Ethics assessment in different fields

Emerging technologies: the case of nanotechnologies

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Annex 2.b.2
Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries
Deliverable 1.1

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Contents

1 EMERGING TECHNOLOGIES

1.1 THE EMERGING TECHNOLOGIES CONCEPT

Emerging technologies are related to completely new fields of investigation in science and the convergence of existing disciplines and technologies, that promise to provide new capacities to science and enable the design of new products and processes. As indicated by the work undertaken by OECD to define and measure emerging technologies, usual metrics and parameters (patents, publications, etc.), as well as fields of research (e.g. biology) may not be sufficient to describe them.[1]

There are several options to define and identify Emerging Technologies (ET). ET might be described as a research or technology area (synthetic biology, quantum computing, nanotechnology, biotechnology, advanced manufacturing systems, additive manufacturing, etc.), as well as by the challenges they aim to address (clean energy tech, ageing society tech, big data).

ET might be seen as enabling and/or disruptive technology[2], "promising to drive radical change in the capabilities of a user or culture" (in the past, for example, electricity, computers, internet), as well as simply technologies alternative to existing ones and promising to provide better solutions for specific problems (e.g. organic PhotoVoltaics cells based on nanotechnology solutions, compared to standard PV systems).

Looking at the acceleration of patents over the years in specific technology or application areas, as well as the priorities in policy areas around the world, are amongst the method used to identify what are ET currently considered by the scientific and industrial community.

Complexity, multidisciplinary and convergence (of traditional disciplines) as well as the uncertainties in evaluating and measuring their potential scientific and societal impact impacts are common aspects of ET. This challenge the assessment of so called Environmental, Health and Safety (EHS) Issues as well as Ethical, Legal and Societal Aspects (ELSA).

There are several EHS issues and ELSA arising from uncertainties related to ET development. Examples include: the risks for the human health related to use of novel materials, devices and products created with ET (for which only preliminary safety data might be available); concerns relating to accountability and transparency of R&I organisations (industry and research) with respect to use (and misuse) of ET; concerns about the impact of ET applications on human life (impacts on human nature, personal identity, and social behaviour of people, etc..).

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[1] OECD, "Emerging Technologies". http://www.oecd.org/sti/outlook/e-outlook/stipolicyprofiles/newchallenges/policiesforemergingtechnologies.htm
[2] Wikipedia, "Disruptive technologies". http://en.wikipedia.org/wiki/Disruptive_innovation

Though there are common issues amongst different ET, the approach to *understand and assess* EHS and ELSA for ET generally needs to be research, technology and application-specific. One of the aspects that deserves particular attention is the maturity level of the technology (also known as technology readiness level). Broadly speaking, during preliminary development stages (e.g. basic research) information available on characteristics and use of potential applications is limited, and thus there are high uncertainties in the assessment of EHS and ELSA; in more advanced stage (e.g. engineering and testing), EHS and ELSA assessment can be more precise[3].

Examples of short lists of emerging/enabling technologies from different sources and perspectives, are included in the Annex.

1.2 BASIC DESCRIPTION OF KETS AND THEIR RELEVANCE FOR SATORI

For the purpose of providing insights on the ethical impact assessment *of ET* (focus of the SATORI project), it is proposed to take as reference the science, technology and innovation domains that are considered nowadays as a priority in the European agenda. A clear vision is given by the emerging and enabling technologies considered along the three pillars of the Horizon 2020 framework program:

1. **Excellence in science:** Future Emerging Technologies[4]
2. **Leadership in Industrial Technologies:** Key Enabling Technologies (KETs)
3. **Societal challenges**[5]

The first two pillars are instrumental for the scope of realising innovations addressing societal challenges of the third pillar. The latter pillar provides a clear shift toward a socio/economic needs/driven R&I policy compared to previous framework programmes.

From an application oriented, industrial perspective priority is given to the second pillar, and in particular to Key Enabling Technologies (KETs). A snapshot of KETs definition and priority issues with respect to EHS issues and ELSA is outlined :[6,7]

- **Photonics and micro-nanolectronics** (ICT) are the main drivers for most advanced ICT applications, such as faster and wider connectivity systems, big data solutions, improved mobile and sensing devices, etc.
    - ICT is a broad and well known area of ethical debate (e.g. on privacy, data protection, etc)

[3] Sandler, Ronald, *Nanotechnology: the social and ethical issue*, Woodrow Wilson Center for Scholars, U.S. PEN 16, Jan 2009.
[4] FET includes: early-stage (novel) science and technology research: promising exploratory research themes (including domains such as cognitive sciences, robotics, cyber-physical systems, quantum technologies, high-performance computing); FET flagship on graphene and the human brain project.
[5] See list of EC societal challenges on http://ec.europa.eu/programmes/horizon2020/en/h2020-section/societal-challenges
[6] European Commission, High Level Group on Key Enabling Technologies. http://ec.europa.eu/enterprise/sectors/ict/key_technologies/kets_high_level_group_en.htm
[7] AIRI, *Key Enabling Technologies: their role in the priority technologies for the Italian industry*, Apr 2013. http://www.airi.it/wp-content/uploads/2013/04/AIRI_Report_KETS_WorkingPaper_apr2013_ENG1.pdf

  - ELSA implications of the ICT field are a separate topic of the SATORI analysis.
  - Micro-nanoelectronics is partially overlapping with the KET nanotechnology, considered in this note.
  - Innovation in ICT is considered as a case study in the report on industry as an ethic assessor

- **Advanced materials** are at the bottom line of the value chain of the majority of high tech products and applications.
  - "Hot" topics in the policy and industry debate relate to safety and sustainability of new materials and processes. A cornerstone is given by REACH[8], considered the most stringent regulation on substances worldwide. The precautionary principle is explictly mentioned and underpin REACH action. A breakthrough aspect of REACH regulation compared to the past (as well as regulations in other countries, such as in the U.S.) is that the burden of proof about the safety of a substance is not on the regulator (as it was in previous EC regulations) but on manufacturers, importers and producers.
  - Advanced materials have a key role in developing solutions for societal challenges and sustainability (e.g. improved materials for more efficient processes and reduced use of resources, susbstitution of critical substances, smart & green transport).
  - Nanomaterials (case study of this note) are partially overlapping, or cross-cutting, with advanced materials.

- **Biotechnology** This area is generally split in three[9]: the two well-established areas of red biotech (biopharmaceuticals) and green biotech (agrifood sectors) and the cross-cutting and emerging area of white biotech (or industrial biotech) including the production of bio specialities, biomaterials, biofuels, chemicals and other bio-based products for a variety of sectors.
  - Biotech is an intense and well known area of debate on ethical and societal issues.
  - Examples of "hot" issues include GMOs in the agrifood, use of personal, human data and predictive medicine in biopharma, competition between food and non food crops (biomasses) in the white biotech.
  - The biotech field is characterized by a strong debate about benefits and concerns. Almost all biotech are based on and/or interact with biological organisms and organs, and have a direct impact on humans and the environment
  - ELSA implications of the biotech field (red biotech) are partially covered by other areas of analysis of the SATORI project.

- **Nanotechnologies** are transversal to the other KETs, covering a broad range of science, technology and applications areas. Their impact is enabling across different sectors and industry and, unlike the other KETs, it is quite difficult to identify a pure

[8] European Parliament and the Council, Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
[9] The European Commission definition of KETs refer to industrial biotechnology.

nanotechnology industry or market. A case by case, application specific approach is generally considered to evaluate their use and impacts[10, 11].

- Since the beginning of its development, nanotechnology has been characterised by an intense debate on ELSA by policy makers, R&I players and (partially) the general public.
- The already well-established stakeholder dialogue on nanotechnology(ies), combined with the early maturity stage of most of applications, seems to represent a unique case to promote responsible and ethical acceptable developments of nanotechnologies.

- **Advanced manufacturing systems** have a broad definition, cross cutting with the other KETs as well as across sectors, technologies and processes[12]. They are an enabling and cross cutting technology: equipments and manufacturing facilities are needed to realize applications of all other KETs, as well as AMS, as a product themselves, are realized making use of the other KETs[13, 14, 15].

  Manufacturing is a key area for the European economy. Increasing manufacturing capacity of EU countries, bringing back to Europe the production of high tech and high added value goods is one of the most challenging targets of the 2020 European agenda (as well as a top priority of the U.S. R&I agenda [16]). How Europe will address this challenge will have a huge impact on trade, jobs and our society in general, including governance of R&I, and related EHS issues and ELSA. Besides these macro-ecomical aspects (that cannot be avoided in the discourse on AMS), the"Factory of the Future" vision (*"affordable, personalised and eco-efficient products"*) promise to revolutionaise the entire business (and social) production models, with approaches such as adaptive and smart manufacturing, additive manufacturing, human-centred manufacturing, customer-focused manufacturing, sustainable manufacturing.[17]

  - Improvement in resources efficiency, reduced environmental impact, economical and social sustainability are seen as a priority and a driver for future AMS developments, in particular in EU policies.

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[10] Business and Industry Advisory Committee (BIAC), Nanotechnology Committee, *Responsible Development of Nanotechnology: Turning Vision Into Reality – Vision Paper*, Feb 2013. http://biac.org/statements/nanotech/FIN09-01_Nanotechnology_Vision_Paper.pdf

[11] Klotz, Gernot, *Nanotechnology: a sustainable basis for competitiveness and growth in Europe*, High Level Group on Key Enabling Technologies, December 2010.

[12] AMS comprise production systems and associated services, processes, plants and equipment, including automation, robotics, measurement systems, cognitive information processing, signal processing and production control by high-speed information and communication systems.

[13] European Commission, "Factories of the Future PPP: towards competitive EU manufacturing", 2013. http://ec.europa.eu/research/press/2013/pdf/ppp/fof_factsheet.pdf

[14] National Initiative on Advanced Manufacturing, U.S. http://www.whitehouse.gov/sites/default/files/microsites/ostp/amp_final_report_annex_1_technology_developm ent_july_update.pdf

[15] Foresight, *The Future of Manufacturing: A new era of opportunity and challenge for the UK* Summary Report, The Government Office for Science, London (UK), 2013.

[16] The U.S. has established in 2011 a national initiative on advanced manufacturing

[17] European Commission, "Factory of the Future". http://ec.europa.eu/research/press/2013/pdf/ppp/fof_factsheet.pdf

- Specific ethical impacts might be considered within the specific technologies embedded in AMS systems, examples are: ICT tech such as big data, cloud computing, internet of things, mobile internet, sensors (e.g. privacy, data protection, control of people behaviours, digital divide); advanced and autonomus robotics (e.g augmentation, enhancment): biomanufacturing (e.g. confidentiality and sharing information, predictive information, etc)
- Additive manufacturing is already recognised as an ET per se, with likely a disruptive character.[18] Peculiar ethical and societal issues have already been put to the fore (such as dual use/misuse, IPR issues) but more are likely to come with the evolution of the technology.

KETs are, generally, knowledge and capital-intensive, multidisciplinary, trans-sectorial, and characterised by high R&D intensity. Common ELSA of ET, outlined by most of the analysis, are related to education and intellectual property rights (IPR).

There will be an increasing need for knowledge based workers, for multi-skilled teams (multi-disciplinary, gender mix, etc), for people with and attitude for continuous learning and for networking (with research partners, suppliers, consumers)[19]. Building, strengthening and retaining in Europe, KETs skills, is a key priority identified for KETs development in EU.

Regarding IPR, a key issue is that of balancing the need for effective IPR protection (as an incentive for intensive R&D efforts in ET) with transparency, access and distributive justice issues (toward the research community, users, consumers etc.).

1.3 Responsible research and innovation and KETs (ethics of emerging technologies)

Societal needs and ethical reflection are nowadays closely integrated in EU policies for Research and Innovation. A common framework, under the collective term 'Responsible Research and Innovation', is being developed to take into account these aspects into the R&I practices and will be increasingly implemented throughout Horizon 2020 and the other EU programmes in the EU[20]. The needs-driven approach of H2020 (pillar 3) already shows the relevance given to these aspects. RRI approaches are included throughout the framework programme, and specific requirements related to the different RRI dimensions (such as or public engagement, ethics, gender, sustainability, etc.) can be found in the programme calls. Other specific policy options are under investigation and are being considered to further enhance ethical reflection in R&I practices.

As a reference for the discourse on the ethical impact assessment of ET, a definition for RRI specifically devoted to technology, applied science and engineering is given below.[21]

> RRI refers to ways of proceeding in Research and Innovation that allow those who initiate and are involved in the processes of research and innovation at an early stage

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[18] U.S. National Intelligence Council, *Global Trends 2030: Alternative Worlds*, ISBN 978-1-929667-21-5, December 2012. http://www.dni.gov/nic/globaltrends
[19] Foresight, op. cit, 2013
[20] Articles 12, 13, 15, 16 of the H2020 Council Decision include explicit reference to the RRI concept.
[21] European Commission, DG for Research and Innovation, *Options for Strengthening Responsible Research and Innovation*, *Report of the Expert Group on the State of Art in Europe on Responsible Research and Innovation*, 2013, pp. 55-56.

- to obtain relevant knowledge on the consequences of the outcomes of their actions and on the range of options open to them and
- to effectively evaluate both outcomes and options in terms of moral values (including, but not limited to wellbeing, justice, equality, privacy, autonomy, safety, security, sustainability, accountability democracy and efficiency) and
- to use these considerations (under A and B) as functional requirements for the design and development of new researches, products and services.

Building on these requirements, in a European context the following points of reference should be reflected in the design of research and innovation processes and products:

1. **Ethical acceptability** which includes compliance with both the EU charter on fundamental rights as well as the safety of products regarding the acceptable risk of products.

2. **Orientation towards societal needs** which includes an orientation towards contributing to achieving objectives of desirable and sustainable development (consisting of economic, social as well as environmental aspects) and contributing to achieving normative objectives such as "equality of men and women" or an improvement of the "quality of life" which are also core European objectives expressed in the Treaty on European Union.

2 THE CASE OF NANOTECHNOLOGIES

2.1 Basic description of nanotechnologies

The International Standard Organization (ISO) provides an authoritative "working" definition of nanotechnologies. It states:

> Nanotechnology is the understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications. Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.

Based on a commonly accepted view, nanotechnologies development is divided into different generations:[22]

1) **Passive nanostructures**
   Ex. coatings, nanoparticles, nanostructured metals, polymers, ceramicas
2) **Active nanostructures and nanodevices**
   Ex. targeted drugs, biomedical devices, adaptive structures, actuators, 3D transistors
3) **Integrated nanosystems (systems of nanosystems)**
   Ex. guided assembly, 3D networking and new hierarchical architectures, robotics, evolutionary systems
4) **Heterogeneous molecular nanosystems**
   Ex. molecular devices "by design", atomic design
5) **Converging technologies**

[22] Roco, M., et al, "US Nanotechnology initiative", *Nanotechnology research directions for societal needs in 2020, Retrospective and outlook summary*, 2011. The original (2004) vision included four generations, the fifth was added in 2011.

Ex. nano-bio-info from nanoscale, cognitive technologies; large complex systems from nanoscale

At least for the first two generations, there are already industrial prototype and examples of products on the market. The development of applications in the latter two stages is instead foreseen in a medium/long term perspective.

In 2006, a report from the International Risk Governance Council[23] clearly outlined the risk governance context related to the different generations, a concept that still remains valid. With the evolution of generations, there is a trend toward increased complexity, dynamics, trans - disciplinarily as well as higher uncertainties on risks and societal concerns. For the 1st and, partially, 2nd generation, risks and concerns are mainly on EHS issues. Starting from 2nd generation ethical and societal aspects will become increasingly more relevant. Issues such as the desirability of innovations, consequences of unexpected/unpredictable developments (control and reversibility of innovation paths), distribution of benefits, interaction with living systems, impact on human nature and definition of life (e.g. human enhancement) will likely enter into the debate.

These two main frames help to distinguish between two quite different approaches that have characterised the discourse on the ethics of nanotechnologies: the reflection on the tension (hopes, ambitions, anxiety) amongst moral and ethical values of our society and the actual applications of nanotechnology (foreseen product and processes in specific fields); a more visionary debate on hypothetical technology developments scenarios and their (hypothetical) ethical and societal impacts.[24]

With respect to preliminary ethical issues identified by the SATORI project[25] and the discourse on *technology ethics*, the first frame is mainly related to *Ethical concerns with impacts of technology,* the second frame also to *Ethical issues intrinsic to technological innovations,* and thus "the moral permissibility of technological innovations themselves, independently from their potential or actual impacts" (being our knowledge on impacts only hypothetical).

An "enabling technology", nanotechnologies could be a key element in the value chain of almost any kind of products or application that involves manufacturing and use of technology. Some of the most relevant areas of applications are expected (or already in place) in the following sectors: [26,27]

- Chemistry & sustainabile chemistry
- Materials
- Health, Medicine, Nanobio
- Security
- Aerospace, Automotive, Transport

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[23] International Risk Governance Council, *White Paper on Nanotechnology Risk Governance*, June 2006.
[24] Pavlopoulos, Marc, Alexis Grinbaum, Vincent Bontems, *Toolkit For Ethical Reflection And Communication*, CEA-LARSIM, June 2010.
[25] Brey, Philip, and Agata Gurzawska, *Quickscan: Ethical Issues in Research and Innovation,* Internal project document, SATORI project, 2014.
[26] Klotz, Gernot, *Nanotechnology: a sustainable basis for competitiveness and growth in Europe*, High Level Group on Key Enabling Technologies, December 2010.
[27] ObservatoryNano Project, *European Nanotechnology Landscape Report*, 2012.

- Construction
- ICT
- Agrifood
- Energy & Environment
- Consumer products: personal care, cosmetics, textiles & clothings, household, appliances, packaging, etc

Analysis of markets and patents shows that most relevant market and application areas include electronics & ICT, chemistry and materials, health, medicine and nanobio, aerospace, automotive, transport, security as well as energy, agrifoods.[28]

An estimate of the share of global market of nano-related products at 2015 by sector is given below[29]:

- Materials: 31%
- Electronics: 28%
- Pharmaceuticals: 17%
- Chemical manufacturing: 9%
- Aerospace: 6%
- Other: 9%

2.2 The nanotechnology debate

Since the early stages of its development, nanotechnologies have been related to revolutionary promises about the possibility to manipulate atoms, mimic nature, realise tailor-made structures and devices and countless number of applications. The fashionable character of nanotechnologies have prompted hopes and fears of any kind.

The starting of the debate on the *"ethics"* of nanotechnology might be related to the concept of "molecular manufacturing" and radical nanotechnology applications (such as self-replicating, thinking, nanomachines), that emerged in a famous scientists debate (between Eric Drexler and the Nobel Prize Richard Smalley) in the early 2000, as well as some best seller narratives published in that period.[30] Both civil society organisations and the public started to gather attention on nanotechnologies. At the same time, funding and investments from governments and industry were increasing rapidly, first products surfaced on the market and some initiatives on EHS started (e.g. the ISO TC 229, International Standard Organization Technical Committee on Nanotechnologies, was established in 2004). Since the first Action Plan on Nanotechnologies (in 2005) the European Commission made clear the need to develop nanotechnology in a responsible way.

A significant document on the impact of nanotechnologies has been the Royal Society and Royal Academy of Engineering's report (2004), *Nanoscience and nanotechnologies:*

[28] Brand, Leif, *Briefing No.20 Statistical Patent Analysis, Patents: an Indicator of Nanotechnology Innovation*, *The ObservatoryNano Project,* 2012.
[29] Roco et al, op.cit, 2011.
[30] http://en.wikipedia.org/wiki/Molecular_nanotechnology#cite_note-31; http://pubs.acs.org/cen/coverstory/8148/8148counterpoint.html

opportunities and uncertainties.[31] The report was instrumental in supporting a thoroughly debate amongst the policy, scientific and industrial community about the responsible development of nanotechnologies, including aspects such as public engagement, regulation and governance.

The discussion evolved in few years toward more specific issues, focusing on uncertainties about EHS and, to a lesser extent ELSA, of more concrete applications of nanotechnology and nanomaterials (the first IRGC frame). Some CSOs made public claims asking for a "moratorium" of nano-related products on the market, unless more clear and sound information and data on their safety were made available. Examples of fierce oppositions to nanotechnologies are the reports from the international civil society organization ETC[32] (the first one in 2003) and the NanoAction Position Paper in 2007, jointly signed by about 40 CSOs in the US and worldwide.[33]

Two mutually incompatible views were on the scene: a self-regulating "laisser-faire" model (mainly from business) and the idea of a total moratorium (mainly from CSOs).

Two milestones in the debate on nanotechnologies have been:

- the publication of the 1st regulatory review of nanomaterials of the European Commission (2008), concluding that the current EU legislative framework —*"covers in principle the potential health, safety and environmental risks in relation to nanomaterials"* and the subsequent non-binding resolution of the European Parliament (April 2009), presented by the European Parliament's Environment Committee and asking for tighter controls on nanotechnologies.[34]
- the publication of the European Commission Code of Conduct on nanoscience and nanotechnologies research from the European Commission.[35]

In the same period authoritative documents were published with respect to specific ethical issues of nanotechnology applications. Most relevant were:

- The European Group on Ethics in Science and New Technologies to the European Commission (EGE), Opinion on the ethical aspects of nanomedicine, January 2007.[36]
- UNESCO, The Ethics and politics of Nanotechnology, 2006.[37]

Prompted by these actions, some national and regional ethical committees, in particular in the area of health and life sciences, analysed the impact of nanotechnologies and in some cases published specific opinions (example are France[38], Italy[39] and Canada[40]).

[31] Royal Society and Royal Academy of Engineering's report (2004), "*Nanoscience and nanotechnologies: opportunities and uncertainties"*. http://royalsociety.org/policy/publications/2004/nanoscience-nanotechnologies/
[32] ETC is the acronym for Action Group on Erosion, Technology and Concentration, a civil society organisations operating at the global political level.
[33] International Centre for Technology Assessment (CTA) and NanoAction coalition, Principles for the Oversight of Nanotechnologies and Nanomaterials, July 2007.
[34] European Commission, *Regulatory Aspects of Nanomaterials, Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures*, June 2008
[35] European Commission, *Commission Recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research*, February 2008.
[36] http://ec.europa.eu/european_group_ethics/activities/docs/opinion_21_nano_en.pdf
[37] http://unesdoc.unesco.org/images/0014/001459/145951e.pdf

Starting from FP6 specific funding have been allocated to ELSA and the governance of nanotechnologies. A 2008 report from the EC counted 20 project in FP6 and 5 new projects in the just started FP7 on ELSA. Increasing resources have been allocated in the following years by the EC and the Member States on both EHS and ELSA of nanotechnology.[41]

An in depth dialogue amongst nanotech stakeholders (research players, social scientist, ethicists, regulators, policy makers, CSOs) helped to smooth controversial positions. The discussion became broader and more articulated, with different opinions and positions depending from the specific materials, products, use and applications considered. Examples include the opinions and position papers published by some CSOs in Europe after 2010[42], mentioning nanomaterials (instead of nanotechnology in general) and/or on specific products and applications (such as nanomaterials in cosmetics, or the safety of nanosilver) and advocating for detailed regulatory actions.

Several stakeholders, including governments and industry, have developed voluntary programs for the safe and responsible development of nanotechnology, and opened up a debate on their actions.[43]

Results from a Eurobarometer survey in 2010, showed a limited awareness on nanotechnology, and no (remarkable) critical attitudes with respect to its development. Respondents were instead critical about biotech issues such as GMOs, animal cloning, gene transfer, synthetic biology and others.[44]

Another survey from the European Commission, including experts and non-experts, showed a general positive attitude toward nanotechnologies. The opinions on the risk- benefit balance varied, depending from the application considered, with (for example) agrifood seen as an area of high risk and low benefit by the public.[45]

Ethicist and social researchers have sketched the discourse on ethics and the public concerns on nanotechnologies (and emerging technologies in general) in the form of cultural narratives.[46] The following figure shows the five narratives identified by the Deepen project.[47]

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[38] National Consultative Ethics Committee for Health and Life Sciences, Ethical issues raised by nanosciences, nanotechnologies and health, Opinion N°96, France, March 2007. http://www.ccne-ethique.fr/docs/en/avis096.pdf

[39] Presidenza del Consiglio dei Ministri (National Bioethical Committee), Nanoscienze e Nanotecnologie, Italy, 2006. http://www.governo.it/bioetica/testi/Nanoscienze_Nanotecnologie.pdf

[40] Commission de l'éthique de la science et de la technologie, *Ethics And Nanotechnology: A Basis For Action: Summary, Recommendations and Commentaries*, Quebec, November 2006. http://www.ethique.gouv.qc.ca/en/assets/documents/Nano/ResumeAvisNanos_EN.pdf

[41] European Commission, *European activities in the field of ethical, legal and social aspects (ELSA) and governance of nanotechnology*, October 2008.

[42] See final position papers published by various CSOs at the end of the NanoCap Project. http://www.nanocap.eu/Flex/Site/Pageac40.html?SectionID=1797&Lang=UK

[43] Mantovani, E., A. Porcari, et al, *Synthesis report on codes of conduct, voluntary measures and practices towards a responsible development of N&N*, NanoCode project, Sept 2010. http://www.nanocode.eu/files/reports/nanocode/nanocode-project-synthesis-report.pdf

[44] Eurobarometer 73.1, *Biotechnology,* Oct 2010. http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf

[45] Klotz, Gernot, *Nanotechnology: a sustainable basis for competitiveness and growth in Europe*, High Level Group on Key Enabling Technologies, December 2010.

[46] Davies, Sarah, Phil Macnaghten, and Matthew Kearnes (eds.), *Reconfiguring Responsibility: Lessons for Public Policy (Part 1 of the report on Deepening Debate on Nanotechnology),* Durham University, Durham, 2009.

1. *'Be careful what you wish for'*
2. *'Opening Pandora's box'*
3. *'Messing with nature'*
4. *'Kept in the dark'*
5. *'The rich get richer and the poor get poorer'*

Figure 1: Five key cultural narratives on nanotechnologies (Source: Deepen project, 2009)

The attention given to the debate on nanotechnologies, together with negative experiences of the past (such as the debate on GMOs), and other parallel debates on ET (such as synthetic biology and ICT), helped to increase the interest for new approaches in addressing the governance issues of emerging technologies.

Stakeholders in Europe acknowledge the importance of a more articulated approach to ELSA of emerging technologies, and the need to develop tools for anticipatory governance and early public engagement to support ET development.[48]

The debate on the ethical and societal impacts of nanotechnologies has, at least partially, moved to the general debate on Responsible Research and Innovation of emerging technologies.

2.3 Values and principles

Three main sources, or evidence papers, have been used in this note to gather a representative view of ethical values and principles considered with respect to emerging technologies, and nanotechnologies in particular. Outcomes of this analysis are listed below, including short notes copied from the references considered.

2.3.1 Basic principles in Responsible Research and Innovation

The extensive work undertaken on the concept of Responsible Research and Innovation has started some years ago from the reflection about EU values and principles underpinning EU policies and how they apply them to science and technology.

The Charter of Fundamental Rights of the European Union[49] provides a reference regarding European commitment to human rights, and establish relevant normative anchor points for ethics and regulation of science and innovation as well.

Below the corresponding areas of values, or rights, are reported together with examples of challenges for Responsible Research and Innovation, as highlighted in a report published in 2012 by an expert group of the European Commission[50]:

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http://www.geography.dur.ac.uk/Projects/Portals/88/Publications/Reconfiguring%20Responsibility%20September%202009.pdf

[47] Pavlopoulos, Marc, Alexis Grinbaum, Vincent Bontems, *Toolkit for Ethical Reflection And Communication*, CEA-LARSIM, June 2010.

[48] Fedrigo, Doreen, Senjen Rye, European Environmental Bureau (EEB), *Shaping innovation:Policy approaches on innovation governance the case of nanotechnology*, Issue 4, September 2010.

[49] European Convention, Charter of Fundamental Rights of the European Union (2000/C 364/01), the Official Journal of the European Communities 02.10.2000. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT

- **Justice**
  - Benefit sharing
- **Dignity**
- **Citizens' rights**
- **Freedoms**
  - Privacy protection
  - Agreement on benefits and assessment
- **Equality**
  - Disparate standards for scientific merit review (scientific integrity)
  - Helicopter research in "ethics-free" zones
  - Global agreement on benefits and assessment
  - New social and cultural values in science
- **Solidarity**
  - Brain drains and research tourism
- **Sustainability**
  - Global competition for resources
  - Best use of scarce public resources

2.3.2 Basic principles for nanoscience and nanotechnologies research

The 2008 European Commission Code of conduct for nanotechnologies[51] provides a significant list of basic principles related to nanoscience and nanotechnologies. They are:

- **Meaning**
  - N&N research activities should be comprehensible to the public. They should respect fundamental rights and be conducted in the interest of the well-being of individuals and society in their design, implementation, dissemination and use.
- **Sustainability**
  - N&N research activities should be safe, ethical and contribute to sustainable development serving the sustainability objectives of the Community as well as contributing to the United Nations' Millennium Development Goals. They should not harm or create a biological, physical or moral threat to people, animals, plants or the environment, at present or in the future.
- **Precaution:**
  - N&N research activities should be conducted in accordance with the precautionary principle, anticipating potential environmental, health and safety impacts of N&N outcomes and taking due precautions, proportional to the level of protection, while encouraging progress for the benefit of society and the environment.
- **Inclusiveness:**
  - Governance of N&N research activities should be guided by the principles of openness to all stakeholders, transparency and respect for the legitimate right of access to information. It should allow the participation in decision-making processes of all stakeholders involved in or concerned by N&N research activities.
- **Excellence:**

[50] The text is an extract from: European Commission, Directorate-General for Research and Innovation, Ethical and Regulatory Challenges to Science and Research Policy at the Global Level, 2012, pp.15

[51] European Commission, Commission recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, C(2008) 424, 7 February 2008 - http://ec.europa.eu/research/science-society/document_library/pdf_06/nanocode-apr09_en.pdf

    - N&N research activities should meet the best scientific standards, including standards underpinning the integrity of research and standards relating to Good Laboratory Practices
- **Innovation:**
    - Governance of N&N research activities should encourage maximum creativity, flexibility and planning ability for innovation and growth.
- **Accountability (responsability)**
    - Researchers and research organisations should remain accountable for the social, environmental and human health impacts that their N&N research may impose on present and future generations.

2.3.3 Basic principles for emerging technologies

An example of basic principles underlying emerging technologies in general is provided by a report published in 2010 by the U.S. Presidential Commission.[52] These are:

- **Public Beneficence**
  The ideal of public beneficence is to act to maximize public benefits and minimize public harm. This principle encompasses the duty of a society and its government to promote individual activities and institutional practices, including scientific and biomedical research, that have great potential to improve the public's well-being. **.** […].
- **Responsible Stewardship**
  […]. The principle of responsible stewardship calls for prudent vigilance, establishing processes for assessing likely benefits along with assessing safety and security risks both before and after projects are undertaken. **.** […].
- **Intellectual Freedom And Responsibility**
  A robust public policy regarding the responsible conduct of science must promote the creative spirit of scientists and unambiguously protect their intellectual freedom. At the same time, responsible science should reject the technological imperative: the mere fact that something new can be done does not mean that it ought to be done. **.** […].
- **Democratic Deliberation**
  The principle of democratic deliberation reflects an approach to collaborative decision making that embraces respectful debate of opposing views and active participation by citizens. At the core of democratic deliberation is an ongoing, public exchange of ideas, particularly regarding the many topics—in science and elsewhere— in which competing views are advocated, often passionately. **.** […].
- **Justice And Fairness**
  The principle of justice and fairness relates to the distribution of benefits and burdens across society. […]. Society as a whole has a claim toward reasonable efforts on the part of both individuals and institutions to avoid unjust distributions of the benefits, burdens, and risks that such technologies bring. . […].

2.4 ETHICAL ISSUES

An in–depth assessment of uncertainties in EHS issues and ELSA of nanotechnologies has been undertaken worldwide in the last years by authorities, policy makers, research and industry players that made evident what are the key challenges to be addressed in the governance of nanotechnologies.

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[52] U.S. Presidential Commission for the Study of Bioethical Issues, *New Directions in the Ethics of Synthetic Biology and Emerging Technologies*, U.S., December 2010.

A first list provides general EHS issues and ELSA for nanotechnologies, as taken (with little changes) from the authoritative report *Nanotechnology research directions for societal needs in 2020, Retrospective and outlook summary*.[53] Very similar points can be found in many other reports. For the purpose of providing a further classification or structure to the analysis, two other lists are considered on specific issues related to different areas of application of nanotechnologies (industrial and consumers). These latter lists are an elaboration from different sources.[54, 55, 56, 57]

2.4.1 General EHS and ELSA for nanomaterials and nanotechnologies

(what investigate, manage, regulate and control). Bullet points adapted from *Roco et al*:[58]

EHS *(key values: precaution, sustainability)*

- Building physico-chemical-biological understanding
- Risk assessment and risk management frameworks
- Life cycle analysis based on expert judgment
- Incorporation of safety considerations into the design and production stages of new nano-enabled products
- Develop and maintain viable international standards, nomenclatures, databases

ELSA *(key values: precaution, inclusiveness, responsibility/accountability)*

- Governance methods under conditions of uncertainty and knowledge gaps
    - Anticipatory governance approaches
- Regulatory challenges for specific nanomaterials and products
    - Materials and chemicals, Cosmetics and healthcare products, Biocides, Pharmaceuticals, Agrifood, Occupation health and safety, etc.
- Use of voluntary codes
- Multi-stakeholder and public participation in nanotechnology development, modes of public participation in decision making
- Patents and other intellectual property protections issues
    - Balancing the need for effective IPR protection (as an incentive for intensive R&D efforts in ET) with the need for transparency (toward the research community, users, consumers, etc)
    - IPR and monopolies created through patents during the initial phase of development of a technology
    - Equal and undiscriminatory access to technological knowledge and products, also with respect to issues of globalisation

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[53] Roco et al, op. cit, 2011.
[54] Davies, Sarah, Phil Macnaghten, and Matthew Kearnes (eds.), *Reconfiguring Responsibility: Lessons for Public Policy (Part 1 of the report on Deepening Debate on Nanotechnology),* Durham University, Durham, 2009.
[55] Mantovani, E., A. Porcari, C. Meili, M. Widmer, *The FramingNano Project, Mapping Study on Regulation And Governance of Nanotechnologies*, January 2009.
[56] The NanoCap Project. http://www.nanocap.eu/
[57] Pavlopoulos, Marc, Alexis Grinbaum, Vincent Bontems, *Toolkit For Ethical Reflection And Communication*, CEA-LARSIM, June 2010.
[58] Roco et al, op.cit, 2011.

- Education system and skilled workforce to address future needs
  - multidisciplinary and convergence of disciplines, increased demand of knowledge workers, etc

Most of ethical concerns related to technology apply, to a different extent, to the various applications of nanotechnologies. Some sector specific highlights are reported hereafter.

2.4.2 Application specific EHS and ELSA, governing tools for nanotechnologies

Nanomaterials in consumer products
Use of nanotechnologies and nanomaterials in sectors such as cosmetics, foods, textiles, personal care products, toys, etc.:

- **Claims on the use of nanotechnologies**
  - Meaning (transparency) and responsability in informing the public about the use of nanotech, including informing about enhancement aspects given by nanotech compared to conventional tech
  - gaining the trust of citizens on actions of authorities and producers dealing with a technology, application or product (institutional and scientific integrity)
- **Labelling of nano-related products**
  - Meaning (transparency), freedom of information and freedom of choice (autonomy) of consumers
- **Proportionality of risks and benefit**
  - Understand whether nanotechnologies provides relevant benefits compared to conventional tech, risk-benefit balance
- **Regulation and control of nano-related products** entering the market, to ensure safety and transparency along the value chain (workers, supplier, retailers, consumers, etc)
  - Precaution, responsability and transparency in R&I activities related to nano-related products
  - Safety of products that came into contact with the body and biological tissues, such as in the food, cosmetics, personal care and medicine areas

Nanomaterials and nanotechnologies for industrial use
Use of nanotechnologies and nanomaterials in sectors such as aerospace, automotive, transports, chemistry & materials, microelectronics & semiconductors, surfaces treatments, etc

- **Regulation and control of nano-related products** entering the market
  - Precaution, responsability and transparency in R&I activities related to nano-related products
  - Safety of nanomaterials as substances in industrial processes and products, in any exposure scenario (workplace, use, etc) where “free” manufactured nanomaterials can be dispersed in the environment;
  - Life cycle of nanomaterials and end of life impacts
- **Information and transparency along the value chain**

  - Set appropriate communication procedures (e.g. materials safety data sheets for nanomaterials) to ensure information and safety along the value chain (workers, suppliers, retailers, consumers, etc)
- **Dual use**
  - Nanotechnologies can help to improve performances of existing materials, realize more powerful, sensible and tiny systems and devices and therefore several of its applications might, in principle, be relevant for dual use. For example, amongst the priority application areas of nanotechnologies of the U.S Nanotechnology Initiative are the security and defense sectors.

Energy, environmental applications
Use of nanomaterials/nanotechnologies to improve efficiency of industrial processes (e.g. catalyst), prepare structural and functional materials for improved performances and reduced use of materials (e.g. lightweight structures), for the substitution of critical raw materials, to realise advanced systems for the production and storage of energy, remediation technologies, etc.

- **Sustainability**
  - *affordability, acceptability in the society, autonomy, distributive justice*
- **Tackling societal challenges**
  - *affordability, acceptability in the society, autonomy, distributive justice*

Safety and security applications
ICT applications enabled by the use of nanotechnologies, such as chemical, physical, biological sensors

No relevant differences with EHS and ELSA of the ICT area

Nanomedicine
Use of nanotechnologies and nanomaterials for drug discovery/delivery, diagnostic systems and regenerative medicine.

This area overlaps with the medicine and biotech areas of the SATORI project. Only few issues are specific for nanotechnologies.

- ***Regulat*ion**
  - Regulatory constrains included in the existing regulation for pharmaceutical and medicine sectors are generally considered adequate to deal with nano-related products
- **Uncertainties in regulation due to identification and classification issues for novel substances, systems and devices**
  - Theranostic devices, overlap between pharma and medical devices regulation
  - An unclear identification of the presence and quantity of active substances (nanomaterials) can challenge the classification of a product from a regulatory point of view
- **Ethical issues on advanced diagnostic and screening systems (high throughput screening devices, etc).**
  - Informed consent

    - Increased personal responsibility related to access to predictive information on diseases, confidentiality and sharing information (predictive information, relative's future health; usage by third parties ex. insurance companies)
    - Inequality and access issues
- **Ethical issues related to non therapeutic human enhancement (convergence of different technologies, including robotics and regenerative medicine)**
    - Bodily integrity, human dignity
    - naturalness and playing god arguments

2.5 INSTITUTIONALISATION

It is widely accepted that ET, and nanotechnologies in particular, have a relevant economical, social and environmental impact, and that an appropriate system should be put in place for the governance of their development.

Several governments and authorities worldwide have defined in the last decade strategies, research agendas, governance approaches devoted to different ET, and in particular for nanotechnologies. The European Commission and EU Member States, as well as other countries, such as US, Japan, Russia, China, Taiwan, have established action plans for nanotechnologies and most of these documents include responsible development as a priority[59].

Regional, national and local authorities are often involved in these actions (due to subsidiary) and/or have developed their own specific strategies for nanotech.

Many other players have been active and are playing a role in planning, monitoring and control of R&I activities in nanotechnologies, such as the various R&I operators (industry and research), as well as watchdog, advocacy, user and consumers groups and the public at large. The system is therefore quite complex and can be referred to as a regulatory pyramid with different levels of intervention that are briefly described in detail below. [60, 61, 62]

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[59] A list of action plans for nanotechnologies is available at: http://statnano.com/strategicplans

[60] Mantovani, E., A. Porcari, M. D. Morrison and R. E. Geertsma, *Developments in Nanotechnologies Regulation and Standards 2012 - Report of the Observatory Nano*, April 2012.

[61] Christou, Carin & Marc Saner, Institute for Science, Society and Policy, *Governance of Emerging Technologies: Scan of International Institutions*, March 2012.

[62] OECD, Directorate for Science, Technology and Industry, *Nanotechnology: an Overview Based on Indicators and Statistics*, OECD Science, Technology and Industry Working Papers, 2009/7. http://www.oecd.org/sti/working-papers

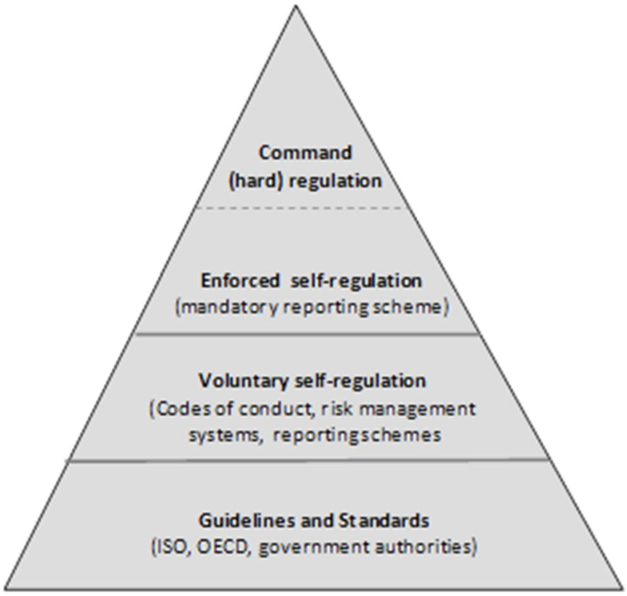

Figure 2: Regulatory pyramid for nanotechnologies (Source:the ObservatoryNano Project)

- **R&I policies**
  Action plans on nanotechnologies have been developed by more than 30 countries worldwide, most of them including specific actions for EHS and ELSA. Examples are the European Commission Plan for Nanotechnologies (now the strategy is included in the policy actions on KETs), the German Action Plan for Nanotechnologies 2015, the U.S. National Nanotechnology Initiative.

- **Hard regulation**
  Regulatory agencies and government department worldwide have been active in the assessment of the application of regulation to nanotechnologies and the definition of specific regulatory actions for nanotechnologies and nanomaterials.
  Amongst the most active countries have been: Europe (European Commission), Germany, UK, Switzerland, U.S.A, Canada, Australia.
  In Europe, specific legislative provisions on nanomaterials are in force with respect to biocidal products, food additives, food contact materials, food information, and cosmetics. An intense debate among Member States is ongoing about a possible revision of REACH for nanomaterials. Both REACH and the Cosmetic regulation explicitly refers to the precautionary principle.

- **Enforced self-regulation**
  Some countries have developed reporting scheme and public registry to understand the impact of nanotechnologies into the market. France (in 2012) was the first country to set a mandatory public registry for nanomaterials. Similar actions have been considered by other EU Member States, as well as authorities in Canada and Australia.

- **Voluntary self-regulation**
  These include: Risk management systems to ensure safe handling and production of nanomaterials; internal industry procedures (e.g. NanoRisk Framework, USA), general guidelines by regulatory agencies, standards bodies, professional organisations (e.g. ICCA Responsible Care, Precautionary matrix, Switzerland, U.S. NIOSH nanomaterials safety at the workplace); certification schemes (e.g Stoffenmanager

Nano in the Netherlands, Cenarios in Switzerland); Codes of conduct (European Commission, German NanoKommission).[63]

- **Public dialogue and engagment, education**
  Most countries with initiatives and R&I programs at the government level have included public and stakeholders engagment and education on nanotechnologies as a priority. Initiatives can be grouped in three categories:[64] 'upstream' public engagement (policy level), 'midstream' engagement (R&D practices), 'downstream' strategies" (communication, outreach, education and training). Examples include the EU projects such as CIPAST - Citizen Participation in Science and Technology, VOICES - Views, Opinions and Ideas of Citizens in Europe on Science, NANOCAP - Nanotechnology Capacity Building NGOs, TIMEFORNANO, national projects such as the Dialogforum Nano (DE), Nano&me (UK), The nanoTruck (DE), the Swiss nano cube (CH).

  Broadly speaking, the U.S has been particularly focused on downstream strategies, in particular education on nanotech for young people. In Europe, the focus has been more on upstream and midstream engagement.

- **Ethical Committees**
  The European Group on Ethics in Science and New Technologies to the European Commission (EGE), UNESCO and Member States ethical committees in the area of health and life sciences, have published opinions on nanotechnologies. Most of the activities refer to the period 2006-2010.[65] Example are the reports from France[66], Italy[67] and Canada[68].

- **International Coordination**
  Different authorities and international organisations have established initiatives to promote cooperation at international level on the governance of nanotechnologies. Most relevant activites are reported in the following paragraph.

2.6 INTERNATIONAL FRAMEWORKS AND PROTOCOLS

International cooperation is pivotal to promote and support the governance of nanotechnologies. A number of international organisations are active on the matter since almost a decade and have published standards, protocols and guideline on the matter.

[63] A full list of voluntary initiatives on nanotechnologies is provided by the NanoCode project. http://www.nanocode.eu
[64] Schuurbiers, Daan et al, *Analysing previous experiences and European projects on nanotechnology outreach and dialogue and identifying best practices*, Nanodiode project, March 2014. http://www.nanodiode.eu/wp-content/uploads/2014/04/NanoDiode_WP1_Best_Practices.pdf
[65] OECD, Working Party on Nanotechnology, *Responsible Development of Nanotechnology, Summary Results from a Survey Activity*, Nov 2013. http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=dsti/stp/nano%282013%299/final&doclanguage=en
[66] National Consultative Ethics Committee for Health and Life Sciences, *Ethical issues raised by nanosciences, nanotechnologies and health*, France, op. cit., 2007.
[67] Presidenza del Consiglio dei Ministri, Italy, op. cit, 2006
[68] Commission de l'éthique de la science et de la technologie , *Ethics And Nanotechnology*, Quebec, op. cit., 2006

The **International Standards Organization** (ISO) Technical Committee (TC) 229, works in liaison with regional and national standard bodies, in particular the **European Committee for Standardization,** Technical Committee on nanotechnologies (CEN TC352). The ISO TC 229 is structured in four working groups:

- Terminology and Nomenclature (WG 1)
- Measurements and Characterization (WG 2)
- Health, Safety, and Environment (WG 3)
- Materials Specification (WG 4)

Besides the WG, a number of task groups are identified in the ISO TC 229, regarding ELSA most relevant are the Consumer and Societal Dimensions Task Group and the Nanotechnologies and Sustainability Task Group.

About 49 documents have been published so far by ISO TC 229, and other 22 are under development. Three of them are of particular interest regarding ELSA and practices for the governance of nanotechnologies. These are:

- Nanotechnologies -- Occupational risk management applied to engineered nanomaterials (ISO/TS 12901-2:2014 and ISO/TR 13329:2012)
- Nanotechnologies-guidance on voluntary labelling for consumer product containing manufactured nano-objects" (ISO/TS 13830:2013)

The **OECD** has established two Working Groups dealing with Nanotechnologies:

- Working Party on Manufactured Nanomaterials (WPMN)[69]
- Working Group on nanotechnology (WPN)[70]

Activites of these WGs include survey, testing programmes, preparation of guidance documents. Most guidance from the OECD WPMN relate to risk management of nanomaterials. A specific Steering Committee within the OECD WPMN deals with "Co-operation on Voluntary Schemes and Regulatory Programmes" and published a survey on the matter.[71]

The OECD WPN activites relate to analysis of policies for nanotechnologies. Within the reports published, are a survey on initiatives regarding the responsible development of nanotechnologies, and a guide on best practices for public engagement and outreach in Nanotechnology.[72]

The **European Commission** published in 2008 the Code of conduct for responsible nanosciences and nanotechnologies research[73], as already discussed in previous paragraphs. Though the EC code has been publicly endorsed only by few organisations, it provides an authoritative and acknowledged reference regarding ethical principles and values for

[69] http://www.oecd.org/science/nanosafety/
[70] http://www.oecd.org/sti/nano/oecdworkingpartyonnanotechnologywpnvisionstatement.htm
[71] OECD, *Nanosafety at the OECD*, January 2011.
[72] http://www.oecd.org/sti/nano/
[73] European Commission, Commission recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, C(2008) 424, 7 February 2008.

nanotechnologies and a telling example of a policy driven voluntary measure on emerging technologies. In order to highlight some key issues emerged by the experience with the Code an excerpt from the NanoCode Project final report is included in the Annex.

Other **international initiatives** on EHS and ELSA of nanotechnologies are listed below:

- International Dialogue on Responsible Research and Development of Nanotechnology (active since 2008)[74]
- US – EU Platform: Bridging Nano-EHS research[75]
- European nanosafety Cluster[76]
- World Health Organization (WHO): Nanotechnology[77]
- Inter-Organisation Programme for the Sound Management of Chemicals (IOMC and UN Strategic Approach to International Chemicals Management (SAICM) – Nanotechnologies and manufactured nanomaterials[78]
- United Nations Institute For Training And Research (UNITAR)[79]
- Food and Agriculture Organization of the United Nations (FAO): Nanotechnology[80]

[74] ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/report_3006.pdf
[75] http://us-eu.org/communities-of-research/overview/
[76] http://www.nanosafetycluster.eu/home/european-nanosafety-cluster-compendium.html
[77] http://www.who.int/foodsafety/biotech/nano/en/
[78] http://www.who.int/iomc/saicm/emerging/en/index3.html
[79] http://www.unitar.org/cwm/nano
[80] http://www.fao.org/food/food-safety-quality/a-z-index/nano/en/

2.7 ORGANISATIONS DEALING WITH ETHICS ASSESSMENT OF NANOTECHNOLOGIES

A partial list of organisations dealing with different aspects of the governance of nanotechnologies is reported below, complementing the references given in the other parts of the report. The list is just a sample of the many organisations dealing with the responsible development of nanotechnologies and emerging technologies in Europe and worldwide.

Industries , Industry associations and professional organisations[81]	
European Chemicals Industry Council (CEFIC)	EU
VCI – German Chemical Industry Association	DE
Federchimica – National Chemical Industry Association	IT
Nanotechnology Industry Association	EU
Business and Industry Advisory Committee (BIAC)	EU
BASF - Nanotechnologies	DE
Evonik- Nanotechnologies	DE
DSM- Nanotechnologies	NL
Academia, research institutes, Technology assessment organisations, "Think Thanks"[82]	
Technology Strategy Board – Micro and Nanotechnology	NL
Tracing Nano for Downstream Users	NL
Centre for Business Relationships Accountability Sustainability and Society (ESRC-BRASS)	UK
International Council on Nanotechnology (ICON)	US
International Risk Governance Council (IRGC)	CH
Woodrow Wilson International Center for Scholars , Project on Emerging Nanotechnologies (PEN)	US
Woodrow Wilson International Center for Scholars, Synbio project	US
Ethics committees	
CCNE (National Bioethics Committee)[83]	FR

[81] Websites of Industries, Industry associations and professional organisations mentioned in the table are (same order as in the table): http://www.cefic.org/Policy-Centre/Environment--health/Nanomaterials/; https://www.vci.de/Downloads/Responsible-Production-and-use-of-Nanomaterials.pdf; http://www.federchimica.it/RicercaEInnovazione/Nanotecnologie.aspx; http://www.nanotechia.org/;http://www.biac.org/policygrp/profile-nanotech.htm; http://www.basf.com/group/corporate/nanotechnology/en/; http://corporate.evonik.com/en/responsibility/eshq/product-stewardship/new-technologies/nanotechnology/pages/default.aspx; https://www.dsm.com/content/dam/dsm/cworld/en_US/documents/nanotechnology.pdf

[82] Websites of Academia, research institutes, Technology assessment organisations, "Think Thanks" mentioned in the table are (same order as in the table): https://www.innovateuk.org/-/micro-and-nanotechnology-centres; http://www.ivam.uva.nl/index.php?id=583; http://www.esrc.ac.uk/news-and-events/features-casestudies/case-studies/26436/Identifying_gaps_in_nanotechnology_regulation.aspx; https://icon.rice.edu/; http://www.irgc.org/issues/nanotechnology/nanotechnology-risk-governance/; http://www.nanotechproject.org/; http://www.synbioproject.org/scorecard/

[83] http://www.ccne-ethique.fr/en/pages/presenting-national-consultative-ethics-committee-health-and-life-sciences#.U0VggFfkEvU

Policy Makers, regulators, Research funding bodies[84]

Risk Analysis and Technology Assessment (RATA) programme-programme NanoNextNL (NL)	NL
German Ministry of Education & Research - Action Plan for Nanotechnologies 2015	DE
UK Department for Environment, Food and Rural Affairs (DEFRA)	UK
Austrian Government – Nanotechnology Action Plan	AT
French Ministry for sustainable development – Public registry on nanomaterials	FR
US Environmental Protection Agency (EPA)	U.S.
UK's Foresight Program	UK
Irish Innovation Board (Forfás)	IE
Swiss Federal Council	CH
Australian National Enabling Technologies Strategy	AU
Research Institute of Science and Technology for Society (RISTEX), Japan Science adn Technology Agency	JP
Emerging Technologies Interagency Policy Coordination Committee, Office of Science and Technology Policy, US Administration	US

Civil society organisations (CSOs): Non-governmental, consumer, public health, environmental, and labour organisations[85]

Environmental Defence (ED) – NanoRisk Framework)	US
ETC Group	INT
European Trade Union Confederation (ETUC)	EU
European Environmental Bureau (EEB)	EU
The European Consumer Voice in Standardization(ANEC) and The European Consumer Organization (BEUC))	EU
European Trade Union Institute	EU
International Centre for Technology Assessment (CTA) - NanoAction	U.S
Friends of the Earth (FoE)	AU

[84] Websites of Policy Makers, regulators, Research funding bodies mentioned in the table are (same order as in the table): http://www.nanonextnl.nl/themes/risk-analysis-and-technology-assessment.html; http://www.bmbf.de/pub/akionsplan_nanotechnologie_2015_en.pdf; http://archive.defra.gov.uk/environment/quality/nanotech/policy.htm; http://www.bmlfuw.gv.at/en/fields/environment/Chemicals-policy/Nanotechnology/nanoactionplan.html; http://www.developpement-durable.gouv.fr/Le-dispositif-national-de; http://www.epa.gov/nanoscience/; http://www.bis.gov.uk/assets/foresight/docs/general-publications/10-1252-technology-and-innovation-futures.pdf; http://www.forfas.ie/aboutus/; http://www.bag.admin.ch/nanotechnologie/index.html?lang=en; http://www.innovation.gov.au/industry/nanotechnology/NationalEnablingTechnologiesStrategy/Pages/default.aspx; http://www.ristex.jp/EN/aboutus/principle.html; http://www.whitehouse.gov/blog/2010/05/15/emerging-technologies-ipc-has-inaugural-meeting;

[85] Websites of Civil society organisations (CSOs): Non-governmental, consumer, public health, environmental, and labour organisations mentioned in the table are (same order as in the table): http://www.nanoriskframework.com/; http://www.etcgroup.org/issues/nanotechnology; http://www.etuc.org/nanotechnologies; http://www.eeb.org/index.cfm/activities/industry-health/nanotechnology/; http://www.anec.org/attachments/ANEC-PT-2009-Nano-002final.pdf; http://www.etui.org/Outils/Tags/Nanotechnology; http://www.icta.org/nanotechnology/; http://nano.foe.org.au/;

2.8 Conclusions

Emerging technologies include a broad and diversified set of sciences, researches, application fields and technologies. There are a few criteria that might help to structure and focus the analysis of ethical impacts of ET:

- The distinction between ethical issues in engineering research, and ethical issues in engineering design (or so called technology ethics). This report focused on the latter aspect, namely the potential impact of ET and their applications on society. This has been discussed in terms of approaches for the governance of ET in relation to EHS issues and ELSA.

- The timescale, or maturity level of the ET. The understanding and assessment of ET impacts is completely different for ET at the level of basic research (e.g cognitive sciences) or applications of ET close to piloting or market entry (some of the applications of nanotechnologies).

- Whether and how ethical issues are related to a technology itself, an application, or to a societal challenge. The *safety of nanomaterials* is a peculiar issue of nanotechnologies; *informed consent and access to predictive information* is related to novel diagnostic tools (though linked to the technologies that enable the design of these tools); *distributive justice, and access* to novel application is typical of ET applications with a disruptive character, having a strong impact on the economy and daily life of people (e.g. ICT, additive manufacturing, will likely be an example in the future); *sustainability* and *ensuring secure, clean and efficient energy* are issues that can be addressed through specific applications and solution related to ET.

This report has tackled the above issues in relation to Key Enabling Technologies, and in particular, nanotechnologies, identified by European Commission as the drivers for industrial development in the near future and in the short medium term.

The debate on nanotechnologies provides a relevant an early example of an anticipatory approach to the governance of ET. All types of stakeholders have been considered in different type of participatory processes, aiming to understand and assess the impact of nanotechnologies. Some of the results drawn by these initiatives provide a reference for all ET. The debate has now evolved and several aspects are considered within the general approach of Responsible Research and Innovation.

As for nanotechnologies, nowadays key issues refer to the risks and safety for the environment and human health (EHS) of nanomaterials, regulation, transparency and accountability in the design, production and marketing of specific nano-related products, application of nanotechnologies for sustainability and tackling of societal challenges.

With the development of third and fourth generation products and devices, ethical and societal issues (ELSA) will become more and more relevant, particularly in spacific areas such as data processing and handling, health care, ageing and assisted living related applications.

2.9 ANNEX 1: EXAMPLES OF SHORT LISTS OF EMERGING/ENABLING TECHNOLOGIES

OECD[86]
Amongst the key emerging/enabling technologies included are:

- Energy (including clean energy, alternative energy, etc)
- Genomics, biotechnology for human health
- Nanotechnology
- ICTs
- Climate change, environmental sustainability and preservation of natural resources
- Physical/material sciences and engineering
- Food, agriculture and industrial biotechnology
- Space exploration
- Development of new modes of housing/habitat
- Safer or more abundant drinking water
- Marine biotechnology
- Security/safety
- Forest resources

Global Trends 2030, U.S.[87]
Amongst the key emerging/enabling technologies included are:

- INFORMATION TECHNOLOGIES
  - Data Solutions from big data
  - Social Networking Technologies
  - Smart City Technologies
- AUTOMATION AND MANUFACTURING TECHNOLOGIES
  - Robotics
  - Remote and Autonomous Vehicles
  - Additive Manufacturing/3D Printing
- RESOURCE TECHNOLOGIES
  - Food and Water
  - GM Crops
  - Precision Agriculture
  - Water Management
- ENERGY
  - Bio-Based Energy
  - Solar Energy
- HEALTH TECHNOLOGIES
  - Disease Management
  - Human Augmentation

[86] OECD – Emerging Technologies webpage, http://www.oecd.org/sti/outlook/e-outlook/stipolicyprofiles/newchallenges/policiesforemergingtechnologies.htm
[87] U.S. National Intelligence Council, *Global Trends 2030: Alternative Worlds*, ISBN 978-1-929667-21-5, December 2012, www.dni.gov/nic/globaltrends

Science and Technology Priorities for the US FY 2015 Budget[88]
Amongst the key emerging/enabling technologies included are:

- advanced manufacturing: robotics, materials development, and cyberphysical systems
- advanced manufacturing: Nanotechnology R&D (nanomanufacturing, solar energy, nanoelectronics, sensors, nanoinformatics and modeling and others)
- Clean energy technologies
- Global climate change (understand, assess and respond to climate-related risks and opportunities)
- Information Technologies
- National and homeland security and Intelligence
- Biology and neuroscience

[88] Available on http://www.whitehouse.gov/administration/eop/ostp/rdbudgets

2.10 ANNEX 2: EXCERPT FROM THE NANOCODE FINAL REPORT

The European Commission Code of Conduct on Nanotechnologies (EC CoC) has been a cornerstone in the debate on nanotechnologies governance and a telling example of a policy driven voluntary measure on emerging technologies. The analysis and consultation on the EC CoC made by the NanoCode project showed both strengths and weaknesses of this initiative and might provide relevant inputs for the debate on ethics of emerging technologies.

Excerpt from the executive summary of the report Nanocode Masterplan: Issues and Options on the Path Forward with the European Commission Code of Conduct on Responsible N&N Research, The NanoCode Project, November 2011 - www.nanocode.eu:

> [....] In this report, selected ideas, options and recommendations concerning revision and implementation of the EU-CoC will be presented and discussed with a focus on stakeholder preference, practicability, need for structural and substantial changes of the EU-CoC, and compatibility with the governance context of the existing EU-CoC.
>
> The NanoCode stakeholder consultation unveiled that awareness and implementation of the EU-CoC remain very limited to date due to:
>
> - Lack of Legitimacy. It was questioned whether N&N (still) deserve their own code of conduct.
> - Difficult Practicability. Deriving concrete and verifiable actions in practice is hampered by the all-embracing and unspecific character of the principles and guidelines of the EU-CoC.
> - Stumbling Blocks. Specific contents, formulations and requirements in the EU-CoC have led to a rejection of parts or the entire EU-CoC among some of its target groups.
> - Lack of Pressure. Many deemed it necessary to associate the EU-CoC with incentives, disincentives or penalties (in case of non-compliance) to encourage stakeholders to adopt and comply.
> - Poor Communication. Communication and dissemination by the European Commission and Member States do not make the impression that the EU-CoC is of high priority.
> - Inadequate Commitment. Commitment, coordination and lead have been lacking in the light of the very different structural preconditions applying for the implementation of the EU-CoC in different national contexts.
>
> In the light of the identified flaws, stakeholders expressed the need for a fundamental revision of the current EU-CoC and the development of an implementation strategy. This can build up on some unambiguous positive aspects of the EU-CoC identified during the consultation:
>
> - The EU-CoC principles: stakeholders largely agree they are essential aspects to be taken into consideration in the development of nanotechnologies (as well as in emerging technologies in general).
> - The voluntary character: the EU-CoC, though acknowledging some weaknesses associated to its voluntary character, is seen as appropriate tool to implement these principles, favouring trust building and confidence amongst stakeholders.
> - The broad scope: the EU-CoC encourages dialogue amongst stakeholders and acts as an early warning system for relevant safety and societal issues.
> - The universal character of the principles is expected to offer necessary flexibility for adaptation to particular scope and target groups.

In order to solve the legitimacy issue of the EU-CoC, it was suggested to extend the scope of the EU-CoC in two dimensions. It was agreed that the principles and most of the guidelines of the EU-CoC are valid universally, beyond N&N research. It is therefore recommended to extend the scope of the EU-CoC (e.g. emerging technologies, or science in general), encompassing perspectives along a product's elaboration and life cycle stages (e.g. an "Innovation CoC") in alignment with the Innovation Union flagship initiative.

Although the present EU-CoC is considered suitable in principle to provide a foundation for a reflection process on responsible research, it is also considered to be of difficult practicability, for the EU-CoC does not offer practical criteria to determine what is good enough and how compliance can be achieved. This renders statements of compliance subject to ambiguity and they remain difficult to be verified.

The recommendation is to revise the EU-CoC with the intention to shift its functionality from being a general framework of behaviours to a voluntary, verifiable standard. Agreeing on concrete criteria thus represents a prerequisite to allow any meaningful form of adoption, verification and monitoring of compliance. Those criteria should be developed in close cooperation with stakeholders and experts and be integrated into the revised EU-CoC. The CodeMeter prototype as well as benchmarking of other standards provides a starting point for the development of such criteria.

With the development and testing of the CodeMeter prototype, feasibility and acceptance of an implementation assistance tool have been evaluated. The CodeMeter helps stakeholders to self-assess their compliance with the EU-CoC's principles and guidelines on the basis of a set of concrete criteria. The CodeMeter also provides context information about important aspects of the guidelines, presents hints at how to improve compliance and allows monitoring and documentation of compliance over time. Since the CodeMeter prototype has been overall well accepted, this approach is strongly recommended to be further developed, adapted and implemented with the revised EU-CoC.

A number of content-related, formal and structural issues seem to be stumbling blocks preventing broader stakeholder acceptance and more widespread adoption of the EU-CoC. In particular, the French and the German translations of the "accountability" principle as "responsibility" earned mistrust as they were interpreted with a connotation of implying legal liabilities as well as suggesting that scientists are held responsible for what is done with their work by decision outside their control or by other actors in the future. This was considered inappropriate in the context of the voluntary EU-CoC. In addition, large parts of the EU-CoC are written in a distinct Commission language which may create problems of understanding. The order of the content elements of the EU-CoC booklet puts a lot of emphasis on the political process rather than on the principles and guidelines themselves. These points represent barriers to an intuitive approach to the EU-CoC which could be improved quite easily

Another fundamental decision must be taken regarding the future role of the EU-CoC in the broader context of governance. The current EU-CoC has been designed as a voluntary measure, thereby with no means to be verified, monitored or enforced, that cause a lack of pressure. It is recommended to keep the EU-CoC voluntary. But by increasing its specificity and practicability with the aforementioned criteria, it could be aligned to play a role as a voluntary standard. Linking, for example, compliance with the EU-CoC to a priority in the allocation of public funding (e.g. in the framework programme) seems to represent a possible, though controversial option for the European Commission to set up a strong incentive to comply with the (revised) EU-CoC. Again, criteria and tools are required to reliably and reproducibly assess compliance with the EU-CoC.

On the level of the European Commission and Member State governments almost complete poor and uncoordinated communication, dissemination and awareness-raising about the EU-CoC was observed. Strengthening dissemination of the current EU-CoC in order to foster its implementation seems pointless in the light of the proposed fundamental revision of the EU-CoC, nevertheless transparency and information should immediately be improved. It is recommended to immediately launch an official EU-CoC information platform, independent from strategic and content-related changes which the EU-CoC might undergo. This platform is to inform about past, on-going and upcoming activities and transparently document the consultation and revision process. It could later serve to host the CodeMeter. Other means of communication (e.g. development of "marketing" and educational materials) should be envisaged later, depending on the outcomes of the on-going revision, and be closely coordinated with the (to-be-renewed) dissemination activities.
Due to the interdisciplinary character of the EU-CoC, now and even more after a revision, multi-agency collaborations are needed to coordinate and lead the dissemination. A clear and unambiguous commitment at EU level, accompanied by a series of (policy) actions to foster Member States and stakeholders to adopt the EU-CoC is necessary to push countries which lack particular coordination actions and clear responsibilities at national level on nanotechnology-related issues. Activities should be clearly assigned to the European Commission, Member States governments and agencies.

In conclusion, the analysis carried out has highlighted specific issues related to the role and scope, the format and contents and the implementation of the EU-CoC that are at the base of the MasterPlan and CodeMeter. They are summarized in the report together with a number (25) of recommendations/options discussed in more detail in the report.

(www.nanocode.eu)