Ethics and Nanotechnology

BEPA
European Commission
The view I express are my own and do not necessarily reflect those of the European Commission.
• In December 2005 at the end of the UK presidency (Hampton Court Summit), security and biometrics were indicated as key actions of the EU. In addition an Independent Expert Group on R&D and has produced this year a rapport on the role of research with regard to the Lisbon agenda.

• The Report indicates the need of affording and reinforcing European values as a main milestone to endorse for an effective EU growth policy, within the EU and with third parties. Equality, health social cohesion and common security are therefore indicated as elements conducive to innovation while not sufficient per se to ensure sustainability.
• These factors are mentioned in several policy documents of the EU as main pillars to endorse. For example the EC Renew Lisbon Strategy.
• Research has then become the 3° EU portfolio with a budget of 53 Billion €, 3 Billion € to nanotechnology
• Respect of fundamental values is a legally binding condition for all EU funded research (Art 6, FP7).
• This condition also applies to multi-centres research trials with EU and non EU countries (integration of ethics within EU funded research activities at EU level and beyond)
The **Berlin Declaration** adopted by the Heads of State and Government of the European Union on the occasion of the 50th anniversary of its founding states:

- "We are striving for **peace** and **freedom**, for **democracy** and **the rule of law**, for **mutual respect** and **shared responsibility**, for **prosperity** and **security**, for **tolerance** and **participation**, for **justice** and **solidarity."**
The Heads of State and Government of the EU have signed on **December 13 the EU Reform Treaty** in Lisbon. The ratification process is ongoing 2008.

The **Reform Treaty** inter alia indicates a set of **European Values**, such as human dignity, freedom, democracy, human right protection, pluralism, non-discrimination, tolerance, justice, solidarity and gender equality. The values above are stated in the **European Charter of fundamental rights** that has been proclaimed by the Presidents of the 3 EU Institutions (Council, Commission and European Parliament) on **December 12**.
• **STEP 1**

  The notion of **Research as an element of the Lisbon agenda**, the role of the EU as a main actor in International affairs (globalisation and global discussion research ethics), the promotion of the **EU approach on research** (responsible use of research in line with fundamental values) explain the Commission intention to **integrate ethics in EU R&D policy.**
STEP 2

The notion of Europe as a community of values and the role of the EU as a main actor in International affairs explain the Commission intention to concentrate effort, in full respect of its Powers and the Institutional role of different International organisations, in global discussions on research and innovation, science and technology, a debate where bioethics play a central role.
embedding of ethics in nanotechnologies: how, when, where?
EGE Opinion on Ethics of nanomedicine

- Nanomedicine is an area of nanotechnology which raises high expectations with regard to its potentials in diagnostics, drug development and delivery, imaging and other health-related applications. It is a major research sector covered by the EU Research and Development Programme.
- Under the 6th EU Framework Programme for research (FP6) the Commission has invested more than €1.36 Billion in nanotechnology (550 projects financed) and under the 7th Framework Programme for research (FP7) some €3.5 billion should be allocated to this research sector.
The European Policy in Nanotechnology: integrated, safe and responsible

http://cordis.europa.eu.int/nanotechnology/actionplan.htm
European Group on Ethics in Science and New Technologies (EGE)

- The EGE is an independent, pluralist and multidisciplinary body which advises the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies.

http://europa.eu.int/comm/european_group_ethics/index_en.htm
Following the request made by President Barroso on 10 November 2005, the European Group on Ethics in Science and New Technologies (EGE) chaired by Swedish philosopher Göran Hermerén handed on January 24 the President its Opinion on the ethical aspects of nanomedicine. In finalising its work the EGE received inputs from a number of hearings with experts in the field, decision makers and relevant stakeholders, as well as a public round table that took place in Brussels, in March 2006. These meetings were organised by the Bureau of European Policy Advisers (BEPA), which acts as the Group's Secretariat.
European Group on Ethics in Science and New Technologies (EGE)

Göran Hermerén, Linda Nielsen, Rafael Capurro, Inez de Beaufort, Pere Puigdomenèch Rosell and Günter Virt, (from the former EGE)
new members: Emmanuel Agius, Diana Bánáti, Anne Cambon-Thomsen
Jozef Glaza, Hille Haker, Julian Kinderlerer, Krzysztof Marczewski
Paula Martinho da Silva, Francesco Busnelli
EGE Opinion on Ethics of nanomedicine

The EGE underlines the vital importance of addressing concern for safety with respect to nanomedical developments (and, in fact, nanotechnology in general) and therefore advocates the need to establish measures to verify the safety of nanomedical products and to ensure that nanomedical devices are properly assessed with regard to public health. The Group proposes that institutions already operating at European and national level to protect the safety of patients and citizens should be charged with the additional task of overviewing the safety and security aspects of new tools and devices in nanomedicine. The Group then underlines the need to properly address risk assessment at national and EU level and invites relevant stakeholders to devote adequate efforts to understanding and preventing risks that may be linked to nanomedicine.
EGE Opinion on Ethics of nanomedicine

- As far as public participation is concerned, the Group argues that transparency (including openness about uncertainties and knowledge gaps) is essential for public trust in nanotechnology. The Group therefore proposes that initiatives should be taken at national and European level to prepare surveys of public perception of the benefits and risks of the applications of nanotechnologies, with special reference to medical sectors. The Group also calls for initiatives to be taken to organise academic and public debates on problems and possibilities of present and near-future nanomedicine.

- Additionally the Group underlines the need for: prospective technology assessment, including consideration of social effects (also in developing countries); interdisciplinary research on the Ethical, Legal and Social Implications (ELSI) of nanomedicine; the establishment of a European Network on Nanotechnology Ethics; and enhanced information exchange between research ethics committees in different Member States or among competent bodies in particular on toxicity studies, ELSI-related aspects of nanomedicine and informed consent procedures with regard to safety.
EGE Opinion on Ethics of nanomedicine

- As far as the legal implications of nanomedicine are concerned, the EGE does not propose any new regulatory structures specifically dealing with nanomedicine at this point, and argues that any changes should be made within existing structures (with focus on implementation of existing regulations). The Group proposes, however, that possible cases of nanomedicine applications where there might be overlap between regulations, which could create uncertainty as to which regulations should be applied, should be explored by the relevant authorities so that the existing regulations can be implemented in an unambiguous way. In addition the EGE calls for comparative research on intellectual property rights and nanomedicine and advocate the needs to look further into the balance between knowledge protection and information dissemination.
And now?
• Issues to further be explored:
  – Informed consent
  – security
  – human enhancement
  – IPR

• ELSA aspects
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**Information available:**
BEPA homepage: http://ec.europa.eu/dgs/policy_advisers/index_en.htm
EGE homepage: http://europa.eu.int/comm/european_group_ethics/index_en.htm