

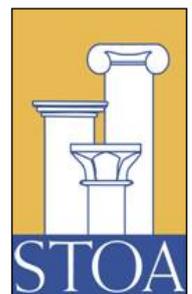


Making *Perfect* Life

**European Governance Challenges
in 21st Century Bio-engineering**

Study Summary

Science and Technology
Options Assessment



The STOA project 'Making Perfect Life' was carried out by the Rathenau Instituut, The Hague (Project co-ordinator); together with the Institute of Technology Assessment (ITA), Vienna; the Fraunhofer Institute for Systems and Innovation Research (Fraunhofer ISI), Karlsruhe; and the Institute for Technology Assessment and Systems Analysis (ITAS), Karlsruhe Institute of Technology (KIT), as members of the European Technology Assessment Group (ETAG).

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ABSTRACT

The STOA project 'Making Perfect Life' looked into four fields of 21st century bio-engineering: engineering of living artefacts, engineering of the body, engineering of the brain, and engineering of intelligent artefacts. This report describes the main results of the project.

The report shows how developments in the four fields of bio-engineering are shaped by two megatrends: "biology becoming technology" and "technology becoming biology". These developments result in a broadening of the bio-engineering debate in our society.

The report addresses the long term views that are inspiring this debate and discusses a multitude of ethical, legal and social issues that arise from bio-engineering developments in the fields described. Against this background four specific developments are studied in more detail: the rise of human genome sequencing, the market introduction of neurodevices, the capturing by information technology of the psychological and physiological states of users, and the pursuit of standardisation in synthetic biology. These developments are taken in this report as a starting point for an analysis of some of the main European governance challenges in 21st century bio-engineering.

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1. Introduction to 'Making *perfect life*' project

The main goals of the STOA project 'Making *Perfect Life*: Bio-engineering (in) the 21st Century' were:

- To identify major overarching trends that are visible in the development of four selected fields of 21st-century bio-engineering, and the societal and political challenges related to these trends, thus fulfilling the function of horizon scanning for weak signals and early warning of upcoming long-term-policy challenges
- To discuss a number of specific developments which exemplify the major trends in the four fields of bio-engineering in more detail with the purpose to alert politicians that despite the long-term character of the megatrends, near-term policy challenges and regulatory questions in these specific developments are already imminent.

To achieve these aims, the project took a trans-technological perspective by describing a broad range of developments in four fields of bio-engineering: the engineering of the human body, the brain, intelligent artefacts (in the field of artificial intelligence) and living artefacts (in the field of synthetic biology). In addition, four specific developments in each of these four fields were analysed: the rise of human whole genome sequencing, the introduction of neurodevices into the market, the capturing of the psychological and physiological states of users by means of information technology, and the pursuit of standardization in synthetic biology.

This extended briefing note summarises the main findings of the *Making perfect life* project. In Chapter 2, we will characterise bio-engineering in the 21st century in terms of two bio-engineering megatrends: 'biology becoming technology' and 'technology becoming biology'. These two trends promise new types of interventions in living organisms and new lifelike artefacts, and are expected to fundamentally broaden the current bio-engineering debate. On the basis of the four case studies of specific bio-engineering technologies, we describe in Chapter 3 how these technologies are being developed and adopted in a wide variety of sociotechnical practices, involving different applications and actors. We further show how these practices are challenging existing regulatory practices and explain how to understand and deal with this multifaceted governance challenge. Chapter 4 concludes that there is a need in European policymaking for a comprehensive strategy involving both bioethics and biopolitics in order to cope with the governance challenges posed by 21st-century bio-engineering. With regards to bioethics European policy makers need to broaden the bio-debate by stimulating scientific reflection and public debate in a way that truly reflects the transformative character of 21st-century bio-engineering. With regards to biopolitics, a dedicated and continuous effort is needed to make the complex workings and failings of the relevant regulatory systems politically transparent with respect to the present and coming years. Although the realisation of the two bio-engineering megatrends is a long-term development spanning several decades, the four case studies described in Chapter 5 show that the need for political action already arises now, and that it is imperative to have a good understanding of the underlying megatrends when dealing with near-term policy challenges of specific developments: this is shown for the case studies whole genome sequencing, neuromodulation, biocybernetic adaptation, and standardization in synthetic biology, respectively – and the specific policy recommendations that result from each case are pointed out.

2. Bio-engineering in the 21st century

This chapter summarises the findings and conclusions of the STOA *monitoring report: Making Perfect Life. Bio-engineering (in) the 21st Century* (2011)

In the 21st-century we see the emergence of a *new engineering approach to life*, which is shaped by the convergence of four key technologies: nanotechnology, biotechnology, information technology and the cognitive sciences (NBIC). An important aspect of NBIC convergence is the increasing interaction between the biological and the physical sciences. This growing interaction can be described in terms of two megatrends: ‘biology becoming technology’ and ‘technology becoming biology’.

2.1 Two bio-engineering megatrends

Biology becoming technology expresses the idea that scientists and engineers increasingly look at living organisms in mechanical terms. It concerns the way in which physical and engineering sciences such as nanotechnology and information technology enable progress in the life sciences. Technology becoming biology is driven by the convergence in the opposite direction, whereby insights into biological and cognitive processes in the life sciences inspire and enable progress within the engineering sciences.

Both megatrends point to a future in which the distinction between *biology* as a science of life and *engineering* as a science of artefacts will gradually disappear. In other words, both trends evoke a future in which we engage in ‘making perfect life’, with ‘life’ conceived of as a phenomenon that can be controlled and constructed. It is important to note that in many respects this future is uncertain and speculative. Still, our trans-technological perspective revealed that all four fields of 21st-century bio-engineering are shaped by these two megatrends, which together constitute a new engineering approach to life.

2.2. New types of interventions in living organisms and lifelike artefacts

The two megatrends manifest themselves in different and specific ways in the four fields of bio-engineering. Biology is becoming technology through engineering tools which allow new and more far-reaching interventions in living organisms, including the human body and the brain. Technology is becoming biology through the creation of artefacts with increasingly lifelike features, including the capacity for self-assembly, cognition and learning. In summary, in 21st-century bio-engineering, the scientific ambition of understanding the living world has clearly become connected with the engineering ambition of *intervening in living organisms* as well as *constructing lifelike artefacts*.

2.2.1 Interventions in living organisms

Today, there are various biologically derived ‘biotech’ tools available or in development which will make possible a new range of diagnostic and therapeutic interventions and the creation of biological systems with new properties. Proteins from the human body can now be produced and engineered on the basis of genetic information and used as drugs, known as biopharmaceuticals. New advanced medical therapies are being developed in which human genes, cells and stem cells are used as therapeutic agents. The emergence of genomics is creating a huge knowledge base for a deeper understanding of health and disease on a molecular level, offering prospects of early diagnosis and prevention of disease, more targeted and individualised therapies, and the identification of new drug targets on a molecular level.

Synthetic biology has emerged as a new engineering science which uses synthetically produced genetic sequences to re-engineer living cells. In the future, complete synthetic genes may be used as a tool to transform cells into biological factories or agents with a highly artificial nature, based on so-called minimal genomes as a cellular 'chassis'.

In addition to new biotech tools, 'infotech' tools which create new options for monitoring and manipulating the human brain are also becoming available. The living brain can be studied with modern neuroimaging technologies and new systems have been developed which enable interventions in the brain by connecting it to electronic devices. What used to be science fiction is now becoming scientific reality: the direct interfacing of the brain with computers. Neuromodulation and brain-computer interfaces are currently being developed which use both invasive and non-invasive tools to support, restore or augment brain or mental functions.

2.2.2 Lifelike artefacts

In most fields of bio-engineering the creation of lifelike artefacts remains a future prospect. As a long-term goal in engineering the body, we can observe a paradigm shift from restoring bodily functions to regenerative medicine - involving the (re)generation of tissues - and eventually to completely biologically derived artificial organs. In the field of synthetic biology, researchers have the long-term ambition of creating 'proto-cells' as artefacts with the properties of life, starting from non-biological molecular building blocks. An important engineering approach in brain research is attempting to mimic the brain with software in virtual representations, hardware in supercomputers and wetware in cultured neuronal networks, thus bringing the fields of IT and neuroscience together with the aim of developing a deeper understanding of the brain. The most tangible, albeit still modest, achievements in creating lifelike artefacts are found in the field of artificial intelligence, where researchers are working on the development of animalistic, humanoid and social robots with capacities to interact and to adapt and learn in response to new situations. In addition, forms of artificial intelligence with the ability to interact with users and also to intervene in their behaviour may be embedded and distributed within smart environments.

2.3. Fundamental broadening of the bio-engineering debate

In the past decades, developments in the life sciences have already given rise to long-standing bioethical debates. As biology and engineering become increasingly intertwined, blurring venerable boundaries between life and non-life or mind and machine, new questions and concerns will obviously be raised, fuelling further debates. Partly such debates are stimulated by highly speculative long-term visions of a future in which human embryos might be created from artificially derived gametes, brain activity might be externally controlled and machines might be given superhuman intelligence. Our analysis, however, has also made clear that, already today, developments in the four fields of bio-engineering raise a variety of ethical, legal and social issues which may challenge current regulatory practices.

We have discussed this broadening of the bio-engineering debate from two interrelated perspectives, emphasizing the transformative social and political character of the trends, 'biology becoming technology' and 'technology becoming biology'.

2.3.1 Blurring boundaries

One perspective highlights the way in which these trends blur the boundaries between nature and technology, the living and the non-living, human and machine. The growing interaction between biology and technology will increasingly challenge familiar, value-laden categories that are deeply rooted in the history of our culture, such as the distinctions between 'life' and 'matter' or 'nature' and 'machine'. The increasing manipulability of nature that the two bio-engineering trends

promise, raises high hopes, but also concerns about the hubris of assuming total control. As a result, the two megatrends may become potential causes for unease and controversy within society and further fuel existing bioethical debates.

2.3.2 Ethical, legal and social issues

The other perspective focuses more specifically on the ethical, legal and social issues raised by both megatrends and the need to anticipate the challenges these will create for European policymaking. From a 'biology becoming technology' point of view, new types of interventions in living organisms, the human body and the brain should prompt policymakers to reconsider established ways of dealing with issues of safety, liability, privacy, bodily and mental integrity and informed consent. The rise of synthetic biology gives new reason for concerns about biosafety, biosecurity and intellectual property. With the rise of molecular medicine, major ethical, legal and social issues have to be addressed, concerning how increasing amounts of personal genetic and medical data are obtained and stored, what the information means and how it can be interpreted or used. Neural engineering of the brain – especially neuromodulation – is a form of behavioural engineering which is still at a very experimental stage and may result in unexpected changes in personality, which makes questions of safety, liability, bodily integrity and informed consent particularly sensitive in this area.

From a 'technology becoming biology' point of view, new kinds of biologically derived and lifelike artefacts raise questions regarding the commodification of bodily materials and the sociopsychological and legal implications of the further penetration of intelligent artefacts into everyday life. The increasing ability to use and engineer materials derived from the human body for technical and engineering purposes requires reflection and deliberation on the ethical and legal status of bodily materials considered as 'goods' and what it means in practice to use this material. The introduction of increasingly independent robots into human environments will raise special safety and perhaps also liability issues, while privacy issues will gain new significance in relation to intelligent systems which collect and store personal data with the aim of becoming more adaptable to the preferences, needs and emotional states of individual human users.

3. European governance challenges

This chapter summarises the findings and conclusions of the STOA study: Making Perfect Life. Bio-engineering (in) the 21st Century. European Governance Challenges in Bio-Engineering (2012)

Given the imminent changes described in Chapter 2, European policymakers are expected to face many new governance challenges in 21st-century bio-engineering. With the aim to identify and discuss these challenges in more detail, we have studied four cases: whole genome sequencing, neuromodulation, biocybernetic adaptation and standardization in synthetic biology. These cases were selected because of their more immediate significance for European policymaking as they may have short term implications for existing regulatory regimes.

The results of the case studies are summarised in Chapter 5. Based on the findings from these studies, the discussion below aims at a more profound understanding of the overall nature and significance of the governance challenges that 21st-century bio-engineering will pose to European policy makers.

3.1 The dynamics of sociotechnical and regulatory practices

To clarify the nature of the governance challenges that European policymakers face, we focus in the case studies on (1) the ways in which established *sociotechnical practices* are being transformed by new bio-engineering technologies and (2) the extent to which current *regulatory practices* may be affected by these transformations. The fundamental governance challenge is to attune these two dimensions. In other words, *how to align the dynamics of sociotechnical and regulatory practices* in the different fields of 21st-century bio-engineering?

To make this governance challenge more transparent for policymakers we have mapped the specific bio-engineering developments studied in the case studies along the two dimensions “extent to which sociotechnical practices are transformed” and “extent to which current regulatory practices are affected”. With regard to both dimensions, three situations can be distinguished. New bio-engineering technologies may be adopted in relatively stable sociotechnical practices, but may also lead to significant changes to established practices or to newly emerging practices. Next we have indicated to what extent these changing sociotechnical practices affect established regulatory regimes. Current regimes of regulation may be perceived as adequate, as being put under pressure, or as no longer adequate, or even lacking (see figure 1).

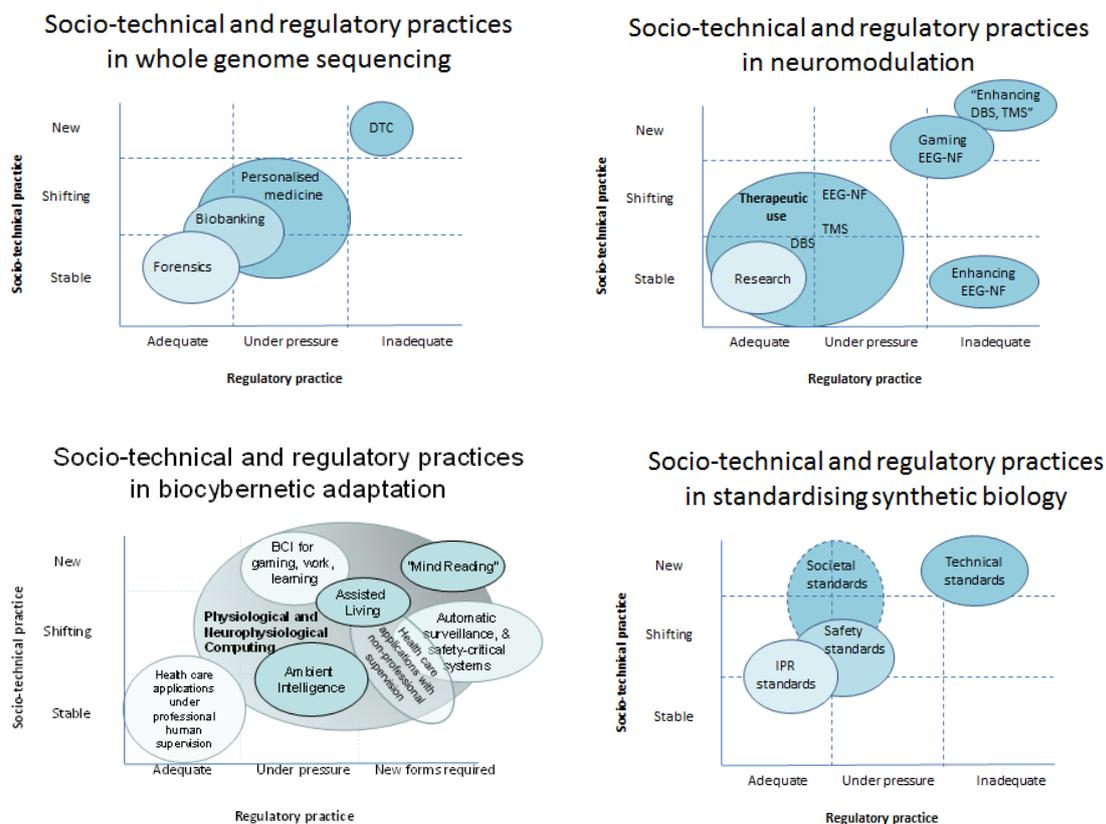
3.1.1 Shifting socio-technical practices and new emerging ones

In Figure 1 the findings from the four case studies – whole genome sequencing, neuromodulation, biocybernetic adaptation and synthetic biology standards – are presented in four diagrams. In total we have identified twenty different sociotechnical practices that are being (re)shaped by or are emerging from the bio-engineering technologies studied in the four case studies.

Whole genome sequencing

Whole genome sequencing is changing established research practices in data collection and storage in biobanks, and in health care it will contribute to the development of new practices of ‘proactive’ and ‘personalised’ medicine. It will also contribute to the expansion of direct-to-consumer genetic testing as a new emerging practice outside the current system of health-care provision. In the more distant future, whole genome sequencing may also find applications in forensics, but for the time being, current practices of forensic DNA profiling will not significantly change.

Figure 1: Sociotechnical and regulatory practices in four fields of 21st century bio-engineering



Neuromodulation

Medical research practices provide an important environment for the development of neuromodulation technologies and it is foreseen that this will lead to more wide-ranging clinical applications. There is already a long-established practice of clinical use for EEG neurofeedback in private health-care settings, including its use for non-medical purposes (cognitive enhancement). Another form of non-medical use is emerging in gaming practices. Transcranial magnetic stimulation (TMS) is currently mainly used for diagnostic purposes, but therapeutic applications are gaining popularity, again mostly in private clinics. As an invasive neuromodulation technology, deep brain stimulation (DBS) is only offered in hospital settings. Medical indications for this treatment are limited, but widening. A more futuristic prospect is the use of both TMS and DBS as tools in practices of cognitive and performative enhancement.

Biocybernetic adaptation

Professional health-care practices and care for the elderly and infirm will be the first realms in which computers may play a supportive role as 'sensitive interaction partners' using biocybernetically adaptive systems with the ability to respond to the needs and behaviours of individuals. Gaming is another area where these systems will find early adoption. In the more distant future, biocybernetically adaptive systems may find application in the comprehensive and unobtrusive environment of 'ambient intelligence', supporting the elderly and the disabled at home without professional supervision. Other more long-term applications might be systems which monitor and measure performance, attention or fatigue in order to intervene in individual

behaviour, such as in driving or military practices. Practices involving ‘mind reading’ should be regarded as highly futuristic.

Synthetic biology standards

As synthetic biology aims at a profound reconstruction of living organisms, creating living ‘machines’ or ‘artefacts’ for useful purposes in a future bioeconomy, the standardization of biological engineering practices has become a crucial issue, with emerging practices of technical standardization fundamental to the facilitation and streamlining the use of ready-made biological parts. It remains to be seen to what extent this standardization can be achieved in the near or more distant future. Standardization is also important in a commercial and regulatory context. An important issue still to be resolved in synthetic biology is the tension between patenting and open access as the two poles of established standards for the protection of intellectual property. Another unresolved question is the extent to which established safety standards for genetic engineering will apply to future achievements in synthetic biology. Last but not least, synthetic biology will have to meet societal standards relating to broader values of sustainability and the common good.

3.1.2 A multifaceted governance challenge

An important question for policymakers is to what extent current regulatory practices are able to adequately respond to the shifting and emerging sociotechnical practices that we have identified. As the case studies have made clear, there is already a patchwork of regulatory practices in place in the different fields of bio-engineering. Figure 1 illustrates to what extent these existing regulatory frameworks are challenged by the variety of shifting and emerging sociotechnical practices. Given the simultaneous impact of bio-engineering technologies on a diversity of sociotechnical practices, the regulatory challenge will often be multifaceted. Existing regulatory frameworks can thus be seen as partly adequate, partly under pressure and partly inadequate, depending on the sociotechnical practice under consideration.

3.2 Aligning sociotechnical and regulatory practices

The findings from the four case studies strongly indicate that bio-engineering in the 21st century will pose a variety of regulatory challenges to European politics and policymakers. How to understand the nature of these challenges and how can policymakers deal with them?

3.2.1 Regulatory zone and wasteland

In considering these questions, we distinguish two different situations in which potential tensions and misalignments between sociotechnical and regulatory practices may occur: the regulatory zone and the regulatory wasteland. In the *regulatory zone*, sociotechnical practices are guided by established regulations that may be considered robust enough to deal with changing or newly emerging practices. In other words, the regulations in place can be considered future-proof in their potential to be adapted to or realigned with changing or new sociotechnical practices. In the *regulatory wasteland*, regulations are lacking or may be seen as inadequate to guide existing, changing or newly emerging sociotechnical practices. In this situation, there will be a genuine need for changes in existing regulations or for the development of new forms of regulation.

3.2.2 Coping with uncertainties

The need for the alignment of sociotechnical and regulatory practices in these different situations poses a governance challenge which is both fundamental and difficult because it relates to future developments which may have a great impact but which are also uncertain in several respects. When dealing with this governance challenge, above all policymakers face *technoscientific*

uncertainty, that is, uncertainty about the speed, direction and nature of technological change in 21st-century bio-engineering. Technoscientific developments may also change the *social and political values* that inform the societal and political debate concerning notions such as autonomy or privacy for example, and thus may create uncertainties about the values that should underpin regulatory initiatives. Finally, policymakers face uncertainty about the adequateness of existing *regulatory frameworks*, that is, about the alignment or misalignment of sociotechnical and regulatory practices in the near or more distant future.

3.2.3 Three options for governance

These various uncertainties lead to different and sometimes conflicting opinions about the potential impact of bio-engineering developments and the regulatory challenges that may arise from them. Therefore, *political* debate is required to determine the nature and urgency of the governance challenges in 21st-century bio-engineering and the ways to deal with these challenges. The recurrent political question is whether future sociotechnical practices enabled by new bio-engineering developments can be considered substantially equivalent to sociotechnical practices with which we are already familiar. We can distinguish three possible responses to this question, implying three options for governance:

- If there are reasons to believe that new bio-engineering developments will not substantially change existing sociotechnical practices, it can be safely assumed that established regulations for these practices will also apply to the new bio-engineering developments and a wait-and-see strategy would be an appropriate option for governance
- If there are reasons for doubt about the equivalence of new sociotechnical practices to already existing forms, the monitoring and assessment of these developments would be an appropriate governance option to determine whether current regulations are adequate
- If new bio-engineering developments lead to sociotechnical practices that are evidently different from present practices, existing regulatory frameworks may have to be revised (within the regulatory zone) or new forms of regulation may have to be developed (within the regulatory wasteland)

3.3. Conclusions from the case studies

The following policy options can be identified as most appropriate in coping with the governance challenges posed by the four bio-engineering developments that have been highlighted in the case studies. More extensive summaries of these findings and conclusions can be found in Chapter 5.

3.3.1 Whole genome sequencing

Whole genome sequencing data will increasingly be linked with comprehensive health and lifestyle information in biobanks, thus enabling the collection, analysis and sharing of an unprecedented amount of highly personal information in research settings. This will considerably broaden the scope of applications for whole genome sequencing within and outside the health-care sector.

The shift to whole genome sequencing in biomedical research undermines traditional mechanisms in the *regulatory zone* that guarantee data protection and privacy, such as restriction to academic research with no commercial interests, and research only on anonymised data and samples. The study concluded that the traditional governance approach requires adjustment with regard to the level of confidentiality and data protection that can be realistically promised to participants and with regard to the process of obtaining informed consent. Today, communitarian values which

emphasise the interests of the community and focus on solidarity, reciprocity and citizenship are increasingly advocated with the purpose of amending current regulatory practices that are primarily based on liberal values related to individual autonomy and privacy. In forensics, whole genome sequencing is expected to play a role only in the long term; however, the study argues that the current regulatory landscape governing forensic DNA profiling and databasing requires improvements with respect to harmonization, standardization and quality assurance.

In the years to come, whole genome sequencing will increase in direct-to-consumer screening practices that have already emerged within a *regulatory wasteland* outside the regulated health-care system. As it is not clear how many people actually use these genetic profiling services and whether this is leading to any harm, the study advocates closer monitoring and assessment of these new practices.

3.3.2 Neuromodulation

Neuromodulation technologies are an important subject of medical research and it is expected that the number of clinical applications for EEG neurofeedback, transcranial magnetic stimulation (TMS), and deep brain stimulation (DBS) will increase in the future. In addition to medical applications, neuromodulation technologies might also be used to enhance cognitive and behavioural performance, as is already the case for EEG neurofeedback.

Neuromodulation technologies that are intended for diagnostic and therapeutic purposes are defined within the *regulatory zone* as medical devices which have to meet the safety and technical requirements found in two European directives on such devices. In an opinion on Ethical Aspects of ICT implants in the Human Body the European Group on Ethics has advocated that invasive technologies such as DBS should be regulated as pharmaceuticals rather than devices. However, contrary to this opinion and based on findings about the manufacturing and clinical practices of the three neuromodulation devices, the case study has identified regulatory issues mostly in regard to non-invasive devices like EEG-neurofeedback and TMS.

With respect to EEG-neurofeedback, it is not clear whether it should be defined and regulated as a non-medical (monitoring) or a medical (therapeutic) device. Market approval for TMS has been based on its stated purpose as a diagnostic and medical research device, but in practice it is also used off-label in private clinics for therapeutic purposes.

Other challenges arise in the *regulatory wasteland* of possible non-medical uses of neurodevices for gaming and enhancement purposes. In this context, the study raises the question of whether devices used for non-medical purposes should not also meet those requirements set for the medical use of neurodevices. In addition to these regulatory issues, a lack of harmonization in reimbursement policies is also noted as an issue to be addressed in European policymaking

3.3.3 Biocybernetic adaptation

Biocybernetic adaptation has become a central concept in achieving the new ambient intelligence (AmI) vision, including the concept of 'ambient assisted living' for the elderly and disabled. Much research is still needed to realise such a vision; however, there is little doubt that the major goals of biocybernetic adaptation will be achieved and this will strongly increase the two-way exchange of information between systems and individual users.

The case study demonstrated that, even today, the situation in the field of IT within the *regulatory zone* no longer accords with the current EU data protection paradigm, which is based on principles of limited data collection and use, purpose specification, security safeguards and accountability. With increasing amounts of personal data generated and stored in computer systems which are often operated by many parties from different countries, it is becoming increasingly difficult to

comply with the above list of 'fair information' principles. The study argues that a widespread introduction of biocybernetically adaptive systems will seriously worsen the already problematic nature of the current regulatory system. Even though public attitudes towards the value of privacy may seem to be diverse and shifting, the study assumes that privacy remains a core principle and emphasises the need for new regulatory approaches aiming for a fair information framework, including strategies of 'privacy by design'. The case study also calls for user empowerment by stimulating public awareness and education and for the establishment of an overseeing body to monitor developments and provide early warnings concerning ethical, legal and social issues.

In order to avoid a future *regulatory wasteland* there is a need for anticipatory governance of the development and use of biocybernetically adaptive monitoring and surveillance systems, not only with regard to privacy, but also with regard to issues of safety and personal autonomy.

3.3.4 Synthetic biology standards

Synthetic biology is an emerging technoscience which aims to introduce engineering principles into biology on the basis of standardizing biological parts and procedures for engineering design. As the case study argues, it is currently far from clear to what extent engineering principles can be fully emulated in biology, especially because of the inherent complexities of life. As it is difficult to judge the potential of synthetic biology, the study discusses three options for policy which correspond to different and conflicting visions of the future among actors in the field. According to these different visions, synthetic biology (1) will not really radicalise current biotechnology, (2) might possibly revolutionise biotechnology or, (3) will become a real game changer. These different perspectives obviously involve very different governance challenges.

If synthetic biology is seen as substantially equivalent to current biotechnology, no real additional public effort will be put into stimulating the field. If it is seen as a real game changer, creating a new 'industrial revolution', it might lead to massive public investment and moves towards technical standardization.

This would indeed suggest that policymakers should anticipate new challenges in the *regulatory zone* with regard to biosafety, biosecurity and intellectual property standards and to seriously invest in institutionalised forms of assessment and debate regarding the ethical, legal and social implications of synthetic biology. Although the study only flags these different possibilities as options that European policymakers might wish to consider, it could be argued that the strategy already supported by the European Commission is in line with the view that synthetic biology might possibly change the field of biotechnology in a radical way.

4. General policy recommendations

From our analysis of the two mega-trends in 21st-century bio-engineering and the major governance challenges arising from the four case studies, we conclude that there is a need in European policymaking for a comprehensive strategy involving both *bioethics* and *biopolitics* in order to cope with these governance challenges.

4.1. The need for bioethics

Our analysis of the two major bio-engineering trends in the 21st century emphasises the need for European policymakers to acknowledge that future bioethical debates will no longer be solely guided by developments in the life sciences, but will also be led by NBIC convergence of the information and cognitive sciences. The European Commission actively stimulates R&D projects in all four fields of bio-engineering and also supports research on ethical, legal and social issues (ELSI). However, across the different bio-engineering fields there is a clear disparity in the extent of institutionalised attention paid to the governance of ELSI. While the Directorate General for Research and Innovation has the Science in Society Programme, focusing on the societal governance of emerging technologies, there is no such programme (apart from standard ethical review of individual projects) in the Directorate General for Communications Networks, Content and Technology (formerly named Directorate General for Information Society and Media), which has a major role in supporting research on the convergence of neuroscience and information technology.

- *Given the need to broaden the bio-engineering debate in our society in response to NBIC convergence, the European Commission should take a more prominent, integral and pro-active role in stimulating research, public awareness and debate in Europe on the ethical, legal and social aspects of bio-engineering in the 21st century.*

4.2. The need for biopolitics

The conclusion from the case studies that bio-engineering in the 21st century poses a major challenge to European policymaking implies that besides bioethics also biopolitics is required, that is the *political regulation* of shifting and newly emerging sociotechnical practices in society. Politicizing bio-engineering developments thus requires not only scientific reflection and public debate, but also more systematic attention to regulatory uncertainties raised by bio-engineering developments.

- *In order to increase institutional reflexivity and strengthen the preparedness of the European Parliament and other European institutions to deal with the governance challenges raised by bio-engineering in the 21st century, politicians and policymakers need to pay more close attention to the experiences of institutions which deal with regulation and its uncertainties (e.g. the EMA, EDPS, EFSA).*
- *To empower the current European political system to democratically guide bio-engineering in the 21st century, a dedicated and continuous effort is required to make the complex workings and failings of the relevant regulatory systems politically transparent with respect to the present and coming years.*

5. Four case studies

5.1. Whole genome sequencing

Over the last two decades, the analysis of the hereditary blueprint of human bodies, which is encoded in the human genome (made up of DNA), has become a top research priority. The analytical technique for deciphering this genetic information is called DNA sequencing. Recent developments in DNA sequencing technology have significantly improved its speed and reduced its costs. Nowadays, the analysis of the whole genome of an individual can be done within days and for as little as several hundred euros, considerably expanding the frequency, purposes and contexts in which genetic analyses might take place in the future.

5.1.1 Sociotechnical practices

DNA sequencing techniques are used in research and biobanking, health care and forensics. These techniques are already firmly established in fundamental and leading-edge biomedical research. In health care, DNA sequencing is currently primarily confined to genetic testing for rare medical conditions, concerning the analysis of only one or a small number of genes. It is expected that in the coming decade DNA sequencing techniques will be established as a routine general purpose diagnostic tool in health care. It will contribute significantly to realizing the concept of personalised medicine, which also comprises genome-wide diagnostic testing and screening. Furthermore, new applications will also emerge: for example, private companies already offer genome analyses to individuals on a direct-to-consumer basis. In forensic analyses (providing evidence in criminal investigations and assisting in identifying victims of crime or disasters), it is unlikely that whole genome sequencing will replace the well-established method of DNA profiling. Probably it will have some role to play in solving specific problems in forensic genetics.

5.1.2 Governance challenges

As genetic information is highly sensitive personal information, the use of whole genome sequencing in research, health care and forensics brings up many ethical issues and privacy concerns. Many of these issues have already been extensively discussed in the context of genetic testing (i.e., the analysis of only one or a small number of genes within a genome). In order to ensure data protection, safeguard genetic information and prevent its misuse, as well as avoid privacy infringements and discrimination, supranational conventions, national regulations and sector or profession-specific guidelines and codes of conduct have been designed. Generally speaking, however, the existing governance models developed for genetic testing were not designed to deal with the challenges posed by whole genome sequencing.

Whole genome sequencing will transform existing sociotechnical practices of leading-edge biomedical research (especially in the context of biobanks), direct-to-consumer genetic profiling and less so in forensics, and will challenge current regulatory practices for various reasons.

Huge amounts of genetic information

Firstly, the amount and comprehensiveness of the information made available by whole genome sequencing goes far beyond the amount of information that can be gleaned from established genetic testing – comprehensive information about potential medical conditions, non-medical traits and ancestry may be revealed.

Provisional nature of interpretation of genetic data

Secondly, the interpretation of whole genome analyses is highly dependent on current knowledge about the relationship of a DNA sequence to a corresponding trait, and it is highly likely that a

subsequent re-analysis of the DNA sequence will reveal additional information not foreseeable at the time of the original DNA sequencing, making the results highly provisional. This also renders established procedures for obtaining informed consent obsolete in certain cases and raises new ethical issues (e.g., dealing with unanticipated findings, benefit-sharing with trial participants and patients who provide their genome information for research), requiring ethical deliberation.

Difficulties to safeguard privacy

Thirdly, as the anonymization of whole genome data is impossible, it will become more difficult to apply established safeguards concerning privacy, with confidentiality not necessarily guaranteed in contexts outside health care.

Internationalisation

In addition, due to internationalization in research and forensics, an increasing amount of DNA and data exchange across borders is occurring, but there are different levels of national safeguards and regulations in place and there is a lack of harmonization of these regulations.

5.1.3 Policy options

The coming decade, whole genome sequencing will have the most impact on research and biobanking as well as health care and personalised medicine. Whole genome sequencing is already established in these fields, or will be in the coming decade, placing existing governance frameworks increasingly under pressure. The foreseeable developments in DNA sequencing and its application significantly increase the possibility and likelihood of the unintended use or misuse of sensitive, personal genetic data, and could lead to discrimination, stigmatization and privacy infringements. If the benefits of the huge investment in genome research are to be realised, the legal, ethical and social framework will also have to evolve accordingly.

More stringent safeguards for data protection and confidentiality

There is a need for even more stringent safeguards for data protection and confidentiality to combat the unauthorised use of data. Therefore, specific national regulations governing whole genome sequencing and databasing in the context of research, biobanks, health care and criminal investigations should be implemented. Moreover, high-quality standards and a stricter monitoring of whole genome sequencing and databasing practices in research, health care, direct-to-consumer genetic profiling and forensics should be implemented.

International harmonization of national regulations and enforcement levels

Given the international networks in which the development of whole genome sequencing takes place and the patchy nature of existing national regulations, the EU should take an active role in striving for the international harmonization of national regulations, and in harmonizing enforcement levels with respect to the relevant regulations in European member states.

Raise public awareness and stimulate ethical deliberation

The EU should actively raise public awareness of the issues and challenges posed by whole genome sequencing for various purposes, and support a broad debate about it, which seeks to engage experts and the general public. The debate should aim for ethical deliberation, it should attempt to strike a fair balance between the public interest in knowledge generation on the one hand, and individual civil rights and liberties on the other, and also focus on determining the cornerstones of the relevant regulations, codes of conduct and sociotechnical practices, thus enhancing public trust in research as well as medical and forensic practices.

5.2. Neuromodulation

Neuromodulation involves altering neural activity in order to change an individual's behaviour or cognition for medical or non-medical reasons, such as the enhancement of cognitive performance. The market for neuromodulating devices is still in its infancy but has grown steadily over recent years. Further growth is predicted, especially since the medical device market is more accessible than the market for psychopharmaceuticals (as there are less stringent regulations), particularly for small companies. Additionally, disappointing research results in relation to new psychopharmaceuticals have also led large pharmaceutical corporations to broaden their activities to include neurodevices. We have explored whether and how this growing market for neuromodulating devices poses new governance challenges to the European Union.

5.2.1. Sociotechnical practices

Devices for neuromodulation (or neurodevices) can be either invasive (e.g., electrodes inside the brain) or non-invasive (e.g., magnetic stimulation of the brain from outside the skull). Some devices directly alter brain activity (e.g., the activity of a large group of neurons is suppressed or stimulated), others work indirectly (e.g., the patient has to learn to change their own brain activity based on visualizations of it). Neurodevices can be used as therapy, but also for diagnostic, research or leisure purposes. We have studied the application of two non-invasive types of neuromodulation devices - EEG neurofeedback and transcranial magnetic stimulation (TMS) - and one invasive device, namely deep brain stimulation (DBS).

EEG neurofeedback

EEG neurofeedback uses EEG equipment to give patients insight into their actual, real-time brain activity, which is usually measured by three electrodes attached to the skull. The aim is to train patients to self-regulate their abnormal brain-wave patterns and thus their behaviour. While its efficacy - except in the case of ADHD - is still disputed, EEG neurofeedback is also used as a treatment for other conditions, such as epilepsy, autism and learning disabilities. The risks, side effects and adverse events associated with EEG neurofeedback treatment range from mild (anxiety, insomnia) to severe (inducing epileptic seizures).

Transcranial magnetic stimulation (TMS)

TMS is a non-invasive technology which alters brain activity near the skull by inducing an electrical field in the brain. This electrical field, in turn, is generated by a large coil generating a magnetic field. TMS is used for research, diagnostic and treatment purposes. TMS therapy for depression has been the most widely studied, and has been shown to be effective in the treatment of severe depression that is resistant to other forms of therapy. The side effects and adverse events associated with its use are relatively rare, but include seizures and psychiatric complications such as hypomania, as well as headaches and hearing loss. TMS is also being explored for the purpose of cognitive enhancement.

Deep brain stimulation (DBS)

DBS is an invasive neuromodulation technology, in which electrodes are implanted deep in the brain. These are connected by leads to a pulse generator placed in the chest or abdomen. DBS alters brain activity and is most commonly used to treat the tremor symptoms of Parkinson's disease. The use of DBS to treat psychiatric conditions such as severe depression or obsessive compulsive disorder is also being investigated. DBS could be used for enhancement purposes, although it is not used for this purpose at present. The implantation of the DBS system requires surgery, and it can have severe side effects, including adverse events such as bleeding, infection or changes in perception or mood.

5.2.2 Governance challenges

In Europe, neurodevices are regulated pre- and post-market by the Medical Devices Directive (MDD, 93/42/EC) and the Active Implantable Medical Devices Directive (AIMDD, 90/385/EC). The MDD and AIMDD are concerned with protecting the safety of users (both doctors and patients) on the one hand, and harmonizing the requirements for bringing medical devices onto the market, thereby promoting trade, on the other. We have explored to what extent the growing market for the above three types of neuromodulating devices poses challenges to these regulatory frameworks. In regard to safety, we looked into issues of intended use as described by the manufacturer, non-medical use, the standardization of treatment protocols, and the training and certification of professional users. Moreover, we addressed in particular the harmonization of reimbursement policies.

Challenges to MDD and AIMDD

We found that the MDD and AIMDD are challenged by issues which in particular concern the non-invasive neurodevices. No specific regulatory issues related to DBS have been identified. With respect to EEG neurofeedback systems, there are three issues: 1) a lack of clarity on the status of these systems (are they a *medical* device or not?), 2) a broad description of the intended use by manufacturers (questioning whether the performance of these systems is actually assessed for all possible medical uses), and 3) the use of these systems for non-medical purposes, such as gaming or enhancing artistic, sporting and cognitive performance (creating opportunities to bypass the MDD regulation). The regulatory issues associated with TMS primarily concern off-label use. The intended purpose of TMS devices, as described by manufacturers, allows for diagnostic or research use, but in some clinics in Europe it is being used therapeutically despite its efficacy and efficiency not yet being proven (except in the case of severe depression). The use of TMS in private clinics therefore might divert patients from currently more established therapies such as cognitive or pharmaceutical therapy.

Reimbursement policies

In most European countries therapies based on EEG neurofeedback and TMS are not reimbursed, and while DBS is reimbursed for Parkinson's, the situation for other conditions varies between countries. European harmonization of national reimbursement policies is required to assist the growth of the market. At present it is difficult for new companies or devices to enter the market, since its potential size is uncertain and the development of new medical devices and neurodevices in particular is a costly process.

Lack of certified training

Professional associations offer training in the use of EEG neurofeedback but this is not mandatory, and there is no standard training in the use of TMS for clinicians. This situation is undesirable, as unskilled use can result in seizures or other unwanted side effects.

Lack of protocols

Another governance issue concerns protocols. There are some standard therapy protocols available for EEG neurofeedback, but not for all conditions. TMS has more standard protocols, but they are not enforced in clinical practice in the way they are in research practice, which requires the approval of a medical ethical committee. Thus, patients must choose their practitioner with great care.

Lack of public access to data on intended use of neurodevices

Finally, our study shows it is difficult to collect data on the exact intended use of the neurodevice or the different regulatory routes that manufacturers of neuromodulation technologies have taken in order to get a CE marking for their medical devices. The database Eudamed which contains this

information only facilitates the exchange of information between the manufacturers, the Competent Authorities and the European Commission. Social scientists, journalists, patient organisations or individual citizens have no access to Eudamed. More transparency might encourage public debate – when needed – on the (questionable) entrance of a particular medical device on the European market at an early stage.

5.2.3 Policy options

The sociotechnical practices associated with the three neurodevices studied here are relatively stable and even becoming more established. For EEG neurofeedback, transcranial magnetic stimulation (TMS), and deep brain stimulation (DBS) an increase in clinical application is foreseen. A widening of clinical applications for DBS is occurring and research on the use of all three types of devices for other medical conditions is being carried out. However, the only really new practice is the use of EEG neurofeedback for gaming purposes. The most important regulatory and governance issues – especially with respect to non-invasive neurodevices – that must be addressed by EU policymakers are the following:

- *Clarification about whether EEG neurofeedback should be seen and regulated as a non-medical device or as a medical therapeutic device*
- *Specification of the intended use of non-invasive neuromodulation devices as described by manufacturers to avoid off-label use and stimulate better assessment of the devices for different conditions*
- *Consideration of whether neurodevices used for non-medical purposes (i.e., for improving performance and gaming) should meet the same, stricter requirements as those set for their medical use*
- *Consideration of the lack of harmonization of national reimbursement policies in Europe, making it an even riskier endeavour for companies to develop new neurodevices, since this involves huge R&D costs with the returns highly uncertain*
- *More public transparency about the way in which the medical use of neuromodulating devices is regulated by making the Eudamed database publicly accessible.*

5.3 Biocybernetic Adaptation and Human Computer Interfaces

Biocybernetic adaptation is a new approach aiming to optimise human-computer interfaces. On the one hand, this has the aim of freeing the user from the effort needed to operate technology. On the other hand, it can also be seen as an attempt to deliberately make a computer appear as a sensitive interactive partner, able to ‘understand’ or ‘anticipate’ user needs. Biocybernetic adaptation has become the single most widespread research topic in artificial intelligence (AI). Recent developments in the technology of human-computer interfaces include sensors of various types able to register visual and vocal cues of human emotion or to pick up chemical, electrical, mechanical, thermal and magnetic signals emitted by the human body as it changes its state. Sensors are employed in approaches such as affective computing or physiological computing, which incorporate knowledge about the user in order to personalise the computer’s behaviour.

5.3.1 Sociotechnical practices

There are many potential fields of application. Most of the applications foreseen are still at the prototype stage with practical experience largely coming from laboratory tests and experiments. The following types of systems are particularly worth distinguishing:

Computer as a sensitive interaction partner

The computer as a sensitive interaction partner, designed to take the place of human communication partners such as parents, teachers, nurses, doctors, friends and so on. Typical applications are in health care, the treatment of patients with neurological disorders, gaming, the

control of systems and e-learning. Such systems already exist, although their practical use is mostly at the clinical testing stage.

Monitoring and measuring human states

Computer systems to monitor and measure human states such as performance, attention, fatigue and boredom, in order to intervene when the state becomes undesirable. Here, we will see applications in driving, aviation and other forms of travel. Applications in surveillance are also conceivable. There are already systems in place to monitor car drivers on the basis of bodily signals, with the reaction on the part of the system triggered by the crossing of a fixed threshold.

Ambient intelligence

Ambient intelligence is an important application area for biocybernetic approaches. In these cases, the user-interface practically disappears and becomes virtually imperceptible. Pioneering applications include ambient assisted living intended to provide greater independence for the elderly and infirm. If such pioneering applications are successful, ambient intelligence will spread to other areas, including 'intelligent' homes, health care and support for the disabled, as well as industry and business. To date, complete systems are not in practical use, but it seems likely that individual components will be adopted as they achieve maturity, so that systems will be built up gradually.

Neurophysiological computing

Neurophysiological computing goes beyond outward evidence of emotion and attempts to identify concealed emotions through the visualization of patterns of brain activity which have been experimentally matched with emotions. Practical uses currently include the control of machines by handicapped persons, but this technology has also captured the imagination of the producers and users of computer games, which are of increasing economic importance and an important leisure-time occupation.

5.3.2 Governance challenges

Potential problematic societal issues are related to the following features of biocybernetically adaptive systems: 1) They collect huge amounts of data on people, and various players have a strong desire to access this for their own purposes, such as marketing and the development and distribution of technology. 2) They interpret this data and draw conclusions about human users, which might be right but also wrong. 3) They make decisions based on this data, which might also be right or wrong. 4) The decision results in an action, which, when right, as it should be in the majority of cases, benefits the user, but if wrong, can potentially cause harm to the user. Moreover, such decisions are based on the complex processing of various types of information, which cannot be predicted or readily validated by the programmers. This raises the question of who is responsible for the decisions?

Accordingly, the most obvious and important social, legal and ethical issues in this kind of application are privacy and data protection. Another major issue is the autonomy of the user; that is, the user may have the feeling that he or she is being manipulated by the technology. Extremely sensitive data on human users is already being collected, such as data related to the user's health or emotional state in medical applications. This can be extended to healthy users, ostensibly for the purpose of making computer applications more user-friendly. The collection of data is a necessary condition for enabling full adaptation by the system. It is obvious that such data can easily be misused or used for purposes other than those for which it was originally collected. Transparency in relation to data collection, processing and use is thus an important requirement. In addition, systems that can intervene may erode skills and reduce user competence. Another concern is the ability of systems to 'read minds'; however, this is not currently on the horizon.

5.3.3 Policy options

Need to develop a 'fair information framework' for networks

The current paradigm of data protection is no longer suitable and will be increasingly challenged by developments in the field of IT, particularly because these developments are increasingly pervasively distributed and of a connected nature. There is a need to develop a 'fair information framework' for networks. This appears to be especially urgent in the application fields of assisted living, ambient intelligence (in practices of care) and even brain-computer interfaces for gaming.

Stimulate privacy, transparency and control enhancing technologies

There is a need for design strategies which embed privacy, transparency and user-control into the architecture of systems. Thus, policy should seek to stimulate research supporting the strategy of 'privacy, transparency and control enhancing technologies'.

Monitor developments and stimulate expert and public debate

There is a need for an overseeing body to monitor developments and provide early warnings relating to ethical, legal and social issues and to stimulate expert and public debate about these issues (also to anticipate challenges which may only become relevant in the longer term).

5.4 Standardizing synthetic biology

Synthetic biology aims to construct living organisms for useful purposes. To do so, it applies engineering principles in a much more fundamental way than traditional biotechnology. One of its aims is to turn existing micro- and other organisms into fully predictable 'living machines' through standardised interventions. Although not living up to all the optimistic predictions, stunning results have already been achieved. In addition, synthetic biology aims to produce 'artificial life' from scratch, using non-living matter and endowing it with all the necessary features. Some progress has been made in building whole bacterial genomes from chemical substances, but thus far the essential information has not yet been 'devised from scratch', nor has the complicated molecular apparatus of a cell been fully reconstructed. Therefore, claims of having 'created life' are, at best, exaggerated.

5.4.1 Sociotechnical practices

Being conceptualised as an engineering field, synthetic biology has the capacity to bridge the gap between basic or applied research and technological development. Even at present, in the early stage of synthetic biology, practical applications are central, serving highly economically relevant purposes, such as fighting malaria or producing energy sustainably. Thus, synthetic biology promises to substantially contribute to a future bioeconomy.

The engineering principles applied follow those governing fields such as electronics or mechanics. One of the most important is standardization, which makes it possible, for example, to use ready-made parts and combine them at will. Methods from molecular biology and information from genomics serve to construct standardised genetic building blocks with known functions, designed to be universally applicable (at least in micro-organisms), substantially increasing the freedom of combination and the variety of ends pursued.

However, all this is based on the reductionist premises that genetic parts can be designed to a sufficient level of standardization, performance and reproducibility, and that organisms are clearly defined by their genome sequence. A substantial section of the synthetic biology community believes this is the case; however, thus far only a few standardised elements have been constructed and been proved to function as intended.

The deliberate engineering approach in synthetic biology invites analogies. In the popular media, standardised genetic elements are often compared to Lego bricks, as both can be freely combined and used in a wide variety of similar tasks. More serious analogies are derived from information technology (IT), especially with respect to standardised building blocks – genetic elements are compared to electronic parts which are assembled into circuits. Taking this comparison further, IT practices, such as separating design, construction and assembly, are also important in synthetic biology. Analogies even pertain to the future technical importance of the field and anticipated benefits. Like IT, some consider that synthetic biology will develop quickly and become immensely powerful and economically important. Whether this will occur is unclear because many obstacles still have to be overcome. Some experts even say that for fundamental reasons this will never occur.

5.4.2 Governance challenges

Appraising the importance of synthetic biology

The main question is how to appraise the importance of synthetic biology in relation to other fields of biotechnology. Across Europe, political reactions have been non-uniform and until recently funding has been patchy in many places. To cope with the existing US dominance, European involvement might entail not only massive funding but also promoting the establishment of technical standards.

Intellectual property

A by-product of the anticipation, realistic or not, that synthetic biology will be hugely important is a controversy over how to handle emerging intellectual property. As in IT, open source or open access approaches stand opposed to a process of extensive protection of intellectual property through patents. Although a mixed practice seems to be emerging, accepted standards are also required here.

Safety and security

Another effect of the anticipated technical power of synthetic biology is the fear of potential misuse and accidents, entailing the demand for new safety standards. Although existing standards appear to be sufficient at the moment, this could change. Synthetic biology itself might contribute to the development of new safety and security methods but only if there are adequate incentives at hand.

Public unease about 'creating life'

Finally, synthetic biology has frequently been attributed with the potential power to blur the boundaries between life and inanimate matter. High-level expert reports have repeatedly addressed concerns, primarily with respect to 'creating life'. This may not only lead to ethical questions but also to public unease, with some fearing that synthetic biology will be rejected by certain sections of the general public in the same way as plant biotechnology. They therefore advocate outreach activities and a public discourse early on to bring potential concerns to the fore. Ultimately, limits to certain applications could be discerned according to societal standards developed in a public debate.

5.4.3 Policy options

The policy challenges posed by synthetic biology can be condensed into options for standard-setting activities in four areas: technical, safety/security, intellectual property management and broader societal standards. Policy options may be grouped into business as usual approaches,

leaving development more or less to its own; moderate governance approaches, steering development without taking too many risks; and active governing approaches, implementing a clear political will.

The authors of this case study, Schmidt and Torgesen, do not put forward a preferred strategy, as they argue that the future of synthetic biology is just too uncertain to promote a particular strategy. We, as editors, would argue that the governance strategy already taken by the European Commission is in line with the assessment that synthetic biology might possibly change the field of biotechnology in a radical way. We would like to advise the European Commission to affirm and explicate that stance and act accordingly. This would suggest the above moderate governance approach, which implies the following policy options.

Technical standard setting

Technical engineering standards would be something relatively new to biology as they are largely absent today. To keep a foot in the door, the European Commission should contribute moderately to the establishment of standards.

Safety standards

Safety standards should set clear rules to ensure technological development while preventing dangerous or unwanted effects. The European Commission should continuously assess whether existing regulation is still adequate.

Intellectual property management

Intellectual property management is a key factor in technology implementation. Today, open source and open access stands opposed to comprehensive patenting. The European Commission should promote research and institutions to facilitate open approaches.

Stimulate public debate

Societal standards should develop out of the public debate, but such a debate may imply the risk of negative public opinion. The European Commission should stimulate public debate to reveal concerns and devise measures.

This document summarises the findings and conclusions of:

- the STOA monitoring report:
Making Perfect Life. Bio-engineering (in) the 21st Century (2011);
- the STOA study:
Making Perfect Life. Bio-engineering (in) the 21st Century.
European Governance Challenges in Bio-Engineering (2012).

The STOA studies can be found at:

<http://www.europarl.europa.eu/stoa/cms/studies>

or requested from the STOA Secretariat: STOA@ep.europa.eu

In addition a short Options Brief is also accessible through the STOA studies website, or via this QR code:



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