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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.

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$).

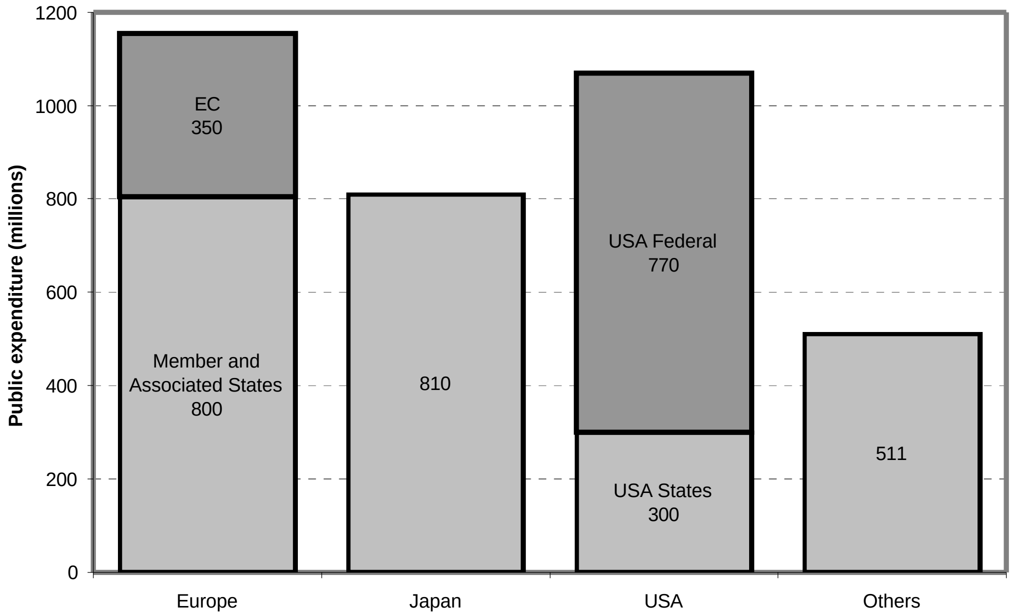
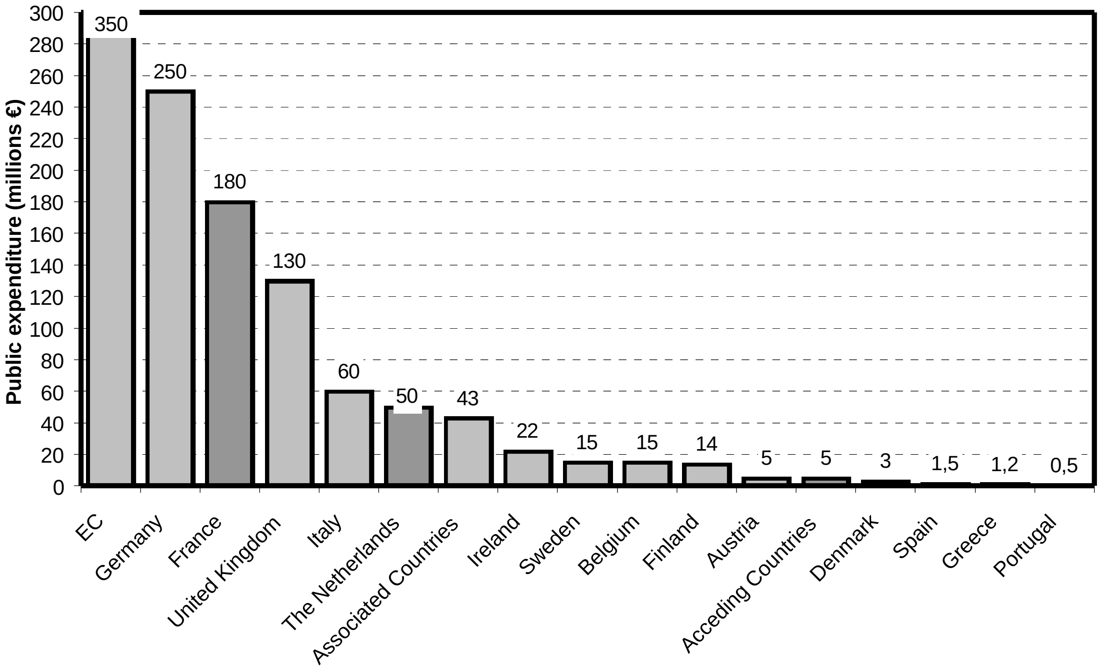


Fig. 2: Level of funding for EU-15 along with some Acceding (CZ, LV, LT, SI) and the main Associated countries (CH, IL and NO) and EC in absolute € terms in 2003.



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.

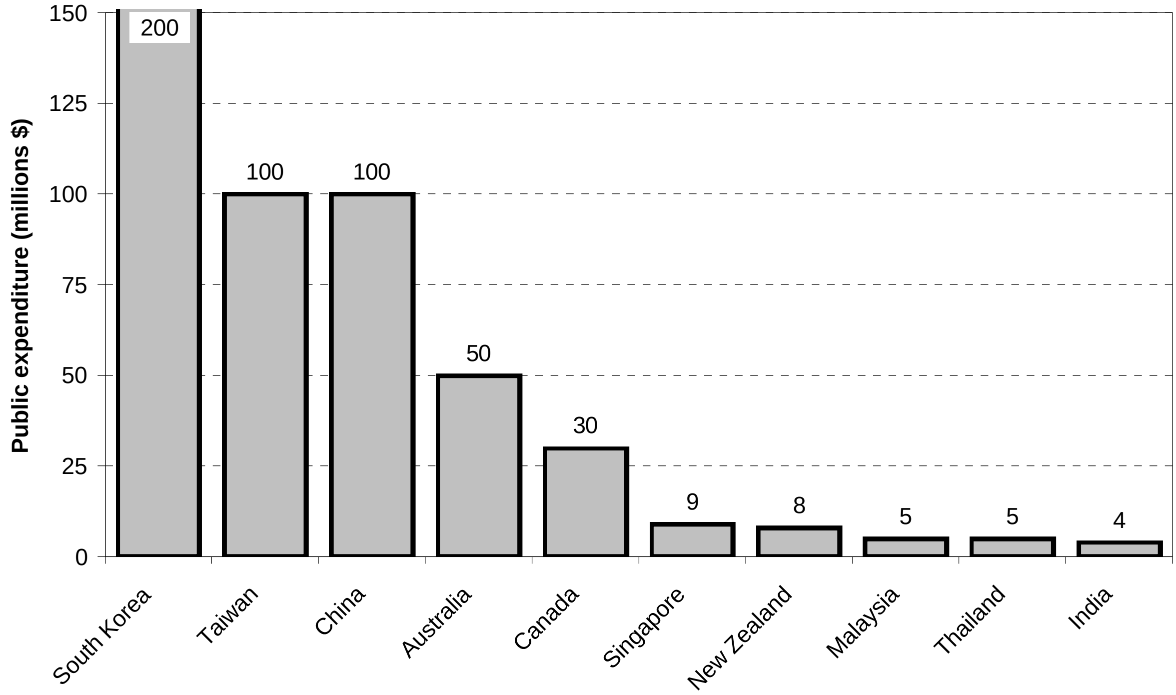


Fig. 4: Comparative funding levels between EU-15, EU-25 some Acceding countries (CZ, LV, LT, SI), main FP6 Associated countries (CH, IL and NO), USA and Japan on a per-capita basis in 2003 (1€ = 1$).