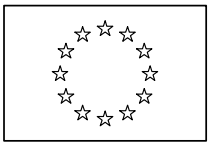

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 07/02/2008
C(2008) 424 final

COMMISSION RECOMMENDATION

of 07/02/2008

on a code of conduct for responsible nanosciences and nanotechnologies research

COMMISSION RECOMMENDATION

of 07/02/2008

on a code of conduct for responsible nanosciences and nanotechnologies research

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 211 thereof,

Whereas:

(1) In its Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions "Towards a European research area" the Commission proposed in January 2000 the creation of a European Research Area[1] with a view to consolidating and structuring European research policy. In May 2007, in the Green Paper "The European Research Area: New Perspectives", the Commission re-launched a broad institutional and public debate on what should be done to create a unified and attractive European Research Area that would fulfil the needs and expectations of the scientific community, business and citizens[2].

(2) The Commission adopted in February 2000 a Communication on the precautionary principle[3], aiming to build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully.

(3) In March 2000 the Lisbon European Council set for the Community the objective of becoming in the next decade the most competitive and dynamic knowledge economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion.

(4) In 2004, with its Communication “Towards a European strategy for nanotechnology”[4], the Commission identified actions aimed at creating the Community added value necessary to remain competitive in this sector while ensuring its responsible development. In its conclusions of 24 September 2004[5], the Council (Competitiveness) welcomed the proposed integrated, safe and responsible approach and the Commission’s intention to draw up an Action Plan for nanotechnology.

(5) Taking into account the results of a public consultation, the Commission drew up in 2005 a Nanotechnologies Action Plan[6] which sets out coherent and interconnected actions for the immediate implementation of an integrated, safe and responsible strategy for nanosciences and nanotechnologies based on the priority areas identified in the Communication “Towards a European strategy for nanotechnology”. Both Communications explicitly acknowledged that

[1] COM(2000) 6, 18.1.2000.
[2] COM(2007) 161, 4.4.2007.
[3] COM(2000) 1, 2.2.2000.
[4] COM(2004) 338, 12.5.2004.
[5] Doc. 12487/04
[6] COM(2005) 243, 7.6.2005.

environmental, human health and safety aspects need to be integrated in all nanosciences and nanotechnologies research.

(6) Following the Nanosciences and nanotechnologies Action Plan, in January 2007 the European Group on Ethics in Science and New Technologies presented an Opinion on the ethical aspects of nanomedicine[7].

(7) Following comments made during a public consultation on a previous opinion, the Scientific Committee on Emerging and Newly Identified Health Risks adopted in March 2006 a Modified Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies[8].

(8) In June 2006 the European Council adopted a revised sustainable development strategy fine-tuning the Community sustainable development strategy launched at the Gothenburg Summit in June 2001 that centred on objectives of environment and health protection and poverty eradication.

(9) In its conclusions[9] of 23 November 2007, the Council (Competitiveness) recognised the need to foster synergies and cooperation between all nanosciences and nanotechnologies stakeholders, including the Member States, the Commission, academia, research centres, industry, financial bodies, non-governmental organisations and society at large.

(10) A first report on the implementation of the Nanotechnologies Action Plan for Europe was presented by the Commission in 2007[10]. In this report the Commission announced its intention to adopt a voluntary Code of Conduct for Responsible Nanosciences and Nanotechnologies Research.

(11) This Recommendation includes the Code of Conduct, aiming to promote integrated, safe and responsible nanosciences and nanotechnologies research in Europe for the benefit of society as a whole.

(12) The general principles and guidelines on actions to be taken outlined in this Recommendation benefited from a public consultation.

(13) This Recommendation provides Member States with an instrument to undertake further initiatives to ensure safe, ethical and sustainable nanosciences and nanotechnologies research in the European Union.

(14) This Recommendation also aims at contributing to proper coordination between Member States with a view to optimise synergies between all nanosciences and nanotechnologies research stakeholders at European and international levels,

HEREBY RECOMMENDS:

1. That Member States be guided by the general principles and guidelines for actions to be taken, set out in the Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, in the Annex, as they formulate, adopt and implement their strategies for developing sustainable nanosciences and nanotechnologies (hereinafter N&N) research, in line with the Commission Nanotechnologies Strategy and Action Plan.

[7] EGE Opinion No 21, 17 January 2007.
[8] SCENIHR/002/05, 10 March 2006.
[9] Doc. 14865/07
[10] COM(2007) 505, 6.9.2007.

2. That Member States endeavour to follow these general principles and guidelines when implementing their national regulatory research and development strategies or developing sectoral and institutional research and development standards, taking into account pre-existing applicable N&N guidelines, good practices or regulations.

3. That Member States consider such general principles and guidelines on research to be an integral part of institutional quality assurance mechanisms by regarding them as a means for establishing funding criteria for national/regional funding schemes, as well as adopting them for the auditing, monitoring and evaluation processes of public bodies.

4. That Member States encourage the voluntary adoption of the Code of Conduct by relevant national and regional authorities, employers and research funding bodies, researchers, and any individual or civil society organisation involved or interested in N&N research and endeavour to undertake the necessary steps to ensure that they contribute to developing and maintaining a supportive research environment, conducive to the safe, ethical and effective development of the N&N potential.

5. That Member States cooperate with the Commission in order to review this recommendation every two years, as well as to monitor the extent to which relevant stakeholders have adopted and applied the Code of Conduct.

6. That the criteria for measuring such adherence to and application of the Code of Conduct be established and agreed with the Member States in relation to similar work undertaken at Community level.

7. That Member States, in their bilateral agreements on research strategies and activities with third countries and in their role as members of international organisations, take due account of this Recommendation when proposing research strategies and taking decisions, and duly coordinate with other Member States and the Commission.

8. That this Recommendation also be used as an instrument to encourage dialogue at all governance levels among policy makers, researchers, industry, ethics committees, civil society organisations and society at large with a view to increasing understanding and involvement by the general public in the development of new technologies.

9. That the Member States inform the Commission by 30 June 2008 and annually thereafter of any measures they have taken further to this Recommendation, inform it of the first results of its application and provide good practices.

Done at Brussels, 07/02/2008.

For the Commission
Janez POTOČNIK
Member of the Commission

ANNEX

CODE OF CONDUCT FOR RESPONSIBLE NANOSCIENCES AND NANOTECHNOLOGIES RESEARCH

This Code of Conduct provides Member States, employers, research funders, researchers and more generally all individuals and civil society organisations involved or interested in nanosciences and nanotechnologies (N&N) research ("all stakeholders") with guidelines favouring a responsible and open approach to N&N research in the Community.

The Code of Conduct is complementary to existing regulations. It does not limit or otherwise affect the possibilities of Member States to grant a wider measure of protection with regard to N&N research than is stipulated in this Code of Conduct.

Stakeholders who adhere to this Code of Conduct should also be inspired, where applicable, by the principles set out in the Charter of Fundamental Rights of the European Union.

The Code of Conduct will be regularly monitored and revised every two years by the Commission in order to take into account developments in N&N worldwide and their integration in European society.

1. SCOPE AND AIM

The Code of Conduct invites all stakeholders to act responsibly and cooperate with each other, in line with the N&N Strategy and Action Plan of the Commission, in order to ensure that N&N research is undertaken in the Community in a safe, ethical and effective framework, supporting sustainable economic, social and environmental development.

The Code of Conduct covers all N&N research activities undertaken in the European Research Area.

The Code of Conduct is voluntary. It offers a set of general principles and guidelines for actions to be taken by all N&N stakeholders. It should facilitate and underpin the regulatory and non-regulatory approaches outlined in the 2005-2009 N&N Action Plan for Europe, improving the implementation of current regulation and coping with scientific uncertainties.

The Code of Conduct should also be a European basis for dialogue with third countries and international organisations.

2. DEFINITIONS

For the purpose of the Code of Conduct, the following definitions apply:

a) Nano-objects: In the absence of recognised international terminology the generic term of 'nano-object' is used all throughout the Code of Conduct to designate products resulting from N&N research. It includes nanoparticles and their aggregation at nanoscale, nano-systems, nano-materials, nano-structured materials and nano-products.

b) N&N research: In the broadest sense understood here, N&N research encompasses all research activities dealing with matter at the nanometric scale (1 to 100 nm). It includes all man-made nano-objects be they engineered or involuntarily generated.

Naturally occurring nano-objects are excluded from the scope of the Code of Conduct N&N research encompasses research activities from the most fundamental research to applied research, technology development and pre and co-normative research underpinning scientific advice, standards and regulations.

c) N&N stakeholders: Member States, employers, research funders, researchers and more generally all individuals and civil society organisations engaged, involved or interested in N&N research.

d) Civil society organisations: In the context of the Code of Conduct, civil society organisations are considered to be any legal entity that is non governmental, not-for-profit, not representing commercial interests, and pursuing a common purpose in the public interest.

3. GENERAL PRINCIPLES

This Code of Conduct is based on a set of general principles which call for actions aimed at guaranteeing their respect by all stakeholders.

3.1 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.

3.2 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[11]. 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.

3.3 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.

3.4 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.

3.5 Excellence

[11] The United Nations Millennium Declaration, General Assembly resolution 55/2, 8.9.2000

N&N research activities should meet the best scientific standards, including standards underpinning the integrity of research and standards relating to Good Laboratory Practices[12].

3.6 Innovation

Governance of N&N research activities should encourage maximum creativity, flexibility and planning ability for innovation and growth.

3.7 Accountability

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.

4. GUIDELINES ON ACTIONS TO BE TAKEN

The guidelines set out in this point are based on the set of general principles described in point 3. They are meant to give guidance on how to achieve good governance, due respect for precaution, as well as wide dissemination and good monitoring of the Code of Conduct. The main responsibilities for action are indicated below, but all N&N stakeholders should contribute to their implementation as much as possible within the scope of their own remit.

4.1 Good governance of N&N research

Good governance of N&N research should take into account the need and desire of all stakeholders to be aware of the specific challenges and opportunities raised by N&N. A general culture of responsibility should be created in view of challenges and opportunities that may be raised in the future and that we cannot at present foresee.

4.1.1 Member States should cooperate with the Commission in order to maintain an open and pluralistic forum for discussion on N&N research at Community level as a means to stimulate the societal debate about N&N research, encouraging the identification and discussion of concerns and hopes and facilitating the emergence of possible initiatives and solutions. Accordingly, Member States should enhance communication on benefits, risks and uncertainties related to N&N research. Specific attention should be paid to the younger and older members of the population.

4.1.2 With due respect for intellectual property rights, Member States, N&N research funding bodies, research organisations and researchers are encouraged to make easily accessible and understandable by lay people as well as by the scientific community all N&N scientific knowledge as well as related information such as relevant standards, references, labels, research on impacts, regulations and laws.

4.1.3 Member States should encourage private and public sector laboratories to share best practices in N&N research, with due respect for the protection of intellectual property.

4.1.4 N&N research organisations and researchers should ensure that scientific data and results are duly peer-reviewed before being widely disseminated outside the scientific community in order to ensure their clarity and balanced presentation.

[12] Directive 2004/9/EC and Directive 2004/10/EC

4.1.5 Given its potential, Member States and N&N research organisations should ensure that N&N research is conducted at the highest level of scientific integrity. Questionable N&N research practices (not limited to plagiarism, falsification and fabrication of data) should be fought as they may entail risks for health, safety and the environment, raise public distrust and slow down the dissemination of benefits from research. Individuals signalling impropriety in research should be protected by their employers and national or regional laws.

4.1.6 Member States should ensure that appropriate human and financial resources are dedicated to the application of existing laws and regulations applicable to N&N research. Organisations performing N&N research activities should demonstrate transparently that they comply with relevant regulations.

4.1.7 National and local ethics committees and competent authorities should evaluate the manner of applying ethical review requirements to dual-use nanotechnology research. They should notably address the fundamental rights implications of any possible restrictions on informed consent and on publication of research results related to human health.

Favouring an inclusive approach

4.1.8 The broad directions of N&N research should be decided in an inclusive manner, allowing all stakeholders to enrich the preliminary discussions on these directions.

4.1.9 Member States, N&N research funding bodies, research organisations and researchers are encouraged to consider, at the earliest stages and through participatory foresight exercises, the future implications of technologies or objects being researched. This could allow the development of solutions to meet potential negative impacts caused by the use of a new object or technology at a later stage. Consultations with relevant ethics committees should be part of such foresight exercises as appropriate.

4.1.10 N&N research itself should be open to contributions from all stakeholders who should be informed and supported so that they can take an active part in the research activities, within the scope of their mission and mandate.

Key priorities

4.1.11 Research authorities and standardisation bodies should endeavour to adopt N&N standard terminology to facilitate the communication of scientific evidence. They should encourage standard measurement procedures as well as the use of appropriate reference materials in order to improve comparability of scientific data.

4.1.12 N&N research funding bodies should devote an appropriate part of N&N research to the development of methods and tools for risk assessment, the refinement of metrology at nano-scale and standardisation activities. In this context, particular attention should be paid to developing methods to assess the risk of second-generation, active nano-structures.

4.1.13 Member States, N&N research funding bodies and organisations should encourage fields of N&N research with the broadest possible positive impact. A priority should be given to research aiming to protect the public and the environment, consumers or workers and aiming to reduce, refine or replace animal experimentation.

4.1.14 N&N research funding bodies should carry out and publish balanced assessments, based on best available scientific data, of the potential costs, risks, and benefits of research areas eligible for funding.

Prohibition, restrictions or limitations

4.1.15 N&N research funding bodies should not fund research in areas which could involve the violation of fundamental rights or fundamental ethical principles, at either the research or development stages (e.g. artificial viruses with pathogenic potentials).

4.1.16 N&N research organisations should not undertake research aiming for non-therapeutic enhancement of human beings leading to addiction or solely for the illicit enhancement of the performance of the human body.

4.1.17 As long as risk assessment studies on long-term safety is not available, research involving deliberate intrusion of nano-objects into the human body, their inclusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment, should be avoided.

4.2 Due respect for precaution

Given the deficit of knowledge of the environmental and health impacts of nano-objects, Member States should apply the precautionary principle in order to protect not only researchers, who will be the first to be in contact with nano-objects, but also professionals, consumers, citizens and the environment in the course of N&N research activities.

4.2.1 Students, researchers and research organisations involved in N&N research should take specific health, safety and environmental measures adapted to the particularities of the nano-objects manipulated. Specific guidelines on the prevention of pathologies induced by nano-objects should be developed in line with the Community Strategy 2007-2014 on Health and Safety at Work [13].

4.2.2 N&N research organisations should apply existing good practices in terms of classification and labelling. In addition, as nano-objects might present specific properties due to their size, they should undertake research on systems (including e.g. the development of specific pictograms) aiming to inform researchers and more generally people likely to come into contact with nano-objects in research premises (e.g. security and emergency staff) so that they may take the necessary and appropriate protection measures in the course of their duties.

4.2.3 Public and private N&N research funding bodies should request that a risk assessment be presented along with each submission of a proposal for funding for N&N research.

4.2.4 N&N research funding bodies' programmes should include monitoring of the potential social, environmental and human health impacts of N&N over a relevant period of time.

[13] COM(2007) 62, 21.2.2007.

Application of the precautionary principle should include reducing the gaps in scientific knowledge, and therefore undertaking further actions in research and development such as the following:

4.2.5 Research funding bodies should devote an appropriate part of N&N research to understanding the potential risks, notably to the environment and human health, induced by nano-objects, encompassing their whole life-cycle, from their creation up to their end of life, including recycling.

4.2.6 N&N research organisations and researchers should launch and coordinate specific N&N research activities in order to gain a better understanding of fundamental biological processes involved in the toxicology and ecotoxicology of nano-objects man-made or naturally occurring. They should widely publicise, when duly validated, data and findings on their biological effects, be they positive, negative or null.

4.2.7 N&N research funding bodies should launch and coordinate specific research activities in order to gain a better understanding of ethical, legal and societal impacts of the new fields opened by N&N. Information and communication technologies and biotechnology should receive particular attention as well as the convergence between these fields and cognitive sciences and N&N.

4.3 Wide dissemination and monitoring of the Code of Conduct

4.3.1 Member States should support the wide dissemination of this Code of Conduct, notably through national and regional public research funding bodies.

4.3.2 In addition to the existence of this Code of Conduct, N&N research funding bodies should make sure that N&N researchers are aware of all relevant legislation, as well as ethical and social frameworks.

4.3.3 As the application of the Code of Conduct should be monitored across the Community, Member States should cooperate with the Commission in order to devise adequate measures to carry out such monitoring at national level and guarantee synergies with other Member States.