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Synthetic Biology & Biosecurity Awareness In Europe

Dr. Alexander Kelle

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Dr. Alexander Kelle
Department of European Studies and Modern Languages
University of Bath
a.kelle@bath.ac.uk

and

IDC Vienna
alexander.kelle@idialog.eu

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Organisation for International Dialogue and Conflict Management (IDC)
Vienna, Austria
http://www.idialog.eu

Department of European Studies and Modern Languages
University of Bath

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Author: Alexander Kelle
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Safety and Ethical Aspects of Synthetic Biology (Synbiosafe)
EU FP6 Project, coordinated by IDC
http://www.synbiosafe.eu

Table of contents:

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1. Introduction

As a NEST High-Level Expert Group pointed out in 2005, synthetic biology, i.e. "the synthesis of complex, biologically based (or inspired) systems which display functions that do not exist in nature … is a field with enormous scope and potential."[1]
Some of the areas where synthetic biology according to the NEST report could have a major impact include biomedicine, a sustainable chemical industry, environment and energy, and biomaterials. However, the report also acknowledges that "[m]uch of the research so far has been pioneered by individual groups in the US, and the European research community has been slow to embrace the field."[2]
If the emerging discipline of synthetic biology can deliver on its promises and become as pervasive as computing has become in the past few decades, we might very well be witnessing a similarly fundamental shift as the one that happened to chemistry with the introduction of the periodic table. Biology ultimately may also become a mechanistic science.

The ability to understand, modify, and ultimately create new life at the molecular level clearly represents a scientific paradigm shift. One problem with similar breakthroughs in the past has been their misuse for offensive military purposes. As Dando has demonstrated, several generations of state biological warfare programs during the 20th century regularly utilized major scientific developments in biology and medicine:

„What we can see over the last century is a continuous process of military programs developing on the back of growth in scientific knowledge. There have been three generations of offensive biological warfare programs this century: the simple sabotage campaigns of the First World War; the major-state programs of the middle years of the century; and the Soviet program following the agreement of the BTWC, where the use of genetic engineering was significant."[3]

A brief look into two specific applications of major impact expected from synthetic biology as described in the above mentioned NEST report – smart drugs, and vectors for therapy – should suffice to illustrate the quantum leap in biological warfare or bioterrorist capabilities that may result from advances in synthetic biology. According to the NEST report, "[a] smart drug includes a diagnostic module that … is capable of directly sensing of molecular disease indicators … it will only become active in cells affected by disease."[4]

1 Synthetic Biology. Applying Engineering to Biology, Report of a NEST High-Level Expert Group, Brussels: European Commission, 2005, p.5.
2 Ibid.
3 Malcolm R. Dando, 'The Impact of the Development of Modern Biology and Medicine on the Evolution of Offensive Biological Warfare Programs in the Twentieth Century', in Defense Analysis, 15(1), 1999, p.51.
4 Synthetic Biology. Applying Engineering to Biology, p.14

The misuse potential of such smart drug technology is obvious: if the sensing mechanism were programmed to detect other, not disease related, indicators and/or the activated chemical compound either were to harm, not cure, or would simply be administered in the wrong dosage, considerable harm could be done with such a device.
Similarly, it is conceivable that newly designed or modified viral vectors that can "deliver healthy genes to the target tissue" or that "can recognize specific cells and target them for destruction"[5] could be easily diverted from their intended benign use to malign applications that would for example aim at delivering pathogenic genes or target not cancer, but nerve or other essential cells.
Although the risks for misuse inherent in synthetic biology are briefly discussed in the above mentioned NEST report[6], it is clear that a thorough analysis and discussion of the misuse potential of synthetic biology for bioterrorist, or offensive military purposes has not taken place. In parallel to the focus of activities in synthetic biology in general, which have been concentrated in the United States, most of the discourse on preventing the misuse of this new field of scientific inquiry also originated there.
In 2004 for example George Church put forward "A Synthetic Biohazard Non-proliferation Proposal" to address some of the biosecurity concerns of synthetic biology.[7]
Since then, the debate on the biosecurity implications of synthetic biology has made some progress, again most notably in the US.[8]
What is needed to develop a similarly lively debate in Europe on these topics is first of all an increased awareness of the dual-use character of their work and the corresponding biosecurity implications on the part of European practitioners in synthetic biology. But what is their level of awareness in the first place? To find an answer to this question is one of the main goals of this study.

In order to accomplish this goal, this report will consist of four sections: the first section will provide some background/context to the analysis of biosecurity awareness of practicing synthetic biologists in Europe by focussing on biosecurity and other regulations applicable to the life sciences and biotechnology sector in Europe. The second section will provide an overview of biosecurity-related activities during SB3.0, mostly focussing on the panel on societal issues which was convened during the second day of the conference. The third section will provide an analysis of 20 interviews which were begun in the run-up to SB3.0 and continued since. The last part will then look at possible future regulatory environments for synthetic biology in Europe, again taking into account responses received during the interviews.

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5 Idem.
6 Ibid, pp.18f.7
7 George Church, A Synthetic Biohazard Nonproliferation Proposal, 18 June 2004, available at http://arep.med.harvard.edu/SBP/Church_Biohazard04c.htm
8 Some of the key developments in this unfolding discourse will be discussed in section 3 below.

2. Biosecurity and other regulations applicable to synthetic biology in Europe

The most fundamental and wide-reaching regulatory instrument to prevent the misuse of biology is the 1972 Biological and Toxin Weapons Convention (BWC), which in Article I prohibits states parties 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 …"[9]

Ever since the entry into force of the BWC in 1975 its states parties – which include all European states – have reaffirmed during the quinquennial Review Conferences that new scientific and technological developments of relevance to the treaty are covered by the scope of Article I.[10] For example, the final declaration the most recent Review Conference in 2006 reaffirmed that "Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the Convention."[11]

According to Article IV of the BWC each state party is under an obligation to implement all aspects of the BWC "within the territory of such State, under its jurisdiction or under its control anywhere". Because there is no international organisation available to oversee BWC implementation and there is no reporting requirement contained in the BWC, up until recently it was difficult to establish to what extent states parties actually lived up to this obligation. However, United Nations Security Council Resolution 1540 of April 2004 required all UN member states to report to a committee of the Council on their actions to

"adopt and enforce appropriate effective laws which prohibit any non-State actor to manufacture, acquire, possess, develop, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, in particular for terrorist purposes, as well as attempts to engage in any of the foregoing activities, participate in them as an accomplice, assist or finance them".[12]

9 Synthetic Biology. Applying Engineering to Biology, Report of a NEST High-Level Expert Group, Brussels: European Commission, 2005, p.5.

10 See Alexander Kelle/Kathryn Nixdorff/Malcolm Dando, Controlling Biochemical Weapons. Adapting Multilateral Arms Control for the 21st Century, Basingstoke: Palgrave Macmillan, especially chapter 3.

11 Sixth Review Conference of the States Parties to the BWC, Final Document, Geneva: United Nations, document BWC/CONF.VI/6, p.9, available at www.opbw.org

12 For details see the website of the so-called 1540-Committee at http://disarmament2.un.org/Committee1540/

The national reports and concomitant legislative database established by the 1540 Committee provide an excellent overview of the extent and density of rules and regulations applicable across Europe.[13]

A further source of stipulations to prevent the misuse of dual-use technologies and material stems from Australia Group Lists and Guidelines and corresponding EU Regulations. The Australia Group was established in 1984 in response to the realisation that exports of dual-use goods had substantially contributed to the Iraqi chemical weapons program and its subsequent use against Iranian troops.

Export controls were thus initially applied to chemical dual-use materials and technologies, but later – in 1990 – expanded to cover biological dual-use items as well.
Since its inception the Australia Group has grown from 15 to over 30 states participating in its activities and the scope of controlled items has equally expanded. The activities of its members are now informed by six control lists and a set of guidelines.[14] Of particular relevance here is that the "List of Biological Agents for Export Control" also covers genetic elements and genetically-modified organisms, in particular:

"1. Genetic elements that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in the list.

2. Genetic elements that contain nucleic acid sequences coding for any of the toxins in the list, or for their sub-units.

3. Genetically-modified organisms that contain nucleic acid sequencesassociated with the pathogenicity of any of the microorganisms in the list.

4. Genetically-modified organisms that contain nucleic acid sequences coding for any of the toxins in the list or for their sub-units."

13 Both national reports and the legislative database, the latter of which contains numerous links to national laws and regulations are available on the 1540-Committee webpage.

14 See www.australiagroup.net for more details.

The Australia Group Guidelines and Lists are supplemented on EU level by Council Regulation (EC) No. 1334/2000 creating a Community regime for the control of exports of dual-use items and technology[15] , and subsequent Council regulations which amend and update this regional export control regime.[16] The purpose of these regulations – which automatically acquire the power of law in member states – is "to prevent competing national systems causing trade problems, to prevent the encouragement of laxity for economic benefit and to allow dual-use items to move freely inside the internal market."[17]

In addition to these security related international instruments, the regulatory environment for synthetic biology in Europe is also influenced by other international agreements such as:

• the 1992 Biodiversity Convention that requires countries to regulate the use and release into the environment of genetically modified organisms that could have an adverse impact on biodiversity;[18]

• the 1995 UNEP Technical Guidelines for Safety in Biotechnology, which point to the need of effective oversight of activities involving organisms with novel traits;[19]

• and the 2004 WHO Laboratory Biosafety Manual, which in its latest edition contains a short section on laboratory biosecurity measures.[20]

In sum, there is a wide variety of international governance structures available to inform the EU-wide or national regulation of the life sciences in order to prevent their misuse. However, it appears that only in the area of export controls a coherent and systematic body of rules and regulations has been set up. Otherwise, as evidenced by the national submissions to the 1540 Committee of the United Nations Security Council, regulations on biological weapons prohibition and bioterrorism seem to exist largely unconnected to rules for the conduct of genetic engineering and biotechnology research and applications.[21] A greater degree of integration seems advisable in order to prevent at all levels the misuse of synthetic biology for hostile purposes.

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15 See Official Journal of the European Communities, Vol.43, 30 June 2000, pp.216f., available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2000/l_159/l_15920000630en02160217.pdf

16 These are Council Regulation (EC) No. 149/2003, available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_030/l_03020030205en00010215.pdf
Council Regulation (EC) No 1504/2004 of 19 July 2004, available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_281/l_28120040831en00010225.pdf;
Council Regulation (EC) No 394/2006 of 27 February 2006, available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_074/l_07420060313en00010227.pdf

17 Genomics Gateway at http://www.brad.ac.uk/acad/sbtwc/gateway/europe/misuse/dual_use.htm

18 See www.biodiv.org for details.

19 See http://www.biosafetyprotocol.be/UNEPGuid/Contents.html for details.

20 See http://whqlibdoc.who.int/publications/2004/9241546506_partII.pdf for details.

21 See http://disarmament2.un.org/Committee1540/report.html.

3. Biosecurity-related issues during SB3.0

The biosecurity-related activities during SB 3.0 were mostly revolving around the panel session on “Biosafety and Biosecurity, Public Perception” during the morning of the second day of the conference.[22]

In his introductory presentation on “Framing the Safety and Security Aspects of Synthetic Biology”, Markus Schmidt, IDC, was setting the scene not only for this panel, but also parts of the later one on Ethical Issues by alluding to the fact that in many languages only one word is used to capture the meaning of both “biosafety” and “biosecurity”. Drawing on definitions put forward by the World Health Organisation he emphasised the element of intentionality to distinguish the two concepts. While biosafety measures aim to prevent the unintentional exposure to pathogens and toxins, or their accidental release, biosecurity measures focus on the prevention of theft, misuse, or intentional release of pathogens and toxins.[23]

In analogy to the rights management for certain computer software Schmidt raised the question whether access to the products of synthetic genomics might be structured in a similar way. In such a scheme “read” operations, i.e. accessing published knowledge, would be least restricted, “write” operations, such as DNA synthesis and screening, would be controlled somewhat more tightly and “execute” operations, like the booting of a cell with synthetic DNA, would face the most severe restrictions.

Addressing different options for countering the intentional misuse of synthetic biology, Schmidt pointed to their dependency on the risk perception involved and alluded to differences in this respect between the US and Europe, with the risk of bioterrorist attacks being judged as more likely in the former. This has led to a higher level of institutional responses in the US, ranging from the creation of the Department of Homeland Security and the National Science Advisory Board for Biosecurity to community based initiatives such as the work carried out by a consortium including the MIT, CSIS and the J Craig Venter Institute (see below) in order to counter this perceived threat. In contrast to the focus on biosecurity in the US, Schmidt expressed the expectation that a European debate on the implications of synthetic biology would focus more on biosafety, bioethical, intellectual property rights (IPR) and less on biosecurity issues.

22 See http://www.syntheticbiology3.ethz.ch/monday.htm

23 For a comparable distinction made in a working paper submitted to the Sixth Review Conference of the Biological Weapons Convention see Biosafety and Biosecurity. Submitted by Germany on Behalf of the European Union. Document BWC/VI/WP.2, Geneva, 20 October 2006, available at www.opbw.org .

From this he concluded that a "global common technology assessment is hardly in sight"[24] and, one might add, a continued dialogue is urgently needed to bridge a potential transatlantic divide.

The following presentation by Michele Garfinkel of the J Craig Venter Institute discussed the draft report 'Synthetic Genomics: Options for Governance' which, besides a focus on biosecurity issues, i.e. the nefarious application and bioterrorist use of the broad array of new capabilities provided by synthetic genomics, also does address environmental and biosafety risks.
Garfinkel stressed that the aim of the report is to offer options to policy makers, not recommendations. The most effective intervention point for preventing the misuse of synthetic genomics identified by the authors of the report is at the level of DNA synthesis itself, i.e. gene synthesis firms, oligonucleotide manufacturers and DNA synthesizers.

Thus, policy options discussed were from a biosecurity point of view assessed in terms of their usefulness in preventing incidents of bioterrorism or by helping to respond to such incidents after they had occurred.
For both gene foundries and oligo manufacturers the authors of the report concluded that a combination of screening orders by companies and the certification of orders by a biosafety/biosecurity officer provide the greatest benefits in terms of preventing incidents.
For helping to respond after an incident had occurred, the storage of order information by firms was regarded as the most useful tool.
Finally, with a view to equipment such as DNA synthesizers, the report concluded that the licensing of both equipment and for the purchase of reagents was best suited to enhance biosecurity by contributing to the prevention of incidents.

Taking a step back from the more focussed concerns of the previous speaker about the benefits and risks of synthetic genomics, Joyce Tait from the University of Edinburgh addressed issues surrounding "Policy, Public and Science Interactions".

Starting from the question of how innovative technologies in general get developed, with a view to synthetic biology she quickly moved on to the issue of how SB should be framed for public consumption, so as to increase levels of acceptance by the public.
From her point of view, however, the SB community was still in a process of framing the issues for themselves.

Therefore, science strategies to ensure public acceptance aren't far developed at this point in time.

24 Markus Schmidt, 'Framing the Safety and Security Aspects of Synthetic Biology' in SB3.0 Conference Proceedings, Zurich, 2007, p.31.

Because of the likelihood of activists who want to impede new technologies getting involved before technology-supporting groups, Tait also questioned the conventional wisdom that early public involvement automatically generates higher levels of public acceptance for innovative technologies. Instead she suggested to rely on the conditioning effects of expert framing of the issues before the public involvement process is started.
This, in Tait's view requires inter alia to make the science work, develop marketable products, create positive market expectations, engage with public stakeholders, develop regulatory systems and cooperate in all these areas internationally. All these steps will enable the SB community to "be ready with effective responses to the emergence of unexpected risks or to illegal behaviour by rogue developers".[25]

This latter concern was then taken up by the following speakers, Gautam Mukunda of the MIT and Scott Mohr of Boston University, who presented a paper on the "Biosecurity Implications of DNA Synthesis and Synthetic Biology".
Their paper was focussing on the differentials introduced by DNA synthesis and Synthetic Biology over genetic engineering in general, and distinguished between three different time frames of up to five years (short term), between 5 and 10 years (medium term) and over 10 years (long term).

For the short term Mukunda and Mohr expected few security implications of available synthetic biology knowledge and tools. For the medium term they pointed not only to risks but also potential defensive benefits of synthetic biology advances that might lead to better biosensors, the identification of new drug targets, and the streamlined production of vaccines and therapeutics.
However, they cautioned that the utility of SB advances might be higher to a potential attacker for whom it might be easier to obtain natural agents or to engineer novel pathogens. Mukunda and Mohr further pointed out that alongside the development of new knowledge, part of the SB research agenda was the diffusion of capabilities and the concomitant "de-skilling" of the manipulation of living organisms.

This, they cautioned, could allow a larger group of scientists to turn a pathogen into a weapon. In addition, they saw the norm against BW coming under increasing threat: first, SB might make biological warfare agents more predictable and controllable and thereby increase the temptation to use them; second, an increase in the threat perception may lead more states to undertake aggressive defensive BW programmes.

25 Joyce Tait, 'Riding a Roller-Coaster: Policy Public and Science Interactions in Synthetic Biology, in SB3.0 proceedings, p.34.

Such activities can be expected to be difficult to distinguish for outside observers, which in turn might then feel forced to embark on extensive defensive BW programmes.
In order to counter the potential negative biosecurity implications of SB, Mukunda and Mohr put forward three policy proposals: first, they proposed a surveillance regime, the details of which would be dependent on the degree of centralization of DNA synthesis.
They secondly advocated the strengthening of norms against BW through both community and policy responses and finally recommended to pursue defensive opportunities provided by SB to the fullest extent possible.

The final presentation of the panel was contributed by Ralf Wagner, Geneart AG, on “Insights into Control Mechanisms on Worldwide Distribution of Synthetic DNA from an Industrial Perspective”. In his presentation he elaborated on the existing regulatory network to control the distribution of synthetic DNA.
This regulatory network is, according to Wagner, composed of three elements: biosafety regulations provide guidelines for the production of genetically modified organisms; biosecurity measures as mandated by export controls and customs regulations; corporate ethics, according to which not everything that can be done should be done.
On the basis of these measures orders are routinely checked (1) against the so-called Hadex exclusion list naming customers that are prevented from receiving dual-use goods, (2) against a country exclusion list for the shipping of dual-use goods, and (3) for the nature of the requested sequence (virulence factors).
With a view to improvements of the current system, Wagner suggested drawing up a “white list” of institutions and companies for which the processing of orders could be simplified, developing a list of pathogenicity and virulence factor associated genes and making the use of screening software, such as the one developed by the International Consortium for Polynucleotide Synthesis (ICPS) mandatory as an industry standard to be applied by all DNA manufacturers. In conclusion, he advocated to leave the screening responsibility to manufacturers who should in case of suspicious orders contact government authorities.

Overall, the panel provided an excellent overview across the three dimensions to be covered: biosafety, biosecurity and public perception. Not only covered the presentations – and subsequent discussion – a broad range of issues from ensuring public support for innovative technologies to detailed proposals for increasing biosafety and biosecurity of synthetic biology technologies and potential applications, but also brought together rather abstract and conceptual papers with reports based on first hand experience of practitioners in the field of DNA synthesis.

Biosecurity issues also featured during the afternoon roundtable on bioethics, mostly through the contribution of Malcolm Dando, from the Department of Peace Studies at Bradford University. Dando started his intervention with the statement that biologists and security analysts inhabit parallel universes.

While security analysts have increasingly become concerned with the dual-use nature and misuse potential of biology and the life sciences, researchers in these areas usually do not share such concerns. Drawing on the history of misuse of progress in the life sciences during the 20th century[26] , Dando raised the question whether misuse of the current revolution in the life sciences, in which the development of synthetic biology takes a prominent place, can be prevented.

Based on responses from 1,600 life scientists during 60 seminars in 8 countries Dando concluded that while this might be a theoretical possibility, attitudes and awareness of life scientists pointed clearly to a repetition of the misuse pattern of the past century.

Life scientists, according to Dando, do not share the threat perception widespread among biosecurity experts concerning bioterrorism or biological warfare.

They don’t think that their own work might contribute to the threat. Life scientists have practically no knowledge of debates within and concerns of the security community and they have no knowledge of legally binding international regulatory instruments, such as the Biological Weapons Convention (BWC).

At the same time, Dando reported, political momentum was increasing to come to terms with the dual-use nature of the life sciences on the national and international levels. Resolutions 1540 and 1673 of the United Nations Security Council and the deliberations of the states parties to the BWC with respect to the national implementation of their treaty obligations were only the most visible manifestations of this trend. Synthetic biologists should not assume that those in charge of drawing up laws and regulations would necessarily have the interests of the scientific community in mind.

It is from Dando’s point of view therefore imperative that life scientists get involved in this process and help identify intervention points if not only the misuse potential of legitimate and benign work is to be minimised, but also favourable framework conditions for such benign work to be maintained.

26 Malcolm R. Dando, ‘The Impact of the Development of Modern Biology and Medicine on the Evolution of Offensive Biological Warfare Programs in the Twentieth Century’, in Defense Analysis, Vol.15, No.1, 1999, pp.43-62.

4. Biosecurity awareness among European synthetic biology practitioners

One of the key pre-requisites of any degree of involvement is, of course, a certain level of awareness of biosecurity issues on part of the synthetic biology community. In order to assess this level of awareness, 18 leading European SB practitioners have been interviewed between June and October 2007.

More specifically, the interviews set out to investigate the awareness of European synthetic biologists of dual-use issues and proposals in relation to:

• The seven categories of problematic experiments, as defined by the so-called Fink Committee of the US National Academies of Sciences (NAS) and the Committee's recommendations;

• The work of the so-called Lemon-Relman Committee of the NAS, especially the 2nd of its recommendations which calls for the adoption of a broader view of the threat spectrum;

• The Declaration of the Second International Meeting on Synthetic Biology, Berkeley, 20-22 May 2006;

• The CSIS-MIT-Venter draft report on the regulation of synthetic genomics;

• Activities of the NSABB in the US, with particular emphasis on the work of its SB working group;

• The University of Maryland project on Controlling Dangerous Pathogens, which advocates a protective oversight system for biotechnology. These manifestations of an increasingly active dicourse on security implications of the life sciences have been selected for their importance in advancing the debate and understanding of the dual-use risks inherent in the revolution in the life sciences in general or with respect to synthetic biology in particular, for the proposed solutions to the identified biosecurity issues, or for both of these reasons. In short, they are the key markers in the emergent biosecurity discourse, which has so far been shaped and led predominantly in the US.

4.1. The Fink Committee and its recommendations.

The work of the Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, chaired by Gerald R. Fink – hence called the Fink Committee – was a reaction to increasing concerns in the US that research in the life sciences might be misused for bioterrorist or biowarfare purposes. These concerns, in turn were fuelled by a number of experiments that triggered substantial debate about the advisability of such research. Whether it should be carried out, or, if carried out, its results should be published. In particular three experiments gave rise to such debates:

• unintentionally potentiating the virulence of the mousepox virus through inserting an IL-4 gene into the mousepox genome.[27] While this experiment resulted in the unexpected result of creating a killer mousepox virus, subsequent work by another scientist, Mark Buller at Saint Louis University, has knowingly carried these experiments one step further by increasing the lethality of the mousepox virus and by carrying out similar manipulations in the cowpox virus.[28]

• synthesis of the poliovirus genome from 'chemically synthesized oligonucleotides that were linked together and then transfected into cells', thereby creating an infectious virus from scratch, combining knowledge of the viral DNA with assembly of the correct chemical compounds.[29]

• transfer of the virulence factor of variola major (which causes smallpox) into the vaccinia virus, which is of much lower virulence and usually used for vaccinations against smallpox.[30]

27 R. J. Jackson et.al., 'Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox', Journal of Virology, 75 (2001) pp.1205-1210; R. Nowak, 'Disaster in the making. An engineered mouse virus leaves us one step away from the ultimate bioweapon', New Scientist (13 January 2001) pp.4-5.

28 M. Buller, The potential use of genetic engineering to enhance orthopoxviruses as bioweapons. Presentation at the International Conference 'Smallpox Biosecurity. Preventing the Unthinkable' (21-22 October 2003) Geneva, Switzerland; J.D. Steinbruner and E.D. Harris, 'When science breeds nightmares', International Herald Tribune (3 December 2003); D. MacKenzie, 'US develops lethal new viruses', New Scientist, 180, 6 (2003).

29 J. Cello, A.V. Paul and E. Wimmer, 'Chemical synthesis of poliovirus cDNA: generation of infectious virus in the absence of natural template', Science, 297(2002) pp.1016-1018.

30 A. M. Rosengard et.al., 'Variola virus immune evasion design: expression of a highly efficient inhibitor of human complement', Proceedings of the National Academy of Sciences USA, 99 (2002) pp.8808-8813.

Against this background the Committee was specifically tasked to 'recommend changes in… practices that could improve U.S. capacity to prevent the destructive application of biotechnology research while still enabling legitimate research to be conducted.'[31]

Based on several meetings involving a number of external experts, the Committee issued its report containing seven recommendations.
Although the NAS is not a government body that can promulgate laws or regulations, its recommendations are often put into practice by the United States or other governments and even more often reverberate in scientific and academic discourse.
In the case of the Fink Committee's seven recommendations this pattern has repeated itself.

The recommendations are:

1. Educating the Scientific Community. To this end the Committee called upon national and international professional societies to create ppropriate programs that would familiarize scientists with the dual-use dilemma inherent in biotechnology research.

2. Review of Plans for Experiments. This review should be entrusted to the already existing Institutional Biosafety Committee infrastructure and be supplemented by an additional "Recombinant DNA Advisory Committee". Experiments of concern are those that:

1. Would demonstrate how to render a vaccine ineffective;
2. Would confer resistance to therapeutically useful antibiotics or antiviral agents;
3. Would enhance the virulence of a pathogen or render a nonpathogen virulent;
4. Would increase transmissibility of a pathogen;
5. Would alter the host range of a pathogen;
6. Would enable the evasion of diagnostic/detection tools;
7. Would enable the weaponization of a biological agent or toxin.[32]

What is noteworthy in this context is the Committee's acknowledgement that this set of experiments represents only a first approximation of what it considered to be the most probable threat scenarios. "Over time, however, the Committee believes it will be necessary to expand the experiments of concern to cover a significantly wider range of potential threats."[33]

31 Biotechnology Research in an Age of Terrorism, p.32.

32 Biotechnology Research in an Age of Terrorism, p.5.

33 Ibid., p.6.

3. Review at the Publication Stage. This was conceived by the Committee as a self governance measure by the scientific community to ensure that national security relevant information would not fall into the wrong hands.

4. Creation of a National Science Advisory Board for Biodefense. Such a body was subsequently created by the US government and was tasked to advise and guide the government in issues associated with advances in biotechnology, and related security, health and ethical issues.[35]

5. Additional Elements for Protection Against Misuse. This involves on one hand the periodic review of existing legislation and regulation and on the other hand the physical protection of biological materials and the oversight of persons with access to these materials.

6. A Role for the Life Sciences in Efforts to Prevent Bioterrorism and Biowarfare in collaboration with the national security and law enforcement communities (in the US).

7. Harmonized International Oversight, which would aim at providing on the international level oversight mechanisms similar to those proposed by the Committee for the US.

34 According to some observers, the impact of this measure is negligible; see Malcolm R. Dando, contribution to the roundtable discussion on “Synthetic Biology and Ethics” at SB 3.0, available at http://www.syntheticbiology3.ethz.ch/monday.htm.

35 See section 4.5. below.

The following table gives an overview of responses given by 20 interviewees concerning their awareness of the Fink Committee report and its recommendations.

Table 1:
Awareness of the Fink Committee report and its recommendations:

Question 1:
Are you aware of the report Biotechnology Research in an Age of Terrorism (2004) of the so-called Fink Committee (of the US National Academies) and its recommendations?

	Yes	No
aware of report	7	13
able to assess	1	

Noteworthy in this context is the fact that of the seven positive responses only one interviewee had not only heard of the report, but also provided an opinion on its above mentioned recommendations: according to this interviewee the Fink Committee's recommendations are sensible and show the difficulty inherent in any attempt to suggest oversight or governance measures for synthetic biology, i.e. that of having to walk a tightrope between measures that are effective enough to prevent misuse and at the same time are not too restrictive so as to limit scientific and technological progress.

4.2. The Lemon Relman Committee and its recommendations

Shortly after the Fink Committee report was published, the US NAS set up the Committee on Advances in Technology and the Prevention of their Application to Next Generation Bioterrorism and Biological Warfare Threats, the so-called Lemon-Relman Committee, named after its two co-chairmen.
Although the report of this second Committee clearly built on the work of the Fink Committee, it expanded the latter's work in three directions: first, its focus was global, not confined to the US; second, it adopted a forward-looking approach, trying to distil scientific and technological trends that would impact on the biothreat spectrum over the next five to ten years, and; third, it rejected the limitation of its work to traditional biowarfare agents as too narrow.
The Committee also rejected a list-based approach, which, it felt, because of "the pace of research discovery in the life sciences is that the useful lifespan of any such list would be measured in months, not years."[36]

36 Globalization, Biosecurity and the Future of the Life Sciences, Report by the Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Washington D.C., The National Academies Press, 2006, p.3.

To emphasise this particular point, the report pointed out that "[n]ew, unexpected discoveries and applications in RNAi and synthetic biology arose even during the course of deliberations by this Committee."[37]

Therefore the Committee developed a classification scheme for scientific and technological advanced containing four different groups, according to the commonalities different technologies are sharing.

These four groups are:

"1. technologies that seek to acquire novel biological or molecular diversity;
2. technologies that seek to generate novel but pre-determined and specific biological or molecular entities through directed design;
3. technologies that seek to understand and manipulate biological systems in a more comprehensive and effective manner; and
4. technologies that seek to enhance production, delivery, and "packaging" of biologically active materials."

Synthetic biology is explicitly mentioned by the Committee in relation to the first two of these categories. A concise discussion of the future applications of synthetic biology in the report acknowledges that "DNA synthesis technology could allow for the efficient, rapid synthesis of viral and other pathogen genomes – either for the purposes of vaccine or therapeutic research and development, or for malevolent purposes or with unintended consequences."[39]

It is thus fair to conclude that the biosecurity community during the deliberations of the Lemon-Relman Committee had clearly identified synthetic biology as on of the technologies that will have a major impact on the future biothreat spectrum. In line with this reasoning the Committee recommended to "adopt a broadened awareness of threats beyond the classical "select agents" and other pathogenic organisms and toxins, so as to include, for example, approaches for disrupting host homeostatic and defense systems, and for creating synthetic organisms."[40]

One would therefore hope that the synthetic biology community is aware that its activities have become the object of, if not outright concern, then at least careful monitoring and analysis by biosecurity experts.

37 Ibid, p.103.

38 Ibid, p.3.

39 Ibid, p.109.

40 Ibid, p.5, 177f.

As table 2 below shows, none of the interviewees had heard of the Lemon-Relman Committee, its report or any of the report's recommendations.
Given the obvious concern of the Committee with developments in synthetic biology and their impact on the future biothreat spectrum, a reciprocal level of awareness would be a prerequisite for the SB community to actively engage in a discourse with biosecurity experts.

Table 2:
Awareness of the Lemon-Relman Committee report and its recommendations:

Question 2: Have you heard of the report Globalization, Biosecurity, and the Future of the Life Sciences (2006) issued by the Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats (the so-called Lemon-Relman Committee)?

	Yes	No
aware of report	0	20
able to assess	0	

4.3. Declaration of the Second International Meeting on Synthetic Biology (SB 2.0)

This is not to argue that there is no awareness of the societal implications of their work on the part of synthetic biology. To the contrary, as the Declaration of the Second International Meeting on Synthetic Biology (and the activities during SB3.0 discussed above) demonstrates, there is such awareness and societal implications are taken seriously by many in the SB community. In case of the SB 2.0 a full day was devoted to discussion of such issues and the subsequently formulated declaration of May 2006 contains four resolutions that clearly aim at addressing some of the dual-use implications of synthetic biology, in particular DNA synthesis that may give rise to safety or security concerns.[41]
The focus on DNA synthesis is also reflected in two of the four resolutions contained in the final declaration. These resolutions support the

"…development of improved software tools that can be used to check DNA synthesis orders for DNA sequences encoding hazardous biological systems adoption of best-practice sequence checking technology, including customer and order validation, by all commercial DNA synthesis companies …

41 See the revised public draft of the declaration at https://dspace.mit.edu/handle/1721.1/18185.

… ongoing and future discussions within international science and engineering research communities for the purpose of developing creative solutions and frameworks that directly address challenges arising from the ongoing advances in biological technology, in particular, challenges to biological security and biological justice …
… ongoing and future discussions with all stakeholders for the purpose of developing and analysing governance options … such that the development and application of biological technology remains overwhelmingly constructive."[42]

In terms of practical next steps to be pursued, the declaration announces the formation of an open working group in support of the improvement of existing software tools for checking DNA sequences, as well as the completion of a study to "develop policy options that might be used to govern DNA synthesis technology".[43]

When asked about their awareness of the declaration of SB 2.0 and its contents, more than half of the interviewees, 12 out of 20, said they were aware of the declaration. This is a markedly higher level of awareness when compared to the previous two studies that were external to the synthetic biology community's own attempts to address biosecurity concerns.
However, of the 12 positive respondents only three felt they were in a position to give an assessment of the four resolutions contained in the SB 2.0 declaration.

Table 3:
Awareness of the SB 2.0 declaration and its resolutions:

Question 3: Are you aware of the existence and contents of the Declaration of the Second International Meeting on Synthetic Biology?

	Yes	No
aware of existence	12	8
able to assess	3	

For one interviewee the self-regulatory approach contained in the resolutions was sufficient to address biosecurity issues related to synthetic biology. The second interviewee concurred with this assessment and pointed out the usefulness of the declaration and its resolutions in organising the work of his own organisation with respect to biosecurity questions. The third interviewee, in contrast, regarded the scope of the declaration as inappropriate, its tone very US-centred and too much concerned with not standing in the way of commercial developments.

42 SB 2.0 public draft declaration, p.3.

43 Details of this study were presented during SB3.0 by Michele Garfinkel of the Venter Institute (see section 3 above)

4.4. CSIS-MIT-Venter draft report on the regulation of synthetic genomics

As the following table shows, half of all interviewees were aware of the CSIS-MIT-Venter (draft) report on Synthetic Genomics, to which the SB 2.0 declaration had made explicit reference.

Table 4:
Awareness of the (draft) report Synthetic Genomics.
Options for Governance.

Question 4: Have you heard of the (draft) report Synthetic Genomics.
Options for Governance, produced by CSIS, MIT and the Venter Institute?

	Yes	No
aware of report	10	10
able to assess	2	

Because some of the interviews were conducted during or after SB 3.0 when the draft report was presented in the panel session on societal issues, these results are likely to have been affected by the timing of the interviews in relation to the presentation.
Support for this assumption can be derived from the fact that two interviewees made explicit reference to Dr Garfinkel's presentation when answering the question.
It is also noteworthy that only two of the respondents who had knowledge of the draft report were able to provide an assessment of the policy options put forward in the report. According to one interviewee the options are "overdone", not amenable to be put into practice easily, and not commensurate to the risks involved. In contrast, the second interviewee found the options discussed "not significant enough" in relation to the problem at hand.

As some of the major findings concerning biosecurity issues of the report have already been addressed in relation to its presentation during SB 3.0,[44] only a few additional comments shall be made as to the study's assumptions and the character of the policy options it is presenting.[45] Noteworthy in this context is the study groups assessment that

"today, any synthesis of viruses, … remains relatively difficult. In the near future, however, the risk of nefarious use will rise because of the increasing speed and capability of the technology and its widening accessibility."[46]

44 See section 3 above.

45 The final version of the report is available since 17 October 2007 and can be accessed via http://www.csis.org/media/csis/pubs/071017_synthetic_genomics_options.pdf

46 Synthetic Genomics. Options for Governance, p.12.

It would therefore appear that there is a window of opportunity available now to devise and implement the most effective governance system to prevent the misuse of synthetic biology in the future.

Given this urgency, it is somewhat puzzling that the authors of the report stress at several points that they are only providing policy options, and are not making recommendations.

On a different level it is also questionable whether this self-selected detachment is actually sustainable: clearly, through presenting and discussing some options, but not others, the issues are framed in a certain way that cannot but influence discussions in the policy-making process.

For doing this in a particular way, the report was immediately criticised from two different groups: while according to the ETC Group the report represented only a "partial consideration of governance by a partisan group of authors" which "overlooks important questions related to power, control and economic impacts of synthetic biology",[47] the Sunshine Project focused on the expanded role foreseen in the report for Institutional Biosafety Committees (IBC) in overseeing synthetic biology.[48]

An additional shortcoming of the report might be seen in its limited geographical focus on the US alone.
This is not necessarily corresponding to the description of the risk in the report itself, which – as quoted above – acknowledges the "widening accessibility" of synthetic biology knowledge and technologies.
It also seems out of step with the realisation of the wider biosecurity community that an exclusive US focus is far too narrow for adequately addressing the dual-use potential of synthetic biology.

Thus, the opening up of the biosecurity discourse beyond US borders that was observable from the work of the Fink Committee to the Lemon-Relman Committee of the NAS seems to have been reversed with this study.

47 See the ETC Group, Syns of Omission: Civil Society Organizations Respond to Report on Synthetic Biology Governance from the J. Craig Venter Institute and Alfred P. Sloan Foundation, press release, 17 October 2007, available at: http://www.etcgroup.org/en/materials/publications.html?pub_id=654

48 The Sunshine Project is a long-standing critic of the performance of IBCs; see their webpage at http://www.sunshine-project.org/

4.5. The Work of the NSABB and its synthetic biology working group

Following one of the recommendations contained in the Fink Committee Report, the US government set up the National Science Advisory Board for Biosecurity in March 2004.[49]

According to its charter, NSABB is to "provide advice, guidance, and leadership regarding biosecurity oversight of dual-use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security." Its activities range from developing "criteria for identifying dual-use research and research results" to "guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results" to the recommendation of "strategies for coordinated international oversight of dual-use biological research."

In order to conduct its work, NSABB can set up working groups to address more specific issues.
One such working group that had been created has focussed its attention on the new field of synthetic biology.
In the first phase of its work, the NSABB synthetic biology working group has sought to address biosecurity implications of the de novo synthesis of select agents.[50]
A preliminary report of the synthetic biology working group was discussed during a NSABB meeting in October 2006 and has subsequently been submitted to the US government and made available to the public.[51]

"This report describes the biosecurity concerns identified by the NSABB Working Group on Synthetic Genomics that are raised by the ability to reconstruct Select Agents de novo, the Working Group's assessment of the adequacy of the current regulatory framework to safeguard against the misuse of this science and its recommendations for addressing these concerns."[52]

49 See www.biosecurityboard.gov for the original charter of NSABB as well as all documents subsequently quoted in this section.

50 Select agents are those biological agents and toxins that can pose a severe threat to public, animal or plant health, or to animal or plant products. For the current list of select agents see http://www.cdc.gov/od/sap/docs/salist.pdf

51 See NSABB, Addressing Biosecurity Concerns Related to the Synthesis of Select Agents, Washington DC, December 2006, available at http://www.biosecurityboard.gov/pdf/Addressing Biosecurity Concerns Related to the Synthesis of Select Agents.pdf

52 Ibid, p.2.

The report recommends to the US government inter alia that

" ... HHS and USDA collaboratively develop and disseminate harmonized guidance to investigators and nucleic acid/gene/genome providers concerning the SAR with respect to synthetically-derived DNA ...
... relevant federal agencies ... develop a process to be used by providers of synthetic DNA for determining the sequences for which to screen (Select Agents or otherwise) ...

... convene a group of experts from the scientific community to conduct an open and in depth examination of the Select Agent classification system to determine if it is possible to reconcile the current controls for Select Agents with the anticipated scientific advances enabled by synthetic genomics ..."[53]

As the following table shows, less than one fifth of interviewees were aware of the NSABB activities and its synthetic biology working group report. Of those who had heard of the report, none was in a position to offer an assessment as to its content or recommendations.

Table 5:
Awareness of the NSABB report Addressing Biosecurity Concerns Related to the Synthesis of Select Agents

Question 5: Are you aware of the NSABB report Addressing Biosecurity Concerns Related to the Synthesis of Select Agents, issued in December 2006?

	Yes	No
aware of report	3	17
able to assess	0	

53 Ibid, p.10-13.

4.6. The Controlling Dangerous Pathogens project at the University of Maryland

Since 2002 a group of scholars at the University of Maryland, led by John Steinbruner, has developed a protective oversight system for dangerous biological agents and research.[54] The most elaborate version of this proposal has been published as a monograph in spring 2007. [55]

Starting from the dual-use dilemma inherent in most, if not all of life sciences research, i.e. that "[t]he same basic science that could in principle be highly beneficial could also be enormously destructive, depending on how it is applied", [56] Steinbruner and colleagues argue the case for "an oversight process designed to bring independent scrutiny to bear throughout the world without exception on fundamental research activities that might plausibly generate massively destructive or otherwise highly dangerous consequences." [57]
This proposal goes far beyond any of the other recommendations considered so far in two ways: first of all, it advocates subjecting all, not just publicly funded, research to independent scrutiny, and second, the proposal's scope is global, not just national.
Steinbruner and colleagues argue further that "inherently dangerous areas of biological research will have to be subjected to a much more systematic process of protective oversight than is yet practiced in any country. That will have to be done globally and therefore will have to be globally formulated and globally implemented."[58]

Such research is then broken down into three categories of activities, each of which will necessitate different levels of scrutiny: activities of potential concern will be subjected to local peer review oversight, activities of moderate concern to national oversight and activities of extreme concern will receive the highest level of scrutiny on the international level.[59]

In order for the peer review process to work at each of the three levels a wide-ranging licensing of relevant individuals and research facilities will be required.

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54 For an early exposition see John Steinbruner, Protective Oversight of Biotechnology: A Discussion Paper, February 2002, available at http://www.cissm.umd.edu/papers/files/biotechoversight.pdf

55 See John Steinbruner, Elisa D. Harris, Nancy Gallagher, Stacy M. Okutani, Controlling Dangerous Pathogens. A Prototype Protective Oversight System, College Park: University of Maryland, march 2007, available at http://www.cissm.umd.edu/papers/files/pathogens_project_monograph.pdf

56 Ibid, p.1.

57 Idem.

58 Ibid., p.6

59 For an elaboration of the three categories see ibid, p.25. Although the title of the report seems to suggest a focus on pathogens only, the definitions used for "agent" of concern explicitly include the categories "genetic element, recombinant nucleic acid, or recombinant organism."

When asked about their awareness of the existence of the Controlling Dangerous Pathogens Project conducted at the University of Maryland 6 of the 20 interviewees responded positively.
As with the previous reports, the level of detailed knowledge about the ”Biological Research Security Oversight System” proposed by the University of Maryland group turned out to be low: the only interviewee who felt in a position to provide an assessment of the groups work thought its approach to the handling of the pathogen issue dates back to the Cold War.

Table 6:
Awareness of the Controlling Dangerous Pathogens Project

Question 6: Are you familiar with the Controlling Dangerous Pathogens Project conducted at the University of Maryland?

	Yes	No
aware of project	6	14
able to assess	1	

In sum, this set of 20 interviews has brought to the fore a low to medium level of awareness in quantitative terms on part of European synthetic biology practitioners in relation to key developments and reports in the biosecurity area.
Around a third of interviewees had heard of the Fink Committee and its report, and none was aware of the Lemon-Relman Committee and its call to broaden our understanding of the biosecurity threat to include synthetic organisms.
The only landmark in the emerging biosecurity discourse among synthetic biologists to receive a level of awareness of more than 50 per cent is the SB 2.0 declaration discussed above, with the CSIS-MIT-Venter report receiving the second highest awareness score.

Awareness of NSABB activities with respect to synthetic biology or the University of Maryland Controlling Dangerous Pathogens Project are below the 50 per cent mark, in case of the NSABB the level of awareness is even down to 15 per cent.

In qualitative terms the picture is even bleaker: only a small part of interviewees, if any at all, were in a position to give an assessment of the various Committees, reports and recommendations addressed in the interview.

Even in the case of the SB 2.0 declaration the level of awareness dropped from 60 to 15 per cent, when considering this qualitative dimension. This somewhat superficial knowledge on part of many who were in principle aware of the unfolding biosecurity discourse with respect to the life sciences in general and synthetic biology in particular poses another obstacle to a constructive participation by synthetic biology practitioners in that very discourse.

Table 7:
Awareness of the Unfolding Biosecurity Discourse Among European Synthetic Biology Practitioners

Question 1 – Fink Committee
Question 2 – Lemon-Relman Committee
Question 3 – SB 2.0 Declaration
Question 4 – CSIS-MIT-Venter report
Question 5 – NSABB synthetic biology WG
Question 6 – Controlling Dangerous Pathogens project

	Q1	Q2	Q3	Q4	Q5	Q6
Yes	7	0	12	10	3	6
No	13	20	8	10	17	14

5. Future governance mechanisms for synthetic biology in Europe – between the desirable and the inevitable?

Future governance mechanisms for synthetic biology in Europe could in principle develop along three different lines: one with a high degree of oversight and controls (possibly along the lines of regulations for GM food in Europe), one with very little regulation and a high degree of reliance on institutional encouragement (like for example nanotechnology seems to evolve), and one which falls between these two poles of possible regulatory environments.
When asked about what they regard as a desirable future governance system for synthetic biology (from a biosecurity standpoint) interviewees tend to favour a lesser degree of regulation, although not many reject the notion of additional governance measures altogether.
In one of the few instances where this latter point was made, it was argued the work with Yersinia pestis posed more dangers than most research in the field of synthetic biology.

In contrast, when asked about the from their perspective most likely synthetic biology governance system that would address biosecurity concerns, expectations expressed by the interviewed SB practitioners are closer to the tighter regulatory end of the spectrum. However, a number of interviewees also alluded to the danger of stifling scientific progress in case a too tight regulatory layer would be imposed on any self-governance activities the scientific community might devise itself.

The vast majority of interviewees were expressing support for a “middle-of-the-road” governance regime somewhere in the middle of the spectrum of oversight and control measures.
While some respondents agree that “some regulation will be needed” and place the emphasis of finding the dividing line between harmless and potentially dangerous experiments, with one suggestion that experiments involving self-replicating systems might serve as a threshold in this context, others advocate the risk assessment for synthetic biology experiments to take into account the context of such research:
according to this latter approach, laboratory experiments might need less stringent rules than those involving the release of agents into the environment.

Among those seeing a somewhat more restrictive governance system as the way forward, there is no doubt that a legal framework is part of a desirable oversight and control regime.

Implementation of such a regime might, according to one interviewee, best be endowed with a higher-level independent organisation, such as the Human Fertilization and Embryology Authority, which "is the UK's independent regulator overseeing safe and appropriate practice in fertility treatment and embryo research." [60]

While this interviewee did not regard as desirable wide-ranging licensing requirements at this point in time, others were more pessimistic about the ability to create an effective oversight system for synthetic biology. According to this latter point of view, short of controlling each and every DNA synthesizer, effective oversight is impossible. For this governments would need to have good intelligence in place and continuously monitor trade patterns.

There are two general points worth making in this context: the first is related to the many constructive ideas and creative potential within the synthetic biology community that became apparent during the conduct of this set of interviews – and an in depth elaboration of which is well beyond the scope of this study. Any future attempt to establish a governance system for synthetic biology that addresses biosecurity concerns, but that does not necessarily stop there, would be remiss if it did not try to utilize this potential. Second, on a more cautionary note, many of the responses suggest that in the minds of a significant number of interviewees there is no sharp distinction between biosafety and biosecurity concerns as the driving force behind a regulatory or governance system for synthetic biology.
This, however, points back to the starting point of this investigation: the level of awareness of biosecurity concerns related to synthetic biology among practitioners in the field.

Given the significant potential for misuse of synthetic biology outlined at the beginning and the strategic instability this may produce and also taking into account the history of advances in medicine and biology having been regularly "hijacked" for offensive military biological weapons programs, the degree of awareness of biosecurity concerns in the synthetic biology community is clearly insufficient.

Thus, there need to be greater efforts to raise this level of awareness. This can be accomplished to some extent as part of more general activities to further define the field of synthetic biology and bring its members together at events like the international Synthetic Biology conferences, or regional events like the European Science Foundation's upcoming research conference on synthetic biology.

60 See http://www.hfea.gov.uk/

However, these are singular events that hardly provide the sustained effort at awareness raising which would be commensurate with the risks involved in the misuse of synthetic biology.

The final declaration of SB 2.0 may serve to illustrate the point: the one-off character of the attempt to unite the community behind a self-regulation approach has led to a declaration the status of which is somewhat unclear – as the version publicly available on the internet is still labelled a draft version.
Given the misuse potential of synthetic biology, a patchwork approach that focuses on self-regulation today and a set of different issues tomorrow is clearly insufficient.
More systematic and sustained efforts at awareness raising and involving synthetic biology practitioners in the biosecurity discourse are required.

This in turn raises the question "after awareness-raising, what?" [61]
Clearly, channels for a regular dialogue between the biosecurity and synthetic biology communities will have to be established, but also for a discourse involving regulatory authorities that are bound to become involved in the governance of synthetic biology.
What the biosecurity community can contribute to this discourse first and foremost is a set of concepts from traditional security studies and the analysis of security regimes that will need to be modified in light of the paradigm shift synthetic biology is to bring about.
An understanding of these updated security-related concepts by the synthetic biology community will be essential for their successful contribution to preventing the misuse of their field of research.

Such a contribution will require a more pro-active involvement in the comprehensive strengthening of the regime to prevent the misuse of biology for hostile purposes.

61 On this point, see also Malcolm Dando & James Revill, 'Life Scientists and a Culture of Responsibility: After Education.What?', Science and Public Policy, [Forthcoming].