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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**

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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 2004¹ 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 Plan² 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.

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 Nanomedicine⁴ and Sustainable Chemistry,

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 Nanoquanta⁶ and Nano2Life⁷ 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

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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<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.

Commission¹⁰ 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.

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 “nanoproductions” 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

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 industry¹⁷ 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

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 http://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).

²² <http://www.fmmt.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.