European Parliament

STOA Working Breakfast

A European Approach to Human Enhancement

Participants' booklet

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Scientific Foresight Unit (STOA)

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STOA working breakfast

A European Approach to Human Enhancement

Participants' booklet

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2 HUMAN ENHANCEMENT: AN INTRODUCTION

From the Introduction of the STOA Study 'Human Enhancement'. European Parliament. Directorate General for Internal Policies. Science and Technology Options Assessment (STOA). May 2009. Available at: https://www.itas.kit.edu/downloads/etag_coua09a.pdf

Science and technology continue to provide more and more means to influence human bodily functions, both mental and physical. Such forms of "human enhancement", in particular "human enhancement technologies" (HET), are being used or developed or are envisioned in several fields of applications as diverse as assistive technology for disabled people, pharmacology, military research, reproductive medicine, and sports.

Human enhancement is thus a phenomenon linking a range of technologies that at first sight appear very different. There is also an ongoing political, social and ethical discussion of human enhancement. Such discussion has not only become a fashionable topic in certain circles, but the literature on it has reached a critical mass, qualifying it as a major topic of ethical research.

The distinction between therapy and human enhancement is usually part of the arguments for or against allowing technological intervention in the human body or mind. Therapy is often defined as the attempt to restore a certain condition (e.g. normality, sanity, health), whereas human enhancement is regarded as transcending these boundaries.

These issues have been discussed for some time now, mainly from the perspective of bioethics and with regard to doping, the non-therapeutic use of drugs and cosmetic surgery. Recently, however, advanced and visionary HET, based on new and emerging neurotechnologies, information and communication technologies (ICT) and other areas of research and development (R&D), have attracted strong public, political and academic attention.

The phenomenon of human enhancement is a highly contested issue. The views on the acceptability and desirability of human enhancement widely diverge. The debate on HET and the visions of their impact raise fundamental questions concerning our views of the human condition and corporality as well as of the future of our societies. A broader debate also concerns the societal role of medicine and the health system, such as the tendencies toward medicalisation and commercialisation, apparently furthering the trend toward human enhancement.

Given the highly visionary and ideological notions, it is obvious that the discussion of human enhancement is not rational. Yet beyond competing worldviews, it is characterised by conceptual diffuseness and a lack of differentiation. For example, with respect to health practice, the question is whether the distinction between human enhancement and therapy is tenable enough for policy purposes.

Some of the differences in the assessment of the state of the art in R&D in HET can be explained by the wide variety of definitions of human enhancement. Given the conceptual problems, there is a need for substantial efforts to develop a pragmatic notion of human enhancement and a heuristic to identify the relevant HET, both of which must be viable for handling the issue and the ongoing developments in a policy context.

Human enhancement can be defined as any 'modification aimed at improving individual human performance and brought about by science-based or technology-based interventions in the human body', distinguishing between i) restorative or preventive, non-enhancing interventions, ii) therapeutic enhancements, and iii) non-therapeutic enhancements.

The effects of HET can be either long term or even permanent (as in the case of genetic enhancements), or temporary (such as the improved concentration brought about by the use of drugs). The aim may be to improve our natural abilities (for example by making us stronger or happier) or to give us characteristics or abilities that no human being has ever had before, such as full night vision or flying.

Much of the discussion revolves around highly visionary ideas which evidently shape the discourse on HET and could raise societal expectations on science, technology, and their future. There are, however, developments which are of rather short-term interest, and some HET already exist.

The role played by human enhancement in some individual strategic discussions about European R&D policies appears to be just a beginning. The ethical, societal, technological and innovation aspects of the topic are becoming increasingly important at all levels.

3 THE NERRI - NEUROENHANCEMENT AND RESPONSIBLE RESEARCH AND INNOVATION PROJECT

NEURO-ENHANCEMENT

Improving the functioning of the brain through different forms of intervention – neuro-enhancement – has a long history. Over several decades, the idea has gained visibility through films and novels and, more recently, in academic debates. However, the futurists' utopian vision of overcoming human limitations has met with concerns over risks to individuals and societies. To some, the idea of enhancement is at odds with what they think is inherently human.

Over the last decade media coverage, taken to be a proxy for public interest, has increased sporadically rather than consistently. Reports on students using prescription drugs to enhance their performance have triggered interest and the activities of young 'brain hackers' experimenting with various neurodevices have raised attention. Elsewhere, potential negative social implications, such as increasing pressure on individuals to perform featured in the debate.

The prevalence of pharmaceutical usage for enhancement is unclear but probably less substantial than media reports suggest. At the same time, a growing number of elderly people hope for efficient treatment of their declining mental conditions, raising the demand for the development of restorative drugs and devices that could eventually be used for neuro-enhancement in the normal population.

Today, the patchy scientific knowledge and doubtful technological feasibility render high hopes as unrealistic as deep fears. At the same time, governments and the European Commission have declared brain research to be strategic, with substantial funding and long-time hopes attached.

THE NERRI STUDY

Funded by DG Research in the European Commission the NERRI consortium, comprising partner institutions in 11 countries, was established to develop a normative framework for neuro-enhancement and to make proposals for responsible research and innovation in this domain.

The NERRI project has conducted more than 60 Mutual Learning Exercises (MLEs) across Europe, bringing together researchers, users, intermediaries, professionals, students, the media and the broader public. The MLE concept involves a process of decentralization; experts and lay audiences debating and learning from each other instead of experts simply informing lay people about 'facts'. The debates focus more on unknowns (futures, risks, possibilities) than on established expert knowledge. Under high uncertainty and ambivalence, this offers advantages as hopes and fears can adequately be addressed before public opinion has crystallised. As a complement, web-based social surveys designed on the basis of the experiences from the MLEs were conducted to provide more detailed insights into the distribution of attitudes and the main points of view within and between countries.

4 EUROPEAN BRAIN COUNCIL

Brain research is at the forefront of science but extensive work is still needed to better understand brain functioning. Brain research and brain diseases are relatively new terms. The former covers neuroscience, neurological, and psychiatric research and the latter includes disorders that might be classified as neurological or psychiatric.

Both terms are better understood by decision makers and the general public and were therefore proposed by the European Brain Council (EBC), an alliance of all major European stakeholders interested in the brain and its health that was formed in 2002. The EBC brings together European organisations in neurology, neurosurgery, psychiatry, basic brain research (neuroscience) as well as patient organisations and industry. As such, it is ideally positioned to champion and promote brain health in Europe and is perfectly placed to drive the agenda in improving the quality of life for all those living with brain diseases.

One of EBC's greatest achievements was to create a single, united voice raising the awareness of brain health and putting it higher on the EU agenda. Until the establishment of EBC, the focus on brain was relatively disparate, often missing out on the support and funding that centralized and focus advocacy can achieve.

Since its creation, the membership of EBC has grown steadily. It is currently made up of various member organisations representing all areas involved in brain health and brain disorders, with a newest member that joined in December 2015: the International Brain Research Organization Pan European Regional Committee. This broad range of knowledge and support is one of EBC's most valuable assets, and something EU policy makers and other stakeholders greatly appreciate.

As example of where EBC initiated real change is the increase in EU funding for brain research during the past ten years, with EU funding for brain research increasing from €85 million (Fifth Framework Programme FP5 – before EBC) to €3 billion (FP7). EBC is grateful to the Commission for this much needed increase.

At the early phase of its existence, EBC recognized that such achievement would not be possible without creating a body of evidence supporting our call to put more priority to brain health. The EBC has produced a number of influential reports, such as Consensus Document on European Brain Research (published in 2006 and updated in 2011) describing needs and achievements of research in Europe and presenting proposals for future research programs. March 2016 will see launch of the most recent update of the Consensus statement with a number of new proposals for brain research, ranging from consciousness to computational neuroscience.

Another best known is the EBC landmark studies "Cost of Disorders of the Brain in Europe" published first in 2005 and then updated in 2011. These publications drew European policy makers' and national governments' attention to the prevalence and high cost of brain diseases as it demonstrated that brain disorders cost Europe €798 billion per year and affect one third of European population, i.e. 165 million people in Europe. The World Health Organisation echoes these concerns and concluded that brain disorders account for 35 per cent of the burden of all diseases in Europe and will become the major medical need of this century.

These figures should be kept in mind when tackling the most pressing societal challenges - the key objective of the Europe 2020 Strategy, designed to turn Europe into "a smart, sustainable and socially inclusive market economy". While economic priorities come first in the current environment, the power of healthy brains is fundamental to the realisation of the Europe 2020 Strategy. Only with the best outputs of healthy brains will we solve many of the challenges that face modern societies. Advancing understanding and improving the health of the brain has a positive ripple effect as it leads to better overall health, which leads to better productivity among the working population, which in turn contributes to increasing Europe's competitiveness.

EBC considers that improved cooperation and coordination are absolutely critical to address in an efficient manner both the challenges and opportunities posed by our brains. With this in mind, in November 2015 we launched a call to foster a dialogue on developing National Brain Plans that would be brought under the umbrella of an EU-wide plan addressing brain health in a comprehensive and collaborative way. Successful examples of strategies in other disease areas already exist in Europe. These efforts will focus on implementing evidence based strategies for research, prevention, early detection and diagnosis, and adequate treatment. The aim is to meet the needs of patients, carers, doctors, researchers and industry.

Our most recent major endeavour has just been launched in January 2016: EBC is carrying out a new research project for 2015-2017 on "The value of Treatment (VoT) for Brain Disorders". Analyses demonstrate that there is a considerable treatment gap in Europe, with only about a third of cases receiving the therapy or medication needed. EBC's VoT project will generate evidence on the socio-economic benefits of healthcare interventions through analysis of case studies in order to build towards closing this treatment gap and develop a workable model of care for brain disorders. The study will produce economic evidence on the socio-economic benefits of health outcomes, demonstrate what interventions are the most cost-effective, develop and validate a coordinated care model and provide policy recommendations on how to implement the cost-effective interventions on brain disorders.

Last, but not least, EBC appreciates the vital role of some twenty National Brain Councils which have been developed with the help of EBC in order to push for according more priority to brain issues at the local level. NBCs provide vital grass root knowledge to the EBC and enable significant progress at country level.

Despite these significant achievements there is still a great deal to be realized. EBC together with its members and partners are determined to reinforce their role as the leading organization in the field of brain health and research in Europe, with the NBCs warranting the same respect and recognition at the local level. EBC will also aim to widen its support base as the world accepts and understands that the brain is responsible for everything the human race has ever achieved. With this in mind, there are no industries, sectors or specialist areas which cannot attribute their success to the brain and so wouldn't benefit from collaboration with the EBC.

5 CHAIR

Paul Rübig MEP, STOA Chair

Paul Rübig was elected as the STOA Chair for the first half of the European Parliament's 8th legislature having previously served as Chair from 2009 to 2012 and as First Vice-Chair from 2012 to 2014. Born in Upper Austria, Paul Rübig has been a member of the European Parliament since 1996 and belongs to the European People's Party (EPP). He is the owner of an Austrian blacksmith company and has a degree in Business Administration, Marketing and Production Engineering from the University of Linz, Upper Austria. He is married and has two children.

Paul Rübig is a full member of the Committee on Industry, Research and Energy and of the Committee on Budgets. He is Vice-Chair of the Delegation for relations with the Korean Peninsula and substitute member of the Delegation for relations with Switzerland, Norway and of the EU-Iceland Joint Parliamentary Committee.

He is also a substitute member of the European Economic Area (EEA) Joint Parliamentary Committee. Furthermore, Paul Rübig is a substitute member in the Committee on Development. Paul Rübig is very active in the field of the small-scale business promotion. He is president of SME Global, a working group of the International Democrat Union (IDU), whose objective it is to support small and medium-sized enterprises (SME) and to improve their business environment.

6 SPEAKERS

6.1 *David Nutt, President, European Brain Council*

Prof David Nutt is currently the Edmond J. Safra Professor of Neuropsychopharmacology and director of the Neuropsychopharmacology Unit in the Division of Experimental Medicine at Imperial College London.

He is Chair of the Independent Scientific Committee on Drugs (ISCD), President of the European College of Neuropsychopharmacology (ECNP), President of the European Brain Council, President-elect of the British Neuroscience Association, the UK Director of the European Certificate and Masters in Affective Disorders Courses and a member of the International Centre for Science in Drug Policy.

In addition, he has edited the Journal of Psychopharmacology for over a decade and acts as the psychiatry advisor to the British National Formulary. He has published over 400 original research papers, a similar number of reviews and books chapters, eight government reports on drugs and 26 books.

He broadcasts widely to the general public both on radio and television including recent BBC Horizon on drug harms and their classification. He also lecturers widely to the public as well as to the scientific and medical communities; for instance has presented three time at the Cheltenham Science Festival and several times for Café Scientifiques. In 2010 he was listed as one of the 100 most important figures in British Science by The Times Eureka science magazine.

Key message

Undergraduates taking pills to get better grades, Silicon Valley programmers pimping their minds, brainhackers using electric devices on their skull to boost gaming scores – media like these stories. Are they the harbingers of pervasive cognitive enhancement to come? Will we transcend the limitations of the human mind? Will the many elderly people with dementia find relief? Will we be forced to take drugs to stay competitive?

The scientific-technical reality is more sober. Drugs (mis)used for enhancement purposes are old and not intended for this. Their performance is doubtful and side effects have not been properly investigated. New drugs are not in the pipeline; despite a rising demand for treating dementia, industry does not invest much in this difficult field. In addition, outright enhancement drugs would not be licensed as they are not against a 'disease'. Electrical and magnetic transcranial stimulation might result in spectacular effects – sometimes the opposite of the intended – and health risks if inappropriately applied.

In short, it is still challenging nowadays to know clearly what human cognition actually is and what makes it unique, what exactly happens in the brain, how to boost it and what the side effects may be. Today and for the near future, reliable and reproducible cognitive enhancement will not be readily available, experts say. Media reports exaggerate the prevalence of today's drug use, the effects on the individual and the consequences for society.

Yet we see new efforts at brain research these days. Big flagship projects promise to deliver paradigm shifts in the understanding of the brain. Discussing enhancement could be timely now, when the technical means are not yet at hand but we have the arguments and positions ready: do we as society want this to happen, and under which conditions? What would we need to know and how could we make research and innovation more responsible, knowing that enhancement research holds promises of therapeutic applications for psychiatric and developmental disorders.

The most well-known examples of therapeutic agents being used off-label as enhancers are intended for the treatment of ADHD and narcolepsy. However, while they may be useful in keeping healthy people awake and attentive for longer, it is still unclear how much of a neuro-enhancing effect these drugs actually have.

We are also challenged with how to find a balance between protecting people and not damaging innovation. For instance dyskinesia drugs for Parkinson led to developing some "legal highs". Regulators, in excessive concern for safety, made further research impossible and thus hampered a promising area of research for people suffering from Parkinson.

- Is it desirable to have cures reaching "healthy populations"? Who would fund the research on "healthy people" outside the therapeutic use?
- The research on human enhancement is not yet at a stage where there is enough interest to invest.
- Safety needs to be ensured (informed decisions are necessary) and discoveries have to come step by step.
- The problems faced are not only a question of money: there is a failure to apply neuroscience to the issues at stake.
- The regulatory process lacks flexibility. This is contradictory to research itself as new data is discovered every year. Yet, scientists have to stick with what was decided and enshrined into legislation years ago.
- There is a set of very different ideas and images regarding brain-related issues across Europe. Therefore, a European consensus might be difficult to reach.

6.2 *Imre Bard, London School of Economics, NERRI Partner*

Imre Bard studied Philosophy and Cognitive Science at the University of Vienna, and Social Studies of Biomedicine at the London School of Economics (LSE).

He is currently a part-time PhD student in Social Research Methods at LSE and a Research Officer on the NERRI Project.

His thesis draws on both quantitative and qualitative methods to study public attitudes towards human enhancement.

Before joining the NERRI project he had worked with Prof Ilina Singh on the final phases of the VOICES project (http://www.adhdvoices.com) and developed the first UK survey on student's views and practices in relation to cognition enhancing drugs.

He is a visiting instructor on the ethics of human enhancement at Yale University's Summer Bioethics Institute.

Imre has an interest in developing new methods of conducting public dialogue and in January 2016 he received a People Award from the Wellcome Trust to carry out the 'Hack the Senses!' project, which will engage members of the public with the neuroscience of perception in an innovative and hands-on manner.

Key message

A number of prevalent points of view were found across Europe. They appear almost everywhere, though with different prominence:

- the efficacy and safety of neuro-enhancement technologies, which raises the demand for systematic research;
- the enhancement of one capacity entailing the potential for damaging other capacities, alluding to the idea of the brain as an interdependent coherent system;
- the distinction between 'natural' (traditional or plant-based) and 'artificial', or between non-technical (education, sleep, training) and technical (pills, devices) means;
- whether people will be swayed by potential benefits and take a proactive stance, or lean towards precaution on account of the potential risks involved;
- evocation of both utopian and dystopian visions of the future: a token of progress and a means to transcend human limitations versus an unnatural and retrograde step;
- the weighing-up of individual freedom of choice against the anticipation of negative societal consequences (increased inter-personal competition, declining social cohesion);

- the age-related division between younger people – safe in their healthy bodies and more open to the new – and elderly with ailments pending, uncertain about new technologies;
- a different focus on either individual consequences such as health risks and competitive advantages, or societal risks such as a change in the way we live together.

Contextual differences: education and work

In educational settings, some consider enhancement technologies equivalent to the introduction of learning aids such as computers. Others consider a quick fix by pills or devices to run counter to the educational mission of building character. Particular, with regard to minors, the parents' role and issues of autonomy and freedom of choice are at stake: how far should the parental freedom go when deciding on neuro-enhancing their children? What of the child's autonomy?

At work, employees in high responsibility occupations may find recourse to neuro-enhancement technologies a benefit, or they may be seen as an antidote to labour market pressures. Others may find themselves forced to engage in what they see as a problematic employment practices.

National differences across Europe

While these points of view are detectable in all participating countries, the dilemmas taking centre stage vary and different positions may crystallise. Experts, stakeholders, politicians and administrators concerned with responsible research and innovation across the involved countries and in the European Commission have to consider this variation as a basic condition for any European governance strategy on neuro-enhancement.

Gauging public sentiment

Finally, the NERRI Consortium is implementing a systematic social survey in eleven Member States focusing on views about cognitive restoration, enhancement and gene editing. It is hoped to present preliminary results at the meeting.

6.3 George Gaskell, London School of Economics, NERRI Partner

George Gaskell is Professor of Social Psychology and Research Methodology, at the London School of Economics.

He is special advisor to the Director of the London School of Economics, following seven years as pro-director planning and resources.

Since 1996 he has coordinated the series of Eurobarometer surveys on Biotechnology and in 2004 joined the International Biotechnology Survey Group which conducts comparative research in the US, Canada and Europe.

He was coordinator of 'Life Sciences in European Society', a European comparative study of biotechnology in the public sphere funded by the European Commission's 5th Framework Programme and is coordinator of an FP7 project on 'Sensitive technologies and European Public ethics.

Gaskell's research focuses on science, technology and society, in particular the issues of risk and trust, social values and technological innovation, and the governance of science and technology. Conceptually this research is informed by a social psychological analysis of individual and collective sense making – the theory of social representations. His research methodological competencies include survey design and both quantitative analysis and qualitative inquiry.

Gaskell also chairs the LSE and Partners Consortium on Behavioural Science, conducting studies in support of European Commission Directives and policy deliberations. Recent studies include tobacco health warnings, energy labelling; environmental footprints, on-line gambling and protective measures for children playing on-line games.

He also leading LSE participation in a twelve country European study on Responsible Research and Innovation (RRI) in neuro-enhancement.

Key message

Towards Responsible Research and Innovation in neuro-enhancement

This distinction between restoration and enhancement is not always easy from a scientific point of view but has a vivid repercussion among the public. It not only impinges on regulatory aspects but also on companies' strategies and, as such, on research and development. Commercial marketing strategies aiming to overcome the distinction might influence whether a restrictive or permissive governance strategy will be more appropriate.

Implications for research strategies and funding programs

Brain research is a strategic field to gain scientific and, in the end, economic competitiveness. Some may be tempted to see neuro-enhancement in this light; a development with economic potential. Such reasoning might find ambivalent responses among the European public.. In

contrast, promoting research aims exclusively linked to curing diseases is welcome. If neuro-enhancement research is to be promoted, unintended effects and health risks must be adequately assessed.

The need for a framework of governance: regulation or not?

Participants in the MLEs often demanded a governance approach that adequately addresses uncertainties and safety concerns as well as societal consequences. In the long run, the lack of governance may cause uncertainty when new technologies emerge or risks become apparent.

Governance not only relies on regulation but deals with an issue in the interests of society using a variety of tools, such as voluntary commercial agreements, negotiations between third party groups, focused education and information campaigns etc. Such an approach is flexible but needs to take into account the diversity of views among stakeholders, experts and different publics as well as across countries.

A subset of participants argued for outright regulation. While some experts consider regulation too early or find it too complicated, inappropriate or unfeasible, others think it is necessary. If a regulatory approach is chosen, it may need to consider whether neuro-enhancement falls under the auspices of medical or consumer regulation or indeed both.

Human and fundamental rights as a basis for a governance strategy

A framework oriented at human and fundamental rights provides a point of departure. In particular, the right to human health in combination with governments' obligations to respect, protect and fulfil this right is topical. The definition of good health follows that of the WHO: a state of complete physical, social and mental well-being, and not merely the absence of disease or infirmity. Such a framework also allows addressing horizontal and long-term social, ethical and economic issues and enhances regulatory consistency.

Public engagement as an integral part

A governance strategy should not be confined to legal considerations or expert deliberation but should integrate novel forms of public engagement to better understand the needs, views and ethical tenets of different stakeholders and publics across Europe.

Gene editing: a novel technology of unclear relevance to brain research

Although gene editing will, for the foreseeable future, not provide any suitable tool to interfere with cognitive abilities, it offers perspectives to mitigate devastating monogenic diseases affecting the brain. Although unrealistic today, this might also raise expectations to intervene in the brains of healthy individuals. One reason for the low probability of realisation is that almost nothing is known about the link between single genes and complex cognitive capacities.

Dealing with new technology: familiar patterns of handling

A survey by the Genetic Alliance UK among patients showed that preferences follow established and pragmatic rules and practices. The patients call for:

- a better informed debate: they are interested in genome editing technologies and would like to learn more;

- prioritizing, in research and clinical settings, applications for treating medical conditions and not for the enhancement of healthy people;

- decisions to be made by multiple stakeholders to ensure an ethical use of the technologies; they want to be involved in this process;

- an informed consent process allowing them to properly understand the risks, particularly if children are to be treated.

Thus, patients incline towards the development and regulation of new technologies that is similar to long established traditions.

7 ABOUT STOA

7.1 *MISSION*

The Science and Technology Options Assessment (STOA) Panel forms an integral part of the structure of the European Parliament. Launched in 1987, STOA is tasked with identifying and independently assessing the impact of new and emerging science and technologies. The goal of its work is to assist, with independent information, the Members of the European Parliament (MEPs) in developing options for long-term, strategic policy-making.

The STOA Panel

The STOA Panel consists of 24 MEPs nominated from the eight permanent parliamentary committees: AGRI (Agriculture & Rural Development), CULT (Culture & Education), EMPL (Employment & Social Affairs), ENVI (Environment, Public Health & Food Safety), IMCO (Internal Market & Consumer Protection), ITRE (Industry, Research & Energy), JURI (Legal Affairs) and TRAN (Transport & Tourism). Ms Mairéad McGuinness MEP is the European Parliament Vice-President responsible for STOA and member of the Panel. The STOA Chair for the first half of the 8th legislature is Paul Rübig, with Eva Kaili and Evžen Tošenovský elected as 1st and 2nd Vice-Chairs.

The STOA Approach

STOA fulfils its mission primarily by carrying out science-based projects. Whilst undertaking these projects, STOA assesses the widest possible range of options to support evidence-based policy decisions. A typical project investigates the impacts of both existing and emerging technology options and presents these in the form of studies and options briefs. These are publicly available for download via the STOA website: www.europarl.europa.eu/stoa/.

Some of STOA's projects explore the long-term impacts of future techno-scientific trends, with the aim to support MEPs in anticipating the consequences of developments in science. Alongside its production of 'hard information', STOA communicates its findings to the European Parliament by organising public events throughout the year.

Focus areas

STOA activities and products are varied and are designed to cover as wide a range of scientific and technological topics as possible, such as nano-safety, e-Democracy, bio-engineering, assistive technologies for people with disabilities, waste management, cybersecurity, smart energy grids, responsible research & innovation, sustainable agriculture and health. They are grouped in five broad focus areas: eco-efficient transport and modern energy solutions; sustainable management of natural resources; potential and challenges of the Internet; health and life sciences; science policy, communication and global networking.

7.2 ADMINISTRATION

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