Nanotechnologies for sustainable development

Brussels – 12 November 2009

On completion of the term of the European Commission's 'Nanosciences and nanotechnologies: An action plan for Europe 2005-2009', nearly 100 delegates met in Brussels, under the auspices of the Swedish EC Presidency, to consider the way ahead, with particular regard to the issues of nanotechnologies in relation to sustainable development.

In a welcome and introduction to the proceedings, **Swedish State Secretary Elisabet Falemo** underlined five main points that her country's Presidency regarded as important issues for consideration:

- **Close the knowledge gap**. New technology is moving fast, but the development of knowledge on the risks of its uses is lagging behind. New research should from the start include consideration of potential threats to health and the environment, while risk research should be linked to existing and future applications.
- **Update test methods and guidelines on harmful properties and exposure.** Development has started within the OECD framework, but cooperation with industrial actors is essential to gain better understanding of properties and effects in order to establish methods for identifying risks.
- **Identify products in the marketplace.** Several countries have experience of voluntary reporting of manufactured nanomaterials, but mandatory registration may need to be considered, aiming for an EU-level system, rather than having different regimes in individual Member States.
- **Consider incentives** to help guide actors in the direction of sustainable applications.
- **Strengthen international cooperation,** both transatlantic and among the entire global community. The Strategic Approach to International Chemicals Management (SAICM) should work to reconcile policies and secure a level playing field.

2nd Implementation Report and the Road Ahead

Herbert von Bose, Director of the Industrial Technologies group at DG Research, responded by confirming the progress made under the 2005-2009 Action Plan, and announcing the Commission's aim to follow it with another covering the period 2010-2014. Focussing on even greater integration and coupling technological progress more closely with the fulfilment of societal objectives, this would align with the Swedish priorities by promoting:

- **Deeper research efforts and roadmaps for key nanotechnology sectors**, to enhance innovation, competitiveness and safety.

- **Further development of infrastructures and the educational system**, consistent with the multidisciplinary character of nanotechnology.
- **Stronger mechanisms for industrial innovation**, stressing the concept of open innovation and facilitating technology transfer for sustainable growth.
- **More direct, focused and continuous implementation of societal dialogue**; and monitoring public opinion and the issues related to consumer, environmental and worker protection.
- **Continuing review of regulation**, engaging where possible with international developments, and adapting as appropriate the implementation instruments.
- **Survey of markets for products of nanotechnology**, their safety aspects, and likely developments.
- **Increased research effort on safety assessment and risk management**, including further development and validation of materials characterisation and test methods.

Research and development

Flemming Besenbacher, iNANO (the interdisciplinary nanoscience centre at Aarhus University) highlighted some of the most promising potential ways in which nanotechnology could contribute to a future sustainable energy supply: by reducing greenhouse gas emissions through more efficient use of existing energy resources; and by the development of new and improved energy production methods.

Global energy consumption is expected to double by 2050, and to triple by 2100 – so increased R&D effort is clearly necessary. Achieving a substantial improvement in energy-efficiency would not be difficult – but, to date, the world is not doing enough. Cost is also inhibiting more widespread adoption of sustainable energy sources, so subsidies may need to be considered as fossil fuels become depleted.

Nanomaterials and devices could markedly improve the efficiency of wind turbines and solar energy capture (the latter tapping a resource that is, in principle, capable of meeting global demand many thousands of times over). Energy storage in the form of batteries and hydrogen generation systems, thermoelectronics and fuel cells are more areas in which nanomaterials are already showing considerable promise.

At present, catalysis remains the major application of nanotechnology, with the high relative surface area of nanoscale particles providing greater process efficiency in many chemical synthesis processes, such as the desulphurisation of mineral oil. This can provide valuable savings in the period before more radical energy strategies can be adopted.

Besenbacher recommends investing more in basic research, establishing proof-of-concept projects, and using university-industry collaborations to move research results from the laboratory to industrial implementation.

Innovation

Representing the industrial viewpoint, **Peter Krüger, Bayer Material Science AG,** remarked on the massive growth rate predicted for nanotechnology as a major force for industrial transformation in the 21st century.

Like Besenbacher, he identified energy conversion, storage and efficient usage as prime application areas. Efficient use of other resources such as water and raw materials are also ranked highly, along with contamination prevention and pollution remediation. These application areas in societal relevant field are strong driving forces for nanotechnology enabled innovations.

Forecasts predict that the market for nanotechnology-enabled products will grow to $1-3 trillion by 2015, at which time they will account for up to 10% of all manufacturing jobs. With the developing economies competing strongly for a share of this lucrative business, Europe needs to avoid fragmentation of the innovation landscape in order to eliminate duplication and build a strong knowledge base. This will require focused efforts in public-private partnerships, involving collaboration between academia and industry and also among industrial partners along the entire value chain.

As an example, Krüger quoted the Innovation Alliance CNT, in which 80 partners have joined forces in establishing a foundation to develop technologies and applications for markets of carbon nanotube-based products in Germany. With a total budget of nearly €80 million, 50% funded by the German government, 18 closely interlinked projects are addressing aspects ranging from the synthesis, functionalisation and dispersion of CNTs, to the exploration of applications in the energy, environment, mobility and lightweight construction sectors. One project is specifically addressing the health, safety and environmental (SHE) issues, demonstrating that safety research for nanomaterials is an essentially integral part of the innovation strategy

Two further conclusions were that broad communication of the responsible use and benefits of nanotechnology is vital to gain public understanding and acceptance for the new approaches, while reliable global standards and regulation environments are needed to allow the transfer of research results to viable nanotechnology enabled innovations.

Infrastructure

Colin Carlile, Lund University, observed that, while Europe has distinguished itself by building large international scientific infrastructures (e.g. CERN, ILL and ESRF) and national facilities supporting research into materials and nanotechnology, the impetus has faltered in recent years. A lack of funding and difficulties in achieving decisions in Europe have meant that the opportunities presented in the road map drafted three years ago by the European Strategy Forum for Research Infrastructures(ESFRI) have not yet fully been realised.

Recently, however, important progress has been made with agreement on the siting of two more large infrastructures: the European Spallation Source (ESS) in Lund, Sweden and the X-ray Free Electron Laser (XFEL) in Hamburg, Germany. These will require ten years to construct, along with

major infrastructural links to facilitate access, but will eventually strengthen Europe's leading position in materials science.

The ESS will set a strong environmental example by employing wind-generated energy and recycling its hot water output via a local district heating system, making it the world's first energy-neutral R&D facility.

Despite these advances, Carlile notes that the EU is still far from meeting its 2010 Lisbon and Barcelona targets. Without decisive action, he maintains, Europe will surely be overtaken by the Far East in the bid for supremacy in nano-manufacturing.

Health and environmental safety

Kenneth Dawson, University College Dublin, introduced his new Centre for BioNano Interactions (CBNI), which is studying the interaction of nanoscale objects with living organisms. This is important, he explained, because, whereas 'conventional' chemicals are free to diffuse around a living body, nano-objects are transmitted by energy-dependent processes that transport them around cells to fixed locations – which may be good or bad news. The fact that particles do not migrate uncontrollably could be regarded as positive, whereas their tendency to accumulate at given sites might prove to be a matter of concern.

The absence of any reports of acute harm so far is striking, Dawson considers. Europe's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) presents no clear evidence of general hazard, but two 'opinions' – respectively linking nanoparticles to protein fibrillation, and some types of CNT to possible mesothelioma (a form of cancer, as caused by asbestos exposure) – underline the need for more research.

Among early problems in what is a relatively immature field are the fact that some of the issues are not clearly defined, that there is not yet a sufficient body of research, and that difficulties remain in achieving consistent quality of nano-manufacture. Batch-to-batch variation in nanoparticles can affect functionality, so poorly regulated suppliers could harm the reputation of nanotechnology as a whole.

All stakeholders need to combine in ensuring that practices are safe, based on underlying research that is reliably neutral, evidence-based and governed by global standards. Without this, potential investors could be deterred by even the perception that dangers may exist.

Dawson sees a need for appropriate new infrastructures to implement 'safety by design', and proposes the introduction of round-robin testing as one means to share knowledge and trust between academia and industry.

He recommends an urgent focus of path-finding research on questions such as chronic exposure and accumulation; harnessing public investment to a broader and more positive range of outcomes; and promoting spin-off from science into new industries where the EU can take a lead.

Regulation

Cornelis Brekelmans, European Commission, DG Enterprise and Industry, described the evolving position of the Commission regarding the development of regulation. This is based on the premise that good R&D forms a basis for good legislation, including its implementation and enforcement, , which should be inherently technology-neutral, but connected to real-world applications by " instruments of implementation" (European Parliament) or 'supporting documents' (European Commission).

Legislation provides a stable structure, whereas instruments of implementation form an evolving framework based on specific provisions related to technologies and properties. They are mostly derived via cooperation between the stakeholders – including authorities, industries, NGOs, standards bodies, etc. In brief, legislation describes what to do; the instruments explain how.

It is also on instruments of implementation that international cooperation and convergence can be achieved.

To the extent that lack of knowledge impedes the elaboration of general guidance, measures, standards and methods, implementation on a case-by-case basis remains the pragmatic approach – enforceable under the principle of 'no data – no market', or 'no risk assessment, no market'.

Whilst regulatory change will be proposed whenever necessary, the Commission considers that the main focus will be on the development of explicit and nano-specific instruments of implementation, which remain necessary also in cases where regulatory change is introduced.
The debate on the EU regulatory framework is influenced by the debate with the European Economic and Social Committee and the European Parliament.

The EECC highlights the need for an integrated regulatory frame of reference and a system of governance providing clear and reliable answers to the emerging needs, particularly with regard to 'common classification methods, metrology and testing, validation of existing protocols, new protocols, and pre-normative and co-normative research'.

Tthe Parliament disagrees with Commission conclusions that the risks relating to nanomaterials are, in principle, covered by current legislation – and that HSE protection should be enhanced mainly by improving its implementation. There is thus a call to address nanomaterials explicitly within the scope of regulation on chemicals (including REACH), food, worker protection and environmental protection, to verify specific legislative issues and to ensure that the specific features of nanomaterials be addressed by regulation or instruments of implementation.

Parliament also requests the introduction of comprehensive, science-based definition, harmonised at the global level; an inventory of the types and uses of nanomaterials on the market, including safety aspects; and better consumer information in the form of mandatory labelling indicating 'nano ingredients' regardless of risks.

The hugely diverse application of nanotechnologies makes it impossible to introduce a single regulatory framework at Community level. The on-going process therefore needs to take account of all the above requirements, while still continuing the development of instruments of implementation.

For the Commission, the review process is an ongoing exercise, on which it will report in 2011, when it will also make available a report on types and uses of nanomaterials.

These challenges should be covered in new Commission Action Plan on Nanosciences and Nano technologies, to be adopted in 2010 under a new Commission.

Social oversight

Sally Randles, Manchester Business School, observed that rising global consumption is overriding technological and economic solutions, to drive sustainability statistics in the wrong direction. Geographical shifts in supply chains are also making it more difficult to police the ethics of business practices and the changes brought about by the adoption of nanotechnology.

With scientific discovery, technological application, manufacturing and distribution, consumption and disposal/re-manufacturing often occurring remotely from each other and involving different actors, each stage brings its own implications for SHE and ELSA (environmental life style analysis).

Drawing on a wider range of social sciences could, Randles suggests, be of value in plugging the knowledge gaps and progressing from the present ISR approach (integrated safe and responsible use of nanotechnologies) to a future 'ISR+'.

The available disciplines and perspectives include:

- processes of **economy**: institutionalisation of *market construction* and how different *routes to commercialisation* are shaped and incentivised;
- processes of **political economy**: power relations, equity, unevenness 'creative destruction';
- processes of **economic sociology** : network analysis, socio-structuration, sociology of practice;
- **cultural sociology**: representations, signs and signifiers.
- processes of **socio-spatial construction**: economic geographies of value chains played out at global-local scales.

Together, these provide opportunities for public engagement to influence decision making, and contribute to representational democracy. In addition, they are beginning to yield tools and methods to aid in the debate on the distributed governance of production-consumption systems.

Randles recommends engaging in more comparative research and upscaling the deliberative processes – which, as experiments in FP7 are demonstrating, can be facilitated via the Internet.

Perspectives from NGOs

Laura Degallaix, BEUC (European consumers' organisation), and **Chiara Giovannini, ANEC** (European consumer voice in standardisation), shared a presentation on measures to ensure the sustainability, safety and transparency of nanotechnology at a time when new nano-products are emerging on the market in a relatively unregulated way and to provide consumer confidence.

According to surveys carried out by national consumer organisations in the last years, there is a general lack of public awareness of nanotechnologies, but as yet no fundamental rejection. Most informed consumers tend to be positive about the health and environmental protection possibilities, yet see safety as a prime concern. It should be noted that consumers are generally informed about the potential benefits of nanotechnologies and nanomaterials and rarely about the potential risks hence their acceptance of the technology is often only driven by stated benefits.

ANEC and BEUC have established an inventory of products claimed to contain nanomaterials or to have been made using nanotechnologies and that are available on the European market. A first, short version of the inventory was published in June 2009 but a long, updated version was published in early November 2009 based on research carried out between September and October 2009. This new inventory showed that some of the products initially promoted as including nano-ingredients in June 2009 subsequently abandoned such claims, possibly indicating a change in the perception of market advantage or fears of negative public perception.

The recently adopted EU Cosmetics Regulation, which should be published in the EUOJ soon, is considered a valuable step forward, as it is the first European legal instrument with nano-specific safety requirements including a notification system, control mechanisms and mandatory labelling. Following this, ANEC and BEUC would like to see a more proactive EC stance in proposing nano-specific requirements in future legislative proposals (including legislation revisions) and above all, in cases of doubt, applying the precautionary principle.

To address the data gaps and ensure the sustainable and safe development and use of nanotechnologies and nanomaterials, they echo the views expressed by other contributors in suggesting:

- The adoption or adaptation of nano relevant legislation and safety requirements
- The development of harmonised legal definitions of nanotechnologies and nanomaterials
- A mandatory reporting system and the establishment of a public inventory of nanomaterials, the products that contain nanomaterials and volumes on the market;
- Increased communication about nanotechnology in general, citing its unknowns/uncertainties, risks and true benefits;
- Labelling of some consumer products (through e.g. an indication of the nanomaterials in the ingredients' lists on products) and regulation of related claims (without placing a burden of decision-making on consumers);
- Effective pubic participatory processes and follow-up actions;
- Regular dialogues between regulators, agencies, stakeholders and third countries;

- The development of adequate and harmonised test methods and metrology standards;
- More research on EHS aspects and ELSI (ethical, legal and social implications) of nanotechnology.

Perspectives from industry

Steffi Friedrichs, Nanotechnology Industries Association, points out that nanotechnology cannot be regarded as a single industry, but rather as a series of enabling technologies bringing added value to existing markets and also capable of helping the development and establishment of new markets. It is as crucial to future competitiveness as were information and communication technologies in the 1990s, and is central to Europe's bid to build a knowledge-based economy.

Nanotechnology publications are increasing at a faster rate than those on all other topics, but the pace is not matched inconversion to patents and eventual commercialisation – so the full potential remains underutilised. This discrepancy is more pronounced in Europe than elsewhere, making nanotechnologies another emerging technology exhibiting the 'European Paradox'. For example, according to the "Revealed Technological Advantage" (RTA) index, Europe shows pronounced nanotechnology-based innovation capabilities in the pharma- and biotechnologies, compared to both its own established technology base and that of other markets, but this phenomenon is not reflected in innovation or funding policies in Europe.

Apart from the widely shared concerns regarding EHS issues, risk assessment and unclear regulatory provisions, top challenges to the exploitation of nanotechnologies are:

- high processing costs
- scalability of R&D for prototype and industrial production
- shortage of skilled human resources
- concerns about environmental, health & safety (EHS) issues (especially the public perception of these)
- uncertainties surrounding risk assessment methodologies (including hazard profiling, exposure assessment, etc.)
- unclear regulatory requirements (i.e. product approval, safety demonstration requirements, etc.)
- lack of (standardised) test-, detection-, and monitoring-equipment (for both QC and EHS applications)

Recommendations to address these shortcomings are to:

- **foster** technology transfer in **support of EU supply-chains** (including coordination of R&D funding between EU Member States
- **foster** (multidisciplinarity in) **education** in sciences and technologies & make careers in sciences and technologies more attractive
- **enhance public knowledge and understanding** of nanotechnologies through balanced communication, including benefits & risks

- **encourage higher investment in private funding**
- **strengthen integration** of experimental research, innovation and industrial exploitation into European R&D strategies
- **support** research-intensive innovations trough provision **'pre-competitive collaboration platforms'**
- **provide clear guidance on regulatory requirements** ('proactive, scientific advice throughout all stages of policy development and delivery')
- **create a climate of favourable trade conditions** (*cf. '*Global Europe strategy')

Ethics

Paula Martinho da Silva, European Group on Ethics in Science and New Technologies (EGE), considered the ethical aspects of nanotechnology. She underlined the EC Decision demanding that 'all the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles', and noted that 11% of FP6 projects have also been subject to ethical review.

The purpose of ethical analysis is to identify the stakeholders, choices and values at stake – as well as to clarify conflicts of interest and ensure compatibility with values such as human dignity, economic equity, integrity, autonomy, privacy, solidarity and justice. At present, this process is hampered by the generally acknowledged regulatory and knowledge gaps, plus difficulties in assessing the sometimes exaggerated performance claims of product developers.

Although the precautionary principle is often invoked, this should not be used as an excuse for inaction or unwarranted prohibition. There can be no 'zero risk' situation. And, as with any new technology, ethical analysis of nanotechnology needs to go beyond risk assessment, since such a narrow focus can prevent other aspects from receiving the attention they deserve.

Questions of dual use, for example, raise a dilemma. There is no clear borderline between medical therapy and possibly unacceptable human enhancement, nor between diagnostic imaging and surveillance or defensive/offensive military applications.

Besides protecting individuals, ethics should provide a background for informed public debate and consent on all of these emerging issues.

Conclusions

Following the above contributions, **State Secretary Elisabet Falemo** closed the proceedings on behalf of the Swedish Presidency with a brief summary of the main conclusions.

Conclusions

(note: a more concise version was presented by State Secretary Falemo during the conference)

(1) The fundamental strategy of ***integrated, safe and responsible*** **(ISR)** nanotechnology development put forward in the Commission Communication "Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009" is still valid today.

(2) However, five years on, with the benefit of new scientific knowledge on the potential applications and risks, and the emergence of nanotechnology-enabled products – some of which are aimed squarely at consumer markets – it is time to re-examine how the key priorities may be furthered, and to **strengthen the ISR strategy towards "*ISR+".***

(3) The possible contribution of nanotechnology to an **eco-efficient European economy,** to sustainable energy systems and to protection of the climate and environment could provide an attractive opportunity for, and stimulus to, the development of suitable nanotechnologies at industrial scale for the benefit of the society.

(4) As a key enabling technology, there are no limits to the potential applications of nanotechnology. However, this potential is as yet far from full realisation – and in many cases, the **viability of industrial-scale production and commercialization needs to be verified**.

(5) Clearly, industry is not interested in nanotechnology in its own right but will use it as a means to achieve general industrial business sustainability and innovation targets. Considering the global resource challenges and the potential new risks posed by the new technology, **incentives** could help to guide industry responding responsively by manufacturing sustainable and safe applications.

(6) **Safety of nanotechnology** must be an integral part of any nanotechnology-based innovation strategy as we already have reasons to be cautious. In the first instance this implies that new application-oriented research and innovation should from the very start include a consideration of potential threats to health and environment. Dedicated research on potential risks should be linked to existing and future applications of the technology;

(7) The technical viability and safety of nanotechnology applications are essential pre-requisites. Yet, **significant knowledge gaps** need to be closed, and more knowledge of what products are on the market or on their way into the market is needed;

(8) Closing the relevant knowledge gaps mentioned today entails continued research efforts towards fundamental understanding of how nanomaterials throughout their life cycle interact with living organisms. In this way, we will be able to ensure a high safety level and protection of human health and the environment. Especially important are standardised and validated results and testing methods. Clearly, **infrastructures** have a key enabling role in supporting this research.

(9) **Future developments in regulation and standardisation should** ensure safety and transparency and thus public trust on one hand, and give to industry sufficient certainty on the other hand, without stifling innovation

(10) **Co-operation** and **participation** to reduce or to avoid fragmentation in the innovation landscape are recurrent themes in the presentations. Close co-operation between the academic world, industry and regulators is required for the development of nanotechnologies for sustainable development. Co-operation between the Member States, as well as wider international co-operation, are both necessary in achieving global standards and avoiding conflict between differing regulations.

(11) Most of the presentations have put emphasis on co-operation, participation and dialogue between different actors on the nanoscene. To build trust that nanotechnology really will contribute to a safe and sustainable development seems of vital importance. Thus, **public engagement and participation** and **social oversight** in a wider context are very important for allowing people to influence decisions potentially having an impact on their everyday lives.

(12) The presentations have highlighted the complexity of the nanotechnology scene and the need for a strengthening of the integrated, safe and responsible European strategy and action. In this context, the Commission's intention to develop a **new nanotechnology action plan** for the next five years, which will be crucial in directing Europe's future nanotechnology development, is timely and welcome.