosafety relevant research; one has to differentiate between the liability of the researcher, research institutions etc. according to the national laws of a State and the liability of a State according to public international law: cf. German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 95 et seq., 104 et seq.

71 Cf. German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 183 et seq.

experiments which enhance the pathogenic effect of a microorganism and thereby create a new risk of an epidemic.

Furthermore, the DURC-Commission shall consult on further measures for reducing risks, shall monitor DURC experiments, and shall evaluate research cooperations and the publication of DURC outcomes.

Contrary to some views from the scientific community, it is not sufficient to broaden or reshape the Zentrale Kommission für die Biologische Sicherheit (ZKBS, Central Commission on Biosafety) which is based on §§ 4 and 5 GentG.<sup>72</sup> Certainly it is correct that the ZKBS is an important commission in Germany to assess *biosafety* concerns; besides the ZKBS is based an act of parliament and has democratic legitimacy. But the focus of this biosafety commission is to answer mainly biosafety questions, not to solve biosecurity problems. In the commission one cannot find any members that have security expertise. Even more importantly: the ZKBS is based on the Genetic Engineering Law (GentG). This law is only applicable to provide protection against harmful effects of genetic engineering work and the handling of genetically modified products. This however does not cover all biosecurity-relevant research and not all experiments that constitute dual use research of concern (DURC). Hence there are major lacunae and structural drawbacks and these problems cannot be solved by broadening or enhancing the ZKBS.

These new legal rules are only proposed for DURC-experiments. This is a crucial limitation: Nobody recommends legal rules of all biosecurity-relevant research (all biosecurity-relevant research shall be encompassed by the code of conduct), but instead only of dual use research of concern. DURC can be defined – as a first step – as research that has significant potential to give rise to knowledge, products, or technologies, which could be directly misapplied as weapons of mass destruction.<sup>73</sup> But since only DURC should be regulated on a legal basis, a more precise definition is necessary. Ten groups of research experiments can be listed and defined, which, considering the international discussion, fall within the area of DURC. These are inter alia “work intended to enhance the harmful consequences of listed agents”.<sup>74</sup> But, these experiments are DURC if and only if they are done with certain dangerous agents.

Hence it is reasonable to recommend for the legal regulation of DURC a combination approach: First, the DURC definition as part as an act of parliament; second, ten groups of experiments included in a statutory ordinance (not an act of parliament), and, third, a list of agents. For the listed agents one can refer to existing lists (for instance included in the German War Weapons Control Act, the Biological Weapons Convention Draft Protocol, and the U.S. Oversight Policy)<sup>75</sup> and to the past and current status of the international discussion. The proposal is, that the *DURC-Commission* shall draw up a list of dangerous agents and keep the list up to date:<sup>76</sup> It is necessary that the list has to be kept up to date in accordance with new knowledge in the life sciences; therefore the list shall not be part of the legislation but be agreed upon by the DURC-Commission so that it can be changed and modified more easily if necessary.

Since these recommendations concentrate on the area of DURC, for which the new commission shall be implemented, this explains why only *one commission* is proposed for all of Germany and why a proposal to have multiple commissions in the respective faculties of the universities is not convincing: There is the estimation based on current data that there will only be very few research experiments that fall in the category of DURC in Germany each year. According to figures from the U.S., one can assume around ten programs per year in Germany. Every decentralization thus seems to neither be very effective nor reasonable. Moreover, each decentralization also has the consequence that uniform criteria for the evaluation of experiments cannot be guaranteed.

After saying this, one has to stress as well that it would be a misconception to assume that the freedom of research is disproportionately restricted if legal rules, besides a code of conduct, are laid down: codes and legal rules complement each other. Codes of conduct can be useful instruments of self-governance; but in the area of DURC, that is in the area of research that carries especially high risks, the parliament as legislator must decide how to balance the fundamental rights in order to guarantee the democratic legitimation of the rules. Legal norms do not deny the freedom of research, but on the contrary acknowledge the significance of the affected fundamental rights, i.e. the freedom of research and the duty to protect the health of the population. These hu-

72 More information is available at: [http://www.bvl.bund.de/DE/06\\_Gentechnik/02\\_Verbraucher/05\\_Institutionen\\_fuer\\_biologische\\_Sicherheit/02\\_ZKBS/gentechnik\\_zkbs\\_node.html](http://www.bvl.bund.de/DE/06_Gentechnik/02_Verbraucher/05_Institutionen_fuer_biologische_Sicherheit/02_ZKBS/gentechnik_zkbs_node.html).

73 Cf. German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, 184.

74 Cf. German Ethics Council, *Biosecurity – Freedom and Respon-*

*sibility of Research*, 2014, 184.

75 For these lists of agents, see German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, 190 et seq.

76 Cf. German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014, 184.

man rights are so important that the parliament must decide in which circumstances and according to which criteria, if necessary, certain research projects should not be funded, should not be undertaken and/or results should not be published.

Therefore the four essential recommendations for the domestic area are: 1. raising the awareness; 2. a biosecurity code of conduct; 3. special rules for research funding; and 4. the legal establishment of a DURC-Commission and of a DURC consultation procedure.

#### 5. European and other international initiatives

The fifth recommendation refers to European and other international initiatives. Even though this recommendation is the last one, this does not mean that it is less important; rather, there was a consensus that uniform standards on a European or international level are generally the most appropriate for solving the biosecurity and biosafety problems connected to research in the life sciences.

For the European and international area, the following is recommended:<sup>77</sup> The discussion within the scientific community concerning the possible benefits and risks of DURC should continue to be pursued in order to reach a consensus on what constitutes responsible research. One should also try to agree on a biosecurity code of conduct on a European or even international level.

On the European level, States should advocate that research funding only proceed according to the previously mentioned criteria and that uniform standards are established for DURC in the member States.

Furthermore, States should strive for an internationally binding definition and classification of DURC, including uniform laboratory safety classifications. It is not convincing for biosecurity and biosafety if in one country certain high risk gain of function experiments can be performed in laboratories with safety classification 2 or 3, but in other countries they can only be performed in the few laboratories with safety classification 4. That this kind of soft harmonization is possible in the area of biosafety and biosecurity-relevant research can be seen in the foot and mouth disease regulation in the EU.<sup>78</sup>

Lastly, there are lacunae in the current international treaty regime. International treaty law does not regulate in a sufficient way the research specific dual use biosecurity questions. The BWC is important but has too many

gaps, and does not contain coherent regulations to minimize the risk of misuse of *peaceful* research. Here Germany together with like-minded States should strive for the conclusion of a special treaty that defines the fundamental principles and limitations of biosecurity-relevant research or – as a first step – at least an international soft law declaration. A good example for a quickly negotiated soft law declaration, which is regulating research, is the UNESCO “Universal Declaration on Bioethics and Human Rights” from 2005,<sup>79</sup> which consists of 28 articles that connect bioethical principles to international human rights. This declaration was negotiated within 15 months.<sup>80</sup>

## V. Conclusion

The goal of this article is to discuss the main legal and ethical rules and to propose a coherent system for reasonable standards of biosecurity-relevant research that is open to future developments and balances the freedom and responsibility of research: there neither may be disproportional limits to research nor shall possibilities for risk minimization be neglected.

To sum up the decisive points:

For any future standard setting, it is decisive how funding of biosecurity-relevant research is regulated: funding is decisive as those who fund research have the key to restrict unethical and illegal research; therefore the funding of biosecurity-relevant research must be limited according to clear rules; no State must allow unethical research to be funded.

Besides, coherence is decisive: It is a principle of justice and a duty according to constitutional law that similar cases have to be treated similarly and different cases have to be treated differently. Therefore, if there are differences between groups of experiments in the life sciences they have to be treated differently; the same is true for agents that are different (that do not have the same pathogenicity etc.). Coherence also means that the same group of experiments must be treated the same at least in one country. Hence it is not convincing to install so many councils and commissions that every university and science organization has its own commission and can decide about its own research.

Harmonization is decisive: There is a need for coherent rules in Europe and world wide; science and society

77 Cf. German Ethics Council, Biosecurity – Freedom and Responsibility of Research, 2014, 188.

78 Council Directive 2003/85/EC of 29.9.2003 on Community measures for the control of foot-and-mouth disease, OJ L 306, 1, 22.11.2003.

79 UNESCO, Universal Declaration on Bioethics and Human

Rights, C/Res 24, 19.10.2005, available at: [http://portal.unesco.org/en/ev.php-URL\\_ID=31058&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html). For further references see H.C. Wilms, Die Unverbindlichkeit der Verantwortung, 2015, 346 et seq.; S. Vöneky, Recht, Moral und Ethik, 2010, 368 et seq.

80 S. Vöneky, Recht, Moral und Ethik, 2010, 368 et seq.

need clear rules on which kind of biosecurity-relevant research can be done in which kind of laboratories.

Legitimation is decisive: One has to differentiate between some kind of output legitimacy, that is whether a regulation can solve a problem in an adequate way and democratic legitimacy, that is whether a regulation is based on an act of parliament. Standards of self-governance can promote some kind of output legitimacy; however, only an act of parliament can promote democratic legitimacy. In the area of human rights, an act of parliament is necessary if the freedom of science and the duty to protect life and health are concerned. Therefore –

as in the area of research on human being in drug trials – in the area of biosecurity-relevant research at least the main elements of a standard setting and the bases of the DURC-Commission must be laid down in an act of parliament; details of the normative standards, like a list of agents, can be agreed on by a commission or other experts in life sciences, if they act on a legal bases.

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