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Joint Committee on the Handling of Security-Relevant Research

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Joint Committee on the Handling of Security-Relevant Research

Preface

This progress report begins with a summary in Chapter A of the developments leading up to the establishment of the Joint Committee on the Handling of Security-Relevant Research by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) and the German National Academy of Sciences Leopoldina in November 2014. Chapter B reports on the tasks of the Joint Committee and its activities up to 1 October 2016, with particular focus on the progress of implementing the DFG and the Leopoldina's "Recommendations for Handling Security-Relevant Research" of June 2014. Chapter C provides an overview of the political debate on security-relevant research in Germany, which was prompted by experiments with highly pathogenic influenza viruses. Finally, Chapter D gives an outlook of the planned future development of the Joint Committee.

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A. Background

1. Freedom and responsibility of research – the dual-use dilemma

Freedom of research as protected by Article 5(3) of the German Basic Law gives researchers the right to raise their own scientific questions and to address these questions independently within the conditions laid out in the Basic Law. Freedom of research plays a fundamental role in expanding human knowledge and in ensuring social progress and prosperity. However, useful research findings and research methods can also be misused for harmful purposes by third parties. One example of this “dual-use dilemma” in research is the discovery of nuclear fission in the 1930s, which also led to the development and use of nuclear weapons of mass destruction. This triggered an intense debate on the responsibility of researchers¹ that still continues to this day.

The dual-use dilemma sparks continuous debate over the benefits and potential risks of specific research projects. In 2012, for example, research into the transmission of highly pathogenic influenza viruses – the so-called avian influenza or “bird flu” viruses of the subtype H5N1 – came to the forefront of international public debate. No human-to-human transmission of the virus had ever been documented and around one hundred people in Asia were infected – presumably through very close contact with

poultry. The infection was fatal in around half of the cases, prompting widespread concern not only among breeders of livestock. At this time, research groups from the Netherlands and Japan/US were publishing findings that showed the genetic mutations the virus would have to undergo for airborne transmission between mammals to occur.² This caused great concern worldwide about the usefulness and risks associated with such research.

The two research groups led by Yoshihiro Kawaoka and Ron Fouchier defended the importance of their work on the transmission of flu viruses, arguing that their findings had made it possible to understand how the virus could develop into a potential threat for humans through spontaneous, naturally occurring mutations. Surprisingly, only five simple point mutations were required for the virus to become airborne transmissible between the ferrets used in the experiment. The two scientists believe that this knowledge makes it far easier to classify the new viruses continually emerging in nature in terms of their potential to spark a pandemic, and to take more targeted protective measures.

Critics of this type of research fear that the pathogens produced for research purposes could escape from the high-security laboratories into the environment through negligent conduct. These risks are addressed in numerous regulations in-

¹ See, for example, the Russell-Einstein Manifesto (1995), available at: www.pugwash.de/rem.pdf, and the Göttingen Manifesto (1957), available at www.uni-goettingen.de/de/54320.html (both last accessed: 21 September 2016).

² See also Herfst S. et al (2012), “Airborne transmission of influenza A/H5N1 virus between ferrets”, *Science* 336.6088: 1534-1541 and Imai M. et al. (2012), “Experimental adaptation of an influenza H5 HA confers respiratory droplet transmission to a reassortant H5 HA/H1N1 virus in ferrets”, *Nature* 486.7403: 420-428.

tended to achieve optimal biological safety, or biosafety.³ Another potential hazard is that publication of such research findings makes knowledge available that may be misused for the purposes of bioterrorism attacks or biological warfare. A number of regulations on this issue, known as biosecurity, are in place to prevent the distribution of chemical and biological weapons. These include regular criminal law, the United Nations' Biological Weapons Convention and the regulations of the German Federal Office of Economics and Export Control (BAFA). Alongside preventative measures on the part of security agencies⁴ and the work of law enforcement authorities, self-governance by the scientific community is also of great importance here (see Chapter A.2 and Chapter A.3). The international debate on the so-called "gain-of-function" experiments outlined above⁵ – that is, experiments in which viruses and other pathogens acquire new gene functions – is still ongoing.⁶

The dual-use dilemma extends far beyond the sphere of the life sciences, affecting all scientific fields. Results from

materials research and nanotechnology could contribute to the development of offensive weapons; research findings on industrial robots could be used in the construction of combat drones; research methods and results gained in the field of protection from computer viruses could also be used to develop strategies for their dissemination; research that includes the extensive collection and analysis of personal data could lead to a violation of personal rights; findings and methods from the behavioural and social sciences could be used to manipulate public opinion in a certain way. The list is almost endless. However, failure to carry out certain research can also be problematic from an ethical point of view if, for example, this hinders the development of treatments, vaccines and other protective measures and prevents important innovations in other fields.

2. Statement by the German Ethics Council on biosecurity and freedom of research

In the summer of 2012, as a response to the gain-of-function debate that had triggered international concern on how to manage biosecurity risks, the German Federal Government commissioned the German Ethics Council to prepare a statement on biosecurity and freedom of research. The central question under scrutiny was whether the relevant German legal regulations as well as the codes of conduct⁷ of science and industry are suitable

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- 3 In particular, in Germany, the Biological Agents Ordinance (*Biostoffverordnung*), the Genetic Engineering Act (*Gentechnikgesetz*) and the Protection Against Infection Act (*Infektionsschutzgesetz*); for more information on laws and regulations relevant in the handling of biological agents, visit: www.vbio.de/informationen/wissenschaft_gesellschaft/thema_biosicherheit/normen_und_gesetze (last accessed: 21 September 2016).
- 4 See comments made by the German Federal Office of Civil Protection and Disaster Assistance, Unit III.2 on CBRN protection, available at: www.bbk.bund.de/DE/AufgabenundAusstattung/CBRNSchutz/Biologie/biologie_node.html (last accessed: 21. September 2016).
- 5 On the importance of gain-of-function experiments, see also the policy report from the European Academies Science Advisory Council (EASAC) "Gain of function: experimental applications relating to potentially pandemic pathogens" (2015), available at: www.easac.eu/fileadmin/PDF_s/reports_statements/Gain_of_Function/EASAC_GOF_Web_complete_centred.pdf (last accessed: 21 September 2016).
- 6 For the current discussion on and progress of implementation of biosafety and biosecurity measures in the US, see the Federal Select Agent Program (available at: www.selectagents.gov), the White House memorandum (2015; available at: www.whitehouse.gov/sites/default/files/docs/10-2015_biosafety_and_biosecurity_memo.pdf) and the National Science Advisory Board for Biosecurity (NSABB) report "Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research" (2016), available at: http://osp.od.nih.gov/sites/default/files/NSABB_Final_Report_Recommendations_Evaluation_Oversight_Proposed_Gain_of_Function_Research.pdf (all last accessed: 21 September 2016).

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- 7 See, for example, "Guidelines and Rules of the Max Planck Society on a Responsible Approach to Freedom of Research and Research Risks" (2010), available at: www.mpg.de/232129/researchFreedomRisks.pdf, the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) (2013) "Arbeit mit hochpathogenen Mikroorganismen und Toxinen", available at: www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2013/130313_verhaltenscodex_dual_use.pdf, the Leibniz Association (2012) "Verhaltenskodex für Biosicherheit für Einrichtungen im Umgang mit biologischen Ressourcen", available at www.leibniz-gemeinschaft.de/fileadmin/user_upload/downloads/Presse/Dokumente/Verhaltenskodex_fuer_Biosicherheit_deutsch.pdf (all last accessed: 21 September 2016).

and sufficient as normative instruments and whether they represent an adequate basis for promoting research. The German Ethics Council took this assignment as an opportunity to carry out a systematic analysis on the topic of biosecurity-relevant research and to put forward recommendations for the future handling of such research and its funding.

The statement “Biosecurity – freedom and responsibility of research”⁸ was published on 7 May 2014. The paper’s key recommendations included measures to increase awareness of biosecurity issues within the scientific community as well as tighter legal regulation of so-called dual use research of concern (DURC) in Germany. The German Ethics Council defined such research as “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 Ethics Council recommended drafting a legal definition of DURC and appointing a legally legitimate central DURC Commission. A prerequisite for private and/or public funding of potential DURC should be that scientists are obliged to seek the advice of the central DURC Commission. The final funding decision should also depend on a DURC Commission vote. Another possible instrument for monitoring and controlling DURC put forward by the German Ethics Council is the transferral of decision-making powers to a federal agency as part of an approval procedure.

3. The DFG’s and the Leopoldina’s “Recommendations for Handling Security-Relevant Research”

In the opinion of the DFG and the Leopoldina, legal provisions offer only a very limited means of controlling the opportunities and risks associated with free research. Research methods and content are constantly changing and research findings, as well as their future application, tend to be almost impossible to predict. The DFG and Leopoldina continuously work to ensure that ethical principles and mechanisms for the responsible handling of freedom of research and research risks are developed in science. As part of the gain-of-function debate, the two organisations appointed a joint interdisciplinary and cross-institutional working group in the summer of 2013 that was tasked with analysing and discussing the complex relationship between freedom of research and research risks.⁹

In discussion with various research organisations and members of the Leopoldina and DFG, the working group developed a set of general guidelines on handling security-relevant scientific research based on the “Guidelines and Rules on a Responsible Approach to Freedom of Research and Research Risks”,¹⁰ which the Max Planck Society approved in 2010. These guidelines were presented to the public on 26 June 2014 in Berlin under the title “Scientific Freedom and Scientific Responsibility – Recommendations for Handling Security-Relevant Research”.¹¹ This document places great importance on instruments of self-governance within the scientific community. The advantage

8 Available at: www.ethikrat.org/publikationen/stellungnahmen/biosicherheit (last accessed: 21 September 2016).

9 For more information, see: www.leopoldina.org/en/policy-advice/working-groups/completed-working-groups/dual-use (last accessed: 21 September 2016).

10 Available at: www.mpg.de/232129/researchFreedom-Risks.pdf (last accessed: 21 September 2016).

11 Available at: www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf (last accessed: 21 September 2016).

of self-governance lies in researchers' high level of familiarity with the given subject and the fact that it allows for a flexible response. The recommendations are intended as an aid for researchers as well as a blueprint for research institutions implementing corresponding regulations and are aimed primarily at the government-funded research sector. However, their principles can certainly also be applied in the private sector.

In the first part of the recommendations, the DFG and Leopoldina urge researchers not to content themselves with just complying with legal regulations. Due to their basic right to freedom, their knowledge and their experience, researchers have a particular ethical responsibility that goes beyond their legal obligations. Every scientist must, therefore, be fundamentally aware of the danger of research misuse. In critical cases, these individuals must make a personal decision about what is responsible with regard to their research. In doing so, they need to weigh the opportunities offered by the research against the risks for human dignity, life and other important values. The recommendations specify these considerations in terms of necessary risk analysis, measures for reducing risk and evaluating the publication of research results. The primary goal is to carry out and communicate research and its results in a responsible way. In isolated cases, a responsible decision on the part of the researcher may also mean that a research project is temporarily suspended or indeed not carried out at all.

The second section of the recommendations is aimed at the research institutions that create framework conditions for ethically responsible research. They need to raise awareness of the problem, convey the required knowledge of legal constraints on research and support corresponding training measures for scientists. Research institutions need to develop eth-

ics rules for handling security-relevant research that go beyond compliance with legal regulations. Each institution should set up a special Committee for Ethics in Security-Relevant Research to implement these rules and to advise its scientists.

B. Status of implementation of the Recommendations for Handling Security-Relevant Research

1. **Mandate of the Joint Committee on the Handling of Security-Relevant Research** the two institutions decided to set up the Joint Committee on the Handling of Security-Relevant Research.

In their Recommendations for Handling Security-Relevant Research, the DFG and Leopoldina offered to establish a joint advisory board to implement the recommendations. In October 2014, In accordance with the decisions made by the Leopoldina Presidium on 25 February 2015 and the DFG Presidium on 18 March 2015, the Joint Committee has the following mandate:

“[...] to promote the effective and sustainable implementation of the recommendations of the DFG and the Leopoldina on ‘Scientific Freedom and Scientific Responsibility’. The Joint Committee shall monitor and proactively advance the status of implementation at research institutions and support them in properly implementing the recommendations by drafting sample texts, for example. This applies in particular to the establishment of the Committees for Ethics in Research (KEFs [German acronym]) as outlined in the recommendations, which should ideally be implemented in all research institutions by 2017.

During the KEFs’ set-up phase, the Joint Committee shall act as a point of contact for any questions and as a platform for sharing experience and knowledge. The responsibility for individual cases under discussion shall lie with the research institutions at which the work is being carried out. In special cases that cannot adequately be appraised by the KEFs, the Leopoldina may appoint ad-hoc working groups with the necessary specialist expertise to carry out a risk-benefit assessment of the research in question in close collaboration with the Joint Committee.

In addition, the Joint Committee shall monitor developments in the field of security-relevant research in Germany and, if necessary, identify potential areas for action and advise the DFG and Leopoldina on these issues. If necessary, Committee members will take part in public discussions. In order to focus attention on this issue over the long term, the Committee shall organise regular symposia on the topic of scientific freedom and scientific responsibility.”

The first of the events mentioned in the Joint Committee's mandate was held on 3 November 2014 in Halle (Saale) under the title "Freedom and responsibility of research: do the prospects of success justify the potential risks?". The event was organised by the DFG and the Leopoldina in collaboration with the German Ethics Council.¹²

The Presidiums of the DFG and Leopoldina appointed the Joint Committee for an initial period of three years. The Committee's mandate may be extended depending on how things develop in the course of these three years. The Committee meets two to three times per year and may invite experts to discuss specific topics at its meetings. In addition, Committee members visit research institutions and participate in public events on the topic of security-relevant research.¹³

¹² Documentation of the event can be accessed at: www.leopoldina.org/uploads/tx_leopublication/2015_Diskussionspapier_Freiheit_Verantwortung_der_Wissenschaft.pdf (last accessed: 21 September 2016).

¹³ The members of the Joint Committee and employees of the Joint Committee office were actively involved in the following events: "Dual Use Research on Microbes: Biosafety, Biosecurity, Responsibility", symposium organised by the Max Planck Society and the Volkswagen Foundation, 10-12 December 2014, Hanover; "Scientific responsibility", public discussion held during a session of the Bundestag Committee on Education, Research and Technology Assessment, 4 November 2015, Berlin; "Dual Use Research of Concern – How well prepared are we for the consequences of the current debate?", workshop organised by the German Research Platform for Zoonoses, 15 September 2015, Berlin; annual assembly of the working group on the "Disarmament and non-proliferation of biological and chemical weapons", 9 November 2015, Berlin; visiting researcher study trip of the Institut Pasteur de Tunis (IPT) and the Military Hospital of Tunis as part of the German Partnership Program for Excellence in Biological and Health Security, 27 January 2016, Berlin; guest lecture at the invitation of the University of Veterinary Medicine Hanover's research ethics committee, 4 February 2016, Hanover; "The culture of responsibility – transparency in science", conference held by the Ministry for Science and Culture of Lower Saxony and the Volkswagen Foundation, 11 May 2016, Hanover.

2. Composition and office of the Joint Committee

The Joint Committee is headed by the vice presidents of the DFG and the Leopoldina or by representatives appointed by the Presidiums. The Committee com-

prises scientists from various disciplines, and at least one member must be an expert on ethical issues and one on legal issues. The Joint Committee's office is based in the Leopoldina's Berlin office at Reinhardtstr. 14, 10117 Berlin.

Chairpersons

Prof. Frank Allgöwer	University of Stuttgart, Institute for Systems Theory and Automatic Control, Vice President of the DFG
Prof. Bärbel Friedrich	German National Academy of Sciences Leopoldina, representative of the Leopoldina Presidium and former Vice President of the Leopoldina

Other members

Prof. Stephan Becker	Institute of Virology, Philipps-Universität Marburg
Prof. Alfons Bora	Faculty of Sociology, Bielefeld University
Prof. Johannes Buchmann	Technische Universität Darmstadt, Department of Computer Science
Prof. Anke Kaysser-Pyzalla	Helmholtz-Zentrum Berlin für Materialien und Energie (HZB)
Prof. Kathryn Nixdorff	Technische Universität Darmstadt, Department of Biology
Dr Lars Schaade	Robert Koch Institute Berlin
Prof. Ulrich Sieber	Max Planck Institute for Foreign and International Criminal Law, Freiburg
Prof. Fritz Strack	University of Würzburg, Professor of Psychology II
Prof. Klaus Tanner	University of Heidelberg, Faculty of Theology
Prof. Jochen Taupitz	University of Mannheim, Faculty of Law and Economics

Office

Dr Johannes Fritsch	Head of the Joint Committee office, German National Academy of Sciences Leopoldina
Yvonne Borchert	Joint Committee project coordinator, German National Academy of Sciences Leopoldina

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3. Establishment of the Committees for Ethics in Security-Relevant Research (KEFs)

The Joint Committee held its constitutive meeting in Berlin on 13 February 2015. The Joint Committee's mandate (Chapter B.1) stipulates that the process of establishing KEFs or of appropriately extending the responsibilities of already existing ethics committees should be largely completed at German research institutions by

the middle of 2017. To initiate and drive this process forward, all 84 DFG member organisations¹⁴ were contacted in May 2015 by the presidents of the DFG and Leopoldina, informed of the Recommendations for Handling Security-Relevant Research and requested to name a con-

¹⁴ These currently comprise 68 universities and 16 non-university research institutes and research associations. Further information is available at: www.dfg.de/dfg_profil/gremien/mitgliederversammlung/mitgliederversammlung_liste (last accessed: 21 September 2016).

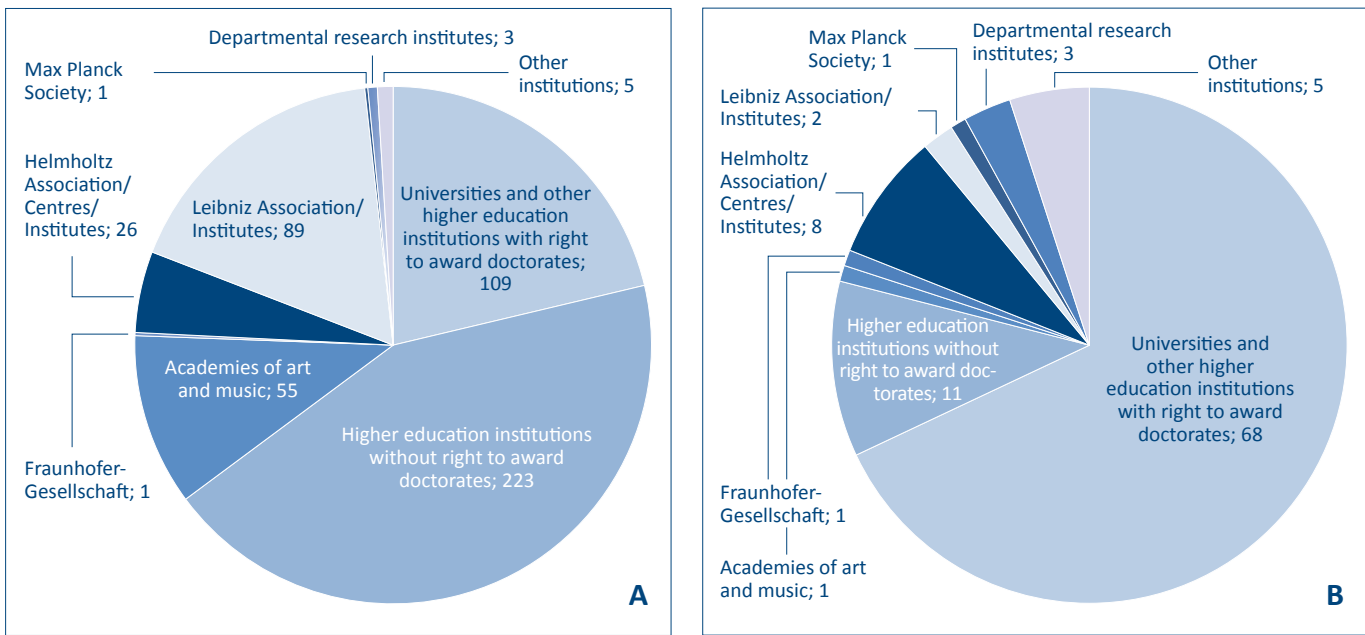


Figure 1: Contacted institutions and the named contact persons for the handling of security-relevant research. A: Number of universities, research institutes and research associations that have been contacted by the Joint Committee to inform them of the recommendations and the opportunity to register a contact person on the website of the Joint Committee (N = 512); **B:** Number of universities, research institutes and research associations that have named contact persons for handling security-relevant research (N = 100)

tact person responsible for the handling of security-relevant research at their institution. The named contact persons were then contacted by the office of the Joint Committee and requested to provide information on efforts made by their institution to implement the recommendations.

In October 2015, the Joint Committee set up a public internet platform at www.leopoldina.org/de/ausschuss-dual-use to fulfil its role as a forum for information exchange between the research institutions and to establish transparency on the implementation of the recommendations. Information on the activities of the Joint Committee is also provided on this platform. The above-mentioned contact persons were requested to register on the platform with a user account to enable them to enter information on the progress being made in setting up a KEF or comparable solution at their institution and to update this information on a regular basis. The overview page based on this information provides both policy-makers and the public with a trans-

parent list of contact persons and committees responsible for security-relevant research.¹⁵ This list is designed to make it easier for contact persons, KEFs and other interested parties to get in contact with each other and to send a clear signal to the public and political decision-makers that German universities, research institutes and research associations are intensively and consistently addressing the problems presented by the dual-use dilemma and making responsible decisions on handling such research following careful consideration and review.

In November 2015 all German universities of applied sciences, teacher training colleges, art academies and the remaining universities (319 higher education institutes in total) were contacted by the Joint Committee and informed of the recommendations and the opportunity to register a contact person on the Joint Committee's website. In December 2015, 88 Leibniz institutes received a letter with

¹⁵ This list is available at: www.leopoldina.org/nc/en/about-us/cooperations/joint-committee-dual-use/list-of-committees (last accessed: 21 September 2016).

the same information from the office of the president of the Leibniz Association. Finally, in January 2016, the Helmholtz Association, seven Helmholtz institutes and the other eight Helmholtz centres that are not members of the DFG received a similar letter from the Joint Committee.

As shown in Figures 1 and 2, 100 German universities, research institutes and research associations had responded to the request of the Joint Committee and named their contact person for the handling of security-relevant research by 1 October 2016. As things stand, 16 committees similar in nature to a KEF have been decided upon or are already established. Four research institutes and the Fraunhofer Society replied that they appoint an ad hoc committee similar to a KEF if required. Thirty-four institutions are currently discussing or already planning the establishment of a KEF. Twenty-four institutions either already have a committee that carries out the tasks of a KEF or are planning to extend the mandate of an already existing committee accordingly. Out of a further 21 contact persons, some have said that there are no plans to establish a KEF at their institution at this stage, while others have not provided any information thus far.

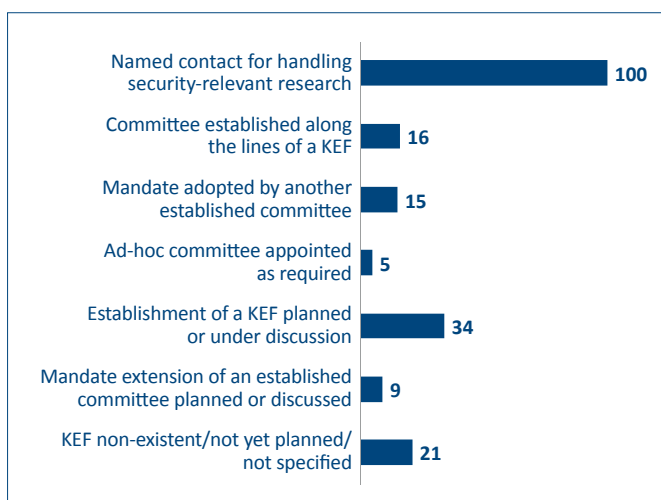


Figure 2: Responses of the contact persons. Information from the responses received by the Joint Committee by 1 October 2016 (N = 100). Further details and the current status can be found online at www.leopoldina.org/nc/de/ueber-uns/kooperationen/gemeinsamer-ausschuss-dual-use/kommissionsliste

4. Model statutes for the KEFs and a workshop on implementing the recommendations of the DFG and the Leopoldina

In order to assist German universities, research institutes and research associations with setting up KEFs and to ensure that the statutory tasks and powers of these committees are as uniform as possible, the Joint Committee drew up a set of model statutes for KEFs (see Appendix) and published these on 18 March 2016.¹⁶ The model statutes define the issues which require regulation in the view of the Joint Committee, but should then be adapted in detail to fit the respective conditions at each location. Where other committees are responsible for carrying out the tasks of a KEF, the recommendations in the model statutes apply to the work of these committees in the field of security-relevant research.

On 14 April 2016 the Joint Committee also organised a workshop¹⁷ on implementing the recommendations of the DFG and the Leopoldina, at which the model statutes were also presented and discussed. The event was directed primarily at the contact persons named by the German research institutions as responsible for the handling of security-relevant research. Additional participants included other members of staff of German universities and non-university research institutions as well as representatives from the political sphere, the press¹⁸ and industry.

¹⁶ The model statutes are also available online at: www.leopoldina.org/fileadmin/redaktion/Ueber_uns/Kooperationen/Mustersatzung_fu%CC%88r_KEFs_2016-03-18.pdf (last accessed: 21 September 2016).

¹⁷ Details about the workshop and the lecture slides of the speakers are available online at: www.leopoldina.org/de/ueber-uns/kooperationen/gemeinsamer-ausschuss-dual-use/dokumentation-infoveranstaltung (last accessed: 21 September 2016).

¹⁸ Press releases on the event are available online at: www.sueddeutsche.de/wissen/sicherheit-in-der-wissenschaft-passt-mal-schoen-auf-1.2949264 and www.tagesspiegel.de/wissen/dual-use-vorsicht-missbrauchspotenzial/13460134.html and www.aerzteblatt.de/archiv/179347 (last accessed: 21 September 2016).

In the opening lectures, the chairpersons of the Joint Committee, Bärbel Friedrich and Frank Allgöwer, explained the dual-use dilemma and the responsibilities and work of the Joint Committee. Reinhard Merkel, member of the German Ethics Council and professor for criminal law and the philosophy of law at Universität Hamburg, then spoke about the complex criteria involved in the sophisticated ethical evaluation of security-relevant research. Jochen Taupitz, professor for civil law, civil procedure law, private international law and comparative law at the University of Mannheim, and Alfons Bora, professor for technology assessment and the sociology of law at Bielefeld University, then spoke about the methodology and powers of ethics committees. Jochen Taupitz reported on “conventional” clinical ethics committees and the possibility of expanding their range of responsibilities to include security-relevant research. Alfons Bora explained the process of establishing KEFs by presenting the model statutes and by describing the special criteria for their composition and methods of advising researchers. He also emphasised the role of the committee’s annual reports to the competent academic decision-making body and the Joint Committee as proposed in the model statutes. These reports would enable the Joint Committee to fulfil its monitoring role in security-relevant research in Germany and be in a position to respond to enquiries from politics and the public.

Kathryn Nixdorff, professor for microbiology and founding member of IANUS, an interdisciplinary working group on natural science-oriented peace research at the Technische Universität Darmstadt, spoke on raising awareness in research and education of the problems associated with the dual use of research findings.

In the second half of the workshop, representatives from the Forschungszentrum Jülich (Jülich Research Centre), the

University of Bayreuth, the Universität Marburg and the Max Planck Institute for Foreign and International Criminal Law in Freiburg spoke about how their institutions handle the dual-use dilemma and reported on progress in establishing KEFs or comparable solutions. The event ended with an informal round of information exchange that gave the contact persons for security-relevant research the opportunity to talk to each other and to discuss with members of the Joint Committee.

C. Political debate on security-relevant research in Germany

In February 2015, the same month in which the Joint Committee was established, the statement of the German Ethics Council on “Biosecurity – freedom and responsibility of research” (Chapter A.2) was forwarded to the following committees of the German Bundestag: Committee on Education, Research and Technology Assessment (coordinator), Committee on Legal Affairs and Consumer Protection, Committee on Economic Affairs and Energy, Committee on Food and Agriculture, Committee on Health, and the Committee on the Environment, Nature Conservation, Building and Nuclear Safety.¹⁹ The committees subsequently received a non-public briefing from the then chairwoman of the German Ethics Council Christiane Woopen on 25 February 2015.²⁰ Members of the German Bundestag Sybille Benning (CDU/CSU), René Röspel (SPD), Nicole Gohlke (The Left Party) and Kai Gehring (Alliance 90/The Greens) served as rapporteurs.

On 30 September 2015, the Alliance 90/The Greens parliamentary group submitted a motion entitled “Improving biosecurity in high-risk research in the life sciences” (Printed Paper 18/6204²¹) to the German Bundestag. In line with the recommendations published by the German Ethics Council (Chapter A.2), the motion

called on the Federal Government to supplement the initiative of the DFG and the Leopoldina by presenting a bill to regulate “the handling of biosecurity-relevant research projects of concern” and to appoint a DURC Commission. If the DURC Commission decides against a research project, no funding is to be awarded.

Next, a public expert discussion on scientific responsibility was held as part of the session of the Committee of Education, Research and Technology Assessment in Berlin on 4 November 2015. Leopoldina President Jörg Hacker and members of the Joint Committee Stefan Becker, Lars Schaade and Jochen Taupitz were among the invited experts at the hearing.²² The other invited experts were Christian Kreiß, Professor of Finance and Economic Policy at Aalen University, and Wolf-Michael Catenhusen, former member of the German Ethics Council. Catenhusen supported the motion’s demand to implement the recommendations in the Ethics Council’s statement in order to address unforeseeable risks in life sciences research. The experts from the Joint Committee described the particular difficulties involved in solving the dual-use dilemma inherent to all areas of research through legal provisions that do not excessively restrict freedom of research. They presented the DFG-Leopoldina initiative and the activities of the Joint Committee as an alternative solution for efficiently minimising research risks through awareness-raising,

¹⁹ See Plenary Minutes 18/85, pp. 8068–8069. Available at: <http://dipbt.bundestag.de/doc/btp/18/18085.pdf> (last accessed: 21 September 2016).

²⁰ See agenda for the 24th session of the Committee on Education, Research and Technology Assessment. Available at: www.bundestag.de/blob/361100/b3579d-f03f97a9c847fde1463dfafc31/to_24--sitzung-data.pdf (last accessed: 21 September 2016).

²¹ Available at: <http://dip21.bundestag.de/dip21/btd/18/062/1806204.pdf> (last accessed: 21 September 2016).

²² The experts’ written statements and further information about the discussion are available at: www.bundestag.de/bundestag/ausschuesse18/a18/fg-wissenschaftl-verantwortung/393616 (last accessed: 21 September 2016).

on-site consultations, and self-governance on the part of scientists.

The Members of the Bundestag were impressed by the scientific community's unexpectedly fast reaction to the debate surrounding the dual-use dilemma and very interested in the measures it had taken, such as the DFG-Leopoldina code of conduct, the establishment of the Joint Committee, the numerous contact partners provided for questions on handling security-relevant research, and the already appointed or planned Committees for Ethics in Security-Relevant Research (KEFs).

About six months later, a debate was held during the German Bundestag session of 9 June 2016 on the Committee of Education, Research and Technology Assessment's Recommendation for a Decision on the motion tabled by the Alliance 90/The Greens parliamentary group.²³

Kai Gehring (Alliance 90/The Greens) declared the following in his speech: “[...] The joint DFG-Leopoldina committee was founded in 2015. We believe the main weaknesses of this construct lie in the fact that it remains non-binding. It is too unspecific for high-risk research, and the code of conduct is not tailored to biosecurity. We therefore regard a voluntary agreement to be insufficient [...]”

Ralph Lenkert (The Left Party) said: “[...] The Bundestag has to consider both the opportunities and risks of synthetic biology. It makes sense to implement the Ethics Council's recommendation for a bioethics code for scientists and introduce an advisory body for risk-benefit analyses [...]. Linking public funding to consultation obligations is not enough. All research in this area has to meet bioethics requirements, otherwise it cannot go ahead [...]”

Stephan Albani (CDU) remarked: “[...] We can see that the scientific research community is very aware of its responsibility and was quick to address this important topic [...]. We support the research community's chosen path involving the key elements of the Committee for Ethics and Research and the Joint Committee on the Handling of Security-Relevant Research. We will continue to pursue this path. We think this is the best way: a voluntary agreement from the scientific community without over-regulation or additional laws [...]”

René Rösper (SPD) continued: “[...] In my opinion, we need to take the approach that the scientists themselves have to be responsible for what they can do and what they are allowed to do. That is the approach we and German research organisations are working with [...]. We will be observing exactly what happens over a period of one to two years – also with support from the Federal Government. If it turns out that German scientists and the responsible researchers are not in a position to act accordingly, we will have to talk about establishing a relevant commission. But that would be the worst and least favourable path to take, which we should perhaps discuss as an emergency solution in one to two years' time [...]”

Sybille Benning (CDU/CSU) rounded off the debate with the following statements: “[...] The DFG and Leopoldina have established a Joint Committee, which, according to my count, has addressed more than 90 research institutes. There are model statutes that the institutes can refer to if they establish their own Committees for Ethics in Security-Relevant Research [...]. A process of scientific self-governance has thus been launched with the goal of creating stable structures for handling security-relevant research in all German research institutes by 2017. Of course, we will then have to assess the extent to which this large and important project has

²³ See Plenary Minutes 18/176, pp. 17424-17429. Available at: <http://dip21.bundestag.de/dip21/btp/18/18176.pdf> (last accessed: 21 September 2016).

been successfully implemented, and draw conclusions from it [...].”

Finally, during the Bundestag session, the committee’s Recommendation for a Decision to reject the Alliance 90/The Greens’ motion on “Improving biosecurity in high-risk research in the life sciences” was approved after the CDU/CSU and the SPD voted in favour, the Alliance 90/The Greens parliamentary group voted against, and the Left Party abstained.

D. Further development of the Joint Committee

In order to adequately perform the tasks outlined in the previous chapters, the Joint Committee will further expand its office. The committee anticipates that by the end of 2017 at least 100 Committees for Ethics in Security-Relevant Research (KEFs) or comparable solutions will have been established at universities, research institutes and research societies across Germany. In accordance with the model statutes for KEFs (see Appendix), they are obliged to submit an annual report on their activities to their academic decision-making body, e.g. the senate, and to the Joint Committee. The Joint Committee will analyse this information, especially the cases investigated, and publish its findings in appropriately anonymous form in annual final reports.

The Joint Committee will also continue to maintain and expand its internet platform (see Chapter B.3). The website is to serve as a source of information for researchers trying to find suitable contact partners and KEFs that already have relevant experience in specific research areas. In the future, the website should also provide information on potentially high-risk research areas, events about relevant topics and other activities.

One of the main challenges facing the Joint Committee is the task of continuously and sustainably promoting awareness-raising and thus contributing to detecting and minimising research risks, since awareness-raising cannot be administratively prescribed. The committee will therefore focus on monitoring awareness-raising and integrating relevant content into university teaching pro-

grammes. Given that young scientists are profoundly influenced by their training, further anchoring the dual use topic in the teaching content and curricula of all relevant university degree courses will be an important step in the right direction. The Joint Committee will assess how much assistance it will be able to provide in this respect. Besides the aforementioned regular events on the topic of scientific freedom and scientific responsibility, the Joint Committee may in the future also compile and provide resources to support relevant content in teaching.

The Joint Committee will also be on hand to support the KEFs should they fail to reach a decision independently on controversial research projects. In these cases, the Joint Committee can, for example, provide contacts to suitable experts or advise the Leopoldina Presidium to set up an ad-hoc working group. Following a detailed risk-benefit analysis of the project and due consideration of the research area involved, the working group will submit recommendations on how to proceed. As outlined in Chapter C, policymakers will continue to observe the self-governing approach taken by scientists in dealing with the risks of free research and review the further development of the Joint Committee and the KEFs.

E. Appendix

Model statutes for Committees for Ethics in Security-Relevant Research

Preliminary remarks

The following model statutes are designed to aid the establishment of Committees for Ethics in Security-Relevant Research (KEFs) at German universities, research institutes and research associations. They are based on the recommendations²⁴ of the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) and the German National Academy of Sciences Leopoldina and were compiled by their Joint Committee on the Handling of Security-Relevant Research. The model statutes set out the issues which, in the opinion of the Joint Committee, require regulation. The details should then be adapted to fit the specific conditions at the individual institution. In cases where a university, research institute or research association has entrusted a different committee with the tasks of a KEF, the following recommendations apply to this committee's work regarding security-relevant research.

Section 1 Committee for Ethics in Security-Relevant Research

The university/institute/association hereby establishes a Committee for Ethics in Security-Relevant Research (KEF).

Section 2 Responsibilities and foundations of the work of the KEF

- (1) The KEF supports efforts to balance scientific freedom and responsibility by providing advice and an evaluation of the ethical and legal aspects of security-relevant research as specified in Section 6.1. The committee also works to raise awareness within the university/institute/association [Name] of aspects of security-relevant research.
- (2) Where the security-relevant project within or outside of the university/institute/association [Name] could lie within the competence of a different committee and the division of competences has not been clearly regulated, the KEF shall communicate with the other committee; the two committees shall then reach agreement on their respective scope of competence.
- (3) Researchers remain responsible for their actions irrespective of the advisory services provided by the KEF.
- (4) The KEF shall work on the basis of the current law, prevailing scientific standards and the respective professional rules of practice. The committee shall observe the relevant national and international recommendations and base its work on the current level of science and technology.
- (5) The following provisions shall apply subject to a different ruling due to higher-ranking law.

²⁴ The paper "Scientific Freedom and Scientific Responsibility – Recommendations for Handling Security-Relevant Research" is available at: www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG_Leopoldina_Wissenschaftsfreiheit_-verantwortung_bilingual.pdf.

Section 3 Composition and members

- (1) The KEF shall comprise a minimum of [five] members from different scientific disciplines and an adequate (at least equal) number of deputy members. The committee members shall have experience in research and in the evaluation of ethical issues in science.
- (2) The members of the KEF and their deputy members shall be appointed by [the competent academic decision-making body, e.g. the senate] of the university/institute/association [Name] for a period of [four] years. Members may be reappointed.
- (3) The chair of the KEF and an adequate number of deputy chairs shall be appointed by the KEF members from among themselves. The members of the KEF shall determine the number and ranking of deputies at the election.
- (4) Each member may leave the committee at their own request and without stating reasons. All committee members, including the chair, may be dismissed from the committee by [the competent academic decision-making body, e.g. the senate] for good cause. The member shall be heard beforehand. The decision shall be communicated in writing and state the reasons for the dismissal. A new member may be appointed to the committee for the duration of the dismissed member's remaining term of office.
- (5) The names of the members of the committee shall be published.

Section 4 Legal status of the KEF and its members

- (1) The KEF and its members shall be independent and not bound by instructions in the exercise of their duties. They shall exercise their best knowledge and judgement.
- (2) The members of the KEF shall not be held personally liable for the work they do for the committee.
- (3) The KEF shall report on its work once a year, in appropriate anonymised form

where necessary, to [the competent academic decision-making body, e.g. the senate] and the Joint Committee on the Handling of Security-Relevant Research of the DFG and the German National Academy of Sciences Leopoldina (hereinafter: Joint Committee).

Section 5 Management

The committee's current business is conducted by the chair. The chair shall be provided with the personnel and administrative resources he/she requires to conduct the committee's administrative work.

Section 6 Initiating proceedings

- (1) Members of the university/institute/association [Name] shall consult the KEF before conducting a research project where such research project is associated with considerable security-relevant risks for human dignity, human life, health, freedom, property, the environment and peaceful coexistence. Security-relevant risks arise in particular in research which will foreseeably produce knowledge, products and/or technology that could be directly misused by third parties. The same applies where such security-relevant risks only become evident during the course of a research project.
- (2) The KEF shall become active at the written request of a member of the university/institute/association [Name] – referred to as “applicant” in the following.
- (3) The applicant may change or retract his/her application.
- (4) The application shall comprise of a short project summary that is comprehensible to non-specialists and a detailed statement of the security-relevant aspects of the project. A declaration shall be enclosed with the application stating any other applications that have been made previously or in parallel with the same or similar content along with the outcome of any such applications

- (5) The KEF can also act on information provided by third parties about security-relevant research. Such information shall also be treated as confidential as set out in Section 7.2. The committee is not obliged to investigate anonymous information. The committee is also responsible for conducting a security assessment if such an assessment by an ethics committee is required for legal reasons.

Section 7 Proceedings

- (1) The chair convenes the KEF and sets the time and place of the meeting. The chair convenes the KEF as often as required by current business and at least once a year. The chair shall give notice of invitation at least 14 days prior to the meeting, unless this notice of invitation has been shortened in agreement with all members. The chair opens, leads and closes the meetings of the KEF.
- (2) The KEF meetings are not open to the public. Committee members are bound to secrecy. The same applies to experts, aides and persons who provide administrative support to the KEF.
- (3) The applicant has the right to submit a written statement at all times and to view the opinions and statements gathered by the committee. The applicant can be heard by the KEF in advance of the written statement; if requested by the applicant, then he/she shall be heard. The KEF can also hear other persons participating in the research project.
- (4) The KEF shall generally come to a decision following an oral discussion. Decisions by written circular are permissible unless this contravenes any legal provisions or is rejected by a committee member.
- (5) The KEF can consult experts from relevant specialist areas and obtain expert reports. The KEF can request supplementary documentation, de-

tails or explanations from the applicant and other parties concerned, also in preparation of its decision. The applicant can also involve experts selected by him/her. Members of the university/institute/association [Name] are obliged to provide the KEF with correct information and grant it access to the relevant documentation. The grounds for refusing to testify and denying the provision of information apply in accordance with the German Code of Criminal Procedure. The legitimate interests of informants shall be protected to the extent possible in a fair proceeding. Their names shall only be disclosed if an affected party cannot defend themselves otherwise or if the credibility of the whistle blower needs to be reviewed.

- (6) The KEF can request consultation by the Joint Committee in cases of fundamental importance. Its request for consultation shall be submitted with a substantiated assessment of its own.
- (7) The outcome of the KEF meetings shall be recorded in minutes.

Section 8 Decision-making procedure

- (1) The KEF shall pass a decision, subject to further legal requirements, that it has consulted on the security-relevant risks of the respective research project. Within the scope of its competence, the committee shall pass judgement on the extent to which, in its opinion, it considers the implementation of the research project, possibly with modifications and requirements, e.g. to minimise risks, which seem legally and ethically justifiable.
- (2) At least [three] of the KEF members must be involved in making a decision. Members who are participating in the respective research project, or whose interests are affected by it to the extent that there is an apprehension of bias are excluded from the discussion and decision-making procedure.

- (3) The KEF shall strive to reach consensus on its respective decisions. If it fails to reach consensus then decisions are made by majority vote. Abstentions from voting are regarded as a rejection of the project. In case of a tied vote, the chair shall have the casting vote.
- (4) Each member of the KEF can submit a dissenting opinion. This shall be attached to the decision.
- (5) In certain cases that should be set out in detail, the KEF can authorise its chair to take a decision alone, or possibly by including a further member. In such cases, the chair shall inform the committee about the decision as soon as possible.
- (6) The decision of the KEF shall be communicated to the applicant in writing, including any dissenting opinions. Negative decisions and recommendations to amend the research project shall be communicated with a statement of the reasons for the decision/recommendations. The chair shall inform the [competent academic decision-making body, e.g. the senate] of all decisions.

Section 9 Notification of unexpected risks and security-relevant aspects

- (1) The chair shall be informed without delay of all serious and/or unexpected risks that become evident during the course of the research project and that could affect the level and objects of protection set out in Section 6.1.
- (2) In this event, the KEF may revoke its positive evaluation in whole or in part or recommend further amendments to the research project. The applicant shall be given the opportunity to comment on the decision.

Section 10 Fees/remuneration and compensation

- (1) No fees shall be charged for the review and consultation of research projects.
- (2) The work as a committee member is part of the official duties of members

of the university/organisation. Members do not receive any compensation for this work.

Section 11 Concluding provisions

- (1) The KEF may establish its own rules of procedure. The rules of procedure can, among other things, set out requirements for an application. The [Administrative Procedures Act] and the [Higher Education Act] of the state [name] shall apply on a supplementary basis.
- (2) These statutes enter into effect on the day after their publication in the [official records].

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