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**COMMUNICATION FROM THE COMMISSION
TO THE COUNCIL, THE EUROPEAN PARLIAMENT
AND THE ECONOMIC AND SOCIAL COMMITTEE**

**Nanosciences and nanotechnologies:
An action plan for Europe 2005-2009**

BACKGROUND

Nanosciences and nanotechnologies (N&N) are new approaches to research and development (R&D) that concern the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.

Advances across a wide range of sectors are being enabled through R&D and innovation in N&N. These advances can address the needs of citizens and contribute to the Union's competitiveness and sustainable development objectives and many of its policies including public health, employment and occupational safety and health, information society, energy, transport, security and space.

Products based on N&N are already in use and analysts expect markets to grow by hundreds of billions of euros during this decade. Europe must avoid a repeat of the European 'paradox' witnessed for other technologies and transform its world-class R&D in N&N into useful wealth-generating products in line with the actions for growth and jobs, as outlined in the 'Lisbon Strategy' of the Union¹.

Health, safety and environmental risks that may be associated with products and applications of N&N need to be addressed upfront and throughout their life cycle.

A better dialogue between researchers, public and private decision-makers, other stakeholders, and the public is beneficial for understanding possible concerns and tackling them from the standpoints of science and of governance, and to promote informed judgement and engagement.

On 12 May 2004 the Commission adopted the Communication *Towards a European Strategy for Nanotechnology*² in which a safe, integrated and responsible strategy was proposed. This aims to reinforce the Union's leading position in N&N R&D and innovation while addressing any environmental, health, safety and societal concerns upfront. In this context, several needs were highlighted:

- increase investment and coordination of R&D to reinforce scientific excellence, interdisciplinarity and competition in N&N together with industrial exploitation;
- develop world-class competitive R&D infrastructure ('poles of excellence') that take into account the needs of both industry and R&D organisations;
- promote the interdisciplinary education and training of R&D personnel together with a stronger entrepreneurial mindset;
- provide favourable conditions for industrial innovation to ensure that R&D is translated into affordable and safe wealth-generating products and processes;
- respect ethical principles, integrate societal considerations into the R&D process at an early stage and encourage a dialogue with citizens;

¹ COM(2005) 24

² COM(2004) 338

- address public health, occupational health and safety, environmental and consumer risks of N&N-based products at the earliest possible stage;
- complement the above actions with appropriate cooperation and initiatives at the international level.

In its conclusions of 24 September 2004³, the Competitiveness Council welcomed the proposed integrated and responsible approach and the Commission's intention to draw up an Action Plan for nanotechnology. The European Economic and Social Committee subsequently adopted an opinion on the 10 November 2004 that supported the Commission's proposed approach⁴.

All stakeholders were invited to provide their opinion on the Commission's proposal via an extensive open consultation that closed on the 15 October 2004. Over 750 responses were received supporting the elements of the Commission's proposal. The outcome of this survey, the largest of its kind in Europe, is described elsewhere⁵.

Taking into account the above, the Commission has prepared this Action Plan, which defines a series of articulated and interconnected actions for the immediate implementation of a safe, integrated and responsible strategy for N&N based on the priority areas identified in the above-mentioned Communication. As far as nanobiotechnology is concerned, this Action Plan complements the Commission's Strategy for Europe on Life Sciences and Biotechnology.⁶

The Commission invites the European Parliament and the Council to endorse the Action Plan and invites the Member States to contribute to its rapid implementation.

1. RESEARCH, DEVELOPMENT AND INNOVATION: EUROPE NEEDS KNOWLEDGE

Bringing together public and private organisations across Europe to perform collaborative R&D is key for the interdisciplinary approach often needed for N&N as well as for optimising resources. National and regional initiatives account for around two-thirds of overall European public investment in N&N R&D. N&N R&D should be reinforced and coordinated for economies of scale and to achieve synergy with education and innovation generating the 'triangle of knowledge' needed for the European Research Area of knowledge for growth.⁷

1.1 The Commission will:

- Reinforce N&N R&D in the European Union's seventh framework programme for research, technological development and demonstration activities (FP7)⁸, and has proposed a doubling of the budget compared to FP6. Interdisciplinary R&D should be strengthened along the entire chain for knowledge creation, transfer, production and use;

³ *Conclusions of the Competitiveness Council* 24 September 2004

⁴ *Opinion of the European Economic and Social Committee* 15 December 2004

⁵ Nanoforum Report, December 2004 <http://www.nanoforum.org>

⁶ COM(2002) 27

⁷ COM(2005) 118

⁸ COM(2005) 119

- b) Propose specific support to research in nanoelectronics under the Information and Communication Technology (ICT) priority of FP7. In line with the research agenda of the European Technology Platform on Nanoelectronics⁹, this will stimulate industrially-relevant research in a technologically mature field, provide the foundation for the next generation of electronics and enable many new ICT applications, whilst drawing on complementary research in other thematic areas;
- c) Boost support for collaborative R&D into the potential impact of N&N, in particular engineered nano-scale entities (e.g. nanoparticles), on human health and the environment via toxicological and ecotoxicological studies as well as developing appropriate methodologies and instrumentation for monitoring and minimising exposure in the workplace, including portable in situ measuring devices¹⁰;
- d) Foster the development of European Technology Platforms in order to implement a strategic R&D agenda for N&N sectors that are important for Europe's competitiveness e.g. in nanomedicine, sustainable chemistry or space (including the possibility of launching European Technological Initiatives).

1.2 The Commission calls upon the Member States:

- a) At policy level, to increase public investment in R&D in N&N, corresponding to increased R&D expenditure to match the '3%' Barcelona objectives¹¹. In line with the subsidiarity principle, the Commission considers the 'Open Method of Coordination' to be an appropriate way to proceed with the utilisation of information exchange, indicators, and guidelines;
- b) At programme level, to enforce effective coordination of R&D programmes at national and regional levels, which could minimise duplication and achieve greater efficiency e.g. via the ERA-NET scheme and its possible successor. Community participation in national programmes, as set out in EC Treaty Article 169, could have a significant impact;
- c) At project level, to promote N&N R&D activities by raising awareness in universities, R&D organisations and industry, and to provide support for their participation in projects at EU level (e.g. FP, COST, ESF, EUREKA) as well as for taking advantage of loans from the European Investment Bank (EIB) 'Innovation 2010' initiative.

⁹ *Vision 2020: Nanoelectronics at the centre of change* Report of the High-Level Group EUR 21149 (June 2004) <http://www.cordis.lu/ist/eniac>

¹⁰ *Research Needs on Nanoparticles*, 25-26 January 2005
http://www.cordis.lu/nanotechnology/src/pe_workshop_reports.htm#particles

¹¹ *CREST Report on the open method of coordination in favour of the Barcelona research investment objective* http://europa.eu.int/comm/research/era/3pct/pdf/3pct-app_open_method_coordination.pdf

2. INFRASTRUCTURE AND EUROPEAN POLES OF EXCELLENCE

World-class R&D infrastructure and ‘poles of excellence’ are essential for the EU to remain competitive in N&N. Europe needs an appropriate, diverse but coherent system of infrastructure that comprises both ‘single sited’ (in one location) and ‘distributed’ (networked) facilities. However, due to its interdisciplinary, complex and costly nature, the infrastructure for R&D and innovation in N&N requires a critical mass of resources that are beyond the means of regional and often even national governments and industry.

2.1 The Commission will:

- a) Establish a map of existing European N&N infrastructure and explore ways of maximising its added value by the exchange of best practice. Special attention will be paid to the needs of industry, in particular, small and medium sized enterprises (SMEs) so to reinforce cooperation with and technology transfer from academic R&D teams to conceive advanced prototypes and validate them in industrially-relevant environments;
- b) Support transnational networking and integration of resources across universities, R&D organisations and industry as a means of assembling critical mass through ‘distributed’ poles of excellence e.g. via the Networks of Excellence and Integrated Infrastructure Initiatives instruments under FP6. Some areas of N&N R&D would particularly benefit from such integration include nanotoxicology and nanoecotoxicology, as well as nanometrology that would support EU competitiveness in this field.

2.2 The Commission calls upon the Member States:

- a) To decide upon and launch the construction of new (or the substantial upgrading of existing) interdisciplinary infrastructure or ‘poles of excellence’ on the basis of roadmaps of future needs e.g. in nanobiotechnology. It is expected that the European Strategy Forum on Research Infrastructure (ESFRI) will provide a valuable contribution through identifying the needs for infrastructure at Community level. The associated financing should encompass private and public sources, including EC Treaty Articles 169 and 171, structural funds, the European Investment Bank (EIB) as well as taking into account the ‘Growth Initiative’¹².

¹²

COM(2003) 690

3. INTERDISCIPLINARY HUMAN RESOURCES: EUROPE NEEDS CREATIVITY

Our capability to generate knowledge depends upon the up-to-date education, training and lifelong learning of researchers, engineers and other skilled personnel. Interdisciplinary R&D in N&N goes beyond traditional concepts and a greater awareness amongst these groups of entrepreneurship, ethical, health, safety (including in the workplace), environmental, and social issues is needed. At the same time, mobility across borders and disciplines and between academia and industry improves the quality of education and training, particularly in N&N where progress is fast and interdisciplinarity plays a determinant role.

3.1 The Commission will:

- a) Promote networking and disseminate best practices for education and training in N&N. A dedicated workshop is taking place in 2005 and the proceedings will be widely disseminated;
- b) Explore how to best encourage the development of relevant supporting activities (e.g. cross-border thematic networks and other actions), in particular through its programmes and specifically the proposed new generation of education and training programmes after 2006¹³;
- c) Promote the creation of an ‘interdisciplinary European award in N&N’ that recognises scientific advances and entrepreneurship and/or progress in the area of safety and the environment, in line with the integrated and responsible approach. Sponsorship from industry and other interested organisations will be sought;
- d) Explore the possibility for dedicated N&N ‘Marie Curie’ actions (e.g. fellowships) that stimulate transnational doctorate-level programmes. Lifelong learning for researchers and engineers will also be promoted by actions aimed at disciplinary and/or sectorial mobility. Special attention will be paid to the participation of women and duly rewarding the hosting institutions.

3.2 The Commission calls upon Member States:

- a) To foster interdisciplinary training and education for R&D in N&N, focusing on physics, chemistry, biology, toxicology and ecotoxicology and engineering, but also including entrepreneurial studies, risk assessment, and social and human sciences where appropriate. Training programmes should also be targeted specifically at SMEs, who often lack the necessary ‘in house’ expertise or resources;
- b) To encourage students, researchers and engineers to take advantage of the wide range of initiatives for undertaking mobility and training in N&N, which is available at national and European levels, including the Marie Curie actions, the European Science Foundation (ESF), and the Human Frontier Science Program (HFSP).

¹³ COM(2004) 156

4. INDUSTRIAL INNOVATION: FROM KNOWLEDGE TO THE MARKET

Due to the enabling character of N&N, advances can be made in virtually all technology sectors. European industry, R&D organisations, universities and financial institutions should work together to ensure that excellence in N&N R&D is translated into commercially viable, inherently safe products and processes.

Standards provide a level playing field for markets and international trade and are prerequisites for fair competition, comparative risk assessments and regulatory measures. The protection of intellectual property rights (IPR) is essential for innovation both in terms of attracting initial investment and for ensuring future revenue.

4.1 The Commission will:

- a) Foster the industrial exploitation of R&D N&N by bringing together stakeholders to exchange best practice for the commercialisation of N&N. Special attention will be paid to the societal, political and psychological barriers to entrepreneurship in Europe e.g. the stigma of failure, as well as how to better facilitate agreement upon licensing arrangements between industry and R&D organisations / universities e.g. the 'Berliner Vertrag' or the Responsible Partnering Initiative;
- b) Increase the industrial involvement in collaborative EU R&D projects for N&N as a means of promoting the transformation of traditional industries as well as the growth of knowledge-intensive SMEs and 'start ups'. Means of providing support for smaller prototype/demonstration projects at EU-level will be explored;
- c) Support the creation of a web-based 'Digital N&N Library' to analyse the diverse landscape of N&N in Europe and to draw together data from a wide range of sources e.g. publications, patents, companies, market data, R&D projects, organisations;
- d) Support pre-normative R&D for N&N in synergy with the activities of European Standards Bodies. It will in particular invite proposals for Specific Support Actions for 'nanometrology' in FP6;
- e) Support the establishment of a N&N Patent Monitoring System e.g. by the European Patent Office (EPO) as well as the harmonisation of practices in the processing of N&N patent applications between patent offices such as the EPO, United States Patent and Trademark Office (USPTO) and Japan Patent Office (JPO).

4.2 The Commission calls upon the Member States:

- a) To put in place measures and incentives for innovation in N&N, also building upon Commission initiatives to investigate the use of public demand (procurement) to promote the uptake of innovation by private companies. SMEs and ‘start ups’ and regional technological clusters integrating industry, R&D organisations / universities, investors and other stakeholders can play a crucial role in particular at regional level. The new ‘Regions of Knowledge’ initiative could contribute towards establishing effective clusters and networks. The involvement of business ‘angels’ or management specialists into N&N ‘start up’ companies can help for improving in-house competencies;
- b) To boost and coordinate activities in standardisation for N&N and welcomes the creation of a working group by the European Committee for Standardisation (CEN)¹⁴;
- c) To reach agreement as soon as possible on the adoption of the Community patent, noting that patenting of N&N inventions in Europe develops slowly compared to other world regions, and to take into due account the importance of globally harmonising the treatment of N&N patent applications with a view to a more efficient global patenting system¹⁵;
- d) To support technology transfer in N&N by taking advantage of the pan-European Innovation Relay Centre (IRC) network¹⁶ which aims at facilitating transnational technology transfer in Europe and promoting innovation at local level.

5. INTEGRATING THE SOCIETAL DIMENSION: ADDRESSING EXPECTATIONS AND CONCERNS

While N&N is bringing about important advances and benefits for our society that improve our quality of life, some risk is inherent, as for any technology, and this should be openly acknowledged and investigated upfront.

An essential element of this responsible strategy for N&N is to integrate health, safety and environmental aspects to the technological development of N&N and to establish an effective dialogue with all stakeholders, informing about progress and expected benefits, and taking into account expectations and concerns (both real and perceived) so to steer developments on a path that avoids negative societal impact.

The Commission wishes to encourage the development of a society where the public, scientists, industry, financial operators and policy makers feel comfortable in dealing with issues associated with N&N. Due to the nature of N&N, societal issues may arise and should be anticipated e.g. for less skilled labour, as regards the risk of a disequilibria amongst different EU regions and as regards ensuring affordable access to the benefits of N&N e.g. in nanomedicine.

¹⁴ CEN Resolution BT C005/2004 <http://www.cenorm.be>

¹⁵ *Science, Technology and Innovation for the 21st Century* OECD Committee for Scientific and Technological Policy at Ministerial Level 29-30 January 2004

¹⁶ <http://irc.cordis.lu>

5.1 The Commission will:

- a) Ensure that Community funded R&D in N&N continues to be carried out in a responsible manner e.g. via the use of ethical reviews. Possible ethical issues for N&N include e.g. non-therapeutic human enhancement, invasion of privacy due to invisible sensors. The integration of ethical concerns, innovation research and social sciences into N&N R&D will help build confidence in decision-making related to the governance of N&N¹⁷;
- b) Ask the European Group on Ethics in Science and New Technologies to carry out an ethical analysis of nanomedicine. This will identify the primary ethical concerns and enable future ethical reviews of proposed N&N R&D projects to be carried out appropriately;
- c) Support studies and foresight activities into future N&N scenarios so to provide useful information about the possible risks to, and potential impact on, society. In the area of nanobiotechnology, synergy can be developed with a study that is being undertaken by the Commission at the request of the European Parliament to assess and conduct a cost-benefit analysis of biotechnology and genetic engineering;
- d) Create the conditions for and pursue a true dialogue with the stakeholders concerning N&N. In support of this dialogue, special Eurobarometer (EB) surveys should study the awareness of and attitudes towards N&N across Member States. This will allow an assessment of the effectiveness of different approaches across Europe as well as providing 'early warning' of particular concerns;
- e) Produce multilingual information material to raise awareness of N&N for different age groups building upon the success of pilot initiatives that have been launched by the Commission including films¹⁸, brochures and other internet-based material¹⁹;

5.2 The Commission calls upon the Member States:

- a) To further develop a regular dialogue on N&N at appropriate level with the public, in particular via the media;
- b) To foster consumer education in application fields enabled by N&N;
- c) To encourage industry to take into account the wider economic, societal, health, safety and environmental impacts of their commercial activities in N&N e.g. according to the concepts of Corporate Social Responsibility and 'triple bottom line' reporting as with the Global Reporting Initiative.

¹⁷

COM (2001) 714

¹⁸

http://europa.eu.int/comm/mediatheque/video/index_en.html

¹⁹

<http://www.cordis.lu/nanotechnology>

6. PUBLIC HEALTH, SAFETY, ENVIRONMENTAL AND CONSUMER PROTECTION

All applications and use of N&N must comply with the high level of public health, safety, consumers and workers protection, and environmental protection chosen by the Community²⁰. The presence of N&N-based products on the market is expected to increase rapidly, including via less controlled internet commerce.

Nanoparticles exist in nature or can be produced by human activities, intentionally or unintentionally. Taking into account that smaller particles have a greater (re)active surface area per unit mass than larger particles, toxicity and potential health effects may also increase²¹. There is therefore concern about the potential impact of nanoparticles on human health and the environment.

Risk assessment related to human health, the environment, consumer and workers should be responsibly integrated at all stages of the life cycle of the technology, starting at the point of conception and including R&D, manufacturing, distribution, use and disposal or recycling. Appropriate *ex ante* assessments should be carried out and risk management procedures elaborated before e.g. commencing with the mass production of engineered nanomaterials. Particular attention should be paid to products that are already or close to being on the market such as household products, cosmetics, pesticides, food contact materials, and medical products and devices.

The European Environment and Health Action Plan 2004-2010²² and the Community Strategy on Health and Safety at Work²³ provide basis for future possible initiatives. The Commission proposal on REACH²⁴ may cover some aspects on nanoparticles produced in very high quantities. Until REACH is adopted, the notification scheme under Directive 67/548/EEC will apply for new substances and notified substances with significantly new uses.

6.1 The Commission will:

- a) Identify and address safety concerns associated with applications and use of N&N at the earliest possible stage. The Scientific Committee on Emerging and Newly Identified Health Risks has been requested to provide an opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of N&N;
- b) Promote safe and cost-effective measures to minimise exposure of workers, consumers and the environment to manufactured nano-scale entities. It will also support a wide range of studies (including epidemiological studies) to (i) evaluate current and future projected levels of exposure, (ii) evaluate the adequacy of current approaches to control exposure and (iii) launch appropriate initiatives, propose measures and/or issue recommendations;

²⁰ See Treaty Articles 152 (health), 153 (consumers), and 174 (environment)

²¹ See Point 22 of Chapter 9 (p. 82) of the 2004 Report by UK Royal Society and the Royal Academy of Engineering “*Nanoscience and nanotechnologies: opportunities and uncertainties*”

²² COM(2004) 416

²³ COM(2002) 118

²⁴ Registration, Evaluation and Authorisation of Chemicals <http://europa.eu.int/comm/environment/chemicals/reach.htm>

c) Develop with Member States, international organisations, European agencies, industry and other stakeholders, terminology, guidelines, models and standards for risk assessment throughout the whole life-cycle of N&N products. Where appropriate, risk assessment and management procedures will need to be adapted accordingly to ensure a high level of protection;

d) Examine and, where appropriate, propose adaptations of EU regulations in relevant sectors in light of the above paying particular, but not exclusive, attention to (i) toxicity thresholds, (ii) measurement and emission thresholds, (iii) labelling requirements, (iv) risk assessment and exposure thresholds and (v) production and import thresholds, below which a substance may be exempt from regulation, are typically based upon mass quantities.

6.2 The Commission calls upon the Member States:

a) To make inventories of use and exposures of N&N applications, in particular, manufactured nano-scale entities;

b) Review and, where appropriate, modify national legislation to take into account the specificities of N&N applications and use;

c) Take nanoparticles into account in the enforcement of the new substances notification scheme under Directive 67/548/EEC;

d) Support the adoption of universally recognised Chemicals Abstract Service registry numbers and Material Safety Data Sheets for nanomaterials.

7. INTERNATIONAL COOPERATION

International cooperation in N&N is needed both with countries that are economically and industrially advanced (to share knowledge and profit from critical mass) and with those less advanced (to secure their access to knowledge and avoid any 'nano divide' or knowledge apartheid). Particular attention will be paid to cooperation with countries covered by the European Neighbourhood Policy and those with existing S&T cooperation agreements.

7.1 In compliance with its international obligations and notably those relating to the World Trade Organisation, the Commission will:

a) Intensify dialogue at international level with a view to adopting a declaration or a 'code of good conduct' for the responsible development and use of N&N. Industry shall be invited to adhere to these principles;

b) Address issues of mutual benefit at global level e.g. on nomenclature, metrology, common approaches to risk assessment and the establishment of a dedicated database to share toxicological and ecotoxicological as well as epidemiological data;

- c) Support the creation of a free and open European electronic archive of N&N scientific and technical publications according to the principles set out in the OECD Declaration on Access to Research Data from Public Funding²⁵.

7.2 The Commission calls upon the Member States:

To increase their support for N&N R&D and capacity building in less developed countries. It highlights the potential of N&N to contribute towards the Millennium Development Goals²⁶ and sustainable development e.g. as regards water purification, providing high quality and safe nutrition, more effective delivery of vaccines, lower cost health screening, more efficient conservation and use of energy.

8. IMPLEMENTING A COHERENT AND VISIBLE STRATEGY AT EUROPEAN-LEVEL

An integrated strategy cannot be implemented in a linear fashion but it requires coherent and coordinated action. In addition, given the increasing interest of citizens in the implications of N&N, it is important that action at EU-level is given appropriate visibility and is effectively communicated.

In response to the calls from the Council for a coordinated management of N&N initiatives at European level²⁷, the Commission will establish a focal point for coordination at EU level for:

- a) Monitoring and overseeing the implementation of this Action Plan, its conformity and coherence with Commission policies (e.g. R&D, education and training, employment, enterprise policies, health and consumer protection), related initiatives throughout the Union and other relevant activities (e.g. the Commission's Biotechnology Steering Committee), so to ensure maximum effectiveness;
- b) Reporting on progress made with the Action Plan every two years to the Council and the European Parliament, making use of indicators, where possible. A revision of the Action Plan, if necessary, shall be envisaged;
- c) Performing a range of activities so to accompany and foster a useful, beneficial, profitable and consensual exploitation and application of N&N in the EU e.g. via dedicated 'horizon scanning' activities, pro-active and responsive dialogue with the public and ad-hoc initiatives at international level.

²⁵ *Science, Technology and Innovation for the 21st Century* OECD Committee for Scientific and Technological Policy at Ministerial Level 29-30 January 2004

²⁶ *Innovation: Applying Knowledge in Development*. UN Millennium Project 2005, Task Force on Science, Technology, and Innovation

²⁷ *Conclusions of the Competitiveness Council* 24 September 2004