COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.10.2009
COM(2009) 607 final

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. Second Implementation Report 2007-2009

{SEC(2009) 1468}

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. Second Implementation Report 2007-2009

Nanotechnology[1] currently underpins many practical applications and has the potential further to enhance quality of life and environmental protection, and boost Europe's industrial competitiveness. Knowledge in the field of nanosciences and the industrial application of nanotechnologies has gradually increased, most noticeably over the last 10 to 20 years. The "integrated, safe and responsible approach" proposed by the European Commission in 2004[2] has been agreed by stakeholders and is now the core of the EU's nanotechnology policy. The Nanotechnology Action Plan 2005-2009[3] has provided an impetus for a variety of developments, in research and innovation as well as in policy making. After the first two years of the Action Plan, progress in almost every area was identified in the First Implementation Report.[4]

This Communication outlines the key developments during 2007-2009 in each policy area of the Action Plan, identifies current challenges, and draws conclusions relevant to the future European nanotechnology policy. Where appropriate, for the sake of completeness and continuity, developments in preceding years are included. Detailed supporting information can be found in the accompanying Staff Working Document.

As a general remark, the past two years have seen a substantial development of nanotechnology, supported by a further growth in research funding and the active development of policy. Novel applications and products of nanotechnology are constantly being realised. In view of this, efforts to address societal and safety concerns must be continued to ensure the safe and sustainable development of nanotechnology.

1. RESEARCH, DEVELOPMENT AND INNOVATION: EUROPE NEEDS KNOWLEDGE

Bringing together public and private organisations across Europe to carry out collaborative research and development is of particular importance in the interdisciplinary approach needed in nanotechnology.

Support for nanotechnology research under the Community's Framework Programmes has continued to grow, from EUR 1.4 billion in the four-year period 2003-2006, to more than EUR 1.1 billion in the two-year period 2007-2008. Further growth is expected in the years up

---

1 In this report, "nanotechnology" is used as short for nanosciences and nanotechnologies. Although several definitions exist, as a working definition used here, nanotechnology is the understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions, where the onset of size-dependent phenomena can emerge and enable novel applications.

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

3 *Nanosciences and nanotechnologies: An action plan for Europe 2005-2009*, COM(2005)243; hereafter "Action Plan"

4 *Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007*, COM(2007)505

to the end of the 7th Research Framework Programme (FP7) in 2013. This investment is complemented by significant public funding in Member States, to the tune of more than EUR 2.5 billion in 2007-2008. Private funding, however, still lagged behind public funding in Europe. At the same time, funding was increasing rapidly in other parts of the world, and dynamic new players were coming on the scene.

The Community funding covered a very wide spectrum, from fundamental nanoscience to industrial applications, with an increasing emphasis on applications. Much of this funding came from the cross-thematic approaches developed in FP7, as nanotechnologies have an interdisciplinary and enabling character and can contribute to different industrial sectors and policy objectives in health, food, environment, energy and transport. The industrial participation in projects is gradually increasing, having reached 40 %.[5] The Commission is also directly engaged in nanotechnology research through its Joint Research Centre (JRC), whose activities are directly linked to a number of related policy areas.

This short Communication cannot do justice to the wealth of results that are being obtained through EU-funded nanotechnology projects. Details are presented in the accompanying Staff Working Document. Some examples of applications can nonetheless be outlined:

– In nanoelectronics, the miniaturisation of semiconductor components enables ever more powerful computers and other digital devices. Even smaller devices now seem possible via novel "bottom-up" techniques.

– In nanomedicine, devices based on "nanobiological" sensors are being developed, for the early diagnosis of common diseases like cardiovascular diseases and cancers. It also seems possible to selectively target drugs to diseased cells, thereby minimising the negative side effects of these drugs in other areas of the body; and to use engineered tissues for regenerative medicine.

– In pilot line projects, some of the most promising laboratory results are being turned into industrial applications, not only to produce new materials but also to improve industrial sustainability.

– In the field of energy, more efficient and less costly solar cells are being developed. Thermoelectric converters could furthermore recover heat, from internal combustion engines for example, which would otherwise be wasted.

– In water remediation, nanotechnology is showing the way to more effective and less costly methods.

Whilst fundamental nanoscience and enabling research must not be neglected, it is appropriate that the funding from the Cooperation part of the Framework Programme should increasingly target nanotechnology research that offers realistic short- to medium-term prospects of producing benefits and safe products, in fields such as health, environment and energy, and of improving industrial competitiveness. To ensure this, an Advisory Group on Industrial Nanotechnologies has been created to provide further assistance in the setting of research priorities. This complements the Expert Advisory Groups of FP7 and the contributions of relevant European Technology Platforms. Furthermore, project clusters are being created in order to consolidate results.

Naturally, priorities need to be set with regard to different areas of nanotechnology research. The Community funding cannot cover all needs, and the public funding from Member and

[5] In terms of the number of different participations, in the nanotechnology projects funded under the NMP theme of FP7 in 2007 and 2008

Associated States, currently accounting for roughly three quarters of the total public funding in this area, is equally vital. It is also essential that the public funding be complemented by increasing private investment.

The Community funding for research on risk assessment and management (including methods and instrumentation) has continued to grow, from EUR 25 million in the four-year period 2003-2006, to more than EUR 50 million in the two-year period 2007-2008. This figure, roughly 5 % of the total nanotechnology funding, is supplemented by the research on safety built into projects that are closer to applications; and the support work on ethical, legal and societal issues. The main areas addressed include nanomaterial characterisation, effects on human health, exposure and environmental impacts. Progress has been made, notably in characterisation and toxicology:

– A number of methods to characterise nanoparticles have been validated, and new reference nanomaterials can now be used by laboratories to improve and demonstrate their proficiency in this field of metrology.

– In the field of toxicology, award-winning research is improving the understanding of the interactions between nanoparticles and the human body.

The EU Scientific Committees have stressed the need for further research on safety for human health and the environment. The Commission intends both to enhance and to consolidate these efforts in cooperation with Member States, industry and international organisations.

2. INFRASTRUCTURE AND EUROPEAN POLES OF EXCELLENCE

Innovative nanotechnology necessitates research infrastructures with critical mass and interdisciplinary character, together with technology transfer mechanisms, to progress beyond research towards industrial innovation.

The Commission has continued to support nanotechnology infrastructures by funding access to existing facilities and the development of new facilities. Moreover, in the past two years, several FP6 Networks of Excellence have led to “durable integration” in the shape of new institutes and virtual infrastructures, such as the European Theoretical Spectroscopy Facility (ETSF).

It is encouraging to note the efforts of several Member States in creating or expanding research infrastructures addressing nanotechnology. Notable amongst these are PRINS, a distributed facility for nanostructures involving Belgian, German and French centres close to the nanoelectronics industry; the new International Iberian Nanotechnology Laboratory in Braga; the French initiative to create “nanotechnology integration centres” in Grenoble, Saclay and Toulouse; and the Gennesys[6] initiative bringing together European neutron and synchrotron facilities for research in nanotechnology applications.

3. INTERDISCIPLINARY HUMAN RESOURCES: EUROPE NEEDS CREATIVITY

Progress in nanotechnology depends on a skilled workforce and interdisciplinary approaches, which necessitate a departure from more traditional education and training schemes. It is reported[7] that industrial players consider the lack of appropriate human resources one of the major obstacles to innovation. Training activities in nanotechnology have continued to be

[6] http://gennesys.neutron-eu.net/

[7] In a recent OECD-WPN study, to be published

funded by the Commission, mainly through the Marie Curie actions of the "People" programme, which provided a total of EUR 125 million to nanotechnology projects in 2007-2008. Other projects, most notably FP6 Networks of Excellence and some European Technology Platforms, have made significant contributions to training. All these contributions have emphasised interdisciplinary approaches and the transfer of results from academia to industry. A further contribution to nanotechnology, around EUR 80 million in 2007-2008, came from the European Research Council (ERC) implementing the "Ideas" programme. This offers opportunities to individual teams through its investigator-driven approach, encouraging scientists to go beyond established frontiers of knowledge and the boundaries of disciplines.

In addition, many European universities are creating nanotechnology courses and Masters Degrees. More needs to be done in the future, in quantitative terms at the very least.

The European Institute of Innovation and Technology (EIT) may offer an impetus for developments in human resources and innovation.[8]

4. INDUSTRIAL INNOVATION: FROM KNOWLEDGE TO THE MARKET

Globalisation has changed the world's economy, bringing new opportunities and new challenges that require Europe to become more creative and innovative. Notwithstanding the large public financing of European R&D in nanotechnology, the corresponding private investment remains low compared with that of Europe's main competitors. And Europe's share of nanotechnology patents does not match its share of nanotechnology publications.

The Commission has supported innovation in nanotechnology through different policies and actions. The main initiatives related to nanotechnology include: Increased emphasis on applications in the research funded under FP7; a continued commitment to regulatory and standardisation activities; and the creation of a nanotechnology observatory, ObservatoryNANO,[9] to study opportunities and risks in various technology sectors. In this context, special attention is paid to SMEs and start-ups.

ENIAC, the Joint Technology Initiative (JTI) in Nanoelectronics, is an example of a pioneering approach in pooling private and public efforts. For the first time ever, the Community and Member States are jointly funding R&D, with a total investment of EUR 3 billion until 2013.

Furthermore, allocations from the Competitiveness and Innovation Programme (CIP), as well as the structural funds of the cohesion policy, can contribute to the development of nanotechnology.

Acceptance of product and performance standards, as well as further science-based development of new products, depends on the development of sound measurement and testing standards, which support product safety and quality. Over the past two years, Member States have contributed to the initial development of nanotechnology standards. Furthermore, the Commission and the Member States have worked jointly with ISO and CEN. In the years to come, further action is expected in this area.[10] The Commission mandated CEN to present a standardisation programme and a list of proposed standards projects has been developed. This is currently being followed-up by a specific standardisation mandate focusing on terminology, characterisation of nanomaterials, and methods to assess and simulate exposure.

---

8 The first call for Knowledge and Innovation Communities, with three priority areas relevant to nanotechnology, closed in August 2009; http://eit.europa.eu/kics-call.html

9 www.observatorynano.eu

10 That is, pre- and co-normative research as well as normative action

Especially at a time of economic downturn, a considerable leveraging effort is needed to maximise the effect of the large public investment in research and infrastructures. This "open innovation" approach would maintain private investment and increase it in the future.

5. INTEGRATING THE SOCIETAL DIMENSION: ADDRESSING EXPECTATIONS AND CONCERNS

An essential element of the integrated, safe and responsible approach is to integrate health, safety and environmental aspects in the development of nanotechnology, and to establish an effective dialogue with all stakeholders. Several actions were undertaken in pursuit of the general objective of taking people's expectations and concerns into account.

In February 2008, the Commission adopted the recommendation for a "Code of Conduct for responsible nanosciences and nanotechnologies research",[11] which provides guidelines favouring a responsible and open approach. As called for by the Council in September 2008,[12] the Commission will regularly monitor the Code, and revise it every two years in order to take into account developments in nanotechnology and their integration in European society.

All proposals that are considered for funding under FP7 and are ethically sensitive undergo a thorough ethical review. They are funded only if they address ethical issues adequately and meet the necessary Community and national requirements – for example the EU Charter of Fundamental Rights. Efforts are made to increase the researchers' awareness of the Commission's Code of Conduct.

A particular requirement in EU policy relates to the promotion of alternatives to animal testing. The Commission funds research into alternative testing methods and strategies in partnership with industry and cooperates within OECD on this issue. The Commission's JRC is also active in the development and assessment of alternative methods.

The likely convergence of nanotechnology with biotechnology, information technology and cognitive sciences increases opportunities for beneficial applications, but also raises important questions relating to ethics, safety, security and respect for fundamental rights. These may need to be addressed by a new opinion of the European Group on Ethics in Science and New Technologies.

Several outreach projects have been funded under FP6 and FP7. These suggest that there is a need for a more permanent public deliberation on nanotechnology in its broad societal context. The Commission has pursued an active policy of engagement and consultation with stakeholders, in particular through the continuous involvement of stakeholders in Commission working groups in charge of coordinating the implementation of regulation; and in the annual Nanotechnology "Safety for Success Dialogue" workshops. Public dialogue and engagement have also been undertaken at national level.

The call for dialogue and engagement in the Action Plan has also been reflected in various other initiatives organised by European Technology Platforms and in special interest forums such as industry and consumers' groups. The existence of diverse forums indicates a need to monitor the debates at national, European and international levels, for instance with support from future FP7 activities, in order consistently to convey messages from public debates to

---

11 *Code of Conduct for responsible nanosciences and nanotechnologies research*, C(2008)424

12 12959/1/08 REV 1 (2891st Council Meeting Competitiveness)

policy makers. On 10 September 2009, the Commission organised a scientific hearing on the risk assessment of nanotechnologies.[13]

The Commission has published a wide range of informative material in many languages and for various age groups. And a specific entry for nanotechnology on the Commission's Europa website helps the public to follow all its nanotechnology activities.

6. HEALTH, SAFETY, ENVIRONMENTAL AND CONSUMER PROTECTION

Nanotechnology products must comply with the high levels of consumer, worker and environmental protection set out in Community legislation. These products will enjoy public acceptance only if these regulations adequately address the new challenges from the technologies; if manufacturers can demonstrate their safety; and if consumers perceive them as safe.

6.1. Regulation

In June 2008, the Commission adopted the Communication "Regulatory aspects of nanomaterials",[14] fulfilling a commitment made in the Action Plan. The Communication was accompanied by a Staff Working Document providing a summary of legislation in relation to health, safety and environmental aspects of nanomaterials, and outlining regulatory research needs and related measures.[15]

This regulatory review concluded that existing Community regulatory frameworks cover *in principle* the potential health, safety and environmental risks related to nanomaterials. Without excluding regulatory change in the light of new information, the Commission stressed that the protection of health, safety and the environment needs to be enhanced mainly by improving the implementation of current legislation. In addition to supporting research on risk assessment, the Commission is working in several regulatory areas to improve implementation, assess the adequacy of existing legislation, and consider whether regulatory change on specific aspects is necessary.[16]

The Communication was examined by both the European Parliament[17] and the European Economic and Social Committee.[18] The European Parliament in particular questions whether, in the absence of explicit provisions for nanotechnology in Community law, legislation can be deemed adequate to cover the risks related to nanomaterials. Given the lack of appropriate data and assessment methods, the Parliament asks that existing regulations be carefully reviewed. At the request of the European Parliament, specific provisions in relation to nanomaterials have been introduced or are being considered for legislation on cosmetics, novel food and food additives.

As planned, the Commission will present an updated regulatory review in 2011, paying particular attention to the points raised by the European Parliament and the European Economic and Social Committee. Depending on needs, the Commission may propose regulatory changes.

---

13 http://ec.europa.eu/health/nanohearing_en.htm

14 *Regulatory Aspects of Nanomaterials*, COM(2008)366

15 SEC(2008)2036

16 For example, the working group for nanomaterials under REACH has made progress and published initial results: http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf

17 Resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI))

18 Opinion of 25 February 2009 on the Communication on Regulatory Aspects of Nanomaterials, INT/456; http://eesc.europa.eu/documents/opinions/avis_en.asp?type=en

6.2. Bridging the knowledge gap

A specific hurdle to overcome is the need for better knowledge in areas like the characterisation of nanomaterials, toxicity, ecotoxicity, safety and exposure assessment. This would allow implementation tools, like integrated testing strategies and guidance documents, to be adapted to take nanomaterials fully into account.

Projects designed to address environmental and health safety issues, under FP7 and in the JRC, have led to a better understanding of the interaction mechanisms of nanomaterials with biological systems, as well as in the development of test methods, for the assessment of exposure for example.

International cooperation in this area is strong. The Commission is heavily involved in the current work within the OECD Working Party for Manufactured Nanomaterials (WPMN), which is developing test methods and guidelines for risk assessment. Moreover, the ISO standardisation work will facilitate a global convergence in standards for the implementation of regulation.

The independent EU Scientific Committees have delivered six opinions in the last five years regarding the risk assessment of nanomaterials. In view of the remaining knowledge gaps, the opinions stress that potential risks of nanomaterials have to be assessed on a case-by-case basis and make recommendations for further research on safety.

From the regulatory point of view, there are a number of urgent needs:

– Research funding should be both increased and consolidated, to keep up with the pace of development and marketing of new applications.

– To obtain relevant data, currently available methods for risk assessment need to be adjusted, validated and harmonised for nanomaterials.

– In particular, methods need to be improved, developed and validated, in the areas of characterisation, exposure assessment, hazard identification, life cycle assessment and simulation. To this end, research will also be needed on fundamental aspects regarding the interaction of nanomaterials with living organisms.

– Suitable reference nanomaterials are needed for method development and validation, as well as for quality assurance.

– Public databases need to be developed, to serve in the safety assessment of nanomaterials.

– Particular focus should be given to research speeding up the development of test guidelines and standards within OECD, ISO and CEN.

Although knowledge about the presence of nanomaterials on the market is increasing, the Commission is aware of the need to obtain a better and more accurate overview. In 2011 the Commission intends to present information on types and uses of nanomaterials, including safety aspects.

7. INTERNATIONAL COOPERATION

In line with the mandate received from the Council in September 2004,[19] the Commission has engaged in an international dialogue on nanotechnology. Since then international cooperation has become an integral part of the Commission's policy in virtually all areas of the Action Plan. The Commission's past and on-going actions on the international front include:

[19] 12487/04 (2605th Council Meeting Competitiveness)

– Collaboration in research projects, including projects on risk assessment.

– Providing support for the involvement of researchers from third countries in EU-funded projects; and for the networking of researchers from third countries in nanotechnology.

– Organising in 2008 the third International Dialogue on the responsible development of nanotechnology. This covered governance, codes of practice, safety and regulation and collaboration.

– Participating in the work of OECD-WPN,[20] on the governance of nanotechnology.

– Active engagement in OECD-WPMN,[21] which is the main international forum for the further development of test guidelines and strategies needed for the proper implementation of regulation.

– In ISO and CEN the Commission contributes to developing globally agreed standards on terminology and physico-chemical characterisation of nanomaterials, to create a basis for a convergent approach in the testing of nanomaterials.

– Regulatory convergence is a standing issue in the dialogues with the EU's main trading partners.

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 requires an efficient structure and coordination, and regular consultation with the Member States and all stakeholders.

A Commission Inter-service Group dedicated to all aspects of the work described in this report was established in 2005 and has been active since that time. A Europa website presents the implementation work carried out by all the Commission services involved, and features regularly updated answers to frequently asked questions, in five languages: ec.europa.eu/nanotechnology

It is encouraging that several Member and Associated States have adopted nanotechnology policies that are fully in tune with that of the Commission, and provide complementary activities, such as funding and infrastructures. These activities are not covered in this report and the accompanying Staff Working Document in a systematic way. Only selected examples have been given, which suggest that the progress in Member States with regard to the implementation of the Action Plan is significant.

To obtain a consistent view of these activities and promote coordination, the internal coordination effort of the Commission has been complemented by the Nanotechnology High-Level Group, bringing together representatives of Member and Associated States and the Commission.

Furthermore, the Commission has cooperated with the EU Presidencies in the organisation of conferences that have provided opportunities to showcase progress and to set further priorities for action.

---

[20] Working Party on Nanotechnology – its general aim is to maximise the societal and economic benefits of nanotechnology

[21] Working Party on Manufactured Nanomaterials

CONCLUSION

Significant progress has been made on all points of the Action Plan. Building on this, it is proposed to continue and consolidate the present actions in the coming years, with emphasis on:

– Deepening the research efforts and roadmaps for key nanotechnology sectors, to enhance innovation and competitiveness.[22] This is considered inseparable from advancing fundamental understanding of how nanomaterials throughout their life cycle interact with living organisms, to ensure a high safety level and protection of human health and the environment.

– Developing infrastructures and the educational system further, consistent with the multidisciplinary character of nanotechnology.

– Strengthening the mechanisms available for industrial innovation, stressing the concept of open innovation and facilitating technology transfer.

– Implementing a more direct, focused and continuous societal dialogue; and monitoring public opinion and issues related to consumer, environmental and worker protection.

– Continuing to review the adequacy of regulation, adapting as appropriate the implementation instruments, proposing regulatory change where necessary, and engaging where possible with international developments.

– Surveying the market for products of nanotechnology, including their safety aspects, and likely developments.

– Stepping up the research effort on safety assessment, including risk management, throughout the product life cycle. Supporting the further development and validation of nanomaterial characterisation and test methods.

– Enhancing coordination and exchange of information with Member States.

Building on achievements so far and with these needs in mind, the Commission is considering proposing a new Nanotechnology Action Plan that would be one of the driving forces of the European Research Area and address important societal and environmental issues.

[22] The President's Political guidelines for the next Commission stress the need for more industry-driven applied R&D, in areas including nanotechnologies, to bring leading edge products and clean technologies to markets and to boost the competitiveness of EU industry: http://ec.europa.eu/commission_barroso/president/pdf/press_20090903_EN.pdf