

"TOWARDS A CODE OF CONDUCT FOR RESPONSIBLE NANOSCIENCES AND NANOTECHNOLOGIES RESEARCH"

CONSULTATION PAPER

Summary:

Nanosciences and nanotechnologies are enabling technologies, more and more pervasive in potentially all technological fields and expected to bring substantial benefits across many sectors, such as chemistry, material sciences, health and energy just to name a few. Industry and research are increasingly using them and some nano-products are already being mass-produced.

Knowledge gaps remain concerning the exposure risks associated with nanomaterials and nanotechnologies. Considered as the next strategic technology, confidence in its safety and consequently public acceptance are preconditions for the application and commercialisation of nanotechnology-based products. The development and use of nanotechnologies should not be unbalanced or left to chance.

Research has a key role to play in this context. On the one hand it develops new technologies for application in industry and throughout society and on the other hand it investigates the potential risks and establishes the appropriate measures to take.

In order to promote safe and responsible nanotechnology research and pave the way to its safe and responsible application and use, the European Commission is planning to adopt a voluntary Code of Conduct for Responsible Nanosciences and Nanotechnologies Research ("the Code of Conduct"). This Code of Conduct would take the form of a European Commission Recommendation and would invite the Member States, industry, universities, funding organisations, researchers and other interested parties to follow its principles. The Commission itself would follow these principles in its own action under the Community research policy.

This consultation aims to provide input to the drafting of the Code of Conduct. Contributions are expected from a broad cross-section of European society, including the scientific community, industry, civil society, policy-makers, media and the general public.

The consultation process will be open from Thursday 19 July 2007 up to 21 September 2007. See the consultation form on SINAPSE:

<http://europa.eu/sinapse/directaccess/science-and-society/public-debates/nano-recommendation/>

1. NANO – POTENTIAL AND CHALLENGES

The potential economic impacts of nanosciences and nanotechnologies research have been highlighted by many analysts, with forecasts varying between US\$150 billion by 2010 (approximately €10 billion) according to a 2002 study by the Mitsubishi Institute, and US\$2.6 trillion (approximately €1.9 trillion) by 2014 according to a 2004 Lux Research Study. The latter scenario would imply that the

market for nanotechnology-based products would be larger than the information and communication technology market and would exceed biotechnology by ten times.

At the same time, some, though not all, areas of nanosciences and nanotechnologies, come with very specific issues, related to their specific properties such as their size, their ability to cross natural bio-boundaries or their potential to connect living creatures and man-made materials and systems. Therefore, the responsible management of nanosciences and nanotechnologies has become an essential region of the science and technology landscape in the last decade, particularly as regards ethics, safety and environment and the fundamental rights of individuals, such as the protection of personal data.

2. WHY A EUROPEAN COMMISSION INITIATIVE?

A European Code of Conduct for Responsible Nanosciences and Nanotechnologies Research is part of the European Commission's ambition to promote a balanced diffusion of information on nanosciences and nanotechnologies and to foster an open dialogue, involving the broadest possible range of interested parties. It follows on the safe, integrated and responsible strategy for nanotechnology which the EU Member States endorsed in 2004 and on the nanosciences and nanotechnologies Action Plan 2005-2009, which proposes, inter alia, the adoption of a code of conduct for the responsible development and use of nanosciences and nanotechnologies.

The Code of Conduct would offer those following it recognition of a responsible approach towards nanosciences and nanotechnologies research, making their actions more visible at a European level.

This voluntary instrument is therefore an appeal to, and a driving force for Member States and the research community to provide a tangible contribution to the good governance of nanotechnology.

3. SCOPE

The Commission's intention is to concentrate the Code of Conduct on research activities. It would invite Member States, industry, universities, research organisations and other interested parties to follow its principles and to take concrete actions for a safe development and use of nanotechnologies. The Code of Conduct would also provide a basis for international dialogue in this area, where Europe has taken a proactive role.

The starting point of the principles to be set out in the Code of Conduct would be the legal guarantees set out in the Charter on Fundamental Rights, as well as the general principles resulting from relevant international treaties such as the Convention on Human Rights (1950), the Convention on Human Rights and Biomedicine (1997), and the Aarhus Convention for Environment (1998).

The Code of Conduct would draw on contributions from the consultation process as well as from on relevant communications from the Commission such as those relating to the Precautionary Principle¹ and the Nanosciences and Nanotechnologies

¹ "Communication from the Commission on the Precautionary principle", COM(2000)1, 02/02/2000

Action Plan². It would draw also on more specific Commission communications and papers (e.g. Data Protection and Privacy³, Protection and Welfare of Animals⁴), and independent opinions of European Commission advisory bodies (e.g. the opinion of the European Group of Ethics on the ethics of nanomedicine⁵). The document would also take into account Codes of Conduct adopted proactively by industries and universities.

4. PRINCIPLES

Nanotechnology, like many other domains, raises issues about protection of fundamental rights. These rights are rooted in the principle of human dignity and shed light on core European values, such as integrity, autonomy, privacy, equity, fairness, pluralism and solidarity.

As stated in many European and international documents, the interests of science are legitimate and justified only as far as they are compatible with human dignity and human rights. New technologies must be scrutinised with respect to the prospects of contributing to improving human well-being and with respect to possible threats to human well-being, be it at European or global level.

In this context, the Code of Conduct could highlight three basic principles, which should frame nanosciences and nanotechnologies developments in the future: precaution, inclusiveness and integrity.

- **PRECAUTION** - As underlined in its 2000 communication on the precautionary principle, "the Commission considers that the Community, ... , has the right to establish the level of protection - particularly of the environment, human, animal and plant health, - that it deems appropriate". The Code of Conduct could make clear that, in the face of scientific uncertainty, the European Commission and the Member States should be invited to take all necessary steps to maintain a high level of protection of individuals, defining proper safety requirements developing and validating further testing methods.

Such a precautionary approach should go beyond the scope of physical damage to the environment, to humans and to animals, extending to protection of human dignity, the right to privacy and to personal data protection. The principle of informed consent should always be respected in any intervention on human beings.

Principles relating to the safety of researchers in the course of their work should receive particular attention.

² "Towards a European Strategy for Nanotechnology", COM(2004)338, 12/05/2004; "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009", COM(2005)0243, 07/06/2005

³ ""Promoting data protection by privacy enhancing technologies (PETs)", COM(2007)228, 2 May 2007

⁴ "Community Action Plan on the Protection and Welfare of Animals 2006-2010", COM(2006)13, 23 January 2006

⁵ "Opinion on the ethical aspects of nanomedicine", European Group on Ethics in Science and New Technologies, Opinion N° 21, 17/01/2007

- **INCLUSIVENESS** - The Code of Conduct could underline the respect of openness and the importance of impartial scientific advice for the development of sound policies. To that end, it could stress that access to nanosciences and nanotechnologies information obtained through public funds should be open and uncomplicated, favouring dissemination while preventing proliferation of sensitive data.

- **INTEGRITY** – Integrity is one of the cornerstones of science. Research integrity may be challenged by new possibilities offered in such a blooming field as nanosciences and nanotechnologies. Commonly agreed standards for publication could be in danger of being disregarded as well as ethical, safety and other issues linked to fundamental rights, e.g. collection of personal information. Therefore, the Code of Conduct could set out that specific measures should be taken by the Community, the Member States and the scientific community to safeguard integrity in nanosciences and nanotechnologies research⁶ in the European Research Area. Researchers could for example be invited to report voluntarily when they are confronted with unsafe or unethical situations and whistle-blowers could be protected.

5. ADDITIONAL ELEMENTS

In addition to the basic principles, the Code of Conduct could set out additional elements that would contribute to the responsible governance of nanotechnology research:

- **BETTER & CONSTANT VIGILANCE** – As suggested above, the rapid development of nanotechnology requires continuous monitoring. The Code of Conduct could stress the need for adequate governance structures – including specific nanosciences and nanotechnologies risk governance structures – allowing society to engage in experiments while safeguarding basic ethical, health and safety requirements.

- **REALISING SOCIETAL BENEFITS** - To get the most out of nanosciences and nanotechnologies, the Code of Conduct could consider actions to encourage societal debate in areas in which societal opinion shaping is still evolving or has not yet begun.

- **CREDIBILITY AND TRUST** - Good governance of nanosciences and nanotechnologies implies an open and transparent public dialogue addressing possible risks and realistic expectations. The Code of Conduct could address the requirement of explicit consideration of the limits of knowledge and control over the development of the technology. It could also highlight the need to avoid economic risk and inappropriate public investments in nanotechnology.

- **PROTECTION OF FUNDAMENTAL RIGHTS** – In nanosciences and nanotechnologies, as in other science and technology areas, there may be fields where a precautionary approach cannot even be considered because physical risks or

⁶ The Commission will have the opportunity to set out its position at an international conference which will be held in September 2007 in Lisbon (16 to 19/09/07), under the Portuguese Presidency of the EU (Ministry of Science, Technology and Higher Education).

commonly accepted ethical standards or fundamental rights may be breached⁷. Such fields could be precisely defined in the Code of Conduct which could also propose that measures be taken by the Member States in order to prevent or to slow down their development until acceptable conditions are met.

6. INVITING INTERESTED PARTIES TO A CONTINUOUS PROCESS

The European Commission intends to adopt the Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research by the end of 2007. As a follow-up to the adoption, a broad dialogue would be promoted between all stakeholders in Europe to enable mutual learning and exchange of best practices on responsible nanotechnology research.

In this context, the European Commission proposes to create an Open Forum, where issues linked to the good governance of nanotechnology research, development and use could be debated and examined with the support of science-based evidences and in full transparency.

In addition, supporting basic principles related to precaution (e.g. proportionality, precedence of health and safety over economic considerations and respect for fundamental rights), reflection on the Code of Conduct could lead to a specific nanosciences and nanotechnologies research agenda which could be implemented through co-operative research processes involving a broad range of actors.

Finally, to promote a coherent international approach to R&D in nanosciences and nanotechnologies, a global dialogue including third countries as well as international organisations would be supported⁸, favouring exchanges on nanosciences and nanotechnologies frameworks, advances and limitations.

⁷ E.g.: Free release of solid insoluble nanoparticles into the environment (without the knowledge of the impacts); Remote control of human behaviour; Physical alteration or enhancement of the human brain or of the heritable genetic code for non therapeutic purposes; Human enhancement with the sole purpose to increase achievements in competitive sports; Non-therapeutic enhancement of human capabilities that create a risk of dependence, or are irreversible or are beyond the range of normal human capabilities.

⁸ UNESCO, OECD, the STS Forum, ISO, etc. and in particular the International Dialogue on Responsible Nanotechnology <http://cordis.europa.eu/nanotechnology/src/intldialogue.htm>

7. QUESTIONS:

- The Code of Conduct will bring added-value in the EU nano landscape. Do you agree with this statement?
- Do you think that the proposed scope of the Code of Conduct is sufficient?
- Do you think that the set of principles suggested in the consultation paper is sufficient to ensure a safe and sound nanosciences and nanotechnologies development in Europe? Would you suggest different principles?
- Do you believe that there are fields of nanosciences and nanotechnologies where research should not be conducted?
- How do you suggest sustaining interest once the Code of Conduct is adopted? What could be the follow-up?
- Would you/your company/organisation be willing to follow the Code of Conduct?