EUROPEAN COMMISSION

Community Research

EU Policy for Nanosciences and Nanotechnologies

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Key documents

Commission Communications on Nanosciences and Nanotechnologies

- **Strategy**, COM(2004)338
- **Action Plan 2005-2009**, COM(2005)243
- **1st Implementation Report 2005-2007**, COM(2007)505
- **2nd Implementation Report 2007-2009**, *late 2009*
- **Regulatory Aspects of Nanomaterials**, COM(2008)366, SEC(2008) 2036

Commission Recommendation on a

- **Code of Conduct for Responsible Nanosciences and Nanotechnologies Research**, C(2008)424

Council Conclusions

- **on Strategy**, 24 Sep 2004
- **on 1st Implementation Report 2005-2007**, 23 Nov 2007

European Parliament Resolution

- **on Action Plan 2005-2009**, 28 Sep 2006

European Economic and Social Committee Opinions

- **on Strategy**, 15 December 2004
- **on Action Plan 2005-2009**, 20 April 2006

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COMMUNICATION FROM THE COMMISSION

Towards a European strategy for nanotechnology

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EXECUTIVE SUMMARY

Nanosciences and nanotechnologies are new approaches to research and development (R&D) that aim to control the fundamental structure and behaviour of matter at the level of atoms and molecules. These fields open up the possibility of understanding new phenomena and producing new properties that can be utilised at the micro- and macro-scale. Applications of nanotechnology are emerging and will impact on the life of every citizen.

Over the last decade the European Union (EU) has established a strong knowledge base in nanosciences. Our ability to maintain this position is in doubt since the EU is investing proportionately less than its main competitors and lacks world-class infrastructure ("poles of excellence") that muster the necessary critical mass. This is despite the fact that investment in national EU programmes is growing in a rapid but independent way.

European excellence in nanosciences must finally be translated into commercially viable products and processes. Nanotechnology is emerging as one of the most promising and rapidly expanding fields of R&D to provide new impetus towards the dynamic knowledge-based objectives of the Lisbon process. It is crucial, however, that a favourable environment for innovation is created, in particular, for small and medium sized enterprises (SMEs).

Nanotechnology must be developed in a safe and responsible manner. Ethical principles must be adhered to and potential health, safety or environmental risks scientifically studied, also in order to prepare for possible regulation. Societal impacts need to be examined and taken into account. Dialogue with the public is essential to focus attention on issues of real concern rather than "science fiction" scenarios.

This Communication proposes actions as part of an integrated approach to maintain and strengthen European R&D in nanosciences and nanotechnologies. It considers the issues that are important to ensure the creation and exploitation of the knowledge generated via R&D for the benefit of society. In this context, the time is right for launching a debate at an institutional-level in view of coherent action to:

- increase investment and coordination of R&D to reinforce the industrial exploitation of nanotechnologies whilst maintaining scientific excellence and competition;

- develop world-class competitive R&D infrastructure ("poles of excellence") that take into account the needs of both industry and research organisations;

- promote the interdisciplinary education and training of research personnel together with a stronger entrepreneurial mindset;

- ensure favourable conditions for technology transfer and innovation to ensure that European R&D excellence is translated into wealth-generating products and processes;

- integrate societal considerations into the R&D process at an early stage;

– address any potential public health, safety, environmental and consumer risks upfront by generating the data needed for risk assessment, integrating risk assessment into every step of the life cycle of nanotechnology-based products, and adapting existing methodologies and, as necessary, developing novel ones;

– complement the above actions with appropriate cooperation and initiatives at international level.

The actions described in this Communication are also in line with the European Councils of Lisbon 2000, declaring the commitment to develop a dynamic knowledge-based economy and society, of Gothenburg 2001, aiming at sustainable development, and of Barcelona 2002, targeting 3% of GDP funding for research[1]. It also contributes towards the development of the European Research Area (ERA) [2] and profits from it.

1. INTRODUCTION

1.1. What is nanotechnology?

Originating from the Greek word meaning "dwarf", in science and technology the prefix "nano" signifies 10^{-9}, i.e. one billionth (= 0.000000001). One nanometre (nm) is one billionth of a metre, tens of thousands of times smaller than the width of a human hair. The term "nanotechnology" will be used here as a collective term, encompassing the various branches of nanosciences and nanotechnologies.

Conceptually, nanotechnology refers to science and technology at the nano-scale of atoms and molecules, and to the scientific principles and new properties that can be understood and mastered when operating in this domain. Such properties can then be observed and exploited at the micro- or macro-scale, for example, for the development of materials and devices with novel functions and performance.

1.2. Why is nanotechnology important?

Nanoscience is often referred to as "horizontal", "key" or "enabling" since it can pervade virtually all technological sectors. It often brings together different areas of science and benefits from an interdisciplinary or "converging" approach and is expected to lead to innovations that can contribute towards addressing many of the problems facing today's society:

– **medical applications** including e.g. miniaturised diagnostics that could be implanted for early diagnosis of illness. Nanotechnology-based coatings can improve the bioactivity and biocompatibility of implants. Self-organising scaffolds pave the way for new generations of tissue engineering and bio-mimetic materials, with the long-term potential of synthesising organ replacements. Novel systems for targeted drug delivery are under development and recently nanoparticles could be channelled into tumour cells in order to treat them e.g. through heating

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[1] Presidency conclusions can be downloaded from http://ue.eu.int/en/Info/eurocouncil/index.htm

[2] "The European Research Area: Providing new momentum - Strengthening - Reorienting - Opening up new perspectives" COM (2002) 565 final

- **information technologies** including data storage media with very high recording densities (e.g. 1 Terabit/inch^2) and new flexible plastic display technologies. In the long-term, the realisation of molecular or biomolecular nanoelectronics, spintronics and quantum computing could open up new avenues beyond current computer technology;

- **energy production and storage** can benefit from, for example, novel fuel cells or lightweight nanostructured solids that have the potential for efficient hydrogen storage. Efficient low-cost photovoltaic solar cells (e.g. solar "paint") are also under development. Energy savings are anticipated via nanotechnological developments that lead to improved insulation, transport and efficient lighting;

- **materials science** developments using nanotechnology are far-reaching and are expected to impact upon virtually all sectors. Nanoparticles are already used for reinforcing materials or functionalising cosmetics. Surfaces can be modified using nanostructures to be, for example, scratch-proof, unwettable, clean or sterile. Selective grafting of organic molecules through surface nanostructuring is expected to impact upon the fabrication of biosensors and molecular electronics devices. The performance of materials under extreme conditions can be significantly improved and advance e.g. the aeronautics and space industries;

- **manufacturing** at the nanoscale requires a new interdisciplinary approach to both research and fabrication processes. Conceptually, there are two main routes: the first starts from micro-systems and miniaturises them ("top-down") and the second mimics nature by building structures starting at atomic and molecular level ("bottom-up"). The former can be associated with assembly, the latter to synthesis. The bottom-up approach is in an early development phase but its potential impact is far reaching with a disruptive potential for current production routes;

- **instrumentation** for the study of the properties of matter at the nano-scale is already having an important direct and indirect impact that is stimulating progress across a wide range of sectors. The invention of the Scanning Tunnelling Microscope was a landmark in the birth of nanotechnology. Instrumentation also plays an essential role for developing the "top down" and "bottom up" manufacturing processes;

- **food, water and environmental** research can advance via nanotechnology-based developments including tools to detect and neutralise the presence of micro organisms or pesticides. The origin of imported foods could be traced via novel miniaturised nano-labelling. The development of nanotechnology-based remediation methods (e.g. photo-catalytic techniques) can repair and clean–up environmental damage and pollution (e.g. oil in water or soil);

- **security** is expected to be enhanced via e.g. novel detection systems with a high specificity that provide early warning against biological or chemical agents, ultimately down to the level of single molecules. Improved protection of property, such as banknotes, could be achieved by nano-tagging. The development of new cryptographic techniques for data communication is also underway.

Several nanotechnology-based products have been marketed including: medical products (e.g. bandages, heart valves, etc); electronic components; scratch-free paint; sports equipment; wrinkle and stain resistant fabrics; and sun creams. Analysts estimate that the market for such products is currently around 2.5 billion € but could rise to hundreds of billions of € by 2010 and one trillion thereafter[3].

With the prospect of obtaining greater performance with fewer raw materials, in particular via the realization of "bottom-up" manufacturing, nanotechnology has the potential to reduce waste across the whole life-cycle of products. Nanotechnology can contribute towards realising sustainable development[4] and to the goals addressed in the "Agenda 21"[5] and the Environmental Technology Action Plan[6].

1.3. Which approach should be adopted to ensure that nanotechnology is safe?

In accordance with the Treaty, applications of nanotechnology will need to comply with the requirements for a high level of public health, safety, consumer[7] and environmental protection[8]. It is important for this rapidly evolving technology to identify and resolve safety concerns (real or perceived) at the earliest possible stage. Successful exploitation of nanotechnologies needs a sound scientific basis for both consumer and commercial confidence. Moreover, all provisions should be taken to ensure health and safety at work.

It is essential that the aspects of risk are addressed upfront as an integral part of the development of these technologies from conception and R&D through to commercial exploitation, in order to ensure the safe development, production, use and disposal of products from nanotechnology. Nanotechnologies present new challenges also for the assessment and the management of risks. It is therefore important that, in parallel with technological development, appropriate R&D is undertaken to provide quantitative data on toxicology and ecotoxicology (including human and environmental dose response and exposure data) to perform risk assessments and, where necessary, to enable risk assessment procedures to be adjusted. Actions related to public health, environment, safety and consumer protection are addressed later in this document.

2. WORLDWIDE FUNDING AND ACTIVITIES IN NANOTECHNOLOGY R&D

Taking into account the potential of nanotechnology, many countries are pursuing R&D programmes with large and rapidly increasing levels of public investment.

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3 See, for example, the figures presented in "New Dimensions for Manufacturing: A UK Strategy for Nanotechnology" DTI (2002) page 24

4 "A Sustainable Europe for a Better World: A European Union Strategy for Sustainable Development" COM(2001) 264. See also the United Nations Millennium Declaration (http://www.un.org/millennium/)

5 See http://www.un.org/esa/sustdev/documents/agenda21/index.htm

6 See http://europa.eu.int/comm/research/environment/etap_en.html

7 Treaty Articles 152 and 153 respectively require that a "high level of human health protection […] be ensured in the definition and implementation of all Community policies and activities" and that "consumer protection requirements […] be taken into account in defining and implementing other Community policies and activities."

8 Treaty Article 174 has, among others, the objectives of "preserving, protecting and improving the quality of the environment", "prudent and rational utilisation of natural resources" and "promoting measures at international level to deal with regional or worldwide environmental problems."

Over the last decade there has been an explosion of interest with public investment rising rapidly from around 400 million € in 1997 to over 3 billion € today. This section provides an overview of publicly funded initiatives in nanotechnology.

While the contribution of private R&D funding of nanotechnology cannot be accurately established, it has been estimated to be close to 2 billion € i.e. implying a total global R&D investment in nanotechnology of around 5 billion €. In this context, it is important to highlight that, with 56% of overall R&D investment from private sources, the EU lags behind the USA and Japan with 66% and 73% respectively[9].

2.1. Nanotechnology R&D in third countries

With the launch of the National Nanotechnology Initiative (NNI) in 2000, the USA embarked on an ambitious R&D programme in nanotechnology and federal expenditure has increased from $220 million in 2000 to around $750 in 2003, with a budget request of $982 million for 2005. Additional support is provided via States' funding of around $300 million.

The long-term federal commitment of the USA has been recently assured by the "21st Century Nanotechnology Development Act", running from 2005-2008 in which almost $3.7 billion is allocated to five agencies (NSF, DoE, NASA, NIST and EPA) and will more than double their current level of funding by 2008. Note that this figure does not include defence-related expenditure (DoD) and other areas that currently account for around one-third of the federal budget for nanotechnology.

Japan identified nanotechnology as one of its main research priorities in 2001. The funding levels announced increased sharply from $400 million in 2001 to around $800 million in 2003, overtaking the USA federal funding and is set to rise further by 20% in 2004. South Korea has embarked upon an ambitious ten-year programme with around $2 billion of public funding while Taiwan has committed around $600 million of public funding over six years.

China is devoting increasing resources to nanotechnology that is particularly significant taking into account their purchasing power. Its share of worldwide publications is increasing rapidly with a growth rate of 200% in the late 1990s and is catching up with the EU and the USA. The Russian Federation is well established in nanotechnology as well as several other Newly Independent States.

Many other regions and countries are paying increasing attention to nanotechnology including Australia, Canada, India, Israel, Latin America, Malaysia, New Zealand, The Philippines, Singapore, South Africa and Thailand.

2.2. Nanotechnology R&D in Europe

Europe recognised the potential of nanotechnology at an early stage and has developed a strong knowledge base in nanosciences with some of the brightest minds in the field. Several countries have dedicated research programmes that date from the mid to late 1990s. Despite the fact that some countries do not have specific nanotechnology initiatives, relevant R&D is often embedded within other programmes (e.g. biotechnology, microtechnology, etc).

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[9] European Commission "Key Figures 2003-2004" (2003)

When comparing Europe, Japan and the USA, there are no established "winners" or "losers" in nanotechnology but some trends can be identified. Europe's strength in nanosciences is demonstrated by the fact, over 1997-1999, the EU shared 32% of worldwide publications, compared to 24% for the USA and 12% for Japan[10]. However, this knowledge does not appear to be always capitalised upon by industry. Analysis of patents reveals that the EU has a worldwide share of 36%, compared to 42% for the USA, demonstrating a weakness in transforming R&D into applications.

Public investment levels vary considerably across the Member States both in absolute and relative terms (see the annex). One can estimate that the level of public funding for nanotechnology R&D in Europe has risen from around 200 million € in 1997 to the present level of around 1 billion € with around two-thirds from national and regional programmes.

In terms of absolute public expenditure, the EU is investing significant financial resources with a comparable level to the USA and Japan. On a per capita basis, however, the average level of public investment for the EU-25 is 2.4€ per citizen (2.9€ for the EU-15), compared to 3.7€ for the USA and 6.2€ for Japan. Similarly, in terms of GDP, the EU-25 invests 0.01% compared to USA and Japan at 0.01% and 0.02%, respectively.

All EU-25 countries, except Ireland, currently have a lower per capita level of investment than both the USA and Japan. One should also take into account the planned increases in the USA and Japan, the former is set to rise to 5€ per citizen by 2006 and the latter to 8€ in 2004. It seems likely therefore that the gap between the EU and its main competitors will widen further.

One of the crucial differences between the EU and our main competitors is that the landscape of European R&D in nanotechnology risks becoming relatively fragmented with a disparate range of rapidly evolving programmes and funding sources. The EC contribution under FP6 of €350 million in 2003 amounts to around one third of the overall European expenditure in nanotechnology.

Our main competitors are characterised by coordinated and/or centralised R&D programmes in nanotechnology. In the USA, for example, over two-thirds of funding is allocated as part of the National Nanotechnology Initiative within the auspices of the federal programme. It appears unlikely that the EU can remain competitive at world-level without better focussing and coordination at Community level.

Nanotechnology research is underway in the Accession Countries and they are involved in projects via the EU Framework Programmes (FP) for Research and Technological Development. Switzerland has a long tradition of nanotechnology R&D and has one of the highest levels of patents and publications per capita. Nanotechnology research programmes have also been established in other FP6 Associated Countries such as Norway.

Numerous collaborative research projects and other initiatives have already been supported via the EU Framework Programmes. These have added an important European dimension by establishing transnational collaborations and have catalysed

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[10] The Third European Report on Science & Technology Indicators, European Commission (2003) http://www.cordis.lu/indicators/third_report.htm

a substantial increase in national and private funding. While the fourth (FP4) and fifth (FP5) programmes have already funded a good number of nanotechnology projects[11], only in the sixth (FP6)[12] has nanotechnology been identified as one of the major priorities.

3. THE ROAD TO THE INFINITELY SMALL: FIVE DYNAMICS TO STIMULATE PROGRESS

In today's global market, economic growth demands innovation which is in turn dependent upon research. World-class R&D is an essential part of this process but there are other factors that need to be taken into account. In this context, five dynamics are identified: R&D, infrastructure; education and training; innovation; and the societal dimension. A set of synergetic actions at Community level is needed in all of these interdependent dynamics so to exploit the potential existing in the European Research Area.

Such an integrated approach to R&D in nanosciences and nanotechnology was one of the main conclusions from the "EuroNanoForum2003" meeting[13] that was organised by DG Research (RTD), in December 2003 and attended by over 1000 participants from around the world. Recent Commission initiatives include a workshop organised by DG Health and Consumer Protection (SANCO) that was held in March 2004 on the potential risks associated with nanotechnologies[14]. Other initiatives, e.g. on roadmaps and foresighting, are ongoing by DG RTD and the Joint Research Centre (JRC).

3.1. Research and Development: building the momentum

Taking into account the intellectual, scientific and technical challenges that are ahead in nanosciences and nanotechnologies, excellence in R&D is essential to ensure that Europe can remain competitive in the long-term. In this respect, the support of R&D through public funding is essential together with the availability of world-class researchers and competition between research teams at European level.

At the same time, knowledge generated via R&D must be translated through nanotechnologies into innovative products and processes that can improve the competitiveness of European industry. In this context, it is necessary not only to maintain excellence in R&D but also to strengthen investment in R&D of industrial relevance, while reinforcing Community level R&D and strengthening the coordination of national policies to ensure critical mass.

3.1.1. Increasing investment in knowledge to improve Europe's competitiveness

To create wealth and new employment in a globalised market and within a knowledge-based economy, the competitive production of new knowledge is essential. While European R&D must be excellent, it should also be timely and carried out at a competitive overall cost, otherwise there is the risk of a delocalisation of industrial activities to areas where production of knowledge is more cost effective.

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11 To obtain further information refer to the project database http://www.cordis.lu/fp6/projects.htm

12 See http://fp6.cordis.lu/fp6/home.cfm

13 See http://www.euronanoforum2003.org/ for further information

14 See http://europa.eu.int/comm/health/ph_risk/events_risk_en.htm for further information.

If we are able to take the leadership in the production of knowledge, it is possible to reverse the current trend and attract knowledge-based industry to Europe.

European public investment in nanotechnology R&D risks becoming significantly lower than our main competitors over the next five years. We are faced with the danger of losing the momentum unless there is substantial increase in European-level investment, by at least a factor 3 by 2010, taking into account the Lisbon objectives. Such investment should not be to the detriment of other R&D programmes but in line with the "3%" objective[15] and focus upon the most challenging aspects, in particular, knowledge-based industrial innovation ("nanomanufacturing"), integration at the macro-micro-nano interface and interdisciplinary ("converging") R&D. Appropriate synergy with the European Strategy on Life Sciences and Biotechnology[16] may also be beneficial.

Investment in R&D should be increased at both Community and Member State level in a complementary and synergetic way. Collaborative research projects at European level are essential for gathering competence and critical mass to further advance excellence. This is particularly important in order to make rapid progress in nanotechnology via interdisciplinary R&D. In this context, one must focus on the synergy of research, infrastructure and education - they are indissociable. Such a "system approach" will boost both knowledge production while also attracting to, and retaining in Europe, the best minds for nanotechnology R&D.

3.1.2. Research at Community level

Research carried out at Community level in a competitive and transparent manner is an essential means to stimulate and support world-class R&D in the European Research Area (ERA). As well as pooling knowledge, it brings the best teams from different disciplines together and provides an interface between industries and universities so as to ensure a dynamic input to the interdisciplinary R&D process that is beneficial for advancing nanotechnology.

Under the EU Framework Programmes, a substantial number of research projects have already been supported in nanotechnology. While significant progress has been made in advancing R&D excellence, only the FP6 is recognising the key role of nanotechnology, concentrating R&D activities under one thematic priority area, thus allowing the Commission to tackle the problem of dispersion, duplication and fragmentation. Two new instruments have been introduced, namely the Integrated Projects (IP) and Networks of Excellence (NE). These are complemented by a range of other instruments and actions[17] including dedicated IPs for SMEs.

Since the launch of the first calls for proposals, more than 20 IPs and NEs for R&D in nanosciences and nanotechnologies have been selected and negotiated. IPs assemble a critical mass of stakeholders and financing to pursue a specific objective. They integrate all aspects of the R&D process, both technical and non-technical and can ensure the transition from nanosciences to nanotechnologies by bringing together the research and industrial communities.

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15 "More Research for Europe: Towards 3% of GDP" COM(2002) 499 final

16 Life Sciences and Biotechnology: A strategy for Europe" COM(2002) 27

17 See http://fp6.cordis.lu/fp6/home.cfm for information on the full range of instruments in the FP6

European Technology Platforms are a newly introduced concept that aims to bring together all interested stakeholders to develop a long-term shared vision, create roadmaps, secure long-term financing and realise a coherent approach to governance. This concept might be appropriate in response to the need for more synergy and coordination between various stakeholders in a specific technological area.

3.1.3. Coordination of national policies

National and regional policies and programmes have an important place in funding nanotechnology R&D in Europe. It is recognised, however, that national capacities are often proving inadequate for the creation of world-class poles of excellence. It is therefore urgent that these programmes are coordinated in a way that effort is consolidated and focussed so to ensure a critical mass and greater impact within the ERA on the three key synergetic axes: research, infrastructure and education.

In order to stimulate the take-up of nanotechnology into applications and to increase and capitalise upon the interdisciplinary nature of nanotechnology R&D, it is important that national programmes of (often) different disciplines and emphasis are coordinated in a way that effort is focussed to ensure critical mass in applied R&D and to mix different scientific competences. This should help to ensure the rapid exploitation of knowledge into innovation in all European regions.

Initiatives such as the Open Method of Co-ordination (OMC)[18]and ERA-NET[19] can stimulate and support the coordination of programmes and joint activities conducted at national or regional level, as well as among European organisations. Such initiatives can be accompanied by appropriate benchmarking as a means of measuring progress.

3.1.4. Roadmaps and foresighting

Technology roadmaps provide a means of defining and assessing progress in nanotechnology and following its penetration into more mature phases of industrial development. The process of preparing roadmaps is useful in itself since it requires all stakeholders to interact and think about possible developments, challenges, impact and future needs. However, a generic roadmap for nanotechnology is unrealistic since the field is too broad. Instead, roadmaps should be applied to market sectors that have reached sufficient maturity. Several roadmaps are being prepared for which the contribution of institutes such as the Institute for Prospective Studies (IPTS) of the JRC is valuable.

To underpin the development of roadmaps as a strategic policy tool, foresighting plays a valuable role in anticipating future developments and planning accordingly. This is especially important for the potentially disruptive nature of nanotechnology, where examination of the potential social impact is needed. For this purpose, a specific methodology is needed and an independent EU high-level expert group is being created: “Foresighting the new technology wave: Converging nano-, bio- and info-technologies and their social and competitive impact on Europe”.

Actions: A European Research Area for nanotechnology

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18 As defined in the Presidency Conclusions of the 2000 Lisbon European Council http://ue.eu.int/

19 See http://www.cordis.lu/coordination/home.html

1. To remain at the forefront of nanosciences and nanotechnologies, the EU should reinforce its commitment to R&D. While ensuring synergy with programmes at national level, the Commission calls upon the Member States to:

(a) substantially increase public investment in nanosciences and nanotechnologies in a coherent and coordinated manner by a factor of 3 by 2010 bearing in mind the Lisbon and "3%" objectives;

(b) promote excellence in nanosciences through competition at European-level;

(c) boost R&D in nanotechnologies with a view to wealth-generating applications with emphasis on the involvement of SMEs;

(d) to maintain a concentration of R&D activities in the next FP in order to secure critical mass and synergy between the development of nanosciences, nanotechnologies, related engineering and safety aspects;

(e) ensure effective coordination of the national programmes;

(f) reinforce roadmap and foresighting efforts at European level with the contribution of centres of excellence and institutes such as the IPTS.

3.2. Infrastructure: European "Poles of Excellence"

Infrastructure refers to facilities and resources that provide essential services to the research community. They may be "single-sited" (in a single location), "distributed" (a network of distributed resources), or "virtual" (the service being provided electronically). State-of-the-art equipment and instrumentation is increasingly crucial for the development of nanotechnology, also to demonstrate whether R&D can be translated into potentially wealth generating products and processes.

To accelerate the development of both nanosciences and nanotechnologies, investment in a wide range of advanced facilities, instruments and equipment are essential. Due to its interdisciplinary and complex nature, the investment for such infrastructure must often be shared between organisations at local, regional, national and private level. It is useful to classify infrastructure into three different investment levels thus:

- up to a few tens of million € of investment, typically at local or regional level, for example, the Interdisciplinary Research Centres in Nanotechnology in the UK and the Competence Centres for Nanotechnology set up in Germany;

- up to 200 million € of investment, typically at national level for which MINATEC in France, IMEC in Belgium and MC2 in Sweden, are good examples and have become centres of both European and global visibility;

- more than 200 million € of investment for which dedicated nanotechnology facilities of this scale do not exist yet within the EU but are under development in third countries[20].

[20] One example is the "California Nanosystems Institute" that is being developed with an investment of around $300 million from federal, state and private funds (see http://www.cnsi.ucla.edu/mainpage.html)

Today's infrastructure does not always meet the requirements of industry. This mismatch can be managerial, geographical, in terms of ease of access, or concern difficulties to agree upon terms for Intellectual Property Rights (IPR). Solutions such as "open laboratories" with easy access for industry are very rare but greatly needed. SMEs, in particular, are often undercapitalised and could benefit substantially from such access to accelerate the R&D process and reduce the "time to market".

3.2.1. New "poles of excellence" for Europe

World-class infrastructure for nanosciences and nanotechnologies of European dimension and interest ("poles of excellence") is urgently needed. Apart from providing access to cutting-edge equipment that may not be locally available, such infrastructure could encompass all aspects of interdisciplinary R&D, education, and prototyping. It could also encompass public-private partnerships and serve as an incubator for new start-ups and spin-offs.

To achieve the necessary critical mass, we need to concentrate our resources in a limited number of infrastructures within Europe. Sectors that can benefit from mutual synergy include nanoelectronics, nanobiotechnology and nanomaterials. However, the need to minimise fragmentation and duplication must be offset against the importance of ensuring competition and thus R&D excellence.

An appropriate balance is needed between infrastructure at European, national and regional level. In the long-term, the development of multiple and/or distributed centres may be an important means of maintaining an appropriate level of competition. The European Technology Platforms together with bodies such as the European Strategy Forum on Research Infrastructure (ESFRI) can provide valuable input to ensure an optimal approach.

3.2.2. The "Initiative for Growth"

In the Communication "A European initiative for growth, investing in networks and knowledge to foster growth and employment"[21], a wide-ranging initiative has been drawn up in collaboration with the European Investment Bank (EIB). To initiate action, a "Quick start programme" has been proposed for which funding is anticipated from a combination of mainly bank loans (via the EIB initiative "Innovation 2010") and private (industrial) sources.

Infrastructure for nanoelectronics is identified as one of the areas for investment in the first wave of proposed "Quick start" projects. One of the other areas is next generation lasers (e.g. free-electron lasers), which have the potential, for example, to take "snapshot" pictures of the atomic structure of single molecules. Such facilities are invaluable for the development of nanosciences and nanotechnology and synergy should be sought with other actions at European and national level.

Actions: Infrastructure

[21] "A European initiative for growth: Investing in networks and knowledge for growth and jobs" COM(2003) 690

2. World-class infrastructure ("poles of excellence") of European dimension and interest is crucial to ensure that the EU increases its competitiveness in nanosciences and nanotechnology R&D. The Commission calls upon the Member States to:

(a) develop a coherent system of R&D infrastructure, taking into account the needs of stakeholders, in particular, developing synergy with education;

(b) take measures in order to maximise the added value of existing infrastructure taking into account the needs of industry, in particular, SMEs.

The Commission highlights the need to:

(c) examine and map existing infrastructure to identify the most urgent needs to accelerate progress in nanotechnology, in particular, for interdisciplinary R&D;

(d) build, if needed, new dedicated nanotechnology European-level infrastructure that gathers sufficient critical mass and takes also into account the needs of industry;

(e) explore the possibility of financial synergy with the European Investment Bank, European Investment Fund and Structural Funds.

3.3. Investing in human resources

To realise the potential of nanotechnology, the EU needs a population of interdisciplinary researchers and engineers who can generate knowledge and ensure that this is, in turn, transferred to industry. To properly assess and manage the human health risks of nanotechnology the EU also needs properly trained toxicologists and risk assessors. Nanotechnology, as a new and dynamic field, presents a golden opportunity to attract a greater number of young scientists and other skilled personnel to careers in research.

According to a recent report[22] there are 5.68 active researchers for every 1,000 active persons in Europe, compared to 8.08 in the USA and 9.14 in Japan. Taking into account the level of human resources associated with reaching the 3% Lisbon objective by 2010, it can be estimated that about 1.2 million additional European research personnel (including 700,000 researchers) would be needed[23]. It is essential that measures are put into place to attract and retain researchers in Europe, including the under exploited potential of women.

3.3.1. Attracting youth to "nano"

An essential ingredient of the approach presented here is to encourage the younger generation to engage in discussions about science from an early age. Anecdotal evidence shows that the likelihood to pursue science careers depends largely on the ability of school teachers, parents and the media to, as put by the Nobel laureate Richard Feynman, communicate the pleasure of "finding things out". Simple concepts of nanotechnology can be introduced by hands-on science experiments and demonstrations.

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22 European Commission "Key Figures 2003-2004" (2003), p. 44. The figure for EU refers to 2001, USA to 1997 and Japan to 2002

23 "Investing in research: An action plan for Europe" COM(2003) 226

Nanotechnology is well suited to pre-college level education since it is often taught at an integrated level and not according to discipline. It is crucial, however, that the younger generation not only gains an appreciation of research but also what researchers "do". This should help students to make informed choices by presenting research as an exciting and responsible future career option with many opportunities. Initiatives such as the "European Year of the Researcher" are valuable[24].

3.3.2. Overcoming disciplinary boundaries

Universities play a central role in the development of the Europe of knowledge[25]. Nanotechnology places great emphasis on an interdisciplinary approach. One can envisage undergraduate courses in which students continue to receive basic training in a range of disciplines regardless of the specific degree course that is being taken. This should ensure that future generations of nanotechnologists are "open-minded specialists" able to interact with their counterparts in other disciplines. Practical "training through research" could become an essential element in nanotechnology.

New forms of training, moving beyond the traditional disciplinary boundaries, should be envisaged for nanotechnology, aimed at providing world-class targeted interdisciplinary teaching at university and postgraduate level. New approaches, providing means to lever public and private funding, along with other forms of academia-industry collaboration, should also be envisaged (e.g. academic "start ups" and "venture capital universities"). This could be in the context of European-level "poles of excellence" (see Action 2) to give students an ideal opportunity for gaining "hands-on" experience of cutting-edge research.

3.3.3. Researchers and engineers with entrepreneurial mindsets

Careers in research have recently received attention at European level and a number of weaknesses highlighted including: recruitment methods; working conditions; and the differences in career opportunities for men and women[26]. In particular, obstacles to the mobility of researchers and engineers between the research and industry sectors (i.e. career evaluation via publications or patents) are cause for concern and may be detrimental for technology transfer and innovation in nanotechnology.

When aiming at a dynamic knowledge-based society, the view that education ends when employment begins is counter productive and addressed by the Action Plan for Skills and Mobility[27]. Nanotechnology is a dynamic field that requires continuous training to follow the latest developments. As nanotechnology moves closer to the market, the need for training to assist in start-up / spin-off creation, the management of IPR portfolios, safety and working conditions (including health and safety at work) and other complementary skills are important to ensure that innovators are better placed to secure funding and take forward their initiatives.

Actions: Investing in human resources

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24 "Researchers in the European Research Area: One profession, multiple careers" COM(2003) 436

25 "The role of universities in the Europe of knowledge" COM(2003) 58

26 "Researchers in the European Research Area: One profession, multiple careers" COM(2003) 436

27 "Making a European area of lifelong learning a reality" COM(2001) 678 and Commission's Action Plan for skills and mobility COM(2002) 72

3. The Commission calls upon Member States to contribute to:

(a) identifying the educational needs of nanotechnology and provide examples of best practice and/or results from pilot studies;

(b) encouraging the definition and implementation of new courses and curricula, teacher training and educational material for promoting interdisciplinary approaches to nanotechnology both at school and graduate level;

(c) integrate complementary skills into post-graduate and life-long training, e.g. entrepreneurship, health and safety issues at work, patenting, "spin-off" mechanisms, communication, etc.

The Commission sees the opportunity to:

(d) explore the feasibility for joint Marie Curie[28] call for proposals in the area of nanosciences and nanotechnology;

(e) create a "European award in nanotechnology" that would contribute towards encouraging the interdisciplinary and entrepreneurial spirit of researchers.

3.4. Industrial innovation, from knowledge to technology

In today's globalised market, long-term economic success is increasingly dependent on the generation, management and exploitation of knowledge. Investment in R&D is needed to produce knowledge and industrial innovation, in turn, needs knowledge to produce wealth. In this way, the loop is closed and fresh private capital can be injected into R&D.

How can European industry capitalise upon our strength in nanoscience to realise wealth generating products and services? The ability to unlock the potential of this knowledge via nanotechnologies is crucial for giving new impetus to industries that are no longer competitive due to strong international competition, as well as cultivating new European knowledge-based industries.

An integrated approach to innovation policy is needed[29] and will be developed in the forthcoming Innovation Action Plan[30]. Aside from common factors[31] that are crucial for all R&D including; functioning and competitive markets, a fiscal policy that supports innovation, financial instruments[32], skilled human resources, public-private partnerships and infrastructure; nanotechnology has to pay attention to three additional factors; patenting of fundamental knowledge, regulation and metrology.

3.4.1. Opportunity and challenges for existing industry

Nanotechnology offers great opportunities for companies to realise both incremental and substantial innovations. At the same time it leaves many companies vulnerable to

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28 See http://europa.eu.int/mariecurie-actions

29 "Innovation policy: updating the Union's approach in the context of the Lisbon strategy" COM(2003) 112

30 See http://europa.eu.int/comm/enterprise/innovation/index.htm

31 See e.g. "Investing in research: An action plan for Europe" COM(2003) 226

32 See e.g. "Access to finance of small and medium-sized enterprises" COM(2003) 713

the risk that they do not recognise its potential early enough and lose their competitiveness. The absence of a strong culture in Europe that supports and encourages entrepreneurial risk-taking in fields such as nanotechnology may be a deciding factor along with unfavourable framework conditions for innovation.

European industries operate in a highly competitive environment. Due to various reasons, they might be under-capitalised and can devote only limited resources to carry out R&D and innovation. Recent data show overall private R&D investment of 1.09% GNP for the EU compared to 1.85% for the USA and 2.2% for Japan[33]. While no such figures for nanotechnology are available, one can assume that the proportion of industrial investment in Europe is proportionately lower than the USA or Japan.

3.4.2. Business creation and risk capital in nanotechnology

Most areas of nanotechnology are at an early stage of their development and successful researchers are frequently turning into entrepreneurs by launching start-up companies. Out of the hundreds of such companies founded in recent years, one-half are located in the USA compared with one-quarter in the EU[34]. Taking into account that SMEs account for around two-thirds of employment in Europe, it is evident that more effort is needed to encourage the creation of new and innovative enterprises[35].

Banks and venture capitalists are very selective when offering risk capital, in particular, for areas that are perceived by them to have a high technical risk, uncertain time-to-market, or could have negative ethical, health or environmental consequences. Patents are normally needed to prove ownership of the knowledge and new entrepreneurs need not only to be at the forefront of nanotechnology but to combine this with management and business strategy acumen.

New entrepreneurs often complain that they are offered credit (instead of risk capital) and that they receive no support in management - this increases their exposure and perception of risk. Despite technological success, start-ups may fail due to lack of financial breakeven – the so-called “death valley”. This problem can be acute for nanotechnology, where the R&D process necessitates a long-term commitment. In this context, the European Investment Bank (EIB) can play an important role in providing loans and strengthening the capital base for nanotechnology enterprises.

3.4.3. Patenting

Ownership of knowledge through IPR is essential for the competitiveness of industry both in terms of attracting initial investment and for ensuring future revenue. Patents in nanotechnology have been growing steadily since the early 1980’s. The management of IPR can be challenging in a field such as nanotechnology where interdisciplinarity brings together researchers and industrialists with different cultures and attitudes.

Due to its strong emphasis on knowledge, nanotechnology is raising fundamental questions as to what should, and should not, be patentable (e.g. on the level of individual molecules). The agreement upon concepts and definitions on European,

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33 European Commission “Key Figures 2003-2004” (2003)

34 “Little science, big bucks” Nature Biotechnology, Volume 21, Number 10, October 2003, p. 1127

35 “Action Plan: The European Agenda for Entrepreneurship” COM(2004) 70

and ideally international level, will play an essential role in maintaining the confidence of investors and avoiding distortions that may arise through different local treatment, or interpretation of IPR.

3.4.4. Regulation

Appropriate and timely regulation in the area of public health, consumer protection and the environment, is essential, also to ensure confidence from consumers, workers and investors. Maximum use should be made of existing regulation. However, the particular nature of nanotechnologies requires their re-examination and possible revision. A proactive approach should be taken. Advancing knowledge in nanosciences through R&D at both European and national level should form the basis for further action in this direction.

Aside from ensuring consistency and avoiding market distortions, harmonised regulation plays a key role in minimising risk and ensuring health and environmental protection. Existing regulation relies frequently upon parameters that may turn out to be inappropriate for certain applications of nanotechnology, e.g. loose nanoparticles. For example, thresholds are often defined in terms of production volumes or mass, below which a substance may be exempt from regulation. The relevance of such thresholds should be revisited and, when appropriate, changed.

3.4.5. Metrology and standards

To ensure that the EU can realise the commercial potential of nanotechnology, industry and society will require reliable and quantitative means of characterisation as well as measurement techniques that will underpin the competitiveness and reliability of future products and services. Metrology and standards need to be developed to facilitate rapid development of the technology as well as providing users with the necessary confidence in their process and product performance.

Innovative developments in measurement techniques are needed to cope with the demands of nanotechnology. This is a challenging area of activity. At the nano-scale, it becomes difficult to disentangle the perturbing effects of measuring instruments on the measurement itself. In certain areas metrology tools are simply not available at present. Considerable pre-normative research and development are required, taking into account the needs of industry in terms of rapid measurement, and control. The European Committee for Standardisation (CEN)[36] has recently launched a working group dedicated to nanotechnology.

Actions: Industrial innovation, from knowledge to technology
4. Emphasising the benefit of a coordinated approach to stimulate innovation and entrepreneurship for nanotechnology in Europe, the Commission:
(a) calls upon the Member States to adopt conditions that promote investment in R&D by industry and new innovative enterprises according to the Lisbon objectives;
(b) highlights the need to deepen investigation into the perspectives and conditions for the successful industrial exploitation of nanotechnologies;

[36] See http://www.cenorm.be/ for further information (CEN Resolution BT C005/2004)

(c) encourages the European Investment Bank and European Investment Fund to contribute to strengthening the capital base for innovation in nanotechnology and calls upon the Member States to explore the use of Structural Funds for R&D initiatives at regional level;

(d) views a strong, harmonised and affordable IPR framework as essential to promote technology transfer and innovation;

(e) calls upon the Member States to forge closer cooperation amongst patent offices towards a more efficient global patenting system[37];

(f) invites the Member States to review existing regulation to take into account any specificities of nanotechnology and adopt a common European approach;

(g) invites the Member States to boost and coordinate activities in metrology, standards and norms in order to strengthen the competitiveness of European industry.

3.5. Integrating the societal dimension

Some people criticise the scientific community for being too far removed from the mechanisms of democracy with a lack of public understanding, public perception of risks versus benefits, and public participation and possibility of control. While the potential applications of nanotechnology can improve our quality of life, there may be some risk associated with it, as with any new technology - this should be openly acknowledged and investigated. At the same time the public's perception of nanotechnology and its risks should be properly assessed and addressed.

It is in the common interest to adopt a proactive stance and fully integrate societal-considerations into the R&D process, exploring its benefits, risks and deeper implications for society. As already identified[38], this needs to be carried out as early as possible and not simply expecting acceptance post-facto. In this respect, the complex and invisible nature of nanotechnology presents a challenge for science and risk communicators.

3.5.1. The responsible development of nanotechnology

Ethical principles must be respected and, where appropriate, enforced through regulation. These principles are embodied in the European Charter of Fundamental Rights[39] and other European and other international documents[40]. The opinion of the European Group of Ethics (EGE)[41], who are examining the ethical aspects of medical applications related to nanotechnologies, should also be taken into account.

Some of the basic ethical values include: the principle of respect for dignity; the principle of individual autonomy; the principle of justice and of beneficence; the

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37 See the final communiqué of the meeting of the OECD Committee for Scientific and Technological Policy at Ministerial Level, 29-30 January 2004 (see http://www.oecd.org/)

38 See, e.g., "Nanotechnology: Revolutionary opportunities & societal implications", 3rd Joint EC-NSF Workshop on Nanotechnology, Lecce, Italy (2002), and "The social and economic challenges of nanotechnology", ESRC, UK (2003)

39 See http://www.europarl.eu.int/charter/default_en.htm

40 See http://europa.eu.int/comm/research/science-society/ethics/legislation_en.html

41 See http://europa.eu.int/comm/european_group_ethics/index_en.htm

principle of freedom of research; and the principle of proportionality. The relevance of such principles towards human and non-human applications of nanotechnology should be understood. In addition, certain applications, e.g. miniaturised sensors, may have specific implications for the protection of privacy and personal data.

An open, traceable and verifiable development of nanotechnology, according to democratic principles, is indispensable. Despite some calls for a moratorium on nanotechnology research, the Commission is convinced that this would be severely counter-productive. Apart from denying society the possible benefits, it may lead to the constitution of "technological paradises", i.e. where research is carried out in zones without regulatory frameworks and is open to possible misuse. Our consequent inability to follow developments and intervene under such circumstances could lead to even worse consequences. The Precautionary Principle[42], as used up to now, could be applied in the event that realistic and serious risks are identified.

3.5.2. Information, communication and dialogue: Understanding the invisible

"What is nanotechnology?" An opinion poll of over 16,000 individuals in 2001[43] indicated that nanotechnology is poorly understood. Since it is complex and concerns a scale that is invisible, nanotechnology may be a difficult concept for the public to grasp. Headlines about e.g. self-replicating nano-robots, that are well beyond our present capability but are often presented as an immediate risk, demonstrate that there is an urgent need to provide information about present-day nanotechnology research and its possible applications. For example, the "nanoTruck"[44] is an excellent example of ways in which the public awareness of nanotechnology can be raised.

Without a serious communication effort, nanotechnology innovations could face an unjust negative public reception. An effective two-way dialogue is indispensable, whereby the general publics' views are taken into account and may be seen to influence decisions concerning R&D policy[45]. The public trust and acceptance of nanotechnology will be crucial for its long-term development and allow us to profit from its potential benefits. It is evident that the scientific community will have to improve its communication skills.

Actions: Integrating the societal dimension
5. Highlighting the need to devote due attention to the societal aspects of nanotechnology, the Commission:
(a) calls upon Member States to pursue an open and proactive approach to governance in nanotechnology R&D to ensure public awareness and confidence;
(b) encourages a dialogue with EU citizens/consumers to promote informed judgement on nanotechnology R&D based on impartial information and the exchange of ideas;

42 "Communication from the Commission on the Precautionary Principle" COM(2000) 1

43 European Commission "Europeans, Science and Technology" Eurobarometer 55.2, December 2001

44 See http://www.nanotruck.net for further information.

45 "Science and Society - Action plan", COM(2001) 714

(c) reaffirms its commitment to ethical principles in order to ensure that R&D in nanotechnology is carried out in a responsible and transparent manner.

4. PUBLIC HEALTH, SAFETY, ENVIRONMENTAL AND CONSUMER PROTECTION

Scientific investigation and assessment of possible health or environmental risks associated with nanotechnology need to accompany the R&D and technological progress. Some dedicated studies are underway to assess the potential risks, which are also examined within FP6 IPs and NEs projects in the field of nanotechnology. In particular, nanoparticles might behave in unexpected ways due to their small size[46]. They may present special challenges, for example, in terms of production, disposal, handling, storage and transport. R&D is needed to determine the relevant parameters and prepare for regulation, where necessary, taking into account the full chain of actors, from researchers, workers to consumers. This R&D also needs to take into account the impacts of nanotechnologies throughout the whole of their life-cycle, for example, by using Life-Cycle Assessment Tools. Since such issues are of global concern, it would be advantageous to systematically pool knowledge at international-level.

More generally, public health, environmental and consumer protection require that those involved in the development of nanotechnologies—including researchers, developers, producers, and distributors—address any potential risk upfront, as early as possible, on the basis of reliable scientific data and analysis, using appropriate methodologies. This presents a challenge since predicting the properties of nanotechnology-based products is difficult because it requires that classical physics and quantum mechanical effects are both taken into account. In many ways, engineering a substance with nanotechnology can be likened to creating a new chemical. As a result, addressing the potential risks of nanotechnologies to public health, the environment and consumers will require evaluating the possible re-use of existing data and generating new, nanotechnology-specific data on toxicology and ecotoxicology (including dose response and exposure data). This also calls for examining and, if required, adjusting risk assessment methods. In practice, addressing the potential risks associated with nanotechnologies necessitates that risk assessment be integrated into every step of the life cycle of nanotechnology-based products.

Actions: Public health, safety, environmental and consumer protection
6. In support of a high level of public health, safety, environmental and consumer protection, the Commission highlights the need:
(a) to identify and address safety concerns (real or perceived) at the earliest possible stage;
(b) to reinforce support for the integration of health, environmental, risk and other related aspects into R&D activities together with specific studies;

[46] See e.g. the EC-funded projects: Nanopathology "The role of nano-particles in biomaterial-induced pathologies" (QLK4-CT-2001-00147); Nanoderm "Quality of skin as a barrier to ultra-fine particles" (QLK4-CT-2002-02678); Nanosafe "Risk assessment in production and use of nano-particles with development of preventive measures and practice codes" (G1MA-CT-2002-00020)

(c) to support the generation of data on toxicology and ecotoxicology (including dose response data) and evaluate potential human and environmental exposure.

The Commission calls upon the Member States to promote:

(d) the adjustment, if necessary, of risk assessment procedures to take into account the particular issues associated with nanotechnology applications;

(e) the integration of assessment of risk to human health, the environment, consumers and workers at all stages of the life cycle of the technology (including conception, R&D, manufacturing, distribution, use, and disposal).

5. A FURTHER STEP: INTERNATIONAL COOPERATION

International cooperation is a key asset to advance R&D and the FP6, for example, is open to the world since it allows research teams from virtually all countries to participate in projects. This is particularly important for nanotechnology, where much basic knowledge is needed and many scientific and technical challenges remain - a global critical mass may be needed. International co-operation can accelerate R&D by overcoming knowledge gaps more rapidly and, for example, helps to pave the way for new metrology solutions and norms.

Several countries have concluded scientific and technical co-operation agreements with the EU incorporating nanotechnology. In particular, one implementing arrangement exists between the European Commission (EC) and the National Science Foundation (NSF, USA), the other with the Ministry of Science and Technology (MOST, China). Such implementing arrangements form a framework for reinforced cooperation and allow joint initiatives to be launched. Since 1999 EC-NSF co-ordinated calls have been launched and some 20 projects launched.

Building upon the experience of the FP6, reinforced international cooperation in nanosciences and nanotechnologies is needed both with countries that are more economically advanced (to share knowledge and profit from critical mass) and less economically advanced (to secure their access to knowledge and avoid any "knowledge apartheid"). In particular, there is an urgent need to share knowledge in the health, safety and environmental aspects of nanotechnology for the benefit of all citizens.

Common shared principles for R&D in nanotechnology could be embodied in a voluntary framework (e.g. a "code of good conduct") to bring the EU together with countries who are active in nanotechnology research and share our commitment to its responsible development. Preliminary exchanges of views with representatives from e.g. USA, Japan, Switzerland and Russia are very encouraging in this respect and could pave the way for further initiatives.

Actions: International Cooperation
7. The Commission will, in compliance with its international obligations and notably those relating to the World Trade Organisation, promote:

(a) international debate or consensus on issues that are of global concern, such as, public health, safety, the environment, consumer protection, risk assessment, regulatory approaches, metrology, nomenclature and norms;
(b) access to basic knowledge in less industrialised countries so to contribute towards the prevention of any “knowledge apartheid”;
(c) monitoring and sharing of information related to the scientific, technological, economic, and social development of nanotechnologies;
(d) the definition of an international “code of good conduct” so as to secure global agreement on base principles for the responsible development of nanotechnology.

ANNEX: AN ESTIMATE OF PUBLIC FUNDING IN NANOTECHNOLOGY

(Note that the data presented in the following have been derived from several sources[47])

Fig. 1: Overall levels of public expenditure in nanotechnology in 2003 for: Europe (including CH, IL and NO as FP6 Associated countries), Japan, USA and others (1€ = 1$).

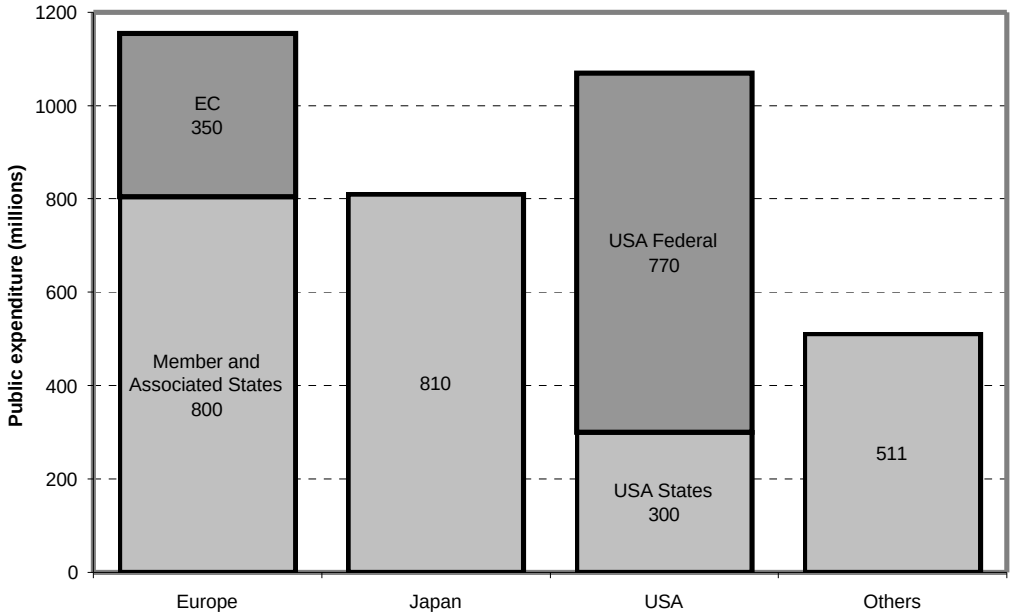
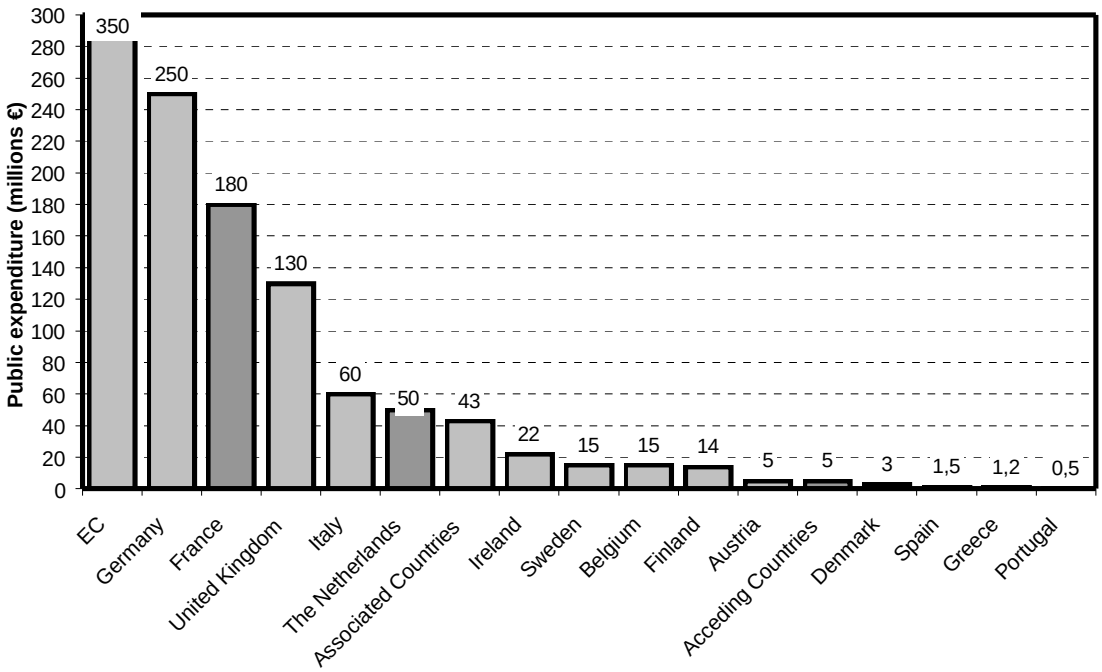


Fig. 2: Level of funding for EU-15 along with some Acceding (CZ, LV, LT, SI) and the main Associated countries (CH, IL and NO) and EC in absolute € terms in 2003.



47 Asia (APNF, ATIP, nABACUS); Europe (Bundesministerium für Bildung und Forschung (Germany), Enterprise Ireland, General Secretariat for Research (Greece), Inspection générale de l'administration de l'éducation nationale et de la recherche (France), Nanoforum, National Contact Points, CORDIS Nanotechnology Database, various sources); USA (NSF); Others (various sources)

Fig. 3: Level of funding for major third countries (excluding USA and Japan) with nanotechnology programmes in absolute $ terms in 2003. The potentially large differences in purchasing power should be taken into consideration when reading these figures.

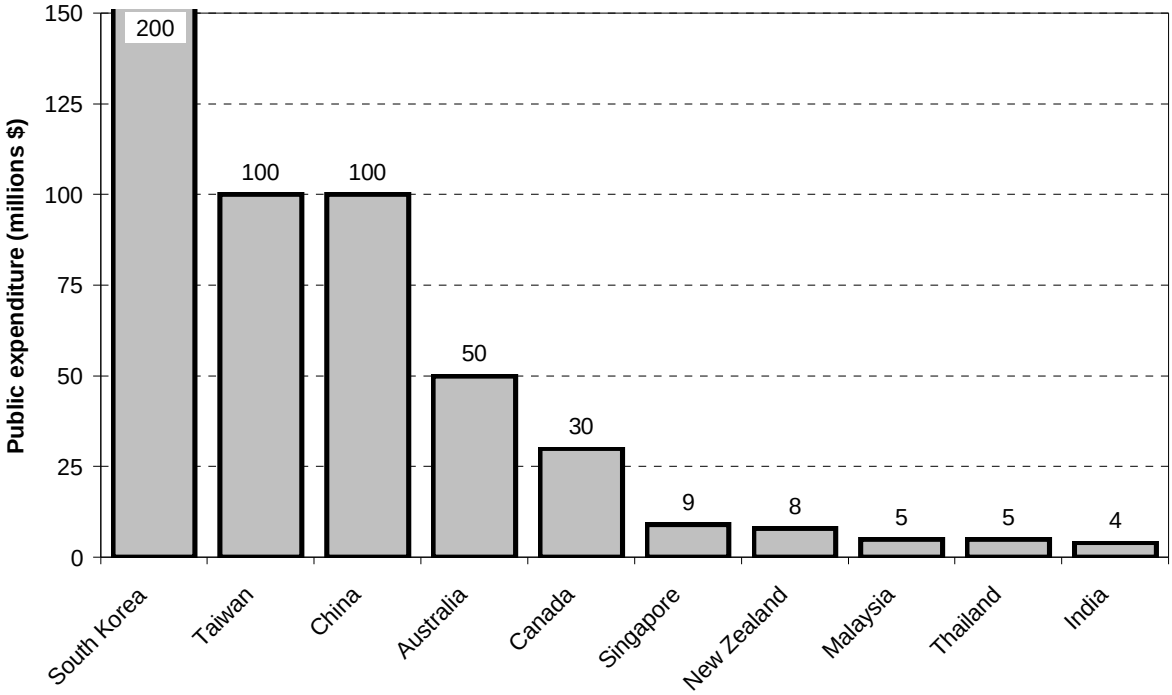
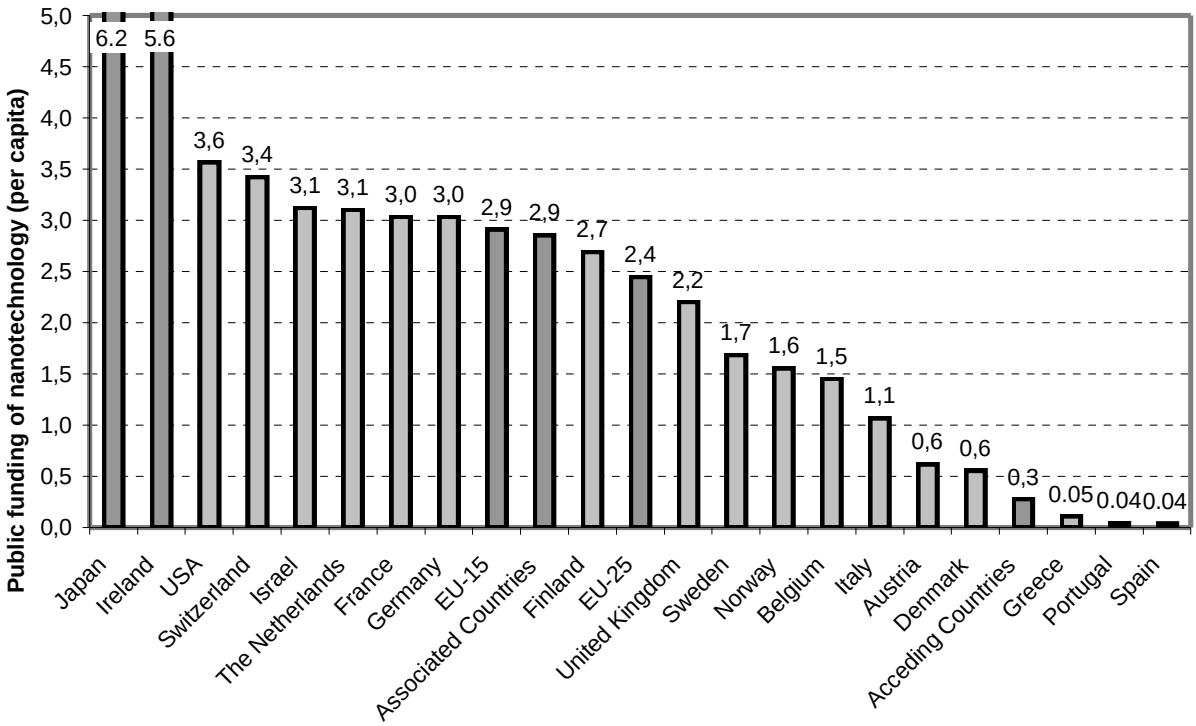


Fig. 4: Comparative funding levels between EU-15, EU-25 some Acceding countries (CZ, LV, LT, SI), main FP6 Associated countries (CH, IL and NO), USA and Japan on a per-capita basis in 2003 (1€ = 1$).



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 7.6.2005
COM(2005) 243 final

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

EN EN

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 Union[1].

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;

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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 2004[3], 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 approach[4].

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 elsewhere[5].

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:

a) 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;

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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 Nanoelectronics[9], 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 devices[10];

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 objectives[11]. 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.

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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].

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[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 2006[13];

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).

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[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 system[15];

d) To support technology transfer in N&N by taking advantage of the pan-European Innovation Relay Centre (IRC) network[16] 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.

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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&N[17];

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 films[18], brochures and other internet-based material[19];

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.

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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 Community[20]. 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 increase[21]. 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 2004-2010[22] and the Community Strategy on Health and Safety at Work[23] provide basis for future possible initiatives. The Commission proposal on REACH[24] 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;

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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 Funding[25].

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 Goals[26] 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 level[27], 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.

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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

COMMISSION OF THE EUROPEAN COMMUNITIES

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

Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007

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

Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007

Nanotechnology provides important potential for boosting quality of life and industrial competitiveness in Europe. Its development and use should not be delayed, unbalanced or left to chance. The European Commission (EC) plays two important roles in the development of nanosciences and nanotechnologies (N&N); as policy maker and as funding body for research and innovation. The "integrated, safe and responsible approach" proposed by the EC in 2004[1] has been agreed by stakeholders and is now the core of the EU's nanotechnology policy. Resources have been mobilised and challenges addressed, as called for by the EC. The Action Plan[2] provided impetus for developments, and progress in almost every area has been identified. While it is difficult to collect all quantitative indicators for the period 2005-2007, a positive impact can nonetheless be seen. Over the last two years, European research in N&N has benefited from considerable financial support, complemented by increased coordination and coherence in relevant policy areas. EU Institutions, Member States, industry, researchers and other interested parties have worked together, sharing information and regularly consulting one another, so that by and large, Europe has been "talking with one voice". Efforts have also been made to work more closely with international partners, bi- and multi-laterally.

International competition increased markedly during 2005-2007, challenging European progress. Some weaknesses are becoming apparent in Europe, in particular a shortage of private investment in research and industrial innovation, a lack of leading interdisciplinary infrastructures, and an increasing risk of duplication and fragmentation in research efforts due to rising investment by the Member States. Such potential duplication and fragmentation should be avoided, and coherence, synergy and subsidiarity should feature in all EU actions. Furthermore, by its own interdisciplinary and novel nature, nanotechnology may challenge established approaches in research, education, patenting and regulation. In the coming years, activities should be consolidated, building on the existing momentum, and paying special attention to the development of interdisciplinary infrastructures; appropriate conditions for the safe and effective use of nanotechnology; and a shared understanding of the responsibility of researchers within an ethical framework.

This report summarises the actions taken and progress made during 2005-2007 in relation to the key areas identified in the N&N Action Plan for Europe 2005-2009.

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1 *Towards a European Strategy for Nanotechnology*, COM(2004)338

2 *Nanosciences and nanotechnologies*: *An action plan for Europe 2005-2009*, COM(2005)243

1. RESEARCH, DEVELOPMENT AND INNOVATION: EUROPE NEEDS KNOWLEDGE

Support for research and technological development (R&D) came from both the EC and EU Member States, with particular emphasis on coordination of policies, programmes and projects. Under the 6th Research Framework Programme (FP6, 2002-2006) funding of almost EUR 1.4 billion was provided to more than 550 projects in N&N. By contrast, the EC contribution was about EUR 120 million in FP4 (1994-1998) and EUR 220 million in FP5 (1998-2002). Over its lifetime, FP6 accounted for almost a third of total public expenditure in Europe for N&N.

Global expenditure in N&N, both public and private, in the period 2004-06 was around EUR 24 billion. Europe accounts for more than a quarter of this worldwide total, with the EC funding directly accounting for 5-6%.

In terms of public funding, Europe has become the largest investor worldwide. In terms of private funding, however, Europe is at a significant disadvantage to the US and Japan. The EU has set a target of investing 3% of its GDP in R&D, with two-thirds coming from industry. However, private spending on R&D currently accounts for about 55% and this trend is also visible in the nanotechnology sector. On the other hand, the private sector is making progress in this area, as part of its activities in the different European Technology Platforms (ETPs) and its various contributions highlighted elsewhere in this document.

Under FP7, EC funding for N&N is expected to increase significantly. The average yearly funding is likely to be more than double that in FP6. This is thanks to increases in the "Cooperation" specific programme and the significant reinforcement of "bottom-up" actions in the "Ideas" and "People" specific programmes. Funding in the latter is almost four times that in the corresponding activities of FP6 (NEST and Marie Curie). In addition to this overall growth, the growing interest in N&N may increase the *share* of the funding from "bottom-up" actions. Additional funding may come from the cross-thematic approaches developed in FP7, as nano-, bio- and information technologies have an interdisciplinary character and can contribute to different industrial sectors and policy objectives (e.g. in health, food, energy, environment and transport).

The first calls for proposals under FP7, published in December 2006, included almost 60 calls and topics directly relevant to N&N, in the broad areas of nanosciences, technology development, impact assessment, societal issues, nanomaterials, nanoelectronics, nanomedicine, as well as training and European Research Council (ERC) grants. Moreover, direct R&D actions related to N&N, in areas such as nanomaterials, nanobiotechnology, risk assessment and metrology, have been included in the Multi-Annual Work Programme of the Commission's Joint Research Centre (DG JRC).

Research into the potential impact of nanotechnologies on health and the environment has been boosted, with emphasis on capacity building. Some EUR 28 million from FP5 and FP6 has been dedicated to projects expressly focused on environmental and health aspects of N&N. Such research will significantly increase in FP7, both in size and scope, subject to absorption capacity. Relevant topics, selected after a public consultation in 2006, were included in the first calls.

Several European Technology Platforms (ETPs) are dedicated to nanotechnology applications, such as Nanoelectronics (ENIAC),[3] Nanomedicine[4] and Sustainable Chemistry,

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[3] http://www.eniac.eu/

[4] http://cordis.europa.eu/nanotechnology/nanomedicine.htm

and have produced vision papers and strategic research agendas. Other ETPs particularly relevant to N&N include Advanced Engineering Materials and Technologies, Hydrogen and Fuel Cell Technology, Industrial Safety (Nanosafety hub) and Photonics21, which includes nanophotonics and nanobiophotonics. ETP priorities are being taken on board in FP7 calls for proposals.

The FP6 ERA-NET scheme supports the coordination of national research programmes, for example Nanoscience Europe (NanoSci-ERA), Micro- and Nanotechnology (MNT ERA-Net) and Materials Science and Technology (MATERA). This scheme will be continued in FP7 and boosted with the introduction of the ERA-NET Plus.[5] The first calls include an ERA-NET Plus for nanosciences. COST, the intergovernmental network for cooperation in science and technology, has also played a valuable role in nanoscience coordination, as demonstrated by the European Nanoscience Forum organised in October 2006 by the EC, COST, ESF, the European Parliament's STOA (Scientific and Technological Options Assessment) and Nanoscience Europe.

2. INFRASTRUCTURE AND EUROPEAN POLES OF EXCELLENCE

The availability of infrastructures of excellence, critical mass and interdisciplinary character is a major challenge for the future progress of R&D and industrial innovation in Europe.

The EC has supported N&N research infrastructures in FP6 (with EUR 40 million) and this support will continue in FP7, in the "Capacities" specific programme. This is for access to existing infrastructures and the development of future infrastructures, but does not extend to their construction. That responsibility lies mainly with the Member States. In September 2006 the European Strategy Forum on Research Infrastructures (ESFRI) adopted its roadmap, which provides vital planning input to the EC and Member States. It identified 35 projects in all areas, including a Pan European Infrastructure for Nanostructures and Nanoelectronics (PRINS). The appropriateness of a novel infrastructure in nanobiotechnology is being explored.

The integration of existing resources and expertise has also benefited considerably from ETPs and collaborative R&D projects, most notably networks of excellence, which may well lead to new European infrastructures (e.g. the Nanoquanta[6] and Nano2Life[7] networks). This indirect effect on capacity building is expected to continue in FP7, in the "Cooperation" specific programme.

3. INTERDISCIPLINARY HUMAN RESOURCES: EUROPE NEEDS CREATIVITY

N&N often benefit greatly from interdisciplinary approaches, which may challenge more traditional education and training schemes. New goods, services and production methods will determine the demand for new and different jobs. A workshop dedicated to the education and research training needs for N&N was held in Brussels in April 2005.

The Commission has been active in this area, with both its educational programmes (managed by DG Education and Culture) and schemes for the mobility and training of researchers

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5 In this scheme the EC contributes to both coordination and the funding of the joint trans-national call, up to 1/3 of the total.

6 http://www.nanoquanta.eu/ http://www.etsf.eu/

7 http://www.nanotolife.com/

(managed by DG Research). These forms of support are expected to increase in the coming years.

Within Erasmus Mundus, Masters Degrees in some areas of N&N have been developed.[8] There has also been significant support for training in N&N through the Marie Curie actions of FP6, with grants of EUR 161 million, some 8% of their total budget.

As to prizes for work in N&N, three of the 20 Marie Curie Awards of FP6 (EUR 50,000 each) were given to researchers for their work in N&N. In some Member States (e.g. Germany and Italy), dedicated awards have been introduced. It thus seems unnecessary for the EC to create a dedicated award.

Training activities in N&N are expected to be funded under the "People" programme of FP7 (e.g. Initial Training Networks), as they were under FP6. Education and training are also often addressed as part of collaborative R&D projects and networks of excellence (e.g. Nanobeams created a European PhD School focusing on characterisation techniques using ions and electrons). The role of women in N&N is the focus of a dedicated FP6 project.

N&N has also attracted the interest of the young, as evidenced by strong participation in EC-funded and other EU activities, such as the German NanoTruck. The Commission has also published a set of slides in 20 languages so far, which proved popular in schools as a tool for explaining N&N.

4. INDUSTRIAL INNOVATION: FROM KNOWLEDGE TO THE MARKET

A specific goal of the Commission's actions in N&N is to improve the competitiveness of European industry. This is done primarily by generating knowledge, to move from a resource-intensive industry to a knowledge-intensive one. It is also done by bringing about step changes through research and supporting the development of new applications resulting from the interplay of different technologies and disciplines. Industrial innovation presents some inertia and one role of public authorities is to implement measures to overcome it.

The Commission is encouraging the participation of industry, and SMEs in particular, in collaborative R&D projects in FP7, as in FP6. FP6 saw a marked increase in the industrial participation in NMP projects related to N&N, from 18% in 2003-2004 to 37% in 2006. In FP7, there is more emphasis on meeting the R&D needs of industry, for example by taking on board elements from the strategic research agendas of ETPs. In the case of manufacturing nano-chips, a joint technology initiative (JTI) has been proposed, building on the work of ENIAC in nanoelectronics.

New important measures are being introduced to foster industrial innovation: The Risk Sharing Finance Facility, undertaken by the European Investment Bank with FP7 support, will improve access to debt finance for participants in R&D projects. The Guarantee Fund (combined with new financial liability rules) in FP7 will facilitate the participation of SMEs in particular. The "Competitiveness and Innovation Programme 2007-2013" (CIP), with a budget of about EUR 3.6 billion, will also support innovation through three specific programmes, all potentially relevant to innovation based on N&N (Entrepreneurship and Innovation Programme; ICT Policy Support Programme; and Intelligent Energy-Europe Programme).

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[8] http://www.emm-nano.org/
http://www.u-picardie.fr/mundus_MESC/
http://www.ens-cachan.fr/monabiphot/

Additional services are being offered to consortia, such as the exploitation strategy seminars for projects funded under the NMP priority, to help them capitalise on their research results. Throughout Europe, several events have been organised to stimulate the interest of industry, such as the EuroNanoForum 2007 in Düsseldorf; or the Nano2Business workshops in Warsaw and Helsinki, both organised by the Nanoforum project.

The development of roadmaps leading to industrial applications (e.g. of nanomaterials) has been supported in FP6 by a wide dissemination of their findings to European industry (e.g. NanoRoadSME and NanoRoadMap). This activity has reinforced the work done by the ETPs, for example ARTEMIS (embedded computing systems), ENIAC (nanoelectronics), EPoSS (smart systems integration), FTC (future textiles and clothing), ManuFuture (future manufacturing technologies), NanoMedicine, Industrial Safety and SusChem (sustainable chemistry). Further examples include the Working Group on Micro- and Nano-Manufacturing (MINAM) and the MNT ERA-Net in the same field. The CONCORDE-NSOCRA coordination action on nano-structured oxide catalysts clearly showed the positive impact of N&N on the energy efficiency of industrial processes and the environment.

The opportunities and risks for future developments of N&N in Europe must be understood. To do so, the markets for nanotechnology products; the composition of the industries affected; the competitiveness of European industry; the implications of the societal and safety dimensions; and the barriers hampering development must be examined. The JRC is coordinating a socio-economic study related to these fields. This study will build upon the output of FP6 projects and other activities outlined above.

There is an important role for standardisation at European and international level. The Commission (primarily through the JRC) plays an important guiding role in the activities of standardisation bodies, namely CEN and ISO.

The Commission has also given mandates for actions to the European standards bodies CEN, CENELEC and ETSI. To ensure transparency and a coordinated position among EU national authorities, the EC adopted a mandate in April 2007 inviting these bodies to present a standardisation programme. This is expected by the end of 2007 and should take account of the need for a revision of existing standards or the development of new ones, in relation to health, safety and environmental protection. Several aspects (e.g. the development of nomenclature, standard test methods) require international collaboration to ensure the compatibility of scientific data and international harmonisation of scientific methods used for regulatory purposes. The mandate therefore clearly expresses the idea that European standards be developed in cooperation with ISO, the international standards body.

Pre-normative R&D (that is, R&D supporting standards and metrology) has been supported in FP6 (e.g. Nanostrand and Nanotransport) and further support will be provided in FP7 (e.g. for the coordination of nanometrology). This coordination at European level will be extended and harmonised through global fora such as VAMAS (pre-normative) and CIPM (metrology).

The European Patent Office (EPO) is facing the challenges presented by the registration of nanotechnology applications, and has introduced a “nano tagging”. Collaboration between the Commission and EPO has increased, leading to the jointly organised international workshop “IPR in Nanotechnology” in April 2007.

Regarding patents, a preliminary comparison of FP5 and FP6 indicates that patent applications originating from N&N projects (in Growth and NMP) more than doubled in the first two years of FP6. In FP7, the scale-up of promising technological solutions will be supported with dedicated funding, such as nanotechnology-based pilot lines.

5. INTEGRATING THE SOCIETAL DIMENSION: ADDRESSING EXPECTATIONS AND CONCERNS

Societal acceptance is a key aspect of the development of nanotechnologies. The Commission's role as a policy making body is to take account of people's expectations and concerns. Not only should nanotechnologies be safely applied and produce results in the shape of useful products and services, but there should also be public consensus on their overall impact. Their expected benefits, as well as potential risks and any required measures, must be fully and accurately presented and public debate must be encouraged, to help people form an independent view. The Commission has played a pivotal role in this area.

The Commission has funded or directly published a wide range of information material in many languages and for various age groups, including films. The intention is that at least basic information be available in the EU languages. Undoubtedly there is a role for scientists here, who can explain the principles and applications of nanotechnology to the general public and the press. To support them in these public outreach activities, the Commission has made available the handbook "Communicating Science, a Survival Kit for Scientists". Two web sites, http://ec.europa.eu/nanotechnology/ and http://www.nanoforum.org, are a useful resource. Studies on social acceptance have been carried out through dedicated projects within FP6. The Nanologue project developed three possible scenarios of the future development of nanotechnologies in its report "The future of nanotechnology: We need to talk", and developed a "NanoMeter" giving guidance on potential ethical and social issues. The NanoDialogue project organised exhibitions on nanotechnology in eight countries, thereby promoting social information and dialogue in the form of focus groups and public debates. Results and recommendations were presented at an open final conference in February 2007. Other projects such as NanoBio-RAISE are continuing with this public dialogue, and support for further actions in this field is expected in FP7.

The methodology of public dialogue in nanotechnology was examined during an international workshop in February 2007, involving science communicators. A final report will be published, taking into account the input received.

Potential ethical issues were examined for all R&D projects considered under FP6, with ethical reviews carried out where appropriate. This practice will continue in FP7. The European Group on Ethics in Science and New Technologies (EGE), an advisory body to the EC President, delivered an opinion on nanomedicine in January 2007.[9] The opinion recognises the potential of nanomedicine in developing new diagnostic, treatment and preventive methods. It places emphasis on conducting research both into the safety and the ethical, legal and societal aspects of nanomedicine. It proposes setting up a European network on the ethics of nanomedicine and suggests further monitoring of the current legal situation, but does not call for specific legislation at this stage. These points will be taken on board in FP7.

Commission[10] and other surveys indicated that much of the European public is still not sufficiently aware of N&N. However, these surveys also show that public confidence in European public authorities' ability to ensure good governance for nanotechnology is higher in Europe than elsewhere.

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[9] http://ec.europa.eu/european_group_ethics/avis/index_en.htm

[10] http://www.ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf

Member States and international organisations have also been active in this field and various initiatives have taken place, such as by Greenpeace and Demos in the UK, and Vivagora in France.

With the intention to strengthen a culture of responsibility, the EC has launched a public consultation to contribute to the definition of some basic principles for the responsible governance of nanotechnology research. The "Augsburg Materials Declaration" and the position taken by Degussa GmbH already reflect this intention.

6. PUBLIC HEALTH, SAFETY, ENVIRONMENTAL AND CONSUMER PROTECTION

While N&N offer a number of beneficial applications, the potential impact on the environment and human health of certain "nanomaterials" and "nanoproducts" is not yet fully understood. The overarching aim of the Commission's work in the area of health, safety and the environment is to enable the safe development and use of N&N and ensure that the public can benefit from the innovations that they may bring, while being protected from any adverse impacts.

Different approaches, both regulatory and non-regulatory, are being pursued to do this:

- Examining whether current legislative frameworks offer sufficient protection, or whether modifications or new legislation is needed.
- Improving the knowledge basis, via research, scientific committees, information sharing and cooperation, including at international level.
- Involving the public through stakeholder dialogues, voluntary initiatives etc.

6.1. Regulatory review

The Commission is finalising a review of current regulation, to establish whether new regulatory action is required to cover risks in relation to nanomaterials. Its initial finding is that current regulation addresses in principle concerns about health and environmental impacts. On the basis of scientific developments or regulatory needs in specific areas, regulatory changes may be proposed. In the course of this exercise, the EC will take account of reports on regulatory gaps produced in various Member States.

Having said that, the primary means to protect health, safety and the environment is by improving the implementation of current regulation. National authorities and the Commission must therefore first ascertain whether it is necessary to update current texts, such as implementing legislation, standards and technical guidance, with regard in particular to risk assessment. In the meantime, and in the light of the continuous generation of new data, existing methods will continue to be used on a case by case basis. Where necessary, existing regulatory mechanisms should be used, in relation to thresholds, authorisation of substances and ingredients, qualification of waste as hazardous, reinforcing conformity assessment procedures, introducing restrictions on the marketing and use of chemical substances and preparations, and so on.

Particular attention must also be given to the various mechanisms that allow authorities and agencies in charge of implementing legislation to intervene, through measures such as safeguard clauses and warning systems, in case risks are identified for products already on the market.

Finally, authorities will have to ensure that regulatory priorities are covered by calls for proposals under FP7 and that the outcome of research is scrutinised for its regulatory usefulness.

6.2. Addressing knowledge gaps

Since 2005, a global consensus has emerged on the urgent need for scientific knowledge of the safety aspects of manufactured nanomaterials. Priorities were identified, at national, EU and international level, and were addressed by a number of initiatives:

– Data on potential risks to humans and the environment, as well as test methods to generate them.

– Data on exposures throughout the life cycle of nanomaterials or products containing them; and exposure assessment methods.

– Measurement, characterisation methods for nanomaterials, reference materials, and sampling and analytical methods to deal with exposures.

On 10 March 2006, at the Commission's invitation, the Scientific Committee on Emerging and Newly Identified Risks (SCENIHR) adopted after public consultation an opinion on risk assessment in relation to nanotechnologies.[11] According to the SCENIHR, although the existing toxicological and ecotoxicological methods are appropriate to assess many of the hazards associated with nanoparticles, they may not be sufficient to address all the hazards. Because of uncertainties, the current risk assessment procedures require modification for nanoparticles. Knowledge gaps have been confirmed in areas such as nanoparticle characterisation, detection and measurement; their fate and persistence in humans and the environment; and all aspects of the associated toxicology and ecotoxicology. These should be addressed to allow satisfactory risk assessments for humans and ecosystems.

The EC therefore requested the SCENIHR to carry out a more detailed analysis of the current risk assessment methodology as laid down in the Technical Guidance Documents for chemicals, and its opinion was adopted after public consultation on 21-22 June 2007.[12] The SCENIHR concluded that, while the current methodologies are generally likely to be able to identify the hazards associated with the use of nanoparticles, modifications of the existing guidance will be necessary. It identifies issues requiring improvements in the technical guidance and methodologies, and proposes a staged strategy for the risk assessment of nanomaterials.

As to cosmetics, the EC invited the Scientific Committee on Consumer Products (SCCP) to review and if appropriate amend its Notes of Guidance for the testing of ingredients and to evaluate the safety of cosmetic ingredients in the form of nanoparticles.[13] The SCCP approved an opinion for public consultation on 19 June 2007,[14] concluding that it is necessary to review the safety of the nanomaterials presently used in sunscreens in the light of recent information; and stressing the possible influence of physiologically abnormal skin and mechanical action on skin penetration.

6.3. Research on safety aspects

Research on safety aspects is expressly addressed by EC funding for N&N (section 1). The general aim is to support the scientific assessment of the potential health, safety and

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[11] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf
[12] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf
[13] http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_nano_en.pdf
[14] http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_099.pdf

environmental risks associated with nanotechnology-based materials and products, at the earliest possible stage, to close knowledge gaps and provide a basis for meeting regulatory requirements. If the need arose, this research could contribute to the development of new requirements for a safe, responsible and sustainable development of N&N. Topics in the first call for proposals of FP7 include easy-to-use portable devices; the impact of engineered nanoparticles on health and the environment with a critical review of the data; a commented database on nanoparticle impact; coordination in studying the impact of nanotechnology-based materials and products; and alternative strategies for the toxicological assessment of nanoparticles used in medical diagnostics.

The JRC, meanwhile, is focusing on the development and harmonization of methods for the characterization and toxicity testing of manufactured nanomaterials (e.g. particle size measurements, *in vitro* testing of a representative set of nanomaterials on critical cell lines); related studies on reference materials and dosimetry; studies on the applicability of computational methods for assessing nanoparticle properties, including toxicity; and database development.

Several documents were produced in the context of the ETP on Sustainable Chemistry (SusChem),[15] such as a code of conduct on nanotechnology; a guide on safe manufacturing and activities involving nanoparticles at workplaces; and detailed information on nanomaterial characterisation. The Nanosafety Hub event held in Brussels in March 2007 by the ETP on Industrial Safety (ETPIS)[16] looked at progress in monitoring technologies related to nanoparticle toxicity; and workplace and environmental safety in connection with nanomaterials. In this context, it is also important to note voluntary approaches by industry[17] in publishing guides on the safe manufacturing and handling of nanomaterials at workplaces.

6.4. International collaboration in the health and environment area

Several safety aspects require international collaboration, such as the development of common nomenclature, standards and test methods, to ensure that data can be compared globally and that methods used for regulatory purposes are internationally harmonised.

A principal forum for the coordination of activities at the international level has been provided by the OECD Working Party on Manufactured Nanomaterials.[18] This has a working programme with six specific projects, tackling *inter alia* knowledge gaps with regard to health and environmental impact, databases, test systems, guidelines, risk assessment methodologies, and the exchange of information on voluntary schemes and regulatory approaches. The Commission, with the support of its Scientific Committees, as well as other European bodies, is expected to continue contributing to these international efforts.

Also important are the activities in ISO/TC 229 to develop standard methods and nomenclature, in which the EC and Member States are already actively involved.

FP7 funding has been opened to research teams from virtually all countries in the world. The possibility of a coordinated call, joining research efforts on both sides of the Atlantic, has been intensively discussed with various US Federal Agencies. It is therefore welcome that the US Agencies EPA, NSF and DoE on their part launched a joint solicitation encouraging US

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15 www.suschem.org
16 www.industrialsafety-tp.org
17 e.g. Basf and Bayer
18 http://www.oecd.org/about/0,3347,en_2649_37015404_1_1_1_1_37465,00.html

researchers to collaborate with European teams.[19] The recommendation to European researchers to work with US teams was included in the first call for proposals of FP7.

A workshop on the life cycle assessment of nanotechnology-based products was jointly organised by the Commission, the US Environmental Protection Agency (EPA) and the Woodrow Wilson International Centre for Scholars in October 2006.[20]

7. INTERNATIONAL COOPERATION

In line with the mandate received from the EU Council in September 2004, the Commission has intensified the dialogue on nanotechnology at international level, at both bi- and multi-lateral levels, conforming to the principle of subsidiarity. This involves economically and industrially advanced countries (to share knowledge and profit from critical mass), and also those less advanced (to secure their access to knowledge and avoid any "nano divide").

In R&D, cooperation appears particularly promising in nanosciences and nanomaterials, as well as in selected targeted fields, such as nanoparticle safety, or actions paving the way to a level playing field for nanotechnology-based products in the globalised market (e.g. pre-normative research). The EC has been attentive to inputs from non-EU or international stakeholders, such as from the initiative "Nanotechnology and the Poor: Opportunities and Risks" of the Meridian Institute.

FP7 – to an even greater extent than FP6 – is open to researchers from outside the EU, with EU funding in the case of most countries. Dedicated pilot actions have been launched, such as NanoForum EU-Latin America and EuroIndiaNet. The mobility of researchers and mutual access to top infrastructures are also addressed.

The possibility of a "code of good conduct" for the responsible development and use of N&N has been explored at international level, but there has not been unanimous worldwide agreement on the Commission's proposals. As mentioned above, the Commission has launched a public consultation addressing basic principles for the responsible governance of nanotechnology research, in which third countries may be interested in participating.

A dedicated international dialogue has been launched with meetings in Alexandria (USA) in 2004 and Tokyo in 2006, and two preparatory meetings in Brussels and Cape Town. The third international dialogue is planned for 2008 in Europe.

The Commission's action has included the following:

- Participating in CEN and ISO, where new groups have been created on N&N standards (CEN/TC 352 and ISO/TC 229), and existing groups have taken up specific related work items (e.g. ISO/TC 24, ISO/TC 146).
- Participating in OECD, where two new Working Parties have been established: the OECD-WP on Manufactured Nanomaterials, under the Joint Chemicals Meeting (section 6); and the OECD-CSTP-WP on Nanotechnology.[21]
- Addressing in FP7 research on the impact of nanoparticles on health and the environment in consultation and/or coordination with US Federal Agencies; the EC

[19] http://es.epa.gov/ncer/rfa/2007/2007_star_nanotech.html

[20] ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/lca_nanotechnology_workshopoct2006_proceedings_en.pdf

[21] www.oecd.org/sti/nano

and Environment Protection Agency have concluded an implementing arrangement which includes nanotechnology.

– Providing in FP7 support for the networking of researchers from third countries in nanotechnology and the creation of a free and open electronic archive of N&N publications, to help prevent a possible "nano divide".

– Creating an ad-hoc working group with Member State representatives to examine progress and challenges for international activities specific to nanotechnology.

8. IMPLEMENTING A COHERENT AND VISIBLE STRATEGY AT EUROPEAN LEVEL

The purpose of the Action Plan is to ensure the best possible governance of the development and use of nanotechnology. Its effective implementation therefore requires an efficient structure and coordination, within a detailed and regular consultation with the Member States and all stakeholders.

The Commission has cooperated with the EU Presidencies in the organisation of conferences providing opportunities to verify progress. In 2005, the UK hosted the EuroNanoForum conference. The UK Presidency also organised a Member State workshop to discuss and examine the initial progress of the implementation of the Action Plan. This event was followed up by the Austrian Presidency in June 2006; and by the Finnish Presidency in September 2006, with the conference "Nanotechnologies: Safety for Success".[22] The German Presidency organised the EuroNanoForum conference in June 2007, and the Portuguese Presidency plans to organise an official event in November 2007.

An EC Interservice Group dedicated to all aspects of the work described in this report has been established. The Commission has also issued a call for the creation of an observatory, to carry out dynamic assessments of nanotechnology development and use; this should enable stakeholders to understand the potential and critical issues, providing an "early warning" function to the EU Institutions and Member States.

A new Europa website presents the implementation work carried out by all the Commission services involved: http://ec.europa.eu/nanotechnology/

In a broader sense, the Action Plan is also a means to ensure that N&N contribute to the realisation of the European Research Area (ERA),[23] and the following achievements may be noted in this respect:

– The broad-ranging European strategy for N&N and the fact that EC funding accounts for a third of European public funding in N&N have resulted in effective coordination and the minimisation of overlaps. Another helpful factor has been the early launching of these initiatives, often before any structured initiatives by Member States (section 1 above).

– Funded projects dedicated to the training and mobility of researchers, and other R&D projects in N&N, have contributed to the creation of high quality human potential in N&N (section 3 above).

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22 http://www.fmnt.fi/ntss/

23 *Towards a European research area*, COM(2000)6

– FP6 has seen increasing industrial participation in R&D projects on N&N, and the creation of several ETPs has strengthened public-private cooperation in N&N. FP7 is expected to lead to further progress (section 4 above).

– Several strategic activities have been carried out to engage the public (section 5 above).

– Selected strategic activities focusing on international collaboration are being undertaken (section 7 above). There is also a small but increasing participation of international partners in R&D projects in N&N.

– These activities have been complemented by wide-ranging efforts to enable the safe development and use of nanotechnologies (section 6 above).

In the coming years, special attention should be paid to the development of interdisciplinary infrastructures; appropriate conditions for the safe and effective use of nanotechnology; and a shared understanding of the responsibility of researchers within an ethical framework.

To promote safe and responsible nanotechnology research and pave the way for its safe and responsible application and use, the Commission is planning to adopt a voluntary Code of Conduct for Responsible N&N Research.

Following its review of current legislation, the Commission may propose regulatory changes, on the basis of scientific developments, or regulatory needs in specific areas where such needs may be identified.

The Commission intends to submit the next implementation report on the N&N Action Plan by the end of 2009.

COMMISSION OF THE EUROPEAN COMMUNITIES

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COM(2008) 366 final

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

REGULATORY ASPECTS OF NANOMATERIALS

[SEC(2008) 2036]

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REGULATORY ASPECTS OF NANOMATERIALS

(text with EEA relevance)

1. INTRODUCTION

In its Communication "Towards a European Strategy for Nanotechnology",[1] the Commission states that R&D and technological progress need to be accompanied by scientific investigation and assessment of possible health or environmental risks associated with nanotechnology. The "Integrated, safe and responsible approach" has become the core of the EU policy for nanotechnology. The Communication "Nanosciences and nanotechnologies: an action plan for Europe 2005 – 2009"[2], specified that all applications and use of nanosciences and nanotechnologies must comply with the high level of public health, safety, consumers and workers protection, and environmental protection chosen by the Community. The Commission therefore announced a regulatory review of EU legislation in relevant sectors. The present Communication reflects this commitment. It covers nanomaterials currently in production and/or placed on the market. In the absence of generally accepted definitions, the term nanomaterials is used in this Communication to cover commonly used terminology such as manufactured (or engineered) nano-sized and nanostructured nanomaterials. The Communication does not address nanomaterials or nanoparticles that occur naturally or are unintentionally produced, e.g. in combustion.

2. REVIEW OF LEGISLATION APPLICABLE TO NANOMATERIALS

Nanotechnologies are enabling technologies, with a high potential benefits for consumers, workers, patients, and the environment, as well as the creation of jobs. On the other hand, nanotechnologies and nanomaterials may expose humans and the environment to new risks, possibly involving quite different mechanisms of interference with the physiology of human and environmental species.

The regulatory challenge is therefore to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained.

Legislation relevant for health, safety and environment aspects of nanomaterials can be grouped under chemicals, worker protection, products and environmental protection, simultaneously applicable. Main elements in relation to risks associated with nanomaterials are described in the annexed Commission Staff Working Document.

Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation.

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[1] COM(2004) 338 final of 12 5 2004,

[2] COM(2005) 243 final of 7 6 2005

Implementation of legislation and use of regulatory instruments created by legislation remains a particular challenge. Documents that support implementation, particularly in relation to risk assessment, adopted within the context of current legislation will have to be reviewed in order to ensure that they effectively address risks associated with nanomaterials and make best use of the information becoming available. Similarly, authorities and agencies will have to pay special attention to risks in relation to nanomaterials where production and marketing are subject to pre-market control.

In order to properly develop, modify or in particular to implement legislation, the scientific knowledge base needs to be improved. This Communication therefore pays attention both to legislation, implementation and bridging the knowledge gap.

In this context, attention is also drawn to the Code of Conduct for responsible nanosciences and nanotechnologies research.[3] This Code is complementary to legislation and provides Member States, employers, research funders, researchers and more generally all individuals and civil society organisations involved or interested in nanosciences and nanotechnologies research with guidelines favouring a responsible and open approach to N&N research in the Community.

2.1. Chemicals

REACH[4] provides an over-arching legislation applying to the manufacture, placing on the market and use of substances on their own, in preparations or in articles. REACH is based on the principle that manufacturers, importers and downstream users have to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

There are no provisions in REACH referring explicitly to nanomaterials. However, nanomaterials are covered by the “substance” definition in REACH.

Under REACH, manufacturers and importers will have to submit a registration dossier for substances that they manufacture or import at or above 1 tonne per year. At or above 10 tonnes/year, the registrant will be obliged to produce a chemical safety report. Furthermore, if deemed necessary for the evaluation of the substance the European Chemicals Agency can require *any* information on the substance, independent of the minimum information requirements of REACH

When an existing chemical substance, already placed on the market as bulk substance, is introduced on the market in a nanomaterial form (nanoform), the registration dossier will have to be updated to include specific properties of the nanoform of that substance. The additional information, including different classification and labelling of the nanoform and additional risk management measures, will need to be included in the registration dossier. The risk management measures and operational conditions will have to be communicated to the supply chain.

In order to address the specific properties, hazards and risks associated with nanomaterials, additional testing or information may be required. To determine specific hazards associated with nanomaterials, current test guidelines may need to be modified. Until specific test guidelines for nanomaterials exist, testing will have to be carried out according to already existing guidelines.

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[3] C(2008) 424 final of 7 2 2008

[4] Regulation (EC) No 1907/2006; OJ L 396 of 30.12.2006

For substances of very high concern[5], an authorisation will be required for their use and their placing on the market. The restrictions procedure allows to take measures with respect to nanomaterials where there is a risk arising from the manufacture, use or placing on the market. Authorisation and restriction schemes apply regardless of quantities manufactured or placed on the market.

The Commission will carefully monitor the implementation of REACH with respect to nanomaterials. Based on information regarding production and marketing, or new knowledge, for instance regarding toxicological or physical-chemical properties, current provisions, including quantitative triggers and information requirements may have to be modified.

Data generated under REACH will serve as input to other regulation, such as worker protection, cosmetics and environmental protection. It complements product legislation (e.g. general product safety) to the extent that this does not cover environmental aspects.

2.2. Worker Protection

Framework Directive 89/391/EEC[6] places a number of obligations on employers to take measures necessary for the safety and health protection of workers. It applies to all substances and work activities including manufacturing and use of chemicals at all levels of the production process, regardless of the number of workers involved and quantities of materials produced or technologies used.

This Directive fully applies to nanomaterials. Employers, therefore, must carry out a risk assessment and, where a risk is identified, take measures to eliminate this risk.

The planning and introduction of new technologies must be subject to consultation with the workers or their representatives, as regards the working conditions and the working environment in accordance with Articles 11 and 12 of the Framework Directive 89/391/EEC.

The Directive foresees the possibility to adopt individual directives laying down more specific provisions with respect to particular aspects of safety and health. Relevant directives thus adopted relate to risks related to exposure to carcinogens or mutagens at work[7], risks related to chemical agents at work[8], the use of work equipment by workers at work[9], the use of personal protective equipment at the workplace[10] and safety and health protection of workers potentially at risk from explosive atmospheres.[11]

As these Directives introduce minimum requirements, national authorities have the possibility to introduce more stringent rules.

2.3. Products

Product legislation lays down requirements regarding specific products, such as medicinal products, plant protection products (PPP), cosmetics, food and feed additives, etc. Consumer products that are not governed by specific legislation have to meet the requirements of the

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5 Carcinogenic, mutagenic or toxic to reproduction (CMR), persistent, bioaccumulating and toxic (PBT) or very persistent and very bioaccumulating (vPvB) or substances giving rise to an equivalent level of concern.

6 OJ L 183, 29.6.1989

7 Directive 2004/37/EC of 29 4 2004; OJ L 158, 30.4.2004

8 Directive 98/24/EC of 7 4 1998; OJ L 131, 5.5.1998

9 Directive 89/655/EEC of 30 11 1989; OJ L 393, 30.12.1989

10 Directive 89/656/EEC of 30 11 1989; OJ L 393, 30.12.1989

11 Directive 1999/92/EC of 16 12 1999; OJ L 23, 28.1.2000

General Product Safety Directive.[12]

Community regulation in these areas contains provisions in relation to health and safety of consumers, workers, patients and users, but not necessarily in relation to environmental protection. To the extent that nanomaterials contained in such products qualify as substances under REACH, they are subject under REACH to an assessment on their environmental impact.

Virtually all product legislation imposes a risk assessment and the adoption of risk management measures. Nanomaterials are not excluded from this obligation.

Where products are subject to a pre-market control or pre-market notification, e.g. medicinal products, novel foods, plant protection products, the assessment and management of risks in relation to nanomaterials can be verified by authorities (or Notified Bodies under the New Approach) before placing on the market. Implementation of these procedures will lead either to implementing legislation (e.g. listing of new substances on a positive or a negative list) or to binding administrative decisions (e.g. market authorisations), that will also specify marketing conditions.

Particularly relevant is the obligation to review, modify or cancel authorisations if there are indications that any of the relevant requirements are not longer satisfied, or if developments in scientific and technical knowledge require such action. Similarly, the holder of an authorisation or certificate must immediately notify the relevant authority or body of all new information on risks.

Where products can be placed on the market without specific pre-market procedural requirements (e.g. cosmetics, consumer products subject to the general product safety directive, various products regulated under the New Approach), compliance with legal requirements must be verified at the level of market surveillance. This does not exclude the possibility to undertake action restricting the placing on the market, or requiring advice from the various EU Scientific Committees. At all times authorities can verify the risk assessment and risk management strategy at the premises of the manufacturer.

In order to increase the level of protection, regulatory change has been proposed with respect to cosmetic products, placed on the market without pre-market control. The requirements regarding the risk assessment will be clarified. Further, manufacturers will be obliged to indicate whether their products contain nanomaterials when notifying their placing on the market and to set up a mechanism in order to monitor the health effects on cosmetic products placed on the market.[13]

As regards medical devices, Commission services will examine the possibility to make the placing on the market of devices presenting risks associated with nanomaterials subject to a systematic pre-market intervention.

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12 Directive 2001/95/EC; OJ L 11, 15.1.2002

13 COM(2008)49 final 2008/0025 (COD); 5.2.2008

2.4. Environmental protection

Environmental regulation relevant in this context relates in particular to integrated pollution prevention and control (IPPC), the control of major accident hazards involving dangerous substances (Seveso II), the water framework directive and a number of waste directives.

The IPPC Directive[14] covers approximately 52,000 industrial installations across the EU and requires installations falling under its scope to operate in accordance with permits including emission limit values based on the application of best available techniques (BAT). In principle, the IPPC Directive could be used to control environmental impacts of nanomaterials and nanomaterials issues at IPPC installations through the inclusion of such considerations into the Commission's BAT Reference Document (BREFs) process should the need arise.

The Seveso II Directive[15] applies to establishments where named dangerous substances (or substances falling within certain classification categories) are present above specific quantities (or thresholds). It imposes a general obligation on operators to take all measures necessary to prevent major accidents and to limit their consequences for man and the environment. If certain nanomaterials are found to demonstrate a major accident hazard, they may be categorised, together with appropriate thresholds, in the context of the Directive.

The Water Framework Directive (2000/60)[16] sets common principles and an overall framework for action to improve the aquatic environment and to progressively reduce the pollution from priority substances and phasing out emissions, discharges and losses of priority hazardous substances to water. A list of 33 priority substances has been established in 2001.[17] Nanomaterials could be included among the Priority Substances depending on their hazardous properties. Environment Quality Standards would in these cases be proposed by the Commission. For groundwater[18], Member States will have to establish quality standards for pollutants representing a risk, in which case nanomaterials may also be included.

Directive 2006/12/EC on waste[19] sets the general framework and imposes an obligation on Member States to ensure that waste treatment does not adversely affect health and the environment. The hazardous waste Directive[20] defines which wastes are hazardous and lays down stricter provisions regarding such waste. Hazardous waste must display certain properties set out in an Annex to the Directive and feature on the European Waste List as hazardous. Wastes containing nanomaterials could be classified as hazardous, if the nanomaterial displays relevant properties which render the waste hazardous.

Specific legislation has been adopted to deal with particular waste streams[21] or specific waste treatment processes, such as incineration[22] and landfill.[23]. Current EU waste legislation covers general requirements for the protection of health and the environment during waste management. It also includes requirements for the management of specific waste materials

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14 Council Directive 2008/1/EC concerning integrated pollution prevention and control; OJ L 24 29.01.2008

15 Directive 96/82 on the control of major-accident hazards involving dangerous substances; OJ L10 of 14.1.1997

16 Directive 2000/60/EC ,OJ L 327, 22.12.2000

17 Decision No 2455/2001/EC, OJ L 331, 15.12.2001

18 Directive 2006/118/EC; OJ L 372, 27.12.2006

19 Directive 2006/12/EC; OJ L 114, 27 4 2006

20 Directive 91/689/EEC; OJ L 377, 31.12.1991

21 E.g. electrical and electronic equipment, end of life vehicles, packaging and packaging materials, batteries, titanium dioxide

22 Directive 2001/80/EC; OJ L 309, 27.11.2001

23 Directive 1999/31/EC; OJ L 182 , 16.07.1999

that may contain nanomaterials whilst not explicitly addressing the risks of nanomaterials. If the need for more specific provisions is established, appropriate action can be proposed or implemented under the current legislative framework. Similarly, action can be taken by Member States in implementing current provisions in the framework of national policies

3. IMPLEMENTATION OF LEGISLATION

Whilst the Community legislative framework generally covers nanomaterials, *implementation* of legislation needs further elaboration. Important elements are the *test methods* and the *risk assessment methods* that serve as a basis for implementing legislation, administrative decisions, manufacturer's obligations or employer's obligations. The scientific basis to fully understand all properties and risks of nanomaterials is not sufficiently available at this point in time.

A number of reviews identifying "knowledge gaps" have been published[24]. The EU Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR)[25] and the Scientific Committee for Consumer Products (SCCP)[26] have pointed to the need to improve the knowledge base, in particular regarding test methods and risk assessment (hazards and exposure) methods. In general, there is a consensus in Member States and at the international level that further research is necessary. An indication is given in the annexed Commission Staff Working Document

Where the full extent of a risk is unknown, but concerns are so high that risk management measures are considered necessary, as is currently the case for nanomaterials, measures must be based on the precautionary principle.

As specified in the Commission Communication of 2 February 2000[27] on the Precautionary Principle, recourse to the precautionary principle does not necessarily mean adopting final instruments designed to produce legal effects. A wide range of activities or measures can be used, like legally binding measures, initiation of research projects or recommendations. Measures adopted under the precautionary principle must be based on general principles of risk management and must therefore *inter alia* be proportionate, non-discriminatory, consistent, on an examination of benefits and costs of action or lack of action, and on an examination of scientific developments.

Against this background, Community action in relation to managing the risks in order to meet regulatory requirements should mainly focus on the following activities.

3.1. Improving the knowledge base

There is a need for a rapid improvement of the scientific knowledge basis to support the regulatory work. Research activities are ongoing under the Research Framework Programmes and in the Joint Research Centre, as well as in EU Member States and internationally. In particular, research is needed in areas underpinning risk assessments and risk management like

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24 E.g. 1st Meeting of OECD's Working Party on Manufactured Nanomaterials (WPMN). http://www.oecd.org/department/0,3355,en_2649_37015404_1_1_1_1_1,00.html and subsequent updates

25 modified Opinion (after public consultation) on The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies; 10 March 2006;http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf

26 http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_099.pdf

27 Com(2000) 1 final

- Data on toxic and eco-toxic effects as well as test methods to generate such data.
- Data on uses and exposures throughout the lifecycle of nanomaterials or products containing nanomaterials, as well as exposure assessment approaches.
- Characterisation of nanomaterials, development of uniform standards and nomenclature, as well as analytical measurement techniques.
- For occupational health aspects, the effectiveness of a range of risk management measures including process enclosure, ventilation, personal protective equipment like respiratory protective equipment and gloves.

The development of standards and test methods requires close international collaboration to ensure that scientific data can be compared globally and that scientific methods used for regulatory purposes are harmonised. A main forum for the coordination of activities at the international level has been provided by the OECD Working Party on Manufactured Nanomaterials. Work is also carried out in the framework of the International Organisation for Standardisation, ISO.

A wide range of activities has been initiated to improve the knowledge base (see the annexed Commission Staff Working Document. and the Commission Communication "Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007.[28]

3.2. Improving the implementation of legislation

Commission working groups, meetings of Competent Authorities and Agencies in charge of coordinating the implementation of regulation will have to examine on an ongoing basis whether and what type of further action is needed. These activities will mainly be reflected in documents that support implementation of existing legislation.

Examples are the setting of thresholds, authorisation of substances and ingredients, qualifying waste as hazardous, reinforcing conformity assessment by reclassification, introducing restrictions on the marketing and use of chemical substances and preparations, etc. In most cases, implementing legislation can be adopted through "Comitology" procedures.

Work is also needed on documents for voluntary use, such as regulatory guidance[29], European or international standards[30], advice from Scientific Committees[31] etc. Similarly, ethical issues have to be dealt with, as indicated by the European Group on Ethics in Science and New Technologies (EGE).[32]

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28 COM(2007) 505 final ; http://ec.europa.eu/nanotechnology/pdf/comm_2007_0505_en.pdf

29 E.g. Technical Guidance Document in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and Commission regulation 1488/94 on risk assessment for existing substances; http://ecb.jrc.it/tgd

30 E.g. EN ISO 14971:2000 Medical devices - Application of risk management to medical devices (ISO 14971:2000) EN ISO 14971:2000/A1:2003

31 E.g. Notes of guidance of the Scientific Committee for Consumer Products for the testing of cosmetics ingredients and their safety evaluation; 6th revision http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_03j.pdf

32 http://ec.europa.eu/european_group_ethics/activities/docs/opinion_21_nano_en.pdf

Similarly, input is required from the relevant Agencies such as the European Medicines Agency[33], the European Food Safety Authority, the European Chemicals Agency or the European Agency for Safety and Health at Work (OSHA).

The annexed Commission Staff Working Document indicates action already undertaken in a number of sectors. The need for further action relates in particular to the implementation of risk assessment. Relevant Commission working groups are therefore requested to give a follow-up to the opinions of the European Scientific Committees on risk assessment. Similarly, the European Standards Bodies have been given a formal mandate to verify existing standards on whether they cover in an appropriate way risks in relation to nanomaterials.

Particular attention will have to be given to those products that are not subject to any pre-market verification. Concerted actions between authorities will have to be promoted to ensure optimal market surveillance. A dialogue has to be organised with stakeholders in specific sectors to ensure transparency on what is expected to meet regulatory requirements and how relevant information can be exchanged.

At international level, risks in relation to nanotechnologies have become a priority for international collaboration in the field of cosmetics, pharmaceuticals, chemicals, food safety and medical devices

Awaiting the adoption of more specific implementing legislation, standards or guidance, existing documents that support implementation will continue to be used on a case by case basis.

3.3. Information to users

There are no provisions in Community legislation dealing specifically with nanomaterials. However, without excluding the possibility that a need would be identified for specific labelling requirements, nanomaterials have to comply with the existing provisions of Community law addressing the labelling of products, warnings to consumers and users based on the properties of products, instructions for use, or any other information requirements.

Also relevant are the provisions in REACH with obligations of data dissemination about environment, safety and health risks via Safety Data Sheets up and down the supply chain, to industrial users and via the Internet to the public at large. Chemical safety reports will be produced for substances placed on the market in quantities at or above 10 tonnes[34] and a data base with the purpose to make publicly available non confidential data about chemical substances will be kept by the European Chemicals Agency.

Attention is also drawn to provisions in Community law creating a right of access to information in relation to programmes mainly implementing legislation on environmental protection.

The obligation to provide information in relation to the use of nanomaterials and nano-technologies should be distinguished from manufacturers' claims regarding the presence of particular characteristics associated with the use of nanomaterials and nano technologies.

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[33] E.g. EMEA Reflection paper on nanotechnology-based medicinal products for Human Use, http://www.emea.europa.eu/pdfs/human/genetherapy/7976906en.pdf

[34] See also Article 14(4) and Annex III of the REACH Regulation (EC) No 1907/2006.

Community provisions on false or misleading advertising could be evoked if such claims are not justified.[35]

3.4. Market surveillance and intervention mechanisms

Special attention will be given to the various instruments in Community legislation that oblige national authorities to exchange information or to intervene when products present or are likely to present a risk, even where they conform with legal requirements. Such instruments take the form of safeguard clauses, health monitoring measures, food, feed and pesticide market controls, formal objections to standards, precautionary measures, vigilance procedures, measures based on new evidence or re-assessment of existing data, mutual exchange of information, alert/early warning systems, etc. At all stages, authorities can therefore intervene in the case that particular risks would be identified with respect to products containing nanomaterials already on the market.

4. CONCLUSIONS

Current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation. The Commission and EU Agencies will therefore in the first place review current documents that support implementation, such as implementing legislation, standards and technical guidance with regard to their applicability and appropriateness to nanomaterials.

Knowledge on essential questions such as characterisation of nanomaterials, their hazards, exposure, risk assessment and risk management should be improved. As knowledge becomes the critical factor for implementation and, eventually, legislation, targeted actions in a number of areas and at different levels, particularly in the field of research and development, were launched as a matter of priority, particularly through FP 6 and 7, and the European Commission's Joint Research Centre. Activities are coordinated with international partners and stakeholders in the appropriate fora, such as the OECD and ISO.

Commission working groups in charge of coordinating implementation of legislation are examining on an ongoing basis whether regulatory change on specific aspects is necessary, taking into account the continuously generated information linked with the identified knowledge gaps. They will take into consideration work that has been carried out in this respect at national and international level.

Authorities and Agencies in charge of implementing legislation should continue to carefully monitor the market, and use Community market intervention mechanisms in case risks are identified for products already on the market.

The Commission intends to report on progress in these areas 3 years after presentation of this Communication.

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[35] Directive 84/450/EEC of 10 9 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising

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.

COUNCIL OF
THE EUROPEAN UNION

EN

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PRESS RELEASE

2605th Council Meeting

Competitiveness (Internal Market, Industry and Research)

Brussels, 24 September 2004

President **Mr Laurens Jan Brinkhorst**
Minister for Economic Affairs
Ms Maria van der Hoeven
Minister for Education, Culture and Science

of the Netherlands

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NANOTECHNOLOGIES - ***Council conclusions***

Following an exchange of views on the Commission communication on an European strategy for nanotechnology, the Council adopted the following conclusions:

"THE COUNCIL OF THE EUROPEAN UNION:

1. RECOGNISES the important role and potential of nanosciences and nanotechnologies in many areas, such as health care, information technologies, materials sciences, manufacturing, instrumentation, energy, environment**,** security, space; and thus their significance for quality of life, sustainable development and the competitiveness of European industry;

2. RECALLS the general context of the Lisbon strategy and the creation of the European Research Area as reflected, notably, in:

– the Commission's Communication of January 2000 on the European Research Area[1] and the subsequent Council Resolutions[2] and Conclusions[3];

– the Conclusions of the Lisbon European Council of March 2000 on the strategy for making the EU the world's most competitive and dynamic knowledge-based economy by 2010 and the elaboration of this strategy by the Stockholm, Gothenburg and Barcelona European Councils;

– the Conclusions of the European Council of March 2003 stressing the need for Europe to do more to turn ideas into real value-added, and Council Resolution[4] of 22 September 2003 on investing in research for European growth and competitiveness;

3. NOTES the Commission's Communication of June 2004 "Science and technology, the key to Europe's future – Guidelines for future European Union policy to support research"[5] which highlighted the need for the integration of research activities, at European level, in highly competitive sectors such as nanotechnology;

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[1] 5643/00.

[2] OJ C 205, 19.7.2000, p. 1, and C 374, 28.12.2000, p. 1.

[3] OJ C 43, 22.2.2003, p.1.

[4] OJ C 250, 18.10.2003, p.2.

[5] 10740/04.

4. WELCOMES the Commission's Communication "Towards a European Strategy for Nanotechnology"[1] and ENDORSES the main message of this Communication, namely the need to develop an integrated and responsible strategy;

5. NOTING the existing European knowledge base and industrial capacity in nanosciences and nanotechnologies, STRESSES that:

– with a view to maintaining and reinforcing European scientific excellence and industrial competitiveness, it is important to continue to generate scientific and technological knowledge in nanotechnology and to encourage its use in industrial applications;

– a coherent and coordinated management of initiatives both at the national and European level is needed, thus ensuring efficiency, effectiveness, synergy, concentration of efforts, critical mass and visibility of actions; it WELCOMES forthcoming initiatives to this effect both in areas of enabling technologies and applications, such as nanomaterials, nanoelectronics and nanomedicine;

– there is a need for a sustainable and responsible development of nanotechnology, addressing its health, environmental, societal, industrial and economic aspects at the earliest possible stage in order to respond to the justified expectations and concerns of European citizens.

6. HIGHLIGHTS the need to pay special attention to actions in the following areas:

– increasing investment in R&D activities in order to capitalise upon the interdisciplinary nature of nanotechnology and to reinforce the industrial application of nanotechnologies;

– creating high-level "poles" of excellence and infrastructures in nanotechnology that can compete on a global level by bringing together academia, research organisations and industry to establish an appropriate critical mass, and to develop possible synergy with other initiatives, in particular the European Action for Growth, in line with the conclusions of the European Council of 12 December 2003 in order to strengthen the capital base for nanotechnology research in Europe;

– promoting interdisciplinary education and training of research personnel together with a stronger entrepreneurial mindset;

– promoting favourable conditions for technology transfer and innovation, especially taking into account the needs of SMEs, noting in this context the importance of intellectual property rights;

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[1] 9621/04.

– integrating societal, environmental and health considerations into the R&D process and assessment of potential risks throughout the life cycle of nanotechnology-based products;

7. INVITES MEMBER STATES to substantially reinforce research, development and innovation for nanotechnology in view of the Lisbon objectives and within the "3%" Barcelona objective, while ensuring maximum effectiveness, efficiency and synergy at European level;

8. WELCOMES the Commission's intention:

– to draw up an Action Plan for nanotechnology during the first quarter of 2005, after having launched a wide-ranging stakeholder debate;

– to engage in a dialogue at international level, with a view to establishing a framework of shared principles for the safe, sustainable, responsible and socially acceptable development and use of nanotechnologies."

COUNCIL OF
THE EUROPEAN UNION

EN

Council conclusions on nanosciences and nanotechnologies

2832nd COMPETITIVENESS (Internal market, Industry and Research) Council meeting
Brussels, 22 and 23 November 2007

The Council adopted the following conclusions:

"THE COUNCIL OF THE EUROPEAN UNION,

NOTING the communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee entitled "Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007",
RECOGNIZING:

- That the role of nanosciences and nanotechnologies is crucial for the improvement of Europe's competitiveness and the quality of life of its citizens, and to achieve the economic, social, and environmental goals of the renewed Lisbon Strategy;

- The need to foster synergies and cooperation between all stakeholders, including the Member States, the European Commission, academia, research centres, industry, financial bodies, NGOs and society at large;

- That progress can only be achieved with the full involvement of the private sector, and that the European Technology Platforms and the ENIAC Joint Technology Initiative are valuable tools to bring forward the R&D efforts in the field of nanosciences and nanotechnologies;

- That greater private investment is needed to support the actions of the European Union, via the Framework Programmes for Research and Development, and those undertaken by the Member States;

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- The potential of integrating the different scientific and technological disciplines within a converging approach to sustain the development of nanosciences and nanotechnologies in Europe, and to provide for seamless cooperation between the actors involved in the implementation of initiatives, encouraging joint calls within the Seventh Framework Programme for Research and Development;

- The need to support the adequate development of interdisciplinary infrastructures and the training of human resources;

- That conditions must be created for the development and further growth of European centres of excellence in nanosciences and nanotechnologies, so that these can attract and retain the best researchers in the world;

- That a safe and responsible development of nanotechnologies is essential, and noting in this context the review of current regulation undertaken by the European Commission and the open consultation it launched among the public and stakeholders on a possible code of conduct;

- And that currently raising world investments in nanosciences and nanotechnologies, particularly by the Union's major competitors, the USA and Asia, requires increased investment and political attention in Europe.

UNDERLINES that a more rapid and successful development of the nanoscience and nanotechnology sector is of vital strategic importance for European competitiveness, and requires stronger co-ordination of the energetic efforts already undertaken by a large number of public and private actors at European, national and regional level;

RECOGNIZES the need to support the adequate development of interdisciplinary infrastructures and the training of human resources, in order to create adequate conditions for the development of European centres of excellence in nanosciences and nanotechnologies, so that these can attract and retain world-class researchers;

STRESSES that not only the public and private efforts in research, technological development and innovation, but also the wider framework conditions for success of the nanotechnology sector in the European internal market require constant and careful attention;
UNDERLINES that a safe, integrated and responsible development and use of nanotechnologies is essential;

RECOGNISES that, where required, new or modified testing methods should be developed for the evaluation of potential risks of nano-projects to the environment or human health;

NOTES in this context the review of current regulation undertaken by the European Commission and the open consultation it launched among the public and stakeholders on a possible code of conduct;

INVITES Member States to provide input to the Commission in view of its regular reporting and to consider comprehensive and integrated approaches to creating the best competitive environment to advanced training and research, by stimulating national and international networks of competence in the fields of the nanosciences and nanotechnologies, involving industry and academia where appropriate.

INVITES Member States to encourage universities, research organisations and industry to cooperate in view of attracting to Europe the best talents in those fields and to boost improvement in industrial products and processes.

INVITES the Commission to:

– Continue monitoring nanotechnology development and use, and promoting the sharing of good practice in regulatory and risk governance issues, in order to keep nanotechnology research and implementation safe and responsible;

– Report regularly and, where appropriate, make recommendations to the Council and the European Parliament on the state of European competitiveness in nanoscience and nanotechnology, and the role of Europe's industry, universities and research institutions.

Such reporting shall draw on inputs from the Member States and on the review of the development of the field at world level. It should cover national policies and intergovernmental activities as well as Community programmes. It could address, among others, technological developments, research capacity, human resources and advanced training, scientific results, pre-normative R&D, socio-economic impact, regulatory measures, risk governance issues, public awareness and scientific culture actions on nanoscience and nanotechnology, and other appropriate dimensions."

P6_TA-PROV(2006)0392

Nanoscience and nanotechnology

European Parliament resolution on nanosciences and nanotechnologies: an action plan for Europe 2005-2009 (2006/2004(INI))

The European Parliament,

– having regard to the Commission Communication of 7 June 2005 entitled Nanosciences and nanotechnologies: An action plan for Europe 2005-2009 (COM(2005)0243),

– having regard to the joint report by the Royal Society and the Royal Academy of Engineering of 29 July 2004 entitled Nanoscience and nanotechnologies: opportunities and uncertainties,

– having regard to the Presidency Conclusions of the Brussels´ Competitiveness Council of 24 September 2004,

– having regard to the opinion of the European Economic and Social Committee on the Commission Communication: Towards a European strategy for nanotechnology[1] and its opinion regarding the above-mentioned Commission Communication of 7 June 2005[2],

– having regard to Rule 45 of its Rules of Procedure,

– having regard to the report of the Committee on Industry, Research and Energy and the opinions of the Committee on the Environment, Public Health and Food Safety and the Committee on Legal Affairs(A6-0216/2006),

A. whereas the Commission has adopted an Action Plan for the immediate implementation of a safe, integrated and responsible strategy for nanosciences and nanotechnologies,

B. whereas nanosciences and nanotechnologies have the potential – as multidisciplinary sectors – to benefit society hugely by the development of new products, materials, applications and services, thereby raising productivity and the quality of life in the EU as a whole,

C. whereas the Council recognises the important role of nanotechnologies in many areas and stresses the importance of continuing to generate scientific and technological knowledge in this area and of encouraging its use in industrial applications,

D. whereas the European Economic and Social Committee believes nanotechnologies could greatly help the EU to achieve the objectives set by the Lisbon Strategy,

1. Welcomes the above-mentioned Commission Action Plan, which defines a series of concrete and interconnected actions for the immediate implementation of nanosciences and nanotechnologies, based on priority areas determined according to future needs;

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[1] OJ C 157, 28.6.2005, p. 22.

[2] INT/277 - CESE 1237/2005.

2. Recognises the important role that nanosciences and nanotechnologies can play as breakthrough technologies in stimulating the achievement of the economic, social, and environmental goals of the EU; acknowledges the fact that nanotechnologies can address the needs of citizens (public health, energy, transport, sustainable development, etc.), as well as contribute to the EU's competitiveness and sustainable development objectives;

3. Notes that technology platforms, expert advisory groups, and action plans are useful instruments for helping to develop commonly agreed research agendas and deployment strategies in the field of nanotechnologies and nanosciences, thereby creating new jobs and enhancing economic growth;

4. Supports the objectives and initiatives set out in the above-mentioned Commission Communication of 7 June 2005; welcomes the clear focus in that Communication and in the above-mentioned Action Plan;

5. At the same time, stresses the need to increase publicly funded investment in R&D; realises that the fragmentary nature of the European research landscape reflects the easy availability and relatively low cost of nanoscience research, but is also aware that funds need to be set aside for the establishment and maintenance of the necessary large-scale facilities, including, in particular, clean rooms, lithographic processes and very costly analytical procedures; in this regard, expresses its concern at the current level of European public investment in nanosciences and nanotechnologies, recommends that the ambitions set out in the above-mentioned Action Plan be appropriately matched in financial terms and supports the Commission's readiness to very substantially increase the resources devoted to research in this field, which is of fundamental importance to Europe's future development;

6. Considers that Europe needs a coherent system of world-class R&D infrastructure in order for the EU to remain competitive in the field of nanosciences and nanotechnologies; draws attention to the fact that, in order to enjoy possible economies of scale, and owing to its interdisciplinary and complex nature, the infrastructure for R&D in nanotechnologies calls for a critical mass of resources that are beyond the means of local governments and industry; recognises, on the other hand, that smaller-scale national R&D policies may often be in a better position to react adequately to changing opportunities and market developments; therefore, urges the Commission and the Member States to reinforce and coordinate their R&D efforts in this field; to this end, recommends, in each Member State and in accordance with each country’s characteristics, the creation of a minimum critical mass of infrastructure and scientists with specific expertise in nanosciences and nanotechnologies, leading ultimately to the creation of specialised centres of excellence in some countries which would be coordinated at EU level;

7. Draws particular attention to nanomedicine as a promising interdisciplinary domain with breakthrough technologies such as molecular imaging and diagnostics, which can offer impressive benefits for the early diagnosis and smart and cost-effective treatment of diseases such as cancer, cardiovascular problems, diabetes, Alzheimer's and Parkinson's; urges the Commission and national and regional authorities to boost their R&D investments in this domain and to coordinate their efforts by means of the Nanomedicine European Technology Platform proposed in the Seventh Framework Programme for research, technological development and demonstration activities (Seventh Framework

Programme), and by means of other instruments, including the Regions of Knowledge proposed in the Seventh Framework Programme, so as to achieve critical mass in this field;

8. Stresses the major role to be played by nanosciences and nanotechnologies in developing molecular biology;

9. Is convinced that multidisciplinary nanosciences and nanotechnologies should be geared to the development of hydrogen energy, including the development of new and effective means of storing hydrogen and efficient fuel cells, as well as information-carrying technologies with much greater capacity than at present;

10. Stresses the considerable progress made in Europe in the field of nanotechnologies, based on a top-down approach, particularly in areas such as nanocomposites, abrasion – and corrosion – proof coatings and layers, and also the production of catalysers and photodiodes, including the so-called blue laser, as well as in the field of nanomedicine, nanocosmetics and nanodiagnosis of diseases;

11. Believes that the level of basic European research can make it possible to find technological tools that will enable a bottom-up approach to be adopted, particularly in nanoelectronics;

12. Believes that actions to accelerate technology development must be complemented by policy measures to ensure the market penetration of existing technologies; notes that standards can provide a level playing field for markets and international trade and are prerequisites for fair competition, comparative risk assessments and regulatory measures; calls therefore on the Commission and the Council to remove any barriers in the form of absent standards or unclear legislation, which unnecessarily hold back the adoption of nanotechnologies and nanosciences in Europe, and to do so without imposing any new bureaucratic hurdles;

13. Stresses the importance of generating the 'triangle of knowledge' (i.e. education,. research and innovation) needed for the European Research Area; considers that in order to achieve the necessary synergy between research, education and innovation, a comprehensive knowledge transfer approach, and also the development of cross-sector human resources, are needed; calls therefore on Member States to develop strategies to improve knowledge transfer and to address the skills shortage by increased emphasis on natural science training and by attracting more students into nanoscience and science-related, multidisciplinary subjects; welcomes the Commission's effort to support research training networks in nanotechnologies and calls on the Member States to create, both in isolation and in close cooperation with each other, multidisciplinary networks to combine nanotechnologies with a broad spectrum of research areas, with the aim of developing new hybrid technologies;

14. Considers that industry, research institutes and financial institutions should work together to ensure that excellent R&D in nanosciences and nanotechnologies is translated into new products and processes; believes that Member States should accelerate and stimulate this process by focussing on improving the business climate for companies in the nanotechnology sector in their country, especially start ups, SMEs and innovative companies; considers, in this regard, that the protection of intellectual property rights is

essential for innovation, in terms both of attracting initial investment and of ensuring future revenue; calls on the Commission to develop standards for the protection of intellectual property rights and models for licensing agreements;

15 Regrets the fact that the patenting of nanoscience and nanotechnology inventions in Europe is developing slowly; calls on the EU to create a nanoscience and nanotechnology patent monitoring system governed by the European Patent Office;

16. Encourages general reforms in the field of the European patent system in order to cut the costs of patenting and to improve accessibility to patents for SMEs; stresses the need for greater transparency and clear limits to the scope of patent protection;

17. Is convinced that Europe's chances of being and staying at the forefront in this field hinge upon its capacity for coordination; reiterates the need for a single Community focal point for coordination and the importance of the EU's speaking with one voice on the international stage, particularly in the light of the challenges presented by patent protection in China; calls therefore on the Commission and Members States to devise mechanisms to effectively coordinate actions in this field; urges the Commission to take into account in its policy making all activities within the OECD (e.g. definitions, nomenclature, risk management) and UNESCO (ethics);

18. Recognises that an essential element of a responsible strategy is the integration of social, health and safety aspects into the technological development of nanosciences and nanotechnologies; in this regard, urges the Commission, the Member States and European industry to engage in an effective dialogue with all stakeholders, so as to steer developments along a sustainable path;

19. Stresses that the technological risks posed (from conception to disposal or recycling) to human health, consumers, workers and the environment must be assessed throughout the life cycle of nanoscience and nanotechnology products;

20. Recommends that lists of ingredients in consumer products identify the addition of manufactured nanoparticulate material;

21. Emphasises the need to respect high ethical principles and welcomes the planned reviews on issues such as non-therapeutic human enhancement and links between nanosciences and nanotechnologies and individual privacy; expects the reviews to be public and to include a thorough analysis of nanomedicine;

22. Supports the setting up of ethical committees which, by providing independent scientific advice, will help ensure that the public is properly informed and help create a climate of trust based on awareness of the possible risks and benefits associated with the use of discoveries in the field of nanotechnologies;

23. Welcomes the consultation conducted for this proposal and encourages the Commission to continue improving its work in order to respond to the increasing demand for better regulation;

24. Welcomes the intention of the Commission to develop appropriate multilingual information material for different age groups in order to raise awareness of the progress and expected benefits of nanosciences and nanotechnologies; encourages the

Commission to do so in close collaboration with Member States; urges the Commission to devise a communications strategy to raise the public's awareness of the enormous opportunities offered by nanotechnology, and to allay their fears; considers that, as part of this communications strategy, the Commission should also make use of ideas such as a roadshow (featuring a 'Nanoscience Truck') or a nanotechnology award;

25. Calls on industry to share in the joint effort and urges it to participate in developing nanotechnologies, taking into account their wider economic, societal, health, safety and environmental effects and acting in accordance with the principles of corporate social responsibility; in this regard, stresses that businesses should help disseminate objective information about scientific discoveries in the nanoscience and nanotechnologies field, about their intended uses, their risks and benefits for society;

26. Emphasises that all applications and uses of nanosciences and nanotechnologies must comply with the high level of protection of human health, consumers, workers and the environment prescribed by the EU and insists on the need for the codification of nanomaterials, which lead to the drawing up of standards, which would in turn boost efforts to identify any risks; calls on the Commission to take the necessary initiatives to this end;

27. Emphasises the importance of the miniaturisation of products with regard to helping reduce waste and ensuring better use of energy;

28. Emphasises that understanding of the potential damage to health and the environment of new, synthetic nanoparticles is still limited and that, consequently, the effects of nanoparticles that are not readily soluble or biodegradable should be investigated, in accordance with the precautionary principle, before such particles are put into production and placed on the market;

29. Calls on the Commission to pay special attention to the development of nanosciences and nanotechnologies in the new Member States, by providing them with the means to define research profiles of their own, while at the same time further enhancing the cutting-edge position of the main European locations with a view to creating a leading global role for Europe;

30. Stresses the importance of international cooperation in the field of nanosciences and nanotechnologies; calls on the Commission to intensify further the already excellent relations with Russian scientists in particular and to investigate the possibilities and limitations of cooperation in this area with the USA, Japan, China and India; calls on the Commission to enhance international cooperation with a view to harmonising nanoscience and nanotechnology patent application processing between the EU, the USA and Japan; stresses that dialogue should be intensified in compliance with the WTO obligations;

31. Instructs its President to forward this resolution to the Council and Commission, and to the governments and parliaments of the Member States.

Opinion of the European Economic and Social Committee on the 'Communication from the Commission: Towards a European strategy for nanotechnology'

(COM(2004) 338 final)

(2005/C 157/03)

On 12 May 2004, the European Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the 'Communication from the Commission: Towards a European strategy for nanotechnology'.

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 10 November 2004. The rapporteur was Mr Pezzini.

At its 413th plenary session of 15 December 2004, the European Economic and Social Committee adopted the following opinion by 151 votes and one abstention.

1. Background

1.1 The Committee is conscious of the fact that this opinion deals with a partly new subject, whose vocabulary is little known or at any rate little used. For this reason, it was deemed useful to provide a brief series of definitions and to detail the state of nanotechnology research and applications in the United States and Asia.

1.2 Index

2. Definitions

2.1 **Nano** — means one billionth of a whole. In this case, nano is used to mean a billionth of a metre.

2.2 **Micro** — means one millionth of a whole. In this case, it means one millionth of a metre.

2.3 **Nanosciences** — The nanosciences are a new approach to traditional science (chemistry, physics, electronic biology, etc.) and deal with the basic structure and behaviour of materials at the level of atoms and molecules. These sciences in fact study the potential of atoms in the various scientific disciplines ([1]).

2.4 **Nanotechnologies** — These technologies enable atoms and molecules to be manipulated so as to create new surfaces and objects that, having a different make-up and arrangement of atoms, have properties that can be used in day-to-day life ([2]). These are technologies that deal with billionths of a metre.

2.5 **In addition to the above definition, it is worthwhile going into greater detail from a scientific point of view. The term nanotechnology** describes a multidisciplinary approach to the creation of materials, mechanisms and systems, by means of the nanometric scale control of materials.

2.6 **Nanomechanics** — The dimensions of an object begin to be important in determining its properties when the scale of its dimensions is of one or a few dozen nanometres (objects made of a few dozen or a few thousand atoms). Within this range of dimensions, an object composed of 100 iron atoms has physical and chemical properties that are radically different to one composed of 200 atoms, even if they are both made of the same atoms. Similarly, the mechanical and electromagnetic properties of a solid made up of nanoparticles are radically different to those of a traditional solid of the same chemical composition and are affected by the properties of the individual constituent units.

2.7 This is a fundamental scientific and technological novelty that changes the approach to making and manipulating materials in all fields of science and technology. Nanotechnology is not therefore a new science, joining the ranks of chemistry, physics and biology, but rather a new way of doing chemistry, physics and biology.

2.8 It follows that a nanostructured material or system is made of units of nanometric proportions (the structures made of individual atoms that we are used to are no longer relevant) and therefore possesses certain properties that can be built into complex structures. Clearly, therefore, production models based on the assembly of individual atoms or molecules that are all alike should be changed and replaced with approaches within which dimensions are a **fundamental parameter**.

([1]) Interview with Commissioner Busquin (summary in IP/04/820 of 29 June 2004).

([2]) See footnote 1.

2.9 To give an idea of the revolutionary impact of nanotechnology, it is equivalent to discovering a new periodic table of elements that is much bigger and more complicated than the previous one, and to finding that the limitations imposed by phase diagrams (for instance the possibilities of mixing two materials) can be overcome.

2.10 These are therefore bottom-up technologies, that shift the emphasis from individual functions to a set of functions. They have an ever-increasing number of applications, in the following fields to name but a few: health, information technology, materials science, manufacturing, energy, safety, aerospace, optics, acoustics, chemicals, food and the environment.

2.11 Thanks to these applications, some of which are already possible and used by the public ([3]), it is realistic to state that *nanotechnologies could significantly improve quality of life, the competitiveness of the manufacturing industry and sustainable development* ([4]).

2.12 **Microelectronics —** This is a branch of electronics that deals with the development of integrated circuits, built within individual semiconductor regions, with minute dimensions. Microelectronics can currently create individual components with dimensions in the realms of 0.1 micrometre, or 100 nanometres ([5]).

2.13 **Nanoelectronics** — This is a science that studies and produces circuits that are made using technologies and materials other than silicon and that work on a substantially different set of principles ([6]).

2.13.1 Nanoelectronics is set to become a cornerstone of nanotechnology, just as electronics today permeates all scientific sectors and industrial processes ([7]).

2.13.2 Development in the field of electric and electronic components has been very rapid. In the space of a few decades, valves have given way to semiconductors, chips, microchips and now nanochips, assembled using elements each made of a few 100 atoms. A nanochip can hold as much information as 25 volumes of the Encyclopaedia Britannica ([8]).

2.13.3 Scientists and electronic component producers quickly realised that the smaller the chip, the faster the flow of information ([9]). Nanoelectronics, therefore, enables information to be managed much more rapidly and contained in extremely small spaces.

2.14 **Scanning tunnelling microscope** — This instrument, which won its inventors the Nobel Prize, has also been defined as the 'lens of the 21st century'. It is used to 'see' material on an atomic scale. To work, the tip of the microscope moves in parallel over a surface. A tunnel effect causes the surface electrons (not the atoms) to move from the surface to the tip. This creates a current, which intensifies as the distance between the surface and the tip decreases. This current is converted by means of an altitude calculation, and gives the nanometric scale topography of the surface of a material.

2.14.1 **Tunnel effect** — In traditional mechanics, a particle with a certain amount of energy cannot get out of a hole unless it has enough energy to jump out. In quantum mechanics however, owing to the uncertainty principle, the situation is very different. As the particle is confined to the hole, the degree of uncertainty as to its position is small, and as a result, uncertainty as to its speed is great. Therefore, the particle has a certain probability of having sufficient energy to escape from the hole, despite the fact that its average energy would not be sufficient ([10]).

2.15 **Carbon nanotubes —** These are the product of a particular way of assembling carbon atoms. They are among the most resistant and lightest materials currently known. They are six times lighter and one hundred times stronger than steel. They have a diameter of a few nanometres and can be several microns long. ([11])

2.16 **Self-assembly of macromolecules —** This is the procedure used in laboratories to imitate nature: 'every living thing is self-assembled'. The self-assembly procedure creates interfaces between electronic circuits and biological tissues and makes a connection between informatics and biology. The goal, which scientists believe is not so far off, is to give hearing to the deaf and sight to the blind ([12]).

([3]) See point 6.15 of the conclusions.
([4]) See footnote 1.
([5]) Micro and nanoelectronics centre at the Politecnico di Milano, Prof. Alessandro Spinelli.
([6]) Ibidem.
([7]) Investment in nanoelectronics currently totals EUR 6 billion, broken down as follows: 1/3 in nano and micro, 1/3 in diagnostics, 1/3 in materials (source: European Commission, Research DG).
([8]) Source: European Commission, Research DG - 2003
([9]) See point 3.3.1.
([10]) Tullio Regge: 'Il vuoto dei fisici', L'Astronomia, No. 18 September-October 1982.
([11]) Source: European Commission, Research DG 2003
([12]) Various experiments are at an advanced stage, and an interface 'dialogue' has already been established between a snail neuron and an electronic chip.

2.17 **Biomimetics** ([13]) — This is the science that studies the laws underpinning molecular structures existing in nature. Knowledge of these laws could enable **artificial nanomotors** to be created, based on the same principles as those existing in nature ([14]).

3. Introduction

3.1 The EESC appreciates the clarity with which the nanotechnology communication has been drafted and shares the Commission's desire to waste no time in making a valid contribution to the debate. It also welcomes the many texts that have been published, including the CD ROMs, aimed at both experts and young people.

3.1.1 The educational CD ROMs in particular are extremely useful cultural vehicles for disseminating the necessary information on nanotechnology to a vast, sometimes uninformed, often young public.

3.2 The EESC takes the view that information on this subject, which may spawn new and fruitful discoveries in many areas of everyday life, should be disseminated using the most universally accessible vocabulary. Furthermore, research on new products must be geared to consumers' needs and demands, never losing sight of sustainable development.

3.2.1 Journalists and mass media operators, particularly from the specialised press, have a special role to play, as they are the first to spread news of success stories as researchers challenge science to obtain real results.

3.2.2 Current progress indicators for nanotechnology focus on four main strands: 1) publications ([15]); 2) patents; 3) new business start-ups; 4) turnover. The EU is in the lead on publications, with a percentage of 33 %, followed by the USA with 28 %. There are no precise figures for China, but publications are seemingly on the increase there. The USA is in first place on patents, with 42 %, followed by the EU with 36 %. As far as company start-ups are concerned, of every 1,000 genuine nanotech firms, 600 start life in the USA and 250 in the European Union. Taken as a whole, data on turnover suggest an increase from the current EUR 50 billion to approximately EUR 350 billion in 2010, reaching EUR 1,000 billion in 2015 ([16]).

3.3 Not only do nanotechnology and nanoscience constitute a new approach to materials science and engineering, they are, above all, among the most promising and important multidisciplinary tools for coming up with production systems, highly innovative inventions and far-reaching applications, for the various sectors of society.

3.3.1 On nanometric scale, conventional materials acquire different properties to their macroscopic counterparts, thus enabling the creation of systems that work and perform better. The radical novelty of nanotechnology lies in the fact that by reducing the scale of a material, its physical and chemical properties are changed. *This makes it possible to achieve production strategies similar to the approach used by nature to make complex systems, with a rational use of energy, minimising the raw material needed and waste products* ([17]).

3.3.2 The production processes associated with nanotechnology should therefore be marked by a new approach, taking full account of these new properties, in order to ensure that the European economic and social system draws the maximum benefit.

3.4 The nanotechnological approach pervades every production sector. The sectors currently applying nanotechnology to certain productive processes are: electronics ([18]); chemistry ([19]); pharmaceuticals ([20]); mechanics ([21]); and the automotive, aerospace ([22]), manufacturing ([23]) and cosmetics sectors.

3.5 Nanotechnologies could go a long way towards helping the EU to achieve the objectives set by the Lisbon European Council, by developing the knowledge-based society, and to become the most dynamic and competitive force in the world, while protecting the environment, promoting cohesion, and generating new businesses, more skilled jobs and new professional and training profiles.

([13]) From the Greek *mimesis*, to imitate nature.

([14]) For instance the independent movement of spermatozoa.

([15]) These are quantitative rather than qualitative data. A more in-depth assessment would be useful, such as that referred to by the UK's Royal Society.

([16]) Source: European Commission, Research DG

([17]) Source: University of Milan, Physics Department, Interdisciplinary centre for nanostructured materials and interfaces.

([18]) See Technology Roadmap for Nanoelectronics, European Commission, IST Programme, Future and emerging technologies, Second edition, 2000.

([19]) Nanostructured additives for polymers, paints and lubricants.

([20]) Nanostructured vectors for active ingredients, diagnostic systems

([21]) Surface treatments for mechanical parts, to improve durability and performance.

([22]) Pneumatics, structural materials, control and monitoring systems

([23]) Technical and intelligent materials.

3.6 According to the Commission, Europe could enjoy pole position in the field of nanotechnologies, but it must first succeed in clinching a real competitive advantage for European industry and society and secure sufficient returns on the necessarily high investment in research.

3.6.1 The real issue is the need to understand the strategic importance of these technologies, which concern broad sectors of the economy and society. Properly joined-up policy is also essential in the field of nanotechnologies and nanosciences and must be given substantial resources and be certain of the support of the private, industrial, financial and training sectors.

4. Gist of the Commission proposal

4.1 The Commission's communication seeks to launch an institutional-level debate on a coherent initiative to:

— increase investment and coordination of R&D to reinforce the industrial exploitation of nanotechnologies whilst maintaining scientific excellence and competition;

— develop world-class competitive R&D facilities ('poles of excellence') that take into account the needs of both industry and research organisations;

— promote the interdisciplinary education and training of research personnel, together with a stronger entrepreneurial mindset;

— ensure favourable conditions for technology transfer and innovation to ensure that European R&D excellence is translated into wealth-generating products and processes;

— integrate societal considerations into the R&D process at an early stage;

— address any potential public health, safety, environmental and consumer risks upfront by generating the data needed for risk assessment, integrating risk assessment into every step of the life cycle of nanotechnology-based products, and adapting existing methodologies and, as necessary, developing novel ones;

— complement the above actions with appropriate cooperation and initiatives at international level.

4.2 More specifically, the Commission proposes the following:

— the establishment of a European Research Area for nanotechnology;

— the development of basic and applied research facilities and high-quality university facilities open to companies, SMEs in particular;

— heavy investment in human resources, at EU/Member State level;

— support for industrial innovation, patenting, metrology and standardisation systems, regulation, and protection of safety, public health, the environment, consumers and investors to secure responsible development;

— the consolidation of a science/society dialogue, based on trust and an ongoing open dialogue;

— maintaining and stepping up strong and structured international cooperation, with common nomenclatures and codes of conduct, and a concerted effort to avoid exclusion from nanotech development;

— Community-level coordination of strategy and joint policy measures, backed up by adequate financial and human resources.

5. Main developments in the USA, Asia and Oceania

5.1 In the USA, the National Nanotechnology Initiative (NNI), a basic and applied research programme launched in 2001, coordinates the activity of a number of American agencies working in the field. It received funding of over a billion dollars for the 2005 financial year, doubling its initial 2001 budget. The main targets for this funding are: basic and applied research, the development of centres of excellence and facilities, and the evaluation and verification of the implications for society, particularly from an ethical, legal and public health and safety point of view, in addition to the development of human resources.

5.1.1 The NNI directly finances 10 federal agencies and coordinates various others. The National Science Foundation (NSF), the Office of Basic Energy Sciences of the Department of Energy (DOE), the Department of Defense (DoD), and the National Institutes of Health (NIH) have all seen significant increases in their budgets, aimed specifically at nanotechnology. The DOE in particular has invested massive sums and has managed to set up five major facilities, i.e. nanoscale science research centres, open to researchers from the entire scientific community. The DoD's nanotechnology programme meanwhile has grown over the years as a result for instance of the services required by the US armed forces.

5.1.2 These major developments were made possible by the passing in December 2003 of basic legislation on American nanotechnology policy with the 21st Century Nanotechnology Research and Development Act. Among other things, this law established a National Nanotechnology Coordination Office, with the following tasks:

— to redefine evaluation objectives, priorities and parameters;

— to coordinate the agencies and other federal activities;

— to invest in R&D programmes in nanotechnology and related sciences;

— to set up, on a competitive basis, interdisciplinary nanotechnology research centres, in various geographical locations, without ruling out State and industrial sector participation;

— to step up the development of applications in the private sector, including company start-up activities;

— to provide for education and certified training, generating and consolidating a technological and engineering culture in the nanosciences;

— to ensure that the ethical, legal and environmental aspects are respected in nanotechnology development and to organise consensus conferences and debates with the public and civil society;

— to promote the pooling of information between academia and industry, the State, central government and regional governments;

— to develop a plan to use the federal programmes, such as the Small Business Innovation Research Program and the Small Business Technology Transfer Research Program, to sustain an all-pervasive spread of nanotechnological development throughout the business fabric, however small the companies involved.

5.1.3 To reinforce the above legislation, the National Institute of Standards and Technology (NIST) has launched a specific programme to develop manufacturing in the nanotechnology sector, centring on: metrology, reliability and qualitative standards, process control, and manufacturing best practice. The Manufacturing Extension Partnership will also enable the results of the programme to be disseminated to SMEs.

5.1.4 The above law also provides for the establishment of an information clearing-house, with the task of:

— managing the commercialisation of nanotechnology and the transfer of technologies and new concepts into commercial and military products;

— demonstrating the best practice of universities and government and private sector laboratories, with a view to transfer to commercial use.

5.1.5 There are also plans for an American Nanotechnology Preparedness Center, with the task of conducting, coordinating, collecting, and disseminating studies on the ethical, legal, educational, environmental and workforce implications of nanotechnology and anticipating any problems so as to prevent potential negative fall-out.

5.1.6 The organisational framework set up by law is made complete by the establishment of a Center for Nanomaterials Manufacturing, to encourage, conduct and coordinate research into new manufacturing technologies and to collect and disseminate the results, in order to facilitate their transfer to United States industries.

5.1.7 The law also provides for the relevant 2005-2008 financial appropriations for the main agencies and federal departments, such as NSF, DOE, NASA and NIST ([24]).

5.2 After the announcement of the American NNI, there were significant changes in scientific research and technological development policy in Asia and the Pacific, with decisions designed to enable the region to take up a strong position in nanotechnology development. Nanotechnology became top priority in a number of Asian and Pacific countries, with overall spending in 2003 of over USD 1.4 billion. Of that figure, 70 % refers to Japan, but major investments were also made in China, South Korea, Taiwan, Hong Kong, India, Malaysia, Thailand, Vietnam and Singapore, not to mention Australia and New Zealand.

([24]) The multi-annual financial appropriations set out by the law of 3 December 2003 break down as follows:

(a) **National Science Foundation**
  (1) USD 385,000,000 for 2005
  (2) USD 424,000,000 for 2006
  (3) USD 449,000,000 for 2007
  (4) USD 476,000,000 for 2008

(b) **Department of Energy**
  (1) USD 317,000,000 the fiscal year 2005
  (2) USD 347,000,000 the fiscal year 2006
  (3) USD 380,000,000 the fiscal year 2007
  (4) USD 415,000,000 the fiscal year 2008

(c) **National Aeronautics and Space Administration**
  (1) USD 34,100,000 for 2005
  (2) USD 37,500,000 for 2006
  (3) USD 40,000,000 for 2007
  (4) USD 42,300,000 for 2008

(d) **National Institute of Standards and Technology**
  (1) USD 68,200,000 for 2005
  (2) USD 75,000,000 for 2006
  (3) USD 80,000,000 for 2007
  (4) USD 84,000,000 for 2008

(e) **Environmental Protection Agency**
  (1) USD 5,500,000 the fiscal year 2005
  (2) USD 6,050,000 the fiscal year 2006
  (3) USD 6,413,000 the fiscal year 2007
  (4) USD 6,800,000 the fiscal year 2008

5.3 Japan has launched a number of five- to ten-year programmes in the field of nanoscience and nanotechnology since the mid-1980s. In 2003, the budget for the R&D programme for nanotechnology and materials stood at USD 900 million, but nanotechnology-related themes are also present in life science, environment and information society programmes. This brings the total budget earmarked for the sector in 2003 to nearly USD 1.5 billion, with an increase of approximately 20 % in 2004. The Japanese private sector is also very much present, represented by two major trading houses, Mitsui & Co and the Mitsubishi Corporation. Most of the major Japanese companies, such as NEC, Hitachi, Fujitsu, NTT, Toshiba, Sony, Sumitomo Electric, Fuji Xerox, etc. have invested heavily in nanotechnology.

5.3.1 Under its current five-year plan for 2001 to 2005, China has set aside a budget of approximately USD 300 million for nanotechnology. According to the Chinese minister for science and technology, about 50 universities, 20 institutes and over 100 companies are active in the sector. To secure an adequate platform for commercialising nanotechnology, an engineering centre and a nanotech industry base have been set up between Beijing and Shanghai. Furthermore, the Chinese government has set aside USD 33 million for the establishment of a national research centre on nanoscience and technology, in order to better coordinate scientific and research efforts in the sector.

5.3.2 In 2002, the Chinese Academy of Sciences (CAS) founded Casnec (the CAS Nanotechnology Engineering Centre), with an overall budget of USD 6 million, as a platform to accelerate the commercialisation of nanoscience and nanotechnology. In Hong Kong, the two main sources of nanotech financing are the Grant Research Council and the Innovation and Technology Fund, spending an overall budget of USD 20.6 million in the period from 1998 to 2002. For 2003 and 2004, the Hong Kong University of Science and Technology and the Hong Kong Polytechnic University have granted their own nanotech centres nearly USD 9 million.

5.3.3 In Australia and New Zealand meanwhile, the Australia Research Council (ARC) has doubled its funding for competitive projects over the last five years, and has plans to set up eight centres of excellence in various locations, with a view to more in-depth research into themes such as quantum computer technology, quantum atom optics, photovoltaics, advanced photonics and advanced optics systems.

5.3.4 In New Zealand, the MacDiarmid Institute for Advanced Materials and Nanotechnology is the national coordinator for advanced research and training in materials science and nanotechnology, working on the basis of close cooperation between universities and various partners, including Industry Research Ltd (IRL) and the Institute of Geological and Nuclear Sciences (IGNS).

5.3.5 The MacDiarmid Institute is focusing on the following sectors in particular: nanoengineered materials, optoelectronics ([25]), superconductors, carbon nanotubes, light materials and complex fluids, sensorial and image systems, and lastly, new energy-storing materials.

6. General comments

6.1 The explosion of nanotechnologies around the world, in America, Asia and Oceania alike, is proof that it is high time that Europe took systematic and coordinated action to secure joint Community and national financing for basic and applied research and its speedy transfer to new products, processes and services.

6.2 A joint European strategy should be based on:

— boosting joint efforts in the field of scientific and technological research, demonstration and training, as part of the establishment of the European Innovation and Research Area;

— maximising interplay between industry and academia (research, education and advanced training);

— speeding up the development of industrial and multisectoral applications, and of the economic, social, legal, regulatory, fiscal and financial context to accommodate the work of innovative new businesses and professional profiles;

— safeguarding ethical, environmental, health and safety interests throughout the lifecycle of scientific applications; promoting the relationship with civil society and regulation of metrological and technical standardisation matters;

— stepping up the European coordination of policies, measures, structures and networks, so that they are able to maintain and improve on current competitive levels of scientific, technological and applications development;

— immediately involving the new Member States in the process of studying and applying nanoscience, by means of targeted measures, using the financial appropriations provided by the ERDF and the ESF ([26]) and joint programmes, managed with existing accredited EU research centres ([27]).

([25]) Optoelectronics is a technique that combines the disciplines of optics and electronics. It studies mechanisms that convert electrical signals into optical signals and vice versa (CD players, laser systems, etc.).

([26]) ERDF, European Regional Development Fund: one of the Structural Funds that, under Priority IV (local development systems), can be used to finance research facilities and equipment.
ESF, European Social Fund, another Structural Fund that, under Priority III (human resources), can be used to finance training for researchers and information for entrepreneurs.

([27]) The CD ROMs and recent publications of the Research DG provide a broad panorama of European research centres and their specialisations. For more information see:
http://cordis.lu/nanotechnology

6.3 The achievement of a large critical mass and high value added should pave the way for the establishment and development of a joint strategy. Manufacturing and service companies, small ones in particular, should be able to use the results of such a strategy for their innovative and competitive development while also contributing by spawning trans-European networks of excellence together with universities, public and private research centres and financial bodies.

6.4 The development of this strategy must be firmly anchored in that of society. This means that the strategy must be firmly warranted by the major contribution it can make not only to the competitiveness of the European knowledge-based economy but also and above all to the health, environment, safety and quality of life of the European public. This also means working on the demand side of nanotechnologies, to solve the problems faced by the public, businesses and organisations, as these are the areas most in need of practical responses.

6.5 The commitment of society as a whole must be secured. This will require transparency and safety in the nanotechnological process, from basic research all the way to the application of results and their demonstration and development in innovative market products and services. It will also require agreements that are clear and comprehensible for the general public, providing an assurance that the entire life cycle of the products, including disposal, is subject to checks and constant risk assessment.

6.6 A positive relationship must be forged between science and society in this sector in order to avoid the emergence of barriers to or stagnation in nanotechnology development, in contrast to what happened during the growth of other new technologies recently.

6.7 The creation of European facilities and of new multidisciplinary scientific and academic profiles is also essential. This too will mean winning the full trust of the tax-payer and of policy-makers, who need to be fully aware of the positive potential of the nanotechnological revolution.

6.8 The development of nanotechnologies is therefore not only a major challenge intellectually and scientifically, but also and above all a challenge for society as a whole. Phenomena for which the scientific principles are known at macro level are being altered, increased, reduced or eliminated at nano level, with consequences that may have an — at times radical — impact on applications. New manufacturing techniques, new approaches, different types of service and new professions to manage them are developing.

6.8.1 This rapid transformation demands a strategy for the creation and/or reskilling of senior managers to manage the transition, set up a new form of governance for the process, generate new professional profiles and attract the best brains, at world level.

6.9 The Community's financial perspectives for 2007-2013, as recently proposed by the Commission, should be assessed and remoulded in the light of the challenges posed by this new technological revolution. Suffice it to say that the American Congress has approved a nanotechnology budget of over EUR 700 million for the 2004 fiscal year alone. According to the estimates of the US National Science Foundation (NSF), civil investment in the sector by various governmental organisations around the world in 2003 exceeded EUR 2,300 million, broken down as follows:

— approximately EUR 700 million in the USA (added to which a further EUR 250 million managed by the Defense Department, DoD);

— EUR 720 million in Japan;

— less than EUR 600 million in Europe, including Switzerland;

— approximately EUR 720 million in the rest of the world.

6.10 As far as the future is concerned, the growth of world industrial output in the sector has been estimated at around EUR 1,000 billion over 10 to 15 years, calling for over two million skilled people to join the sector's workforce.

6.10.1 This confirms the principle that nanotechnology = progress for the employment strategy ([28]). The development of the knowledge-based society will be measured against its capacity to tap sensitively and intelligently into the new sources of employment and progress.

6.11 For the EU's strategy in this area to be certain of success, therefore, it is essential to build up financial and human resources and coordination at Community level.

([28]) See the Luxembourg (1997), Cardiff (1998), Cologne (1999) and Lisbon (2000) processes, on the use of development to increase and improve employment.

6.12 In both Asia and the USA, a joined-up approach to the various policies directly or indirectly concerning the sector's development has proved indispensable, in order to be proactive vis à vis the need for new entrepreneurship, new training, and a new regulatory and technical-legal framework.

6.13 As has been shown by the many studies already carried out ([29]), nanotechnology enables the production, manipulation and positioning of objects, while also securing a proactive technological approach on a large scale at competitive processing and production costs.

6.14 In the long term, science will be able to provide instruments to assemble nano-objects, so that they can form complex systems able to carry out functions that the individual parts cannot. The time-to-market of this ultimate goal is as yet difficult to estimate, but it must be pursued with the appropriate support instruments.

6.15 Various 'intelligent' materials ([30]) have been made and are already available to consumers:

— highly durable materials for the automotive and aerospace sectors;

— high-performance lubricants;

— friction-reducing nanoparticles;

— the surface processing of mechanical parts;

— extremely small *Intelligent Sticks*, with memory capacity of 1,000 MB ([31]);

— flexible CDs that can hold over 20 hours of music;

— self-cleaning fabric, ceramic and glass surfaces ([32]);

— glass with electrically-adjustable transparency;

— heat-proof glass that can withstand extremely high temperatures;

— scratch- and corrosion-resistant nanostructured sheet metal;

— diagnostic systems;

— special paints to protect walls and buildings;

— graffiti-proof paint for walls, train carriages and other objects.

6.15.1 Many new applications, in addition to those described above, are already in use or are at the fine-tuning stage and will very soon be part of everyday life. They point to progress or even a revolution in 'domotics' ([33]) and will contribute to improving the public's quality of life.

6.16 Thanks to biomimetics, the study of the possibility of interfacing electronic circuits with biological tissues, in the near future it will be possible to restore hearing to hearing-impaired and sight to sight-impaired organisms.

6.16.1 Various types of micromotor ([34]) are already at the laboratory stage. They are able to reach a predetermined target, such as an infected cell, and destroy it in order to prevent it from contaminating other cells. Currently however, the action taken on unhealthy cells also affects healthy cells, often causing considerable damage to organs.

6.16.2 Scientific applications of the technique are already able to supply a number of practical results that are directly applicable to daily life. Unfortunately, the costs are still too high however. In order for them to become affordable, awareness of these new possibilities must become common knowledge, in order to alter deep-rooted procedures and habits that more often than not obstruct and delay change.

6.17 The traditional textiles/clothing/footwear sector has been in crisis throughout the European Union not least because of competition from products from countries that do not uphold basic labour standards or take into consideration the cost of environmental protection or of health and safety in the workplace.

6.17.1 Intelligent and/or technical fabrics, including those designed with the help of nano powders, are on the increase in many European countries and showing growth of around 30 % a year. Particularly important are fabrics designed to enhance all aspects of safety: from road safety to protection from pollution, chemical agents, allergenic products and atmospheric agents, etc. ([35]).

([29]) European Commission, Research DG

([30]) These are nanostructured surfaces that have different properties to traditional surfaces.

([31]) These are extremely useful instruments that can store an enormous quantity of data, photographs and music.

([32]) The way the surfaces are structured and enriched with certain types of atoms prevents dirt and dust from coming into direct contact with the fabric, ceramic or glass.

([33]) From the Latin *domus* (house), domotics is the science that studies all aspects of development in the home.

([34]) The University of Grenoble has already run experiments on a number of types of micromotor, based on kinesin.

([35]) See Opinion CESE 967/2004 (OJ C 302, 7.12.2004) and studies conducted by the Universities of Ghent and Bergamo (textiles sector).

6.18 Nanotechnology is also revolutionising medicine, especially regarding the early diagnosis and treatment of serious tumours and neurodegenerative diseases associated with old age. Specifically designed nanoparticles can be used as markers for the highly effective diagnosis of infectious agents or metabolite properties, or as vectors for drugs to be deposited in certain areas or organs affected by highly localised diseases. Systems of this kind are already being used in various experiments.

7. **Specific comments**

7.1 The nanotechnological approach to new materials means creating new functions by using nanoscale components. A good example is that of technologies for the production and processing of durable and efficient materials for the automotive and aeronautics sectors, areas in which Europe has the edge over its main competitors. It has been clearly demonstrated that nanostructured systems can significantly reduce friction between two connecting surfaces, and thus reduce wear and tear.

7.1.1 Just one of many examples of nanotechnology's various commercial applications is that of the development of nanostructured materials and surfaces to reduce friction and wear and tear. These systems play a key role in the development of new, highly efficient industrial processes with a low environmental impact. Approximately 25 % of the energy used in the world is lost through friction ([36]), and losses owing to mechanical parts becoming worn out are estimated at between 1.3 % and 1.6 % of an industrialised country's GDP. The costs associated with problems of friction, wear and tear and lubrication can be estimated at approximately EUR 350 billion a year, broken down between the following sectors: land transport (46.6 %), industrial processes (33 %), energy supply (6.8 %), aeronautics (2.8 %), domestic consumption (0.5 %), other (10.3 %) ([37]).

7.1.2 New technological platforms must therefore be created on the basis of approaches that take into account the peculiarities of nanotechnologies and, in particular, the fact that functions and dimensions coincide, i.e. control over dimensions coincides with control over functions. **For instance, in the case of lubrication: if nanometric particles of the right dimensions are built into a surface, there is no longer any need to lubricate, as that function is carried out by the nanoparticles, by means of their dimensions.**

([36]) Source: Oakridge National Laboratory, USA.
([37]) Ibidem.

7.1.3 Nanostructured materials and coatings, whose ingredients are of nanometric dimensions, can significantly reduce the above percentages. For instance, a decrease of 20 % in the friction coefficient in a car's gearbox could reduce energy losses by a percentage varying between 0.64 % and 0.80 %, yielding savings of EUR 26 billion a year in the transport sector alone.

7.1.4 Surface testing and engineering is a key technology in terms of sustainable growth. A report from the UK's Department of Trade and Industry describes the state of the surface engineering industry in the 1995-2005 period and in 2010 ([38]). The report shows that in 1995, the English market for surface modification processes totalled approximately EUR 15 billion, and involved the production of goods for a value of around EUR 150 billion, of which EUR 7 billion was linked to the development of technologies for the protection of surfaces from wear and tear. The prediction for 2005 is that in the UK this sector will be worth approximately EUR 32 billion, involving industrial processes valued at around EUR 215 billion.

7.1.5 Projecting these figures on to the European market gives EUR 240 billion for surface processing, and spin-offs to other production sectors of approximately EUR 1,600 billion.

7.2 In order to benefit from nanotechnology ([39]), industrial development must be based on the capacity to marry traditional manufacturing processes and technologies (top-down) with innovative processes able to create, manipulate and integrate the new nanometric ingredients, using existing or new platforms.

7.2.1 An approach based on governance is of fundamental importance. In addition to general initiatives taken with consumers in mind, others must be developed and aimed at industry associations, local administrators and non-profit organisations, so as to tie in the warp and weft of the economic, political and social fabric. Competence centres could play an important role here ([40]), laying the foundations for greater coordination of local and European initiatives and generating a climate that is conducive to nanotechnological innovation. In this context, action must be taken to assess the impact of nanotechnologies on health and the environment, and any EU (top-down) initiatives should dovetail with action determined and promoted locally (bottom-up).

([38]) A. Matthews, R. Artley and P. Holiday, 2005 Revisited: The UK Surface Engineering Industry to 2010, NASURF, Dera, 1998.
([39]) NB: There is no such thing as the industrial development of nanotechnology, but rather development that benefits from nanotechnology.
([40]) Cf. the experience of Servitec, the Dalmine 'innovation pole' in Bergamo.

7.3 The EESC wishes to stress the great potential of developing nanoscience and nanotechnology as part of the application of the Lisbon Strategy. Uniting the scientific disciplines around an approach based on nanoscale units of matter will lay new foundations for the integration of knowledge, innovation, technology and development.

7.4 Coordination is still rather fragmented at European level despite efforts made under the sixth framework programme. The focus appears to be on rationalising the use of resources. While there is strong backing for basic research and also for the development of new industrial processes, there is as yet a lack of direction and backing for initiatives to generate real progress in mass production technologies. Support for efforts to develop European governance in the area is more embryonic still.

7.5 In the Member States, genuine coordination is essential but it has thus far been absent, especially when it comes to applying research. In many European countries, businesses, SMEs especially, are encountering the following difficulties:

— a lack of basic knowledge of nanoscience and nanotechnology,

— a lack of professionals able to relate to companies' needs,

— an incapacity to assess the impact of the new technologies in terms of technological and market processes,

— difficulties in locating and assessing nanostructured raw materials,

— the inability to insert nanotech processes into traditional production processes,

— difficulties in assessing the development of the market for nano products,

— inadequate links with universities and innovation centres.

7.6 The EESC believes it is very important to use research to design useful systems in the field of public health and everyday life, always adhering to the principle of mimesis, i.e. imitating nature.

7.7 The EESC welcomes the birth of the 'Nanoforum' network ([41]) and hopes that the network's publications will be translated and disseminated in all the Member States. As far as possible, the language used in the publications must be simple and accessible to a wide audience. Universities and research centres should be able to use the forum's findings.

7.7.1 The EESC is also convinced that the 'European nanoelectronics technology platform', suggested by the high level group ([42]), will be all the more successful providing it can avoid unnecessary and costly overlaps in research, working in close cooperation with the Commission.

7.8 It is also the EESC's opinion that by 2008 investment in these sectors in the EU will have to rise from the current EUR 3 billion a year, to EUR 8 billion, with periodical checks by the Commission on the following aspects:

— increase in market quotas,

— public and private investment in research,

— increase in the number of students studying nanotechnology.

8. **Conclusions**

8.1 The EESC fully agrees with the conclusions of the Competitiveness Council of 24 September 2004 on the important role and potential of nanoscience and nanotechnology. The results achieved to date suggest that it is important to sharpen up the expertise and build the instruments that enable atoms to be worked on, in order to produce new structures and modify the properties of existing ones.

8.2 In this respect, the EESC recommends **the immediate launch of a joint, integrated, responsible, European-level strategy**, to focus in particular on: the development of joint efforts in RTD and scientific and technological demonstration and training; interaction between industry and the academic world; the accelerated development of industrial and multisectoral applications; and greater European coordination of policies, measures, structures and networks. As part of this strategy, a special effort must be made from the outset at international level too, to safeguard ethical, environmental, health and safety interests throughout the lifecycle of scientific applications and to promote appropriate technical standardisation.

([41]) The Nanoforum network's members are: the Institute of Nanotechnology (UK), which is acting as coordinator; UDI Technologiezentrum (DE); CEA-LETI (FR); CMP Científica (ES); Nordic Nanotech (DK); and Malsch Techno Valutation (NL). http://www.nanoforum.org.

([42]) See previous footnote: 'Vision 2020' report, published on 29 June 2004.

8.3 The EESC would emphasise the need for this **strategy to be firmly anchored in the development of society**, making a positive contribution not only to the competitiveness of the European economy but also, and above all, to human health, the environment and safety, not to mention quality of life.

8.3.1 On this note, the EESC would stress the importance of **securing the responsible and sustainable development** of nanotechnology, **from the outset**, in order to meet the justifiable expectations of civil society with regard to environmental, health, ethical, industrial and economic aspects.

8.3.2 The EESC recommends a substantial **increase in the resources earmarked for basic research**, as technological and industrial excellence is always based on scientific excellence.

8.3.3 **The 3 %** [43] **objective decided at Barcelona** should be implemented, making a priority of concentrating resources in the field of nanoscience, the development of its applications, and the convergence between nano-, bio- and info- technology and knowledge-based technology.

8.3.4 The Community's **financial perspectives for 2007-2013**, recently published by the Commission, should be assessed and remoulded in the light of the challenges posed by this new nanotechnology revolution.

8.3.5 The increase in funds hoped for must be reflected in an appropriate financial provision under the forthcoming seventh framework programme. The figures should reflect those earmarked in other countries, such as the USA.

8.4 The EESC is convinced that Europe should launch **a high-level action plan with a definite road map and timetable and a joined-up approach,** securing the necessary consensus among all civil society players on a **shared vision**. This vision must be translated into clear and transparent objectives for responding to the requirements of economic and social progress, and improved quality of life, safety and health for all.

8.5 In the Committee's opinion, there is a need to establish **technological platforms with a large critical mass and high European value added**, bringing together public and private players from the worlds of science, finance and administration who are active in the various specific fields of application.

8.6 The Committee would reiterate the urgent need to **set up high-level European facilities and to strengthen the competence centres (CCs)**. Their location and specialisation would be determined on the basis of close coordination between European and local bodies, so as to pinpoint homogeneous industrial areas for local product specialisation, where a critical mass of R&D may already have taken root.

8.6.1 The **CCs** should be able to **carry out and transfer high-quality research** aimed at application and innovation, using nanotechnology, particularly in fields such as **nanoelectronics, nanobiotechnology and nanomedicine**.

8.7 Researchers must be certain that their intellectual property is protected, particularly in such a sensitive field. The EESC believes that solving the patenting issue in a clear and satisfactory way is a top priority if the success of applied research in the field of nanotechnology is to be secured. No time must be wasted in **establishing a European-level Nano-IPR helpdesk,** to meet the needs of researchers, companies and research centres.

8.8 The Commission, in conjunction with the Member States, must step up its efforts and promote in-depth studies in universities and research centres, to ensure that the patenting process appears feasible, with straightforward and inexpensive procedures, particularly in such an innovative sector.

8.8.1 As far as international cooperation is concerned, work on safety and the standardisation of measures and processes should be stepped up in conjunction with non-EU countries. Special attention should be given to China, which is investing heavily in the field of nanotechnologies. The USA and Japan, meanwhile, have a very aggressive policy in this area (cf. the agreement between China and the State of California on the development of centres of excellence for biomedical nanotechnologies).

8.8.2 The EESC believes that an additional effort must be made, not least through the **European initiative for growth** launched in December 2003, **to increase the number of nanotech companies** in the EU. To this end, the relationship between universities, **nanotechnological innovation centres** and companies must be constantly promoted and improved.

8.8.3 Measures are needed to target the development of nanotechnology-based industrial processes (from nanotechnology to nanomanufacturing), for companies both large and small. Europe should follow the American example of developing a plan to use federal programmes such as the Small Business Innovation Research Program and the Small Business Technology Transfer Research Program, in order to sustain an all-pervasive spread of nanotechnological development throughout the business fabric, however small the companies involved.

[43] 3 % of European gross domestic product should be spent on research and development by the public sector (the Member States and the Community) and industry.

8.8.4 Industry associations can play an important part here both nationally and locally. The Research and Enterprise DGs could jointly promote a number of **intensive awareness-raising campaigns**, **involving all the economic and social players**, on the basis of the positive experience developed in Trieste ([44]).

8.8.5 In the EESC's view, the establishment of a European information clearing-house ([45]) would be a very important mechanism to facilitate:

— the commercialisation of nanotechnology and the transfer of technologies and new concepts into commercial and military products,

— the dissemination of the best practice of universities and public and private laboratories, with a view to transfer into commercial use.

8.9 Alongside and in connection with the European forums, there should be a number of **worldwide forums**, open to UN countries, and able to deal with **issues relating to**:

— patents,

— ethical rules,

— social consensus,

— environmental aspects,

— sustainable development,

— consumer safety.

8.10 The **European Investment Bank (EIB)**, possibly with the practical support of the European Investment Fund (**EIF**), should set up credit facilities, to be managed in conjunction with credit institutions, regional financing bodies specialised in company loans, venture capital companies and guarantee cooperatives, in order to facilitate the birth and growth of companies that are centring their production on nanotech products.

8.10.1 The *Growth and Environment* **Programme** was a positive experience that yielded excellent results in the past (though mainly in the environmental sector). It could be imitated, in order to encourage growth in new types of **nanotechnology**-based production ([46]).

8.11 Research and its spin-offs for products should be geared towards the requirements of the public and sustainable development. In this context, action must be taken to **assess the impact of nanotechnologies on health and the environment**, and any EU (top-down) initiatives should dovetail with action determined and promoted locally (bottom-up).

8.12 There must be an ongoing and scientifically well-founded **dialogue with the public**. The new technologies that are growing out of the use of atoms must be transparent and provide the public with an assurance that there are no hidden dangers for health or the environment. History has taught us that, very often, fear and concern regarding new products are born more out of ignorance than reality.

8.12.1 This is one of the reasons why the EESC hopes that there will be an unceasing and direct connection between research results and universally-recognised **ethical principles**, for which an **international dialogue** will be necessary.

8.13 As the technology forums ([47]) are in their formative stage, special **attention** must be **given to the new members of the European Union**, ensuring they are fully represented and that they have a direct link with the European centres of excellence.

8.14 The EESC believes that the **coordination** of research in the vast field of nanoscience should be the **responsibility of the Commission —** albeit with basic research activity being the responsibility of the future European Research Council ESR. The Commission, in agreement with the Parliament and the Council, can secure the best possible added value for the European public including a wider and more far-reaching and objective use of research results.

8.15 The EESC asks the Commission to provide it with a biennial report on nanotechnological development, in order to check the progress of the action plan adopted and to suggest possible changes and updates.

Brussels, 15 December 2004.

The President

of the European Economic and Social Committee

Anne-Marie SIGMUND

([44]) Nanoforum in Trieste, in 2003, attended by over 1,000 people.

([45]) See: American nanotechnology legislation of December 2003.

([46]) The Growth and Environment Programme, managed by the EIF in conjunction with various European financial institutions, helped to improve the environmental credentials of micro-, small and medium-sized enterprises, by means of co-financing and credit facilities.

([47]) See point 6.3.

European Economic and Social Committee

INT/277

Nanosciences and nanotechnologies

Brussels, 20 April 2006

OPINION

of the
European Economic and Social Committee
on the

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

COM(2005) 243 final

INT/277 - CESE 582/2006 IT/PM/hn

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On 7 June 2005 the European Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

> *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*
> COM(2005) 243 final.

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 28 March 2006. The rapporteur was Mr Pezzini.

At its 426th plenary session, held on 20 and 21 April 2006 (meeting of 20 April), the European Economic and Social Committee adopted the following opinion by 117 votes with four abstentions.

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1. Background

1.1 In its previous opinion[1] on nanosciences and nanotechnologies, the EESC recognised that it would be helpful to include a brief definition of the main terms used, reflecting the fact that the opinion dealt with a partly new subject, whose vocabulary was little known or at any rate little used. Those definitions should therefore be restated at the beginning of the present opinion.

1.1.1 Many other European programmes which started in 2000 are still in force in 2006, alongside the sixth framework programme. Consequently, it is worth indicating in the notes which main programmes have implications for N&N, especially those programmes that are of particular importance to the new Member States, who did not have the opportunity to follow their inception and the debate on their objectives before 2004.

1.2 Definitions[2]

1.2.1 **Nano** - means one billionth of a whole. In this case, nano is used to mean a billionth of a metre.

1.2.2 **Micro** - means one millionth of a whole. In this case, it means one millionth of a metre.

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1 OJ C 157 of 28.6.2005.

2 Ibid.

1.2.3 **Nanosciences** - The nanosciences are a new approach to traditional science (chemistry, physics, electronic biology, etc.) and deal with the basic structure and behaviour of materials at the level of atoms and molecules. These sciences in fact study the potential of atoms in the various scientific disciplines[3].

1.2.4 **Nanotechnologies** - These technologies enable atoms and molecules to be manipulated so as to create new surfaces and objects that, having a different make-up and arrangement of atoms, have properties that can be used in day-to-day life[4]. These are technologies that deal with billionths of a metre.

1.2.5 **In addition to the above definition, it is worthwhile mentioning another, more significant one from a scientific point of view. The term nanotechnology** describes a multidisciplinary approach to the creation of materials, mechanisms and systems, by means of the nanometric scale control of materials. In accordance with this multidisciplinary approach, a broad knowledge-base in electronics, physics and chemistry is required to establish a nanotechnology qualification.

1.2.6 **Nanomechanics -** The dimensions of an object begin to be important in determining its properties when the scale of its dimensions is of one or a few dozen nanometres (objects made of a few dozen or a few thousand atoms). Within this range of dimensions, an object composed of 100 iron atoms has physical and chemical properties that are radically different to one composed of 200 atoms, even if they are both made of the same atoms. Similarly, the mechanical and electromagnetic properties of a solid made up of nanoparticles are radically different to those of a traditional solid of the same chemical composition and are affected by the properties of the individual constituent units.

1.2.7 **Microelectronics** - This is a branch of electronics that deals with the development of integrated circuits, built within individual semiconductor regions, with minute dimensions. Microelectronics can currently create individual components with dimensions in the realms of 0.1 micrometre, or 100 nanometres[5].

1.2.8 **Nanoelectronics** - This is a science that studies and produces circuits that are made using technologies and materials other than silicon and that work on a substantially different set of principles[6].

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3 Interview with Commissioner Busquin (summary in IP/04/820 of 29 June 2004).

4 See footnote 2.

5 Micro and nanoelectronics centre at the Politecnico di Milano, Prof. Alessandro Spinelli.

6 Ibid.

1.2.9 Nanoelectronics is set to become a cornerstone of nanotechnology, just as electronics today permeates all scientific sectors and industrial processes[7].

1.2.10 **Biomimetics**[8] - This is the science that studies the laws underpinning molecular structures existing in nature. Knowledge of these laws could enable **artificial nanomotors** to be created, based on the same principles as those existing in nature[9].

1.3 **Conclusions and recommendations**

1.3.1 The Committee welcomes the proposals presented by the Commission to implement by 2009 an action plan for N&N in particular with regard to:

- the need to apply a sustainable, competitive, stable and durable model of development;
- the perceptible acceleration at global level of investment in nano-scale R&D and its applications;
- the need to analyse the risks and opportunities of the nano-scale approach, and the urgent need for a widely shared vision on the part both of the social partners' political and official decision-makers and, ultimately, of the general public and the media. This is in order to ensure the success of N&N, on account of their usefulness for the general public's health, safety and quality of life;
- the call for high-quality facilities and infrastructure, integrated European networks and shared databases;
- the need to provide qualified human resources in the scientific, technical and economic fields, together with scientific and industrial specialists capable of interacting with N&N;
- the advisability of creating a European focal point for promotion and coordination to serve as a stable, proactive partner for connecting industry and science in particular, both within the Union and internationally, to be supported by an operational office.

1.3.1.1 Focal point staff must possess in-depth, proven scientific and management skills, and be particularly well attuned to the general context in which N&N development takes place.

1.3.1.2 It is also true of N&N that "Community-funded research and development activities create considerable European added value. They open up potentials that plainly go beyond the capacities of individual Member States and have already facilitated European developments

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7 Investment in nanoelectronics currently totals EUR 6 billion, broken down as follows: 1/3 in nano and micro, 1/3 in diagnostics, 1/3 in materials (source: European Commission, Research DG).

8 From the Greek *mimesis*, to imitate nature.

9 For instance the independent movement of spermatozoa.

of global importance"[10]. This illustrates the importance of a Community focal point which can manage the sector, with clearly-allocated responsibilities.

1.3.2 In the light of the N&N revolution, the Committee is convinced that Europe's chances of being at the forefront in a setting where new players are constantly – and aggressively – entering the world market hinges upon its capacity for coordination and upon the creation of a securely-based European critical mass of nanotechnology.

1.3.3 In the Committee's view, it is crucial that the European Union should succeed in shaping an **N&N action plan** capable of mobilising a collective drive for **governance**, and of uniting the Community, national and regional levels in complying with the subsidiarity principle. More specifically, the plan should provide:

- a visible, transparent dialogue with civil society, ensuring awareness based on objective evaluations of the risks and opportunities presented by N&N;
- constant vigilance to protect ethical and environmental aspects, together with the health and safety of workers and consumers;
- a single Community focal point, capable of ensuring close coordination of the various policies and between the various areas of action;
- a single voice at international level to promote initiatives for joint declarations and codes of conduct, in order to guarantee the responsible use of N&N, to ensure cooperation in basic scientific research;
- action to prevent the emergence of a "nano-divide" (exclusion from developing N&N knowledge), together with the less developed nations;
- legal and regulatory certainty for research, application and innovation efforts on the N&N market;
- a calendar and detailed timetable for the planned actions at both Community and Member State level, with machinery to check on implementation, and with clearly-allocated responsibilities.

1.3.4 The Committee calls for the Community action plan to be accompanied by **national action plans**, providing coordination and regular benchmarking of convergence and synergies in various fields: infrastructure; training and education; risk assessment; harmonisation of standards and patents; and, lastly, dialogue with civil society, especially consumers.

1.3.5 The Committee believes that **European industry** should expand and intensify N&N research and application efforts, increasing investment to levels at least equal to those of its more advanced competitors. This could be achieved by means of the following actions: development of European technology platforms; incentives for the protection and industrial exploitation of N&N; encouragement for targeted training for small-scale entrepreneurs;

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10 OJ C 65 of 17.3.2006.

development of European N&N innovation and application networks; support for multidisciplinary qualification schemes for workers and technical specialists; establishment of "business nanotechnologies" and prototyping and certification laboratories; and creation of a common framework for technical standardisation and intellectual and industrial property.

1.3.6 The two-yearly monitoring report on the implementation of the Community action plan and its consistency with other EU policies should, in the Committee's view, be accompanied by an annual scoreboard detailing compliance with the adopted timetable, and should include the Member State reports on the implementation of the national action plans.

1.3.7 The report should be submitted to the European Economic and Social Committee as well as to the EP and the Council.

2. Reasons

2.1 Nanosciences and nanotechnologies (N&N) represent a rapidly-expanding field which holds great promise for the conversion of basic research into successful innovation. The sector is highly significant in terms of both boosting the competitiveness of European industry as a whole, and creating new products and services capable of enhancing the well-being and quality of life of society and individual citizens.

2.2 Most analysts are convinced that by 2015 N&N-based materials, products and services will be able to generate a global market worth hundreds of billions of euros each year[11] provided that (i) scientific excellence can be successfully translated into commercially viable products, processes and services, and (ii) as emphasised by the Commission itself[12], "a repeat of the European 'paradox' witnessed for other technologies" can be avoided.

2.3 In order to achieve this, there is, in the Committee's opinion, a need to:

- reinforce and coordinate R&D through greater investment,
- create world-class R&D infrastructure,
- ensure careful risk assessment through the scientific and application-related life cycle,
- uphold complete respect for ethical principles,
- promote a favourable, proactive climate for innovation in all parts of the economic fabric and especially among small and medium-sized enterprises,
- develop qualified human resources,
- adjust normative and patent systems,
- promote partnership between public and private organisations.

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11 C.f. *Nanotechnologies and nanosciences, knowledge-based multifunctional materials & new production processes and devices*¸ submitted to the Euronanoforum, Edinburgh, September 2005.

12 COM(2005) 243 final and COM(2005) 24 final.

2.4 The Committee issued an earlier opinion on this subject[13], which included the following recommendations:

- the development of joint Community/national efforts in RTD and scientific and technological training with close interaction between industry and the academic world; a special focus on industrial and multisectoral applications; greater coordination of policies, structures and stakeholder networks; safeguarding of ethical, environmental, health and safety interests; and appropriate technical standardisation;
- a strong link between N&N and society, to ensure that research results make a positive contribution to economic competitiveness, human health, the environment, safety and the quality of life;
- provision of appropriate resources under the new financial perspectives for 2007-2013 and in particular in the Seventh framework programme for R&D (FP7), and reinforcement of European technology platforms;
- the launch of a high-level Community action plan containing a clearly defined road map and timetable and an approach that ties in with that of the Member States, in order to secure consensus among all civil society players on a shared vision;
- the establishment of high-level European infrastructure for research and technology transfer geared to innovation and the markets;
- optimisation of intellectual property arrangements and the establishment of a European-level Nano-IPR Helpdesk, to meet the needs of researchers, companies and research centres and, most importantly, of civil society;
- stepping up international cooperation on the ethical, risk, safety, standards, patents and metrological aspects;
- actions designed to develop N&N-related industrial processes and increase awareness of their use, with the establishment of a European information clearing-house, product commercialisation, technology transfer and sharing of best practice;
- an ongoing dialogue with the media and public opinion, based on dissemination of scientific knowledge, to provide the public with an assurance that the potential dangers for health or the environment are being monitored, and also to forestall misunderstandings concerning nanotechnological developments.

2.5 **N&N in the new Member States**

2.5.1 Over the last five years, the European Commission has used Community resources to support some 30 centres of excellence in connection with the various thematic priorities under the

13 CESE 1629/2004 (OJ C 157 of 28.6.2005).

Community's Framework Research Programme: many of these centres involved in developing N&N[14] are linked to universities, research bodies and enterprises in the new Member States.

2.5.2 The Committee considers it important for the European Joint Research Centre to continue providing support and encouragement for centres of excellence in the new Member States and the applicant countries, particularly in the N&N sector, specifically including this aspect in their work programmes.

2.5.3 In the Committee's view, the Commission should also support the growth of European N&N innovation, application and prototyping networks, especially for small businesses, which represent the bulk of Europe's industrial fabric.

2.5.4 More specifically, specific service packages should be provided to help entrepreneurs to identify opportunities and links in N&N applications, and multiply successful initiatives such as Gate2Growth[15] and Minanet[16]; new sources and methods of risk funding should therefore be identified, together with guarantee systems to supplement existing ones.

2.5.5 The Committee also believes that the PHANTOMS Community initiative – a network of excellence on nanotechnologies set up under the IST/FET Community programme – for Information Society Technologies merits further development and a higher profile.

2.5.6 Furthermore, the EESC considers that, in the light of the need to give greater impetus to research and innovation in the new Member States and applicant states, greater synergies should be built up with the EUREKA and COST initiatives, under which many of these countries are conducting N&N activities.

2.6 The international picture

2.6.1 **Overall spending** at global level by governments, businesses and the financial world on research and development in the N&N sector was estimated to stand, in January 2005, at some EUR 7 billion per annum[17] (more than half from public funds), of which approximately

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14 Leading centres of excellence include the DESMOL Centre of Molecular Studies, the High Pressure Research Centre and the CELDIS centre of the Polish Academy of Science's Institute of Physics; the KFKI-Condensed Matter Research Centre and the Research Institute for Solid State Physics and Optics of the Hungarian Academy of Sciences; and the Centre for Advanced Material Research and Technology (CAMART) of the University of Latvia's Institute of Solid State Physics.

15 The Gate2Growth Community initiative provides a package of services and networks to help make access to investment for new innovative businesses faster and cheaper, through pan-European thematic networks of investors and intermediaries, such as I-TecNet.

16 Minanet is an accessible on-line database on European research projects in the field of microsystems and nanotechnologies. It includes N&N projects in the Czech Republic, Poland, Slovakia, Hungary, Bulgaria, Lithuania, Latvia, Cyprus and Romania.

17 Lux Research and Technology Review on Nanotechnology 2005.

35% was spent in North America, 35% in Asia, 28% in Europe and 2% in the rest of the world.

2.6.1.1 Although the differences in public investment at the end of the 1990s were, in per capita terms, very small (roughly EUR 1 in the US and Japan, in the EU half this amount), by 2005 per capita spending in the US stood at EUR 5, in Japan at EUR 6.5 and in the EU at EUR 3.5. Forecasts to 2011 suggest a level of more than EUR 9 in the US and Japan, and EUR 6.5 in the EU[18].

2.6.2 **Spending by industry** at world level amounts to more than EUR 3 billion per annum, of which 46% is carried out by US companies, 36% by Asian companies, 17% by European companies and less than 1% by businesses from the rest of the world. Some 1 500 companies have declared a strong commitment to N&N research and development: of these, 80% are represented by start-ups, of which more than half are North American. Media coverage of nanotechnology affairs has risen from about 7 000 articles a year to the current 12 000[19].

2.6.3 Over the five years between the end of 2000 and the present, the federal government of the **United States** has invested more than US $ 4 billion in nanotechnologies. For 2006 alone, the Bush administration has requested US $ 1 billion for N&N research to be allocated to the eleven federal research agencies. As pointed out in the 2005 report on *The National Nanotechnology Initiative at Five Years*, "the United States is the acknowledged leader in nanotechnology R&D" at world level, with annual public and private investment of US $ 3 billion, accounting for approximately one third of world spending.

2.6.3.1 The US also comes first in the number of business start-ups, publications and patents. At federal level, it is felt that spending on new knowledge and infrastructure is both "appropriate and wise", likely to generate "substantial economic payoffs over the long term".

2.6.4 Annual spending in **Japan** in 2003 stood at about EUR 630 million, with 73% provided by the Ministry of Education and 21% by the Ministry for the Economy, Trade and Industry. Research is focused primarily on nanomaterials. In terms of nanotechnology venture capital, Mitsui has decided to invest almost EUR 700 million over the next four years, while the Critical Technology Fund will channel some EUR 30 billion to N&N research[20].

2.6.5 Still in Asia, **Taiwan** too plans to invest more than EUR 600 million between now and 2008, with 800 companies involved with N&N; it is expected that production will rise to EUR 7.5 billion in 2006, with a rise in the number of businesses in the sector to 1 500 and

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18 C.f. http://cordis.europa.eu.int/nanotechnology; European Commission, Research DG, Unit G4 (8.12.2005).

19 Lux Research and Technology Review on Nanotechnology 2005.

20 In terms of private N&N investment, some 60 Japanese companies spend approximately EUR 170 million annually on nanotechnology R&D, an increase of 20% since 2003.

new product development of up to EUR 25 billion in 2012, particularly in the various nanoelectronics sectors.

2.6.5.1 The prerequisite for this expansion to take place is that intellectual and industrial property problems be resolved.

2.6.6 **South Korea** is one of the first countries whose companies have successfully marketed N&N based products[21]. The country, which has a potential domestic nanotechnologies market estimated to be worth some EUR 2 billion, has launched a Next Generation Core Development Program on N&N, with a budget of EUR 168 million. Its priorities include nanomaterials, nanocomposites and bionanotechnologies.

2.6.7 More than 30 N&N companies have been set up in recent years in **Australia**, and their numbers are continuing to grow by 50% a year. Public and private spending on N&N research amounts to nearly EUR 60 million a year, focusing mainly on new materials, bionanotechnology and medical and therapeutic applications.

2.6.8 According to a report recently published in Beijing on nanotechnology development in **China** in the 2005-2010 period, with forecasts up to 2015[22], the country is one of the world's leaders in terms of new N&N business registrations, publications and patents, with an internal market for N&N products and systems estimated at more than EUR 4.5 billion, and set to grow to more than EUR 27 billion by 2010, and more than EUR 120 billion by 2015[23].

2.6.9 The EESC believes that the international picture serves to highlight the importance of ensuring a proactive climate favourable to research and innovation in all EU countries, in order to be able to share successfully in research and development investment in the sector.

3. Comments

3.1 The Committee has always argued that stronger efforts to achieve an increase in absolute and relative terms of R&D investment in Europe are necessary as part of the effort to achieve the 3% Barcelona objective. In the light of international trends, it is convinced that such an effort is necessary first and foremost in the N&N sector.

3.1.1 The Committee believes that the effort would be weakened if not made as part of a robust process of European-level coordination of national and regional N&N research programmes,

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21 Samsung launched its Flash Memory Chips, containing 90 nanometric components, as far back as 2002.

22 Beijing Report 2005 on Nanotech Development to 2010-2015.

23 According to the above report, China's share of the world market will be more than 6% in 2010 and 16% in 2015. The race to bring out finished products will depend heavily upon convergence in nanobiotechnological and nanoscientific applications, and on the practical research of the three major national research centres and more than 20 nanotechnology institutes.

partly via the ERA-NET and ERA-NET PLUS[24] schemes. It should be backed by actions to raise awareness and support for research centres, industries and universities through the COST[25], ESF[26] and EUREKA[27] programmes, and with EIB loans.

3.1.2 The Committee is of the view that such **European coordination** and cooperation should also cover **Member State actions** designed to develop interdisciplinary infrastructures and centres of N&N skills and excellence, which should also aim to link up with a pan-European network to multiply synergies and prevent wasteful duplication.

3.2 **Community level**

3.2.1 The Committee is convinced that if the Community action plan is to be effective and credible, it should contain a calendar and detailed timetable, which would facilitate more stringent checks on the progress achieved in the following spheres:

- increasing investment in N&N research, innovation and training, at Community, Member State and regional level, always however tied in with a robust European coordination process conducted by the Commission, and with a stronger commitment on the part of industry;
- including a focal point for European coordination into FP7, to serve as a stable, proactive partner both within the Union and for the purposes of international cooperation and dialogue, with a European "Nano-Janus"[28] centre equipped with sufficient resources;
- providing qualified human resources with multidisciplinary profiles in the scientific, technical and economic fields, and boosting the presence of scientific and industrial specialists aware of the N&N approach;
- ensuring the acceptability and success of nanosciences and nanotechnologies through a visible and transparent dialogue with civil society, not only for the sake of their contribution to European competitiveness, but also of their usefulness in terms of citizens' health, safety and quality of life;
- introducing toxicological and ecotoxicological risk assessment mechanisms and the appropriate training mechanisms to cover all phases from the drawing board to implementation;

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24 European Research Area: cooperation and coordination of national or regional research activities. The ERA-NET programme, with a budget of EUR 148 million, provided for calls for proposals every six months, up to 2005, targeting projects in which legal entities of at least three Member States were involved. ERA-NET Plus has been introduced for the coming years, building upon its predecessor.

25 COST: European Co-Operation in the field of Scientific and Technical research.

26 ESF: European Science Foundation.

27 EUREKA: European initiative for the development of market technologies.

28 Cf. the National Nanotechnology Office set up in the US in 2003 under the Nanotechnology Development Act.

- submitting research and public funding proposals to an ethical monitoring system, as already envisaged for the framework programme, to identify all ethical issues which may arise in connection with N&N;
- preserving the proper balance between the need, on the one hand, for social development, dissemination for scientific and practical purposes, and health protection and, on the other, the demands of intellectual and industrial property.

3.2.2 The Committee strongly advocates a substantial increase in investment in N&N research, innovation and training, at Community, Member State and regional level, in parallel and in close coordination with the Member State and regional levels.

3.2.2.1 In this connection, the Committee would emphasise that, in contrast to the situation in other research sectors, the amount of Community funding channelled to N&N is equal to that from the Member States (where, for general research, Community resources account for 4-5% of overall European research expenditure, while Member State resources represent 87%).

3.2.3 The Committee considers that no less than 10% of the resources allocated to the specific "Cooperation" programme under FP7 2007-2013 should be earmarked for the N&N thematic priority.

3.2.3.1 Within the "Capacities" programme, due place should be accorded to SMEs for N&N research and innovation, particularly for "nanotechnology districts", infrastructure for excellence and N&N foresight activities.

3.2.3.2 The proper place should be given to training and mobility for N&N researchers, within the specific "People" programme, and the same should apply to the work of the Joint Research Centre with regard to safety and metronomy, as well as to prospective technological studies.

3.2.4 For its part, the Competitiveness and Innovation Framework Programme should, from 2007 onwards, be able to devote – even with the limited resources available to it – some of its efforts to fostering a culture of entrepreneurship geared to the organisational applications of N&N research.

3.2.5 The Committee strongly supports the establishment of European technology platforms, modelled on those already in place for nanoelectronics and nanomedicine; these platforms are in fact ideal instruments for mobilising all the public and private players across the different sectors (science, training, technology, industry, finance) in Community, national/regional or joint projects and initiatives, underpinned by a shared and proactive forward-looking vision.

3.2.6 The Committee considers investment in advanced education and training to be crucial. The new post-2006 Community programmes should make specific provision for areas of action providing multidisciplinary support for N&N.

3.2.7 The Commission should facilitate industrial exploitation by introducing the following by 2007, under the FP7 N&N work programme:

- a Nano-IPR Helpdesk, as proposed by the EESC in its previous opinion on N&N;
- a European clearing house for exchange of best practices and monitoring of patents and new applications on the world market;
- a Digital Library, as proposed in the communication under discussion;
- CEN-STAR[29] tenders for pre-legislative and co-normative technical research projects;
- pilot schemes to demonstrate the industrial applications of N&N.

3.2.8 The Commission should immediately strengthen the ethical monitoring system, to ensure that all ethical issues are identified which may arise in connection with N&N, especially in the fields of medicine, the agri-food industry and cosmetics.

3.3 **Member State level**

3.3.1 The Committee emphasises how important it is for Community action plans to be matched by national **action plans**, which are to be submitted to the European Parliament, the Council and the Commission by the end of the first half of 2006. The purpose is to ensure coherence and synergies in the fields of infrastructure, training and education, as well as harmonisation of standards and patents, risk assessment and, lastly, dialogue with civil society, consumers and the media.

3.3.2 The Committee believes that the Member States should allocate a greater proportion of their available public and private investment to N&N, and should submit regular reports to the EP and the Council on the progress made in investment and in implementing national plans.

3.3.3 These reports should be included in the two-year Community report, with specific reference to:

- the creation of a regulatory and legislative environment which is favourable to the new cycle of industrial applications of N&N to new business concepts, new qualifications and training requirements for entrepreneurs, workers and technical specialists, standards, product certification, ethical issues and transparency, particularly with regard to medical and scientific training, accessibility and equal opportunities;
- incentives for innovative N&N applications at local and regional level, with the development of networks of prototyping, certification and risk assessment laboratories which are accessible to all businesses, official bodies, universities and research centres; to this end, dedicated start-up and venture capital measures of a financial nature should be

29 CEN: European Committee for Standardisation. STAR: working group on standardisation and research.

implemented, especially in cohesion regions, and information centres with a public profile should be set up to explain the risks and opportunities generated by N&N;

- the introduction of initiatives to prevent a "nano-divide", particularly in structural and cohesion fund intervention areas and in island and outlying regions, accompanied by measures to prevent less developed third countries being excluded from N&N development.

3.3.4 The Committee considers that the Member States should act to preserve a proper balance between two imperatives: on the one hand, the need for cooperation and dissemination for scientific and practical purposes, geared to health and environmental protection and, on the other, the need to safeguard the confidentiality of inventions and intellectual and industrial property.

3.3.5 In the Committee's view, this again highlights the disadvantages of the lack of a Community patent and a single Community patent law. This concerns not only the question as to what can be patented in the Member States, in terms of inventions in bionanotechnology, but also simple access for stakeholders to information about new inventions and patents.

3.4 **International level**

3.4.1 The Committee fully supports the guidelines set out in the action plan for building up structured cooperation and dialogue at international level. It would add the following suggestions:

- holding regular international forums under EU auspices to broaden opportunities for dialogue, exchange and communication, with a view to strengthening the international scientific, industrial and academic community;
- developing European leadership skills in order to promote initiatives for joint declarations and codes of conduct regarding the responsible development and use of N&N;
- creating an electronic archive within the EU of worldwide scientific and technical publications on N&N by 2008;
- including capacity-building actions for partners in developing countries, training actions for scientific personnel and actions to prepare local skills to receive N&N in European development cooperation policy guidelines: the purpose of these actions being to prevent the emergence of an "N&N divide" (exclusion from developing N&N knowledge);
- fostering user-friendly synergies with European initiatives – such as EUREKA – and international initiatives – such as Human Frontiers – in the N&N field.

3.5 **Company, labour and civil society level**

3.5.1 The Committee believes that companies, especially SMEs, can derive enormous benefit from N&N research work and its direct dissemination to technology transfer, especially by taking on board energy efficiency and environmental technologies, IT nanotechnologies, new

materials applied to processes, products and services, and the converging nano-, bio-, and infotechnologies.

3.5.2 The Committee considers that **European industry** should expand and intensify N&N research and application efforts, increasing investment to levels at least equal to those of its more advanced competitors: this effort should be given strong backing by the creation of a favourable regulatory and legislative environment at both Community and national/regional level.

3.5.3 The Committee is convinced that this approach, which advocates strong business involvement, is vital to N&N research and development and application, provided that arrangements are made for support actions at European, national/regional and, most of all, the joint level, aimed at:

- transparent, simple and clear information on nanotechnology scouting of research results, applicable in a permanent and safe manner for workers, technical specialists, consumers, the environment and health; these results must be guaranteed by certification which is fully acceptable to both society and the market;
- implementing training initiatives focusing on the difficulties of businesses, especially small ones, through the assimilation and informed use of N&N, complying with the requirements of the new production processes which apply them[30];
- supporting multidisciplinary training and qualification schemes for technical and scientific personnel, on the new business concept and organisation applying new nanotechnological production processes and related services, and on the necessary precautions to counter toxicological and ecotoxicological risk;
- sounding out, in a clear and predefined way, the opportunities and limits of industrial and intellectual property to guarantee a proper balance between cooperation and competition; production confidentiality and the dissemination of N&N-related progress, publication and free movement of new knowledge within the European and international scientific community, and protection of intellectual property rights;
- facilitating access by businesses, especially small ones or those located in island and outlying regions, to JCR[31] institutes, to prototyping, certification, measurement and testing laboratories and infrastructures. Access to national and European technical standards bodies, which are authorised to draw up internationally recognised and accepted standards will also be important;
- under the EIB, EIF, CIP[32] and the Community's Structural Funds, strengthening access for businesses, especially SMEs, to financial support measures, start-up and venture

30 The EESC welcomes the paper and CD format publications of the DG responsible for innovation, and their educational content, which is addressed to an interested, but so far uninformed, public.

31 JCR: Joint Research Centre.

32 CIP: Competition and Innovation Framework Programme (c.f. EESC opinion INT/270, rapporteurs: Mr Welschke and Ms Fusco.

capital, and initiatives to promote spin-off from academic research, with a view to creating new enterprises and jobs in the N&N sector and the setting up of acquisition, production and distribution networks for N+N services;

- establishing closer links between universities, research centres and businesses, especially SMEs, by establishing joint management skills centres for the various application sectors, taking on nanotech experts in businesses, and organising training courses under the new Marie Curie Programme actions.

3.5.4 The Committee emphasises that, especially in the field of N&N, workers and technical and scientific specialists represent – and must continue to represent – the greatest asset of socially responsible businesses.

3.5.4.1 The Committee would also highlight, in this respect, the importance of steps to ensure safe production environments and processes, appropriate training for the relevant human resources, particularly in the medical diagnostics and therapeutics sectors, with a special focus on prevention and *ex-ante* risk prevention and assessment aspects. This could be achieved with the help of technical conduct manuals, certified at European level.

3.5.4.2 The impact on workers of the new working patterns needed to apply N&N in economic life, and of the training and health and safety requirements, must be carefully evaluated and researched by the European Foundation for the Improvement of Living and Working Conditions in Dublin.

3.5.5 The European N&N dialogue with all stakeholders should be put on an official footing by 2007, by establishing a consultative body or forum which should have the necessary visibility and transparency to act as a qualified and recognised partner for the media and civil society.

3.5.6 The successful awareness-raising pilot initiatives should be consolidated by 2007. They should be made visible as of now by linking them to the Europa web portal, and publicised among the European institutions, particularly the EP and the Council. They should also be given an international dimension with the establishment, in 2008 of the "Interdisciplinary N&N Prize", to be awarded annually on the occasion of "European N&N week".

3.5.7 In 2006 the Commission should introduce certified methodologies to identify risks in the application and/or use of N&N and, in the first half of 2008, propose European guidelines in this area.

Brussels, 20 April 2006

The President of the European Economic and Social Committee	The Secretary-General of the European Economic and Social Committee
Anne-Marie Sigmund	Patrick Venturini