RRI Country Requirements Matrix

Nanotechnology, Synthetic Biology, ICT

Authors in alphabetical order[1]
David Coles, Margret Engelhard, Bing Han, Amit Kumar, Kelly Laas, Miltos Ladikas,
Ren Lin, Doris Schroeder, Ravi Srinivas, Jaci van Niekerk, Mary Walker, John Weckert

Citing suggestion: David Coles et al (2014) RRI Country Requirements Matrix - Nanotechnology, Synthetic Biology, ICT - Report for FP7 Project "Progress", progressproject.eu.
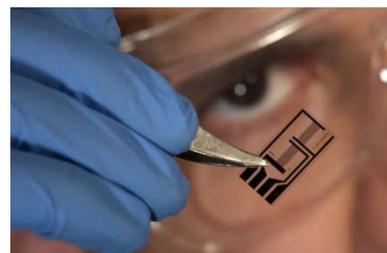
---

[1] Thanks to Julie Cook Lucas for editorial input.

Table of Contents

1. Executive Summary and Conclusions

To act *responsibly* in research and innovation should cover all relevant activities; i.e. research on new children's toys as well as advanced astronomy; innovations in cancer diagnostics as well as in water filtration. However, responsible conduct is particularly pressing in areas of new technologies with the potential for unforeseen and undesirable consequences for humankind and the environment. The European Commission is continuing to support a programme which links research and innovation to societal concerns and interests. The "Science with and for Society" programme has produced one of the most influential responsible research and innovation (RRI) definitions in Europe:

> RRI is an inclusive approach to research and innovation (R&I), to ensure that societal actors work together during the whole research and innovation process. It aims to better align both the process and outcomes of R&I, with the values, needs and expectations of European society. In general terms, RRI implies anticipating and assessing potential implications and societal expectations with regard to research and innovation.[2]

A definition of RRI which has been used globally, was developed by René von Schomberg:

> [A] transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products(in order to allow a proper embedding of scientific and technological advances in our society).[3]

---

[2] Science with and for Society. 2013. *Responsible Research and Innovation*. http://ec.europa.eu/programmes/horizon2020/en/h2020-section/science-and-society.
[3] von Schomberg, René. 2013. A Vision of Responsible Research and Innovation. In *Responsible Innovation* edited by Richard Owen, John Bessant, and Maggy Heintz, 51-74, London; John Wiley.

This report provides an overview of how efforts to achieve ethical acceptability, sustainability and societal desirability can be mapped onto three technologies, namely: nanotechnology, synthetic biology, and information and communication technology (ICT). Information tables are provided for Australia, China, Germany, India, South Africa, the United Kingdom and the United States, giving a spread of all continents.

For the purpose of this report, we assigned codes of conduct, ethics guidelines and sustained public engagement efforts to the theme of ethical acceptability; legal instruments focusing on environmental protection and health & safety to the theme of sustainability, and efforts to address a country's Grand Challenges to the theme of societal desirability. We define Grand Challenges as major problems that a country needs to overcome rather than strategic goals (e.g. climate change is a Grand Challenge, whilst becoming a world-leader in biotechnology is, rather, a strategic goal).

RRI Element	Definition with reference to innovation:	Identifiable through:
Ethical acceptability	Innovation which respects fundamental values without discrimination.	Codes of conduct, ethics guidelines and sustained public engagement efforts
Sustainability	Innovation "which meets the needs of the present without compromising the ability of future generations to meet their own needs"[4].	Environmental protection and health & safety
Societal desirability	Innovation which benefits all without discrimination.	Grand challenges

All countries reported on have both environmental protection and health and safety regulations, hence these are not repeated in the brief country summaries given below.

Australia
Nanotechnology is regarded as one of the fastest growing areas of research and technology. At the same time, Australian regulators (Therapeutic Goods Administration) are less committed to labelling nanotechnology products than their European counterparts. For instance, there is no requirement to note the size of ingredients in sunscreen. Synthetic biology is hardly mentioned in Australian policy documents and is treated as part of biotechnology. Both nanotechnology and synthetic biology are covered in the 2009 *National Enabling Technologies Strategy*,[5] which aims to, "provide

---

[4] Modified definition from Brundtland, 1987 ("innovation" replaced for "development": http://www.worldbank.org/depweb/english/sd.html

[5] http://consumersfederation.org.au/national-enabling-technologies-strategy/

a responsible framework for the development of enabling technologies such as nanotechnology, biotechnology and other emerging technologies". The main concern in ICT is data protection in connection with the National Broadband Network, an initiative to increase Australian competitiveness.

China

The *National Center for Nanoscience and Technology* of China was co-founded by the Chinese Academy of Sciences and the Ministry of Education in 2003. Since then China has formally developed 15 nanotechnology standards, including 11 national standards and 4 industry standards. Synthetic biology is treated as part of biotechnology without specific regulations. For all emerging technologies, improved public participation mechanisms are being developed, but not yet rolled-out on a larger scale. ICT is intended to be used for improved communication between national and local government representatives and Chinese citizens. Long-term strategies link particular technologies to particular challenges. For instance, the *12th Five-Year Plan of Biotechnology Development* developed by the Ministry of Science and Technology in 2011,[6] states that the government shall progressively explore applications of synthetic biology in medicine and energy.

Germany

Germany has made an effort to develop public participation regarding nanotechnology, with the *Nano Dialogue* being started in 2006, and involving industry and trade, civil society groups, research institutions, public authorities and government ministries. In terms of codes of conduct, industry self-regulation in synthetic biology is relatively advanced in Germany. The Grand Challenges of health, climate change and energy supply are noted as targets for nanotechnology and ICT by the federal government. The goals and challenges to be addressed with synthetic biology are – in most cases – the same as those for genetic engineering.

India

Expert-level dialogues on nanotechnology have taken place nationwide and citizen engagement is planned in the future. The Grand Challenges of safe drinking water, healthcare and energy are specifically mentioned as targets for nanotechnology. There is no major regulatory or policy activity on synthetic biology. ICT is regarded as an efficient interface with citizens to provide for delivering speedy services, as well as information to them.

South Africa

South Africa has a recent, draft *Code of Conduct for Nanosciences and Nanotechnologies Research* which still requires approval by the government. A programme to raise awareness of nanotechnology and provide a platform for public discussion is also currently being rolled out. The *National Nanotechnology Strategy[7]* envisions a match of nanotechnology research and innovation to Grand Challenges in energy (e.g. clean energy production) and health sectors (e.g. clean water, diagnostic tools for HIV and tuberculosis). There is little engagement and regulation on synthetic biology, despite serious concerns, for instance, over safety, but also over threatened livelihoods when products are synthesised that are currently harvested or cultivated by poor communities. ICT policy contributes to the Grand Challenge of energy, as South Africa actively encourages the

---

[6] http://www.most.gov.cn/fggw/zfwj/zfwj2011/201111/t20111128_91115.htm
[7] http://www.gov.za/documents/national-nanotechnology-strategy

development of Green Sustainable ICTs – defined as those which produce low levels of carbon emissions.

United Kingdom

The UK is active in obtaining stakeholder input into nanotechnology research and innovation through the *Nanotechnology Strategy Forum*. Public perception research has also been commissioned by the Food Standards Agency for nanotechnologies in the food sector. Whilst there are no legal regulations for synthetic biology, a Synthetic Biology Roadmap Coordination Group has been set up. Both nanotechnology and synthetic biology are expected to provide solutions in the Grand Challenge areas of health, environment and energy. ICT is primarily seen as a means rather than an object of public participation.

United States

The US has two research centres that focus on the ethical, legal, and social issues related to nanotechnology. Feedback from citizens is mostly obtained through the Internet. The *Open Government Initiative,* [8] for instance, includes an effort to develop a *US Public Participation Playbook*[9] that collects best practices in developing public participation strategies and programs for use by government agencies. Whilst the President's Council of Advisors on Science and Technology recommended that a list of candidate nanotechnology Grand Challenges linked to significant societal needs should be identified, this has not yet been undertaken. In the area of synthetic biology, no such direction from the Council of Advisors exists, nor any specific policies linking Grand Challenges to the technology.

Several **conclusions** can be drawn from the comparative analysis of the reported country-specific requirements for RRI:

- None of the countries covered in this report have adopted any specific legal instruments governing synthetic biology (yet). This stands in contrast to the "unanimous decision of 194 countries, the United Nation's Convention on Biological Diversity …, [which] formally urged nation states to regulate synthetic biology" in October 2014. [10] At the same time, the latter is a relatively quick reaction by policy makers, given that this young subfield of biotechnology only started to develop after a founding conference in 2004.[11]

- As noted in earlier ProGReSS reports,[12] ethical acceptability and sustainability are the more clearly regulated elements of RRI, with societal desirability being the more contentious. This can be observed here too: nearly all countries under investigation foresee provisions for risk and environmental protection management as well as for considerations of ethical issues in new and emerging technologies. However, amongst the country set examined, public engagement, as part of efforts to achieve ethical acceptability, was the least practiced RRI element.

---

[8] http://www.whitehouse.gov/open/documents/open-government-directive
[9] http://www.whitehouse.gov/blog/2015/02/03/announcing-us-public-participation-playbook
[10] http://www.etcgroup.org/content/regulate-synthetic-biology-now-194-countries-0
[11] http://syntheticbiology.org/Synthetic_Biology_1.0.html
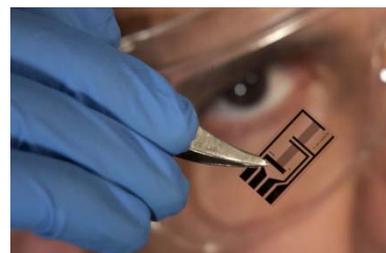[12] http://www.progressproject.eu/project-deliverables/

- Coping with Grand Challenges is a common but very general motive of most countries examined with regard to societally desirable research and innovation. To align societal desirability with addressing Grand Challenges may however be hampered by two impediments. First, there are only vague references, if any, in national policies to link specific technologies with specific Grand Challenges. This might indicate that basic research is still the preferred option in emerging technology research. Second, given this limitation, it is unclear how one would assess industry's contribution to societal desirability. It is conceivable that most of the societal benefits of this type of research remain uncertain until their ex-post evaluation is possible.

- The above mentioned asymmetry between governing on behalf of ethical acceptability and sustainability on the one hand and governing for positive outcomes for humankind on the other hand might not be that surprising. Simplified, by contrast to the "do no harm" prerogative in individual or collective (innovative) action, the "do good" prerogative unfolds in a more open space of multiple options, which corresponds to a wider spectrum of diverse expectations of citizens. The degree of freedom of desirable choices is comparably larger.

2. Introduction

To act *responsibly* in research and innovation should cover all relevant activities; i.e. research on new children's toys as well as advanced astronomy; innovations in cancer diagnostics as well as in water filtration. However, responsible conduct is particularly pressing in areas of new technologies with the potential for unforeseen and undesirable consequences for humankind and the environment. The European Commission is continuing to support a programme which links research and innovation to societal concerns and interests. The "Science with and for Society" programme has produced one of the most influential responsible research and innovation (RRI) definitions in Europe:

> RRI is an inclusive approach to research and innovation (R&I), to ensure that societal actors work together during the whole research and innovation process. It aims to better align both the process and outcomes of R&I, with the values, needs and expectations of European society. In general terms, RRI implies anticipating and assessing potential implications and societal expectations with regard to research and innovation.[13]

A definition of RRI which has been used globally, was developed by René von Schomberg:

> [A]transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products(in order to allow a proper embedding of scientific and technological advances in our society).[14]

This report provides an overview of how efforts to achieve ethical acceptability, sustainability and societal desirability can be mapped onto three technologies, namely: nanotechnology, synthetic

---

[13] Science with and for Society. 2013. *Responsible Research and Innovation*.
http://ec.europa.eu/programmes/horizon2020/en/h2020-section/science-and-society.
[14] von Schomberg, René. 2013. A Vision of Responsible Research and Innovation. In *Responsible Innovation* edited by Richard Owen, John Bessant, and Maggy Heintz, 51-74, London; John Wiley.

biology, and information and communication technology (ICT). Information tables are provided for Australia, China, Germany, India, South Africa, the United Kingdom and the United States, giving a spread of all continents. For the purpose of this report, we assigned codes of conduct, ethics guidelines and sustained public engagement efforts to the theme of ethical acceptability; legal instruments focusing on environmental protection and health & safety to the theme of sustainability, and efforts to address a country's Grand Challenges to the theme of societal desirability.

RRI Element	Definition with reference to innovation:	Identifiable through:
Ethical acceptability	Innovation which respects fundamental values without discrimination.	Codes of conduct, ethics guidelines and sustained public engagement efforts
Sustainability	Innovation "which meets the needs of the present without compromising the ability of future generations to meet their own needs"[15].	Environmental protection and health & safety
Societal desirability	Innovation which benefits all without discrimination.	Grand challenges

The remainder of the report details government-driven efforts at ethical acceptability, sustainability and societal desirability by country: Australia, China, Germany, India, South Africa, the United Kingdom and the United States.

---

[15] Modified definition from Brundtland, 1987 ("innovation" replaced for "development"): http://www.worldbank.org/depweb/english/sd.html

3. Australia

Australia is a high income country with per capita GNI (Gross National Income)[16] of US$65,390 in 2013. Life expectancy at birth was 82 in 2012.[17] The Grand Challenges identified in the 2012 Australia *National Research Investment Plan* are as follows:

- **Environment**: marine, terrestrial, atmospheric;
- **Resources**: minerals, petroleum, fisheries, forestry, water;
- **Security**: biosecurity, cybersecurity, critical infrastructure, disaster management;
- **Communities**: demography, regional, Indigenous, built environment, transport;
- **Health**: disease prevention, treatment, service delivery;
- **Food**: production, technology, processing, security;
- **Energy**: clean technologies, sustainability, distribution;
- **Competitive industries**: business processes/services, innovative technologies, advanced manufacturing.[18]

Nanotechnology is regarded as one of the fastest growing areas of research and technology.[19] At the same time, Australian regulators (Therapeutic Goods Administration) are less committed to labelling nanotechnology products than their European counterparts.[20] For instance, there is no requirement to note the size of ingredients in sunscreen.[21]

3.1 Nanotechnology

Ethical Acceptability: Nanotechnology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
Australia has developed the **National Enabling Technologies Strategy,**[22] which aims to, "provide a responsible framework for the development of enabling technologies such as nanotechnology, biotechnology and other emerging technologies". Developed in 2009, it recognises that innovations have the potential for significant social and economic benefits, but at the same time "pose new health, safety and environmental risks and have ethical and social impacts".
The Strategy seeks to promote a nationally coordinated approach to managing such risks and impacts, through supporting regulatory agencies, supporting engagement between such agencies and policy bodies nationally and internationally, and commissioning and conducting research on potential risks and impacts. Community consultations, public attitude research and education programs are part of the Strategy.
For Australian Research Council (ARC) -funded researchers, compliance with principles such as those outlined in the *Australian Code for the Responsible Conduct of Research* (2007); the *National Statement*

---

[16] Gross National Income (GNI) is the ttotal domestic and foreign output claimed by residents of a country, consisting of gross domestic product (GDP), plus incomes earned by foreign residents, minus income earned in the domestic economy by nonresidents.

[17] http://data.worldbank.org/country/australia

[18] http://www.industry.gov.au/research/Documents/NationalResearchInvestmentPlan.pdf, p.51.

[19] http://www.ausnano.net

[20] http://www.abc.net.au/science/articles/2013/09/03/3840184.htm

[21] http://www.scfa.edu.au/skin-conditions/skin-protection/spf-labelling-and-nanotechnology

[22] http://consumersfederation.org.au/national-enabling-technologies-strategy/

on Ethical Conduct in Human Research (2007)[23]; and similar documents is required, as clearly stated in funding rules and contracts.

There is no specific nanotechnology regulation that only focuses on this technology.

The Australian section of Friends of the Earth[24] are lobbying for an overarching regulatory body that governs nanotechnology. In a submission to the Australian government, they noted that:

"We recognise that for certain areas, or categories of chemicals, it makes sense to have an overarching body charged with ensuring that regulation across the various agencies is consistent and sufficient to protect the health of people and environment. This is the case ... in relation to nanotechnology."

Sustainability: Nanotechnology
Safety and environment regulations

The *Australian Code for the Responsible Conduct of Research*[25] includes the principle of respect for the environment, saying that researchers should, "conduct their research so as to minimise adverse effects on the environment". Institutions are expected to train researchers in environmental protection. Risks to the environment from any specific research proposal is evaluated by institutional research ethics committees, approval from which is required for any research project. It also requires researchers to comply with laws and regulations relevant to sustainability.

The *Code* specifies that institutions have responsibilities to, "maintain an environment that fosters responsible research", andthis includes the provision of a research governance framework that demands compliance with laws and regulations. In Australia, such laws and regulations cover the broad range of areas characteristic of industrialized nations, including areas relevant to sustainability such as work, Health and Safety, and the environment, including hazardous substances. As legislatively required, the ARC also reports on, "Measures being taken to minimise the impact of the ARC's activities on the environment".[26]

Societal Desirability: Nanotechnology
Grand Challenges intended to be targeted through this technology

Specific technologies are not linked to particular challenges.

The Strategic Research Priorities, developed specifically to guide research investment towards meeting identified challenges, are clearly linked to societally desirable outcomes. For example, to address the challenge of 'living in a changing environment', research is to identify either, "the level of environmental change human and natural systems can tolerate before fundamental ecological processes are irreversibly changed" (first criterion); develop options for "managing change in the linked human and natural environment" (second criterion); and/or "develop options for the change required to mitigate and/or adapt to environmental change" (third criterion).[27]

The recently announced *Industry Innovation Competitiveness Agenda*[28] will be charged with pursuing

---

[23] https://www.nhmrc.gov.au/guidelines-publications/e72

[24] http://www.foe.org.au

[25] http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf

[26] http://www.arc.gov.au/pdf/ARC%20Annual%20Report%202011-2012.pdf

[27] http://www.industry.gov.au/research/Documents/SRP_fact_sheet_web.docx

[28] https://www.pm.gov.au/media/2014-10-14/growth-centres-boost-competitiveness

"global excellence in areas of competitive strength", focusing on food and agribusiness; mining, equipment and technology services; oil, gas and energy resources; medical technology and pharmaceuticals; and advanced manufacturing sectors.

3.2 Synthetic Biology

Ethical Acceptability: Synthetic Biology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
There is little specific mention of synthetic biology in policy documents, regulations, etc. in Australia. Anything in this area comes under biotechnology, which is well-developed.

Sustainability Synthetic: Biology
Safety and environment regulations
See above.

Societal Desirability: Synthetic Biology
Grand Challenges intended to be targeted through this technology
See above.

3.3 Information and Communication Technology (ICT)

Relevant to all sections is the **National Broadband Network** (NBN), a project which seeks to provide a minimal level of broadband services Australia-wide. It involves progressively upgrading existing internet and phone line infrastructure using a range of technologies to suit the needs of different areas.

Ethical Acceptability: ICT
Codes of conduct, other legal instruments and/or sustained public engagement efforts
Currently there is a great deal of ongoing public discussion and policy development surrounding government collection of metadata via the NBN.[29] Recently legislation was introduced into Parliament requiring metadata to be retained by Internet companies for two years. The government is requiring this data to be retained for law enforcement and counter-terrorism purposes, raising privacy and security concerns. The amount of discussion has been fuelled further by recent terrorist attacks.

Sustainability: ICT
Safety and environment regulations
In Australia data protection, or the use of personal information, is primarily covered by the ***Privacy Act 1988*** (amended in 2014).[30]
ICT use at work is recognised under work health and safety rules. Employers have obligations to ensure that people are using computers in ergonomic ways. Such regulations are primarily issued as state and territory legislation rather than Commonwealth.[31]
Guidelines on working with ICT are published under ***Guide to Health and Safety in the Office***.[32]

Societal Desirability: ICT
Grand Challenges intended to be targeted through this technology
The NBN was motivated in part (perhaps primarily) as a means of increasing productivity and efficiency, but it has also been regarded as desirable from an environmental perspective, particularly with respect to enabling more people to work from home thereby reducing travel to and from the workplace.
Additionally, uses for other societally desirable purposes are also being investigated. These include tele-health uses (e.g. video-conferenced doctor's consultations in remote areas; remote monitoring of patients), which are particularly useful in Australia and relate to one of the above named Grand Challenges, namely health.[33],[34]

---

[29] "Metadata retention scheme: Telstra warns data storage plan will attract hackers", 2015, http://tinyurl.com/orfafed; "Australia's Privacy Commissioner Tim Pilgrim fears telco metadata breaches", 2015, http://tinyurl.com/me6w6e8; "Law council urges metadata retention rewrite", 2014, http://tinyurl.com/ko2xuhp
[30] http://www.comlaw.gov.au/Details/C2014C00076
[31] http://www.safeworkaustralia.gov.au/sites/swa/model-whs-laws/pages/jurisdictional-progress-whs-laws
[32] http://www.comcare.gov.au/__data/assets/pdf_file/0006/39570/Officewise_OHS1_Apr_10.pdf
[33] Department of Health 2014, *Telehealth Pilots Programme*, Australian Government, Canberra. http://health.gov.au/ehealth-nbntelehealth.
[34] Banks, L, "NBN 101: A broadband-driven education revolution?", *Computerworld*, May 26, 2011. http://www.computerworld.com.au/article/388011/nbn_101_broadband-driven_education_revolution.

4. China

China is an upper middle income country with per capita GNI of US$6,560 in 2013. Life expectancy at birth was 75 in 2012.[35] In January 2015, Reuters reported that China overtook the US to become the world's "top magnet" for foreign investment.[36]

Despite the considerable success in poverty reduction in China in recent decades, China is still facing some Grand Challenges, such as district imbalance, aging society, and environmental protection, which the *Twelfth National Five-Year Plan* is meant to tackle.[37] China is applying high tech-innovation to tackle these challenges. Advanced technology is from the concept and research into applied results, the most typical areas: Nanotechnology, Synthetic Biology, and Information and Communication Technology.

4.1 Nanotechnology

The National Center for Nanoscience and Technology (NCNST) of China was co-founded by the Chinese Academy of Sciences (CAS) and the Ministry of Education. The center was officially launched on 31 December 2003, by CAS, Peking University and Tsinghua University as its initiators and co-founders. It has since built a technological platform and research base for nanoscience, which owns state-of-the-art equipment and is open to both domestic and international users.[38]

Ethical Acceptability: Nanotechnology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
The Information Platform for national nanotechnology was founded on 25 July 2011. One of its objectives is to promote the establishment of standards, testing standards and safety evaluations of nanotechnology products. [39] Since the **National Nanotechnology Standards Committee** was established in April 2005, China has formally developed 15 nanotechnology standards, including 11 national standards and 4 industry standards.[40]

Sustainability: Nanotechnology
Safety and environment regulations
The *12th Five-Year Plan of Standardization Development* issued by the National Standardization Management Committee, has set out how the risks of nanomaterials to human health and the environment will be assessed.[41]

---

[35] http://data.worldbank.org/country/china

[36] http://www.reuters.com/article/2015/01/29/us-economy-fdi-idUSKBN0L225120150129

[37] http://www.gov.cn/zwgk/2011-12/20/content_2024895.htm, access date: 2014.11.18.

[38] http://english.nanoctr.cas.cn/au/bi/

[39] http://www.sipqts.gov.cn/nami/web/index.php/aboutus.html

[40] http://www.chinawuliu.com.cn/zixun/uploadfiles/2012-01/201201041028382617.pdf

[41] http://www.chinawuliu.com.cn/zixun/uploadfiles/2012-01/201201041028382617.pdf

Societal Desirability: Nanotechnology
Grand Challenges intended to be targeted through this technology
The *Long-and Medium-Term Scientific and Technological Development Plan* (2006-2020) published by the State Council of China, states that "Nanotechnology brings great development space to the field of materials, information, green manufacturing, biotechnology and medicine".[42]

4.2 Synthetic Biology

The *12th Five-Year Plan of Standardization Development* developed by the *National Standardization Management Committee*, points out that the government shall strengthen the development of standards in biological agriculture, bio-manufacturing, marine biology and biomedical engineering areas and promote the healthy development of the biotechnology industry.[43]

Ethical Acceptability: Synthetic Biology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
The *12th Five-Year Plan of Science and Technology Development* developed by the Ministry of Science and Technology in July 2011, states that in order to deepen the reform of science and technology management, the government shall further improve public participation mechanisms to promote more democratic decision-making.[44]

Sustainability: Synthetic Biology
Safety and environment regulations
China's existing regulations to oversee the research, manufacture and use of synthetic biology products and modified organisms include: - *Environmental Protection Law of the People's Republic of China* (issued in1989, revised in 2014) - *Genetically modified organisms safety management regulations* (2001) - *Genetic engineering safety management approach* (1993) - *Interim Measures for the Management of Human Genetic Resources* (1998) - *The new biologics approval approach* (1999) - *Pathogenic microbiology laboratory biosafety regulations*(2004)

---

[42] *The Long-and Medium-Term Scientific and Technological Development* (2006-2020), http://www.gov.cn/jrzg/2006-02/09/content_183787.htm
[43] http://www.chinawuliu.com.cn/zixun/uploadfiles/2012-01/201201041028382617.pdf
[44] http://www.most.gov.cn/kjgh/sewkjfzgh/

Societal Desirability: Synthetic Biology
Grand Challenges intended to be targeted through this technology
The **12th Five-Year Plan of Biotechnology Development** developed by the Ministry of Science and Technology in November 2011[45] points out that, "health, food, energy, environment and other issues facing the development of human society are getting worse in the 21st century. Modern life sciences and biotechnology provide scientific and feasible solutions and programs to address these significant challenges." It also states that the government shall progressively explore applications of synthetic biology in medicine and energy.

4.3 Information and Communication Technology (ICT)

Ethical Acceptability: ICT
Codes of conduct, other legal instruments and/or sustained public engagement efforts
Enhancing the governance efficiency and effectiveness of the National People's Congress (NPC) of China through ICT advancement is reflected in the following aspects: - The National People's Congress and local people's congresses at different levels have set up an Internet website, which safeguards people's access to the work of the NPC information. - The National People's Congress and local people's congresses at all levels are using ICT to guarantee the efficient and convenient collection of public opinion. - ICT is also used to invite members of the Committee of the National People's Congress and some other agencies that are responsible for legislation, supervision and other issues of public concern to have online communication with citizens and answer their questions.

Sustainability: ICT
Safety and environment regulations
China's laws on data security are as follows: In accordance with the **Decision of the Standing Committee of the National People's Congress on Preserving Computer Network Security**（issued in 2000, revised in 2009), anyone who in violation of the law, intercepting, tampering with or deleting other persons' emails or other data, thus infringing on citizens' freedom and privacy of correspondence, which constitutes a crime, shall be investigated for criminal responsibility in accordance with the relevant provisions in the Criminal Law.[46] China's existing provisions for security of ICT data are as follows: - *Regulation of the People's Republic of China on Telecommunications* (issued in 2000, revised in 2014) - *Regulations of the People's Republic of China for Safety Protection of Computer Information Systems* (Decree No. 147 of the State Council, issued in1994, revised in 2011)

---

[45] http://www.most.gov.cn/fggw/zfwj/zfwj2011/201111/t20111128_91115.htm
[46] http://www.miit.gov.cn/n11293472/n11294912/n11296092/11904851.html

- Measures for Security Protection Administration of the International Networking of Computer Information Networks (issued in 1997, revised in 2011)

Additional specific regulations in China are as follows:

- Regulation on the Administration of Commercial Cipher Codes (1999)

- Management Measures for Testing and Sales License of Special Products of Computer Information System Security (1997)

- Management Measures for Computer Virus Prevention (2000)

- Interim Management Measures for Secrecy of Computer Information Systems (1998)

Societal Desirability: ICT
Grand Challenges intended to be targeted through this technology
The Ministry of Industry and Information Technology's ***12th Five-Year Plan of Software and Information Technology Services Industry*** points out that the software and Information Technology service industry can promote economic and social development and provide technical support for enhancing social management and public service levels.[47]

---

[47] http://www.miit.gov.cn/n11293472/n11293832/n11293907/n11368223/14542600.html

5. Germany

Germany is a high income country with per capita GNI of US$47,270 in 2013. Life expectancy at birth was 81 in 2012.[48] The Grand Challenges identified in the *High Technology Strategy 2020[49]* and refined and augmented by social dialogue[50] are:

- Climate and energy
- Health and nutrition
- Mobility
- Security
- Communication
- Ageing societies

5.1 Nanotechnology

Ethical Acceptability: Nanotechnology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
In Germany the ***Nanodialog*** is the central instrument to promote the societally acceptable development of nanotechnology. To provide a national platform for the dialogue, the **NanoKommission** was established by the German Federal Government in 2006. Its mandate was to foster exchange among the various societal groups on the potential benefits and risks of nanotechnologies and thereby promote the responsible use of nanomaterials.   The **NanoKommission** supported two dialogues: 2006 – 2008[51]; 2009 – 2010.[52] Subsequently, the German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety organized a series of expert dialogues (Nanodialog 2011–2012 and 2013-2015)[53].   The **NanoKommission** and the expert dialogues had contributors from industry and trade, civil society groups, research institutions, authorities and ministries.

Sustainability: Nanotechnology
Safety and environment regulations
Germany has no specific health and safety regulation for nanomaterials. The general German ***Hazardous Substances Ordinance*** (*Gefahrstoffver-ordnung*) and the ***Technical Rules for Hazardous Substances*** governing its implementation in practice (*Technische Regeln für Gefahrstoffe* – TRGS) apply.   However, the **NanoKommission** has published guidance specific to the responsible use of nanotechnology.[54]

---

[48] http://data.worldbank.org/country/germany
[49] http://www.bmbf.de/pub_hts/HTS_Broschure_Web.pdf page 11
[50] E.g. *Dialog der Bundeskanzlerin* https://www.dialog-ueber-deutschland.de/DE/30-IDF/10-Hintergrund/hintergrund_node.html , and *Bürgerdialoge* (http://www.buergerdialog-bmbf.de/index.php).
[51] http://ec.europa.eu/health/ph_risk/documents/nanokommission.pdf
[52] http://tinyurl.com/m4ofkuj *Responsible Uses of Nanotechnology*, German Nanokommission
[53] http://tinyurl.com/m3kb4wa *The Nanodialog Documentation*
[54] http://tinyurl.com/m4ofkuj *Responsible Uses of* Nanotechnology, German Nanokommission

In the cosmetics industry, *EU Regulation (EC) No 1223/2009* on cosmetic products has been in force ssince 2013. It applies to cosmetics containing nanoparticles. If there are any safety concerns with any particular product or process, the European Commission can require safety data. The *Cosmetics Regulation* also includes the requirement to append the word "nano" to the substance name on the product.[55] Hence, labeling requirements are strong.

With respect to food safety, three regulatory areas are relevant: novel foods, additives, and food contact materials. These areas are regulated at the EU-level.[56] Most of the relevant legal frameworks have undergone revision to increase the specificity of the existing provisions with regard to the use of nanomaterials in food.

Societal Desirability: Nanotechnology
Grand Challenges intended to be targeted through this technology

The Federal Government launched an *Action Plan Nanotechnology 2015*.[57] The goals include:

- to use the possibilities of nanotechnology for **health;**
- to secure the contributions of nanotechnology **to protect the environment and the climate and to secure future energy supply;**
- to achieve mobility in more environmentally friendly and energy saving ways, and
- to use the possibilities of nanotechnology for **sustainable agriculture and food safety.**

5.2 Synthetic Biology

Ethical Acceptability: Synthetic Biology
Codes of conduct, other legal instruments and/or sustained public engagement efforts

The International Association Synthetic Biology (IASB) based in Heidelberg, was founded by a consortium of biotech companies whose products and services are related to synthetic biology. In November 2003, the IASB finalized the *Code of Conduct for Best Practices in Gene Synthesis* in collaboration with a panel of stakeholders. For the first time a comprehensive set of best practice for DNA sequence screening, customer screening and ethical, safe and secure conduct in gene synthesis had been adopted by a diverse consortium of industry players. The *Code* presents an important example of self-regulation in industry.[58]

A public discussion on synthetic biology is only in its infancy: With a joint position paper on the opportunities and risks posed by synthetic biology, the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation); acatech (the German Academy of Science and Engineering); the German Academy of Scientists Leopoldina; and the National Academy of Sciences, now want to initiate this dialogue.[59] In addition the German ethics council has organised a series of workshops on this matter.[60]

---

[55] http://tinyurl.com/m4ofkuj *Responsible Uses of Nanotechnology*, German Nanokommission
[56] http://tinyurl.com/m4ofkuj *Responsible Uses of Nanotechnology*, German Nanokommission
[57] http://www.bmbf.de/en/131.php
[58] http://tinyurl.com/yj8l9fp *Code of Conduct for Best Practices in Gene Synthesis, IASB*
[59] http://tinyurl.com/qgtwdao *Synthetische Biologie - Standpunkte*
[60] http://www.ethikrat.org/themen/forschung-und-technik/synthetische-biologie

Sustainability: Synthetic Biology
Safety and environment regulations
At the legal level synthetic biology is covered - in most cases - by the legal framework for genetic engineering. The basis for assessing the risks of genetically modified organisms is the *Gentechnikgesetz* (*Genetic Engineering Act*, GenTG), which implements the *EU directives 98/81/EC*[61] and *2001/18/EC*[62].

Societal Desirability: Synthetic Biology
Grand Challenges intended to be targeted through this technology
Applications for synthetic biology with respect to Grand Challenges are part of the *National Research Strategy BioEconomy 2030*. This strategy is striving towards a biobased economy that, amongst others, tackles the problems of climate change.[63] It is noteworthy that the goals of synthetic biology and genetic engineering are - in most cases - the same. As a result medical, industrial, agricultural and basic research applications of both can be linked to Grand Challenges. The main exception connected with synthetic biology is that these goals are meant to be achieved in a cheaper, quicker and more flexible way. Synthetic biology is therefore in the first case an **enabling technology**.

5.3 Information and Communication Technology (ICT)

Ethical Acceptability: ICT
Codes of conduct, other legal instruments and/or sustained public engagement efforts
No specific code of conduct or sustained public engagement effort exists in the context of ICT in Germany. However in the German ICT strategy *Digital Germany 2015*, ICT is seen as an important instrument to promote public engagement by improving citizens' digital competency. Internet technologies are meant to be used for public participation in policymaking, also enabling greater consideration of the special concerns of persons with disabilities for accessible and barrier-free use of ICT services.[64]

---

[61] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:330:0013:0031:EN:PDF
[62] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32001L0018
[63] http://www.bmbf.de/pub/Natinal_Research_Strategy_BioEconomy_2030.pdf
[64] http://tinyurl.com/oyfxq7t *Digital Germany 2015*, page 25.

Sustainability: ICT
Safety and environment regulations
In the ICT strategy ***Digital Germany 2015***, it is stated that: "The Internet must be a medium where freedom and legal certainty are assured", and where, "security and transparency in handling electronic identities in the digital environment" is guaranteed.[65] The general data protection requirements in Germany are laid down in the ***Federal Data Protection Act***.[66] Adherence to data protection laws and regulations by federal authorities and other public bodies is monitored by the **Federal Data Protection Commissioner**.[67]

Societal Desirability: ICT
Grand Challenges intended to be targeted through this technology
The ICT strategy ***Digital Germany 2015*** was developed by the Federal Ministry of Economics and Technology in coordination with other relevant ministries. In the Federal Government's ***High-Tech Strategy 2020***[68], research funding focuses on five fields of action: **climate/energy; health/nutrition; mobility; security and communication**. Key technologies, including information and communication technologies, form the basis of new products, processes and services which can contribute to meeting the challenges that our society is currently facing.

---

[65] http://tinyurl.com/oyfxq7t *Digital Germany 2015*, page 17.
[66] http://www.gesetze-im-internet.de/englisch_bdsg/englisch_bdsg.html
[67] http://www.bfdi.bund.de/DE/Home/home_node.html?__lang=en
[68] http://www.hightech-strategie.de/de/The-new-High-Tech-Strategy-390.php

6. India[69]

India is a low middle income country with per capita GNI of US$1,570 in 2013. Life expectancy at birth was 66 in 2012.[70] The 2010 Vision Document, *India as a global leader in Science,*[71] prepared by the Science Advisory Council to the Prime Minister, mentions the following "pressing problems of India", which can be equated with Grand Challenges:

- Energy independence
- Health-care for all
- Efficient water management
- Food security
- Mitigating effects of possible climate change

6.1 Nanotechnology

Ethical Acceptability: Nanotechnology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
The Department of Science and Technology (DST), the Ministry of S&T, under its Nano Mission, has been holding expert-level national dialogues to promote R&D in the development of standards for nanotechnology, and for laying down a ***National Regulatory Framework Road-Map for Nanotechnology*** (NRFR-Nanotech). As far as public engagement is concerned, there is no such effort to date. However, DST says that stakeholder consultations and a White Paper will be undertaken in the near future.[72]

Sustainability: Nanotechnology
Safety and environment regulations
There is no specific regulation that deals with nanotechnology safety. There are various broad laws, rules and regulations that need interventions or changes to encompass nanotechnology-related safety concerns. DST has formed a Task Force for developing regulatory frameworks on nanotechnology and this task force has recently completed two things: (i) "appeal for responsible development of nanotechnology", and (ii) guidelines and best practices for safe handling of nanomaterials in research laboratories and industries". Both documents are not in the public domain yet, however, safety guidelines have been circulated by the Ministry. Also, many of the public R&D centres are made compliant with OECD's *Good Laboratory Practices* (GLP) system to ensure safety.

[69] All non-referenced information is based on personal communications. RIS, the partner in Progress, is a government-associated think tank linked to the Ministry of External Affairs.
[70] http://data.worldbank.org/country/india
[71] http://www.dst.gov.in/vision_document.pdf
[72] www.dst.gov.in and personal communication with Nano Mission Head.

Societal Desirability: Nanotechnology
Grand Challenges intended to be targeted through this technology
The government, while launching the Nano Mission in 2007, categorically mentioned that the Nano Mission will strive for the development of products and processes to facilitate national development, especially in areas of national relevance such as safe drinking water, healthcare and energy. DST has been funding R&D projects in these areas since 2007. Some of the successful results from these projects have also been commercialized.

6.2 Synthetic Biology

Ethical Acceptability: Synthetic Biology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
There are no codes of conduct or legal instruments that are specific to Synthetic Biology. Synthetic Biology is regulated under the regulatory norms applicable for biotechnology. India has initiated steps to evolve a **Code of Conduct for Scientists** who might be engaged in Dual Use Research or research that would be directly relevant for the provisions of the *Biological and Toxin Weapons Convention* (BTWC).[73]

Sustainability: Synthetic Biology
Safety and environment regulations
The current regulations for biotechnology and genetic modification are applicable for synthetic biology. The frame is described briefly below. The **Environment (Protection) Act 1986**[74] specifies the rules and procedures for manufacture, import, use, research and release of genetically engineered organisms and their products. At the national level, the following institutions govern biotechnology and enforce the *Environment Act*: (a) Recombinant DNA Advisory Committee (RDAC); (b) Institutional Biosafety Committees (IBSCs); (c) Review Committee on Genetic Manipulation (RCGM); and (d) the Genetic Engineering Approval Committee (GEAC). RDAC and the RCGM are under the Department of Biotechnology, and the GEAC is with the Ministry of Environment and Forests. The RDAC reviews national and international developments in biotechnology and advises the government on policy imperatives. At the level of institutions engaged in research and/or activities that are governed by the rules of the *Environment Act*, it is mandatory to have an IBSC, which is the first level regulator and monitor of biosafety. IBSCs are mandated to follow the **Recombinant DNA Safety Guidelines, 1990**[75]. As Synthetic Biology is not yet fully developed in India there are no moves to enact new rules.

---

[73] http://www.un.org/disarmament/WMD/Bio/
[74] http://envfor.nic.in/legis/env/env1.html
[75] http://dbtbiosafety.nic.in/guideline/pdf/guidelines_90.pdf

Societal Desirability: Synthetic Biology
Grand Challenges intended to be targeted through this technology
No developments to date.

6.3 Information and Communication Technology (ICT)

Ethical Acceptability: ICT
Codes of conduct, other legal instruments and/or sustained public engagement efforts
ICT is controlled and regulated by a host of different legal instruments, regulations, guidelines and best practice procedures. The Government of India has formulated the **National E-Governance Plan** with the vision of providing all government services in an integrated manner at the doorstep of the citizen, at an affordable cost. There are policies/Acts such as the **Right to Information Act 2005**, **National Policy on Electronic Accessibility**, **Common Services Centers Scheme** (CSC) etc which operate at the interface with citizens and provide for delivering speedy services, as well as information provision to them.

Sustainability: ICT
Safety and environment regulations
The following Acts govern data protection and the safe handling of ICT in India: **Information Technology Act 2000**[76]; **Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules 2011**; **National Cyber Security Policy 2013**.

Societal Desirability ICT
Grand Challenges intended to be targeted through this technology
The government has been a key driver for increased adoption of IT-based products and IT-enabled services in public services (Government to citizen services, citizen identification, public distribution systems); Healthcare (telemedicine, remote consultation, mobile clinics); Education (e-Learning, virtual classrooms, etc); and Financial services (mobile banking / payment gateways).

---

[76] http://www.dot.gov.in/act-rules/information-technology-act-2000

7. South Africa

South Africa is an upper middle income country with per capita GNI of US$7,190 in 2013. Life expectancy at birth was 56 in 2012.[77]

The Department of Science and Technology's *Ten-Year plan*[78] identified five Grand Challenge areas, of which three fall under the Progress definition of Grand Challenges (major problems the country faces, rather than strategic goals). These three are: energy security, climate change, and human and social dynamics.[79] The latter challenge focuses on chronic poverty, service delivery and how technological innovation can be translated into improvements for the country that take account of the dynamics of human and social behaviour at all levels.

7.1 Nanotechnology

Ethical Acceptability: Nanotechnology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
In South Africa, a national research programme on nanotechnology was established through the ***National Nanotechnology Strategy***[80] (NNS) in 2006. In line with the strategy, two centres for nanotechnology were created in 2007 - the National Centre for Nano-Structured Materials (NCNSM) and the Mintek Nanotechnology Innovation Centre (NIC). A draft ***Code of Conduct for Nanosciences and Nanotechnologies Research*** has been developed with stakeholder input being given at national consultation workshops.   The Department of Science and Technology (DST) is currently working on getting approval for the Code of Conduct.[81] In terms of public engagement on nanotechnology, very little had been carried out by 2011,[82] however currently, according to the DST, a **Nanotechnology Public Engagement Programme** is being rolled-out by SAASTA (the South African Agency for Science and Technology Advancement). The purpose of the programme is to disseminate nanotechnology to the broader public as well as providing a platform for public engagement on the topic.[83]

Sustainability: Nanotechnology
Safety and environment regulations
One of the key features of the NNS implementation plan is the responsible development and application of nanotechnology in the country.[84] Around 10% of overall investments in nanotechnology are directed towards environmental, health and safety issues and possible ethical, legal and social implications.[85]

---

[77] http://data.worldbank.org/country/south-africa

[78] https://www.environment.gov.za/sites/default/files/docs/tentear_innovation_plan.pdf

[79] The remaining two are: becoming a world leader in biotechnology, and a contributor to global space science.

[80] http://www.gov.za/documents/national-nanotechnology-strategy

[81] DST 2014. *Nanotechnology in SA*. Unpublished document. Personal communication 2 February 2015.

[82] Mbali, C. 2011. *The Big Issue with Nanotech*. The Mail & Guardian, 27 May 2011.

[83] DST 2014. *Nanotechnology in SA*. Unpublished document. Personal communication on 2 February 2015.

[84] DST 2014. *Nanotechnology in SA*. Unpublished document. Personal communication 2 February 2015.

[85] http://tinyurl.com/p49eodt OECD. *Responsible Nano*.

The first **South African National Workshop on Nanotechnology Risk Assessment** was held in March/ April 2009. The workshop aimed to establish a national research platform network and "raise the level of awareness of a diverse group of stakeholders on the need for evidence-based risk assessment to support nanotechnologies and nanosciences".[86]

Food: No safety assessment or regulations specific to nanomaterials in the food and agriculture sectors have been developed.

Medicine: A DST initiative, the **Nano Health, Safety and Environment** (Nano-HSE) research platform is "developing an inventory database on the toxicity, ecotoxicity, phototoxicity, cytotoxicity, persistence, bioaccumulation, and other behavioural as well as physiological effects that nanomaterials may induce in organisms. The platform also supports research on environmental effects and exposure assessment, epidemiology/toxicology in mammalian systems, and risk assessment and risk management".[87]

Societal Desirability: Nanotechnology
Grand Challenges intended to be targeted through this technology
The first indicator listed in the NNS is "to improve the quality of life for the disadvantaged", and by focusing on nanotechnology applications in the manufacturing, energy and health sectors, the NCNSM aims to facilitate the application of its research outputs and outcomes in support of national priorities and needs.[88,89] More specific research questions related to the Grand Challenges are outlined in the DST's **Nanoscience and Nanotechnology 10-year Research Plan**, launched in 2013.[90] Within the 'social cluster', nanotechnology research will focus on issues such as water pollution and availability; clean energy production and delivery to remote rural communities; as well as the development of health diagnostic tools to help combat the heavy HIV and TB burden in the country.

7.2 Synthetic Biology

Ethical Acceptability: Synthetic Biology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
The South African scientific community has been involved recently in international discussions with regard to the interface between synthetic biology and conservation, but no specific codes of conduct exists. There is an active biotechnology community in South Africa, however it seems there has been little active engagement on the topic of synthetic biology.

---

[86] http://www.csir.co.za/nre/pollution_and_waste/nano_workshop.html
[87] http://www.csir.co.za/nre/pollution_and_waste/nano_hse.html
[88] http://ls-ncnsm.csir.co.za/index.html?lf=1;pg=2
[89] http://www.mintek.co.za/technical-divisions/advanced-materials-amd/nanotechnology/
[90] http://www.gov.za/sites/www.gov.za/files/nanotechnology%20Research__Plan__Final_small_reduce.pdf

Sustainability: Synthetic Biology
Safety and environment regulations
Industrial biotechnology is regulated through the ***Genetically Modified Organisms (GMO) Act 15 of 1997***.[91] However, South Africa does not yet have any safety regulations in place to monitor synthetic biology. There are institutions in place which could monitor possible invasions, such as the South African Biodiversity Institute, which monitors GMO introductions; a Centre of Excellence in Invasion Biology; and the Biosafety South Africa platform, "which supports strategic biosafety research, and advises government, industry and academia on biosafety best practice".[92] According to Professor Karen Esler, head of the Conservation Ecology and Entomology department at the University of Stellenbosch, the introduction of novel organisms to novel environments has caused many issues in South Africa in the past, and she sees cause for concern as she views synthetic organisms as an extension of the same challenge.[93]

Societal Desirability: Synthetic Biology
Grand Challenges intended to be targeted through this technology
Given that there are few, if any, synthetic biology products to date, its application is largely theoretical and based on potential. There is considerable concern about its potential impacts on livelihoods through the synthesis of products currently harvested or cultivated by poor communities.

7.3 Information and Communication Technology (ICT)

Ethical Acceptability: ICT
Codes of conduct, other legal instruments and/or sustained public engagement efforts
The Electronic Communications Act Act 36 of 2005,[94] deals with consumer issues, and requires ICASA (the **Independent Communications Authority of South Africa**) to prescribe codes of conduct for licensees and broadcasting service licensees. ICASA issued ***Code of Conduct Regulations***[95] in 2008 and 2009, which set out standards of conduct by licensees in respect of consumers. Recognising the need for "an enforceable code of conduct and legal rules to incentivise implementation across government and society of good cybersecurity practices and address liability for cyber breaches such as identity theft and/or cyber financial theft", the Department of Telecommunications and Postal Services (DTPS) has established the ***Cybersecurity Hub*** in line with the National Framework. Further, "ICASA requires broadcasters to provide regular information about the code of ethics and how to complain if they believe standards have been breached. ICASA also has in place a ***Code of Conduct on Persons with Disabilities***, which it is currently in the process of updating".[96]

---

[91] http://www.saflii.org/za/legis/num_act/gmoa1997286/
[92] http://tinyurl.com/pu2y4ny Ministerial speech. GM.
[93] Personal communication Karen Esler.
[94] http://www.saflii.org/za/legis/consol_act/eca2005270.pdf
[95] https://www.icasa.org.za/LegislationandRegulations/CodeofConduct/tabid/524/Default.aspx
[96] DTPS 2014. *National Integrated ICT Policy Discussion Paper*. http://www.ellipsis.co.za/wp-content/uploads/2014/11/National-Integrated-ICT-Policy-Discussion-Paper.pdf

Sustainability: ICT
Safety and environment regulations
Data or personal information held by public and private bodies in South Africa is protected by the ***Protection of Personal Information Act, Act 4 of 2013***, which was partially enacted in April 2014. The *Act* contains a Security Safeguards condition which "underlines the obligation of the responsible party to ensure that personal information of a data subject in its possession or under its control is appropriately safeguarded against loss, destruction or unlawful access."[97]

Societal Desirability: ICT
Grand Challenges intended to be targeted through this technology
Recognising the substantial contribution the ICT industry makes to Green House Gas (GHG) emissions (1.9% of the total global GHG emissions in 2011),[98] and expecting exponential growth of the sector in the future, ICT policy in South Africa actively encourages the development of Green Sustainable ICTs – defined as those which produce low levels of carbon emissions.[99]

---

[97] http://tinyurl.com/osbzry9 *Protection of Personal Information Act*.

[98] *Global e-Sustainability Initiative SMARTer 2020 Report*.

[99] DTPS 2014. *National Integrated ICT Policy Discussion Paper* http://www.ellipsis.co.za/wp-content/uploads/2014/11/National-Integrated-ICT-Policy-Discussion-Paper.pdf

8. United Kingdom

The United Kingdom is a high income country with per capita GNI of US$41,680 in 2013. Life expectancy at birth was 82 in 2012.[100]

Addressing the challenges noted in the *Lund Declaration* (2009)[101] has been the policy of the UK government with regard to Grand Challenges. These are:

- Tightening supplies of energy, water and food
- Pandemics
- Ageing societies
- Global warming
- Public health
- Security

8.1 Nanotechnology

Ethical Acceptability: Nanotechnology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
The Nanotechnology Strategy Forum (NSF) has been established to facilitate discussion and engagement between the government and key stakeholders on strategic issues for the responsible advancement of the UK's nanotechnologies industries. The NSF is an ad hoc expert advisory body with a membership drawn from industry, regulators, academia and NGOs; it reflects a wide range of stakeholder perspectives. NSF discussions and comments are attributable and on the public record for reasons of transparency. *Food*:The UK Food Standards Agency (FSA) commissioned an independent research company to carry out research into UK consumer awareness and attitudes of nanotechnologies in the food sector, and has set up the **Nanotechnologies and Food Discussion Group,** which commissions research in this area. The UK House of Lords Committee on Science and Technology also produced a *Report on Nanotechnologies and Food (2010).*[102]

Sustainability: Nanotechnology
Safety and environment regulations
The UK Government has accepted the recommendation of the **Royal Society and Royal Academy of Engineering** that nanomaterials be "treated as new chemicals", which required safety testing; "that factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous", and that, "the release of nanoparticles and nanotubes to the environment is avoided as far as possible".[103]

---

[100] http://data.worldbank.org/country/united-kingdom

[101] http://tinyurl.com/og7tqtj *Lund Declaration* 2009.

[102] http://www.publications.parliament.uk/pa/ld200910/ldselect/ldsctech/22/22i.pdf

[103] http://www.raeng.org.uk/publications/reports/nanoscience-and-nanotechnologies-opportunities

*Medicine:*The UK **Medicines and Healthcare Products Regulatory Agency** (MHRA) believes that current EU regulations for medicines and medical devices are sufficiently stringent and broad in scope to cover theoretical risks associated with nanotechnologies, although it anticipates that nanotechnology-specific guidance will be created in the future, once there is enough data to allow for the creation of systematic guidance.[104]

*Food:*The UK **Food Standards Agency** (FSA) states that if nanotechnology is used to develop novel foods and processes, approval would be required under the ***Novel Foods Regulation*** (Regulation (EC) No 258/97)[105] to ensure products are safe. The FSA takes advice from an independent advisory committee, the **UK Advisory Committee on Novel Foods and Processes** (ACNFP).

Societal Desirability: Nanotechnology
Grand Challenges intended to be targeted through this technology
In health, nanotechnology "is likely to have a wide impact on medical devices and medicinal products, with the potential for the development of new therapies, such as smaller implantable devices or improved dosing and targeting of medicines" (MHRA).[106]   The UK Research Councils published a series of Grand Challenges calls which are intended to provide a focus for UK nanotechnology research by addressing societal and/or economic issues where nanotechnology can make a unique and significant contribution. These are:[107]   Energy; Water purification and environmental remediation; Healthcare;[108] and Digital Economy.   Each Grand Challenge will be an integrated, interdisciplinary activity encompassing basic research through to scale up such that the technology can actually be deployed. Active participation of end users in helping to define and deliver the challenges are regarded as essential. Each Grand Challenge will be developed around a 'road map', showing how the challenge would evolve over its lifetime, from an initial focus on more basic research through to research addressing the scale up and application issues. This road map is meant to facilitate a 'stage gate' approach. Integral to each of these will be a consideration of the issues of public confidence and safety, and the UK Economic and Social Research Council (ESRC) has indicated its willingness to fund these aspects of each of the challenges.

8.2 Synthetic Biology

Ethical Acceptability: Synthetic Biology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
In 2009-10 the UK Biotechnology and Biological Sciences Research Council (BBSRC) and the UK Engineering and Physical Sciences Research Council (EPSRC), supported by the UK Government Department for Business, Innovation and Skills (BIS) commissioned UK policy research organisation TNS-

---

[104] http://www.mhra.gov.uk/Howweregulate/Nanotechnology/

[105] http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31997R0258

[106] http://www.mhra.gov.uk/Howweregulate/Nanotechnology/

[107] UK Engineering and Physical Sciences Research Council (October 2006), *Report of the Nanotechnology Strategy Group*, Appendix 3 p19.

[108] For instance, *Nanotechnology for Healthcare* has identified its key elements as, "Nanotechnologies for the targeted delivery of therapeutic agents & Nanotechnologies for diagnostics".

BMRB[109] to carry out a series of public workshops and stakeholder interviews on the science and issues surrounding synthetic biology.

Findings from the dialogue showed there was conditional support for synthetic biology - while there was great enthusiasm for the possibilities of the science; there were also fears about control; who benefits; health or environmental impacts; misuse; and how to govern the science under uncertainty.[110] The report also concluded that participants felt that the Research Councils have a significant role in the governance of synthetic biology but that the process of funding 'good science' was generally seen as focusing on technical excellence. However, participants also wanted to see a broader definition of good science in a normative or social sense.

Sustainability: Synthetic Biology
Safety and environment regulations
While there is no specific safety or other regulation on synthetic biology *per se*, this is an area which the UK Government, the research community and industry are aware needs attention. In 2012 the UK Technology Strategy Board produced a report by the UK **Synthetic Biology Roadmap Coordination Group**.[111] An important element of this report addresses **the need for continuing responsible research and innovation**: including the need for awareness, training and adherence to regulatory frameworks.

Societal Desirability: Synthetic Biology
Grand Challenges intended to be targeted through this technology
The UK **Technology Strategy Board** report on a *Roadmap for synthetic biology* states that, it "is a rapidly developing technology applicable to a wide range of biological systems, and has developed over the last decade due to the confluence of a number of factors. It could help to solve a number of major global challenges including in the fields of healthcare, energy and the environment".[112]

8.3 Information and Communication Technology (ICT)

Ethical Acceptability: ICT
Codes of conduct, other legal instruments and/or sustained public engagement efforts
ICT is controlled and regulated by a host of different legal instruments, regulations, guidelines and best practice procedures including ISOs (International Organization for Standardization).   The public interest and protection of personal data is overseen by the **Information Commissioner's Office** (ICO).   Public engagement in the area of ICT tends to operate on multiple levels. At one level there may be specific applications of ICT where public engagement may be sought in connection with its implementation.[113] At another level, ICT is itself seen as an enabling technology to increase opportunities

---

[109] Taylor Nelson Sofres, British Market Research Bureau.

[110] http://www.bbsrc.ac.uk/web/FILES/Reviews/1006-synthetic-biology-dialogue.pdf.

[111] http://www.rcuk.ac.uk/RCUK-prod/assets/documents/publications/SyntheticBiologyRoadmap.pdf.

[112] http://www.rcuk.ac.uk/RCUK-prod/assets/documents/publications/SyntheticBiologyRoadmap.pdf.

[113] http://www.ppgis.manchester.ac.uk/downloads/caj_paper.pdf

for public engagement on a whole range of public initiatives including services, policies and e-government,[114] which may include, but not be limited to, ICT-based applications.

Sustainability: ICT
Safety and environment regulations
The collection, storage and use of the data element of ICT is regulated primarily under the **Data Protection Act 1998**[115] and subsequent amending legislation such as **The Freedom of Information Act 2000**.[116] These legislations are enacted in compliance with the EU **Data Protection Directive 95/46/EC**.[117] However this Directive together with the national legislation is likely to be superseded by a new pan-European **EU Data Protection Regulation** during the course of 2015. In the UK the use of personal medical data is also regulated under the **Health and Social Care Act 2012**.[118] Guidelines on health and safety issues associated with the use of and access to computer hardware and software particularly in education and the workplace is governed by guidelines such as **Working with Display Screen Equipment**.[119]

Societal Desirability: ICT
Grand Challenges intended to be targeted through this technology
There are many Grand Challenges that have been associated with ICT, including very clear applications to the Grand Challenges of Medicine, Energy, Environment and Food and Agriculture. However, as ICT is not only all-pervasive and crosses all technology boundaries, other Grand Challenges might also be identified where ICT is considered to have a pivotal enabling role. These include health and wellbeing, productivity and innovation, cultural heritage, social inclusion[120] and sustainability. Further specific challenges have also been considered, such as traffic management and safety, service robots and intelligent buildings, security and law enforcement, to name but a few. The UK Government also has an ongoing strategy for increasing efficiency and accessibility in the public sphere through the implementation of ICT technology.[121] However, evaluating the effectiveness of the 'information society' itself may also be considered a Grand Challenge".[122]

---

[114] http://tinyurl.com/pmxp78v Citizen participation e-government services.

[115] http://www.legislation.gov.uk/ukpga/1998/29/contents

[116] http://www.legislation.gov.uk/ukpga/2000/36/contents

[117] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

[118] http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted

[119] http://www.hse.gov.uk/pubns/indg36.pdf

[120] Israel, B. A., Schulz, A. J., Parker, E. A., & Becker, A. B. (2001). Community-based participatory research: policy recommendations for promoting a partnership approach in health research. *Education for health*, *14*(2), 182-197.

[121] http://webarchive.nationalarchives.gov.uk/+/http://www.cabinetoffice.gov.uk/media/317444/ict_strategy4.pdf

[122] http://www.tandfonline.com/doi/abs/10.1080/01972240600903904#.VMlF4mjF-So

9. United States

The United States is a high income country with per capita GNI of US$53,470 in 2013. Life expectancy at birth was 79 in 2012.[123] The US has not identified a national set of Grand Challenges. While many of its policies pursue socially desirable goals such as improving health care and promoting clean energy use, it is job growth, international competitiveness, and national prosperity that are the explicitly stated goals.[124]

9.1 Nanotechnology

Ethical Acceptability: Nanotechnology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
The National Nanotechnology Initiative has funded two centres that focus on the ethical, legal, and social issues related to nanotechnology[125] The Center for Nanotechnology in Society at Arizona State University, and the Center for Nanotechnology in Society at the University of California Santa Barbara. Consistent with ***US Executive Order 12866***[126], all agencies must provide the public with a meaningful opportunity to comment through the Internet on any proposed information for at least 60 days, and provide timely online access to the rulemaking docket on regulations.gov including relevant scientific and technical findings. In 2011, the Office of Science and Technology Policy put out a memorandum for the heads of executive departments and agencies that described the new ***Principles for Regulation and Oversight of Emerging Technologies***. These outline a number of guidelines on how agencies should make every effort to actively communicate with the public about potential benefits and risks, and provide ample opportunities for stakeholder involvement and public participation in the development of new regulation.[127]

Sustainability: Nanotechnology
Safety and environment regulations
The US uses existing regulations to oversee the manufacture and use of nanomaterials. See ***Executive Order 13563*** and ***Policy Principles for U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials*** (11 June, 2011).[128]

[123] http://data.worldbank.org/country/united-states
[124] United States, National Economic Council, Council of Economic Advisors and the Office of Science and Technology Policy, 2011. *An American Strategy for Innovation: Securing Our Economic Growth and Prosperity*. (February 2011).: http://www.whitehouse.gov/sites/default/files/uploads/InnovationStrategy.pdf
[125] United States, National Nanotechnology Initiative (2014), *Ethical Legal and Societal Issues*. http://www.nano.gov/you/ethical-legal-issues
[126] http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo12866_10041993.pdf
[127] United States. Office of Science and Technology Policy. (2011). Principles for the Oversight of Emerging Technologies (11 March 2011) http://bioethics.gov/synthetic-biology-report
[128] United States, Office of Science and Technology Policy (2011). *Policy Principles for U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials* (11 June, 2011).

Societal Desirability: Nanotechnology
Grand Challenges intended to be targeted through this technology
In the *Fifth Assessment of the National Nanotechnology Initiative*, the President's Council of Advisors on Science and Technology recommended that the National Nanoscale Science, Engineering, and Technology Subcommittee and the Office of Science and Technology Policy should identify a list of candidate nanotechnology Grand Challenges that address significant societal needs.[129] As of January 2015, these Grand Challenges have not yet been defined. The 2011 *American Strategy for Innovation: Securing our Growth and Prosperity* included the following Grand Challenges: Drive breakthroughs in health care technology, utilize biotechnology, nanotechnology and advanced manufacturing to improve health care quality and delivery.

9.2 Synthetic Biology

Ethical Acceptability: Synthetic Biology
Codes of conduct, other legal instruments and/or sustained public engagement efforts
In 2010, the **Presidential Commission for the Study of Bioethical Issues** released the report, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* which concluded that while there may be limited risks associated with the further development of synthetic biology, no additional federal regulations were needed at the time of the report's publication.[130] A year later, in 2011, the Memorandum entitled *Principles for the Oversight of Emerging Technologies*[131] called for public participation and stakeholder involvement in the continued development of synthetic biology. However, no specific government initiatives are currently aimed at public engagement.

Sustainability: Synthetic Biology
Safety and environment regulations
The US uses existing regulations to govern the manufacture and use of synthetic biology products and modified organisms.[132] See *Executive Order 13563*. The approach to regulation focuses not on the production process, but on the properties of products as regulated under existing statutes.[133]

---

http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf

[129] United States. President's Council of Advisors on Science and Technology (2014). *Fifth Assessment of the National Nanotechnology Initiative*.
http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_fifth_nni_review_oct2014_final.pdf (p.5).

[130] United States. Presidential Council for the Study of Bioethical Issues 92010. New Directions: The Ethics of Synthetic Biology and Emerging Technologies. http://bioethics.gov/synthetic-biology-report.

[131] United States. Office of Science and Technology Policy. (2011). Principles for the Oversight of Emerging Technologies (11 March 2011) http://bioethics.gov/synthetic-biology-report

[132] See Executive Order 13563 http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order

[133] OECD (2014), "National policies for the development and application of synthetic biology", in OECD, *Emerging Policy Issues in Synthetic Biology*, OECD Publishing DOI: 10.1787/9789264208421-10-en p. 148.

Societal Desirability: Synthetic Biology
Grand Challenges intended to be targeted through this technology
None

9.3 Information and Communication Technology (ICT)

Ethical Acceptability: ICT
Codes of conduct, other legal instruments and/or sustained public engagement efforts
The Open Government Initiative, begun in 2009, makes much more government information available freely online in open formats that can be retrieved, downloaded, indexed and searched by commonly used web search applications. In May of 2013, President Obama signed an executive order that made open and machine-readable data the new default for government information.[134]   This initiative also includes an effort to develop a *US Public Participation Playbook* that collects best practices – both digital and in person – in developing public participation strategies and programs for use by government agencies.[135]

Sustainability: ICT
Safety and environment regulations
In the US, there is no single comprehensive law regulating the collection and use of personal data. Instead, a handful of federal laws exist supplemented by laws passed by a number of states that offer further protections, such as California's *Do Not Track* law passed in 2013.[136] **The Federal Trade Commission** (FTC) is the main body that both sets guidelines for the protection of consumer information and enforces federal privacy regulations. These regulations include the *Children's Online Privacy Act*[137] that gives parents control over what information websites can collect from underage children, and the *US Safe Web Act*[138], which allows the FTC to investigate companies and individuals who use fraudulent spam, spyware, and misleading advertising in marketing.   A major issue being discussed is that of national security and privacy, especially after May 2013 when Edward Snowden leaked government documents to the *Guardian,* revealing the extent of the US National Security Administration's harvesting of data from email and instant messaging contact lists, content from personal email and social media accounts, and the tracking and mapping the location of personal cell phones.

---

[134] *Open Government Directive*. January 21, 2009, http://www.whitehouse.gov/open/documents/open-government-directive . Executive Order –*Make Open and Machine Readable the New Default for Government Information*. May 9, 2013. http://www.whitehouse.gov/the-press-office/2013/05/09/executive-order-making-open-and-machine-readable-new-default-government-

[135] United States White House. *Help Shake Public Participation*. White House Blog. November 25, 2014. http://www.whitehouse.gov/blog/2014/11/25/help-shape-public-participation.

[136] California State Legislature (2013). *Assembly Bill No. 370*, Chapter 390. http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140AB370

[137] http://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/childrens-online-privacy-protection-rule

[138] http://www.ftc.gov/enforcement/statutes/us-safe-web-act

Societal Desirability ICT
Grand Challenges intended to be targeted through this technology
The White House *Strategy for American Innovation* includes the following Grand Challenges associated with ICT: **Wireless Initiative**: Expanding and improving high-speed wireless access to help create an interoperable public safety network and facilitate the rapidly growing wireless revolution that will help support wireless innovation in health, education, transportation and other application areas. The National Security Council and Homeland Security Council have also developed a strategic framework to help enhance cyber security of the nation's ICT grid. **Health Care**: Drive breakthroughs in health care delivery, harnessing the power of data and technology to help prevent medical error, improve care quality, and reduce costs. **Education Technologies:** Foster innovations in technologies that drastically improve student performance and increase access to lifelong learning and training for American workers. Department of Education to launch the Advanced Research Projects Agency that will support the use of ICT in education.[139]

---

[139] National Economic Council, Council of Economic Advisors and the Office of Science and Technology Policy, 2011. *An American Strategy for Innovation: Securing Our Economic Growth and Prosperity*. (February 2011). [http://www.whitehouse.gov/sites/default/files/uploads/InnovationStrategy.pdf