



## SCIENCE AND TECHNOLOGY OPTIONS ASSESSMENT OPTIONS BRIEF No 2012-08, December 2012

### Making Perfect Life European Governance Challenges in 21st Century Bio-engineering

#### Background

The general aim of the STOA project 'Making Perfect Life' was to identify major overarching trends that are visible in the development of four selected fields of 21<sup>st</sup>-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. A number of specific developments were studied, 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.

#### General recommendation

From the analysis of major trends in the four fields of 21<sup>st</sup>-century bio-engineering and the governance challenges arising from these trends, it can be concluded that there is a need in European policy-making for a comprehensive strategy involving both *bioethics* and *biopolitics*, in order to cope with these governance challenges.

#### The need for bioethics

The analysis of the major bio-engineering trends in the 21<sup>st</sup> century clearly shows the need for European policy-makers to acknowledge that future bioethical debates will no longer be solely guided by developments in the life sciences, but will also be led by convergence of the life sciences with the information and cognitive sciences, so-called NBIC convergence. The European Commission actively stimulates R&D projects in all four fields of bio-engineering – engineering of the human body,

engineering of the brain, engineering of intelligent artefacts and engineering of living artefacts – 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 institutionalized 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 21<sup>st</sup> century.*

#### The need for biopolitics

The studies of more specific developments in the four fields of bio-engineering again clearly show that bio-engineering in the 21<sup>st</sup> century poses a major challenge to European policy-making. From the findings of the case studies it can be concluded that, besides bioethics, also biopolitics is required, that is the *political regulation* of shifting and newly emerging socio-technical practices in society.

Politicising 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 21<sup>st</sup> century, politicians and policy-makers need to pay closer attention to the experience of institutions dealing with regulation and its uncertainties (e.g. EMA, EDPS, EFSA).*
- *To empower the current European political system to democratically guide bio-engineering in the 21<sup>st</sup> 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.*

### **Specific recommendations related to the four fields studied**

Major governance challenges arising from specific developments in the four fields of bio-engineering are the following:

#### **Whole genome sequencing**

- Existing frameworks for data-protection and informed consent in biobank research need to be revised and harmonised.
- Novel forms of consent and genetic counselling need to be developed for whole genome analysis in health care, without compromising patient autonomy.
- There is a need for regulatory oversight in direct-to-consumer genetic testing.
- Current regulation of forensic databases is patchy and needs to be harmonised.
- Public awareness of the issues and challenges raised by whole genome sequencing should be fostered.

#### **Neuromodulation**

- From a regulatory perspective, it should be clarified (1) whether EEG-neurofeedback has to be considered a medical (therapeutic) device, and (2) whether there is a need to regulate neurodevices for non-medical purposes in a similar way as neurodevices for medical use.

- In the field of transcranial magnetic stimulation there is a clear tension that needs to be addressed between regulated research and unregulated (off-label) use.
- Attention is needed at the European level for the lack of transparency of market approval data and a lack of harmonisation of reimbursement schemes.

#### **Biocybernetic adaptation**

- The current data and privacy protection framework needs to be revised, given current developments in the field of IT and the developments envisioned in the context of non-professional health care and gaming.
- There is a need for design strategies which embed privacy, transparency and user-control in the architecture of biocybernetic systems.
- There is a need for an overseeing body to monitor developments and provide early warnings relating to societal issues and to stimulate expert and public debate about these issues.

#### **Synthetic biology**

- Given the high level of uncertainty about the prospect of robust and reliable engineering standards in the emerging field of synthetic biology, an open, pro-active and critical approach to issues of standardisation – including technical, safety and intellectual property issues – seems to be the most appropriate governance strategy.

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