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Success and Outcomes from the Finnish Presidency Conference on "Nanotechnologies – Safety for Success",

14-15 September 2006, Espoo, Innopoli, Finland

Introduction

The conference "Nanotechnologies: Safety for Success" organized by the Finnish Presidency on 14-15 September 2006 in Espoo, Innopoli, Finland, won great interest among specialists from all over Europe. The simultaneous recognition that nanotechnologies have a tremendous potential both as lead markets and a means to improve the quality of life, and that their safety must be considered upfront to ensure consumer confidence, uptake by the market, and economic profitability prompted the organization of the conference.

The audience consisted of almost 200 people with interest in nanotechnologies and risk management from 20 countries, including USA. For the first time, a Presidency conference on nanotechnologies brought together representatives from public administrations from within and outside the EU, a broad range of industries, the research community as well as citizens', consumers', and environmental organizations. The balanced representation of various stakeholders ensured a constructive discussion of actions needed to make nanotechnologies an area of safe and successful innovation.

Objectives

The aim of the conference was to explore how to ensure that innovation in nanotechnologies takes place in a safe, integrated, and responsible way. Minister Hyssälä highlighted, "The development of high technology, such as nanoscience and technology, requires public engagement and trust". Indeed, demonstrating safety plays a determining role in achieving consumer confidence and acceptance of major technological innovations as consumer resistance to GMOs in the EU teaches us.

Integrating safety and the development of new products is also in line with the Finnish Presidency top priority *demand driven innovation* and the EU Action Plan for "*Nanosciences and Nanotechnologies"*.

Highlights from the discussions

Nanotechnologies pose immense innovation potential. Rapidly emerging, evolving and enabling nanotechnologies offer huge economic opportunities in the improvement of existing products and development of revolutionary new products and services in almost all sectors of economy and society.

Nanomaterials are small in an absolute sense, by definition. They are also small in a relative sense compared to natural barriers to the entry of foreign objects into organisms and their mobility within them. Moreover, they can exhibit fundamentally new properties as compared with those that the same substance might have in bulk form. Today, scientists are still unable to predict these new properties.

Notwithstanding this multitude of challenges in nanosciences and nanotechnologies, it is essential to "do it right the first time". The development of appropriate characterization and risk assessment as well as the systematic search for inherently safe designs must be sped up to avoid that unknown risks of nanomaterials create bottlenecks, jeopardize the uptake of nanotechnologies and the reaping identified benefits for the citizens, the economy, and the environment.

The European Community Framework program for Research and Technological Development allocated MEUR 470 to R&D in nanosciences and nanotechnologies in 2005. This makes it the single most important public source of funding for nanosciences and nanotechnologies. However, Europe lags behind the US and Japan when totaling all sources of public and private financing (MEUR 2,420 for Europe vs. MEUR 3,700 for the US and MEUR 2,700 for Japan). R&D themes encompass medicine and health, information technology, energy capture, production, distribution, and storage, material sciences, food, water, and the environment, and instruments.

Conference participants were unanimous about the need for allocating funds to safety. This money should support multidisciplinary research on safety and risk assessment. It should also ensure that pre-competitive research projects deliver safe prototypes. Last but not least, public monies should promote inherently safe designs including the development of techniques such as fullerene passivation or carbon nanotube cloaking. Cooperation in research is essential and funding agencies should promote this cooperation both with the EU and between the EU and its partners. Finally, researchers called attention on the urgency to develop standards and reference materials. Their absence could bring promising R&D in nanosciences and nanotechnologies to a standstill.

Market analysts foresee huge economic opportunities for nanotechnologies. Figures ranging from 1 to 3 trillion euros have been quoted for revenues generated by nanotechnologies by 2015. And, even if these figures may be criticized especially as far as what they actually refer to, they attest to a very likely significant impact on innovation, growth and employment. To maximize their chances of attracting the streams of profits expected from nanotechnologies, individual corporations and industry associations are taking proactive measures to ensure product safety (cf., in particular, "product stewardship" initiatives). Recently, the "Magic

Nano" and "Finy" glass and ceramic sealants caused a "nano" scare in Germany and Switzerland. As it turned out, the German Federal Institute for Risk Assessment (the Bundesinstitut für Risikobewertung or BfR for short) from two specialist laboratories indicated that the "Magic Nano" products and the "Finy" product did in fact not contain nanoparticles. This incident gave corporations and industry associations a welcome opportunity to demonstrate their responsible behavior, respectively by recalling the product voluntarily without delay and by helping with the risk assessment of the products.

Public authorities are not only funding advancements in nanosciences and nanotechnologies but also monitoring their development and taking actions to ensure that nanotechnologies are safe for the public, workers, and the environment. These actions include but are not limited to requests to European and national scientific committees for scientific advice (on nanosciences and nanotechnologies in general, on risk assessment, on family of products like cosmetics, on Technical Guidance Documents, etc.), undertaking legislative reviews, organizing stakeholder dialogues, and coordinating international efforts. Scientific opinions reveal, in particular, the need to examine risk assessment methodologies on a case-by-case basis to make certain that the methods, testing strategies, and instruments are appropriate to assess hazard and exposure. Scientific opinions also highlight the need to check that regulation accounts for the differences in properties that can exist between a substance in bulk form and in "nano" form. Finally, scientific opinion underscore the need for toxicological and ecotoxicological data for hazard assessment and for data on exposure to engineered nanoparticles.

Legislative reviews converge on a set of three generic conclusions. First, European and national regulatory frameworks in place seem appropriate overall. Second, implementation needs to be examined carefully. Both the annexes to regulations (hard law) and Technical Guidance Documents (soft law) must be looked at with great care and, when required, modified. Third, some areas reveal gaps that must be filled.

A number of important messages emerged concerning the societal involvement in the development of nanotechnologies. Firstly, the conference revealed a favorable social outlook on nanotechnologies qualified by requests for safety and questions regarding the safety of nanomaterials, in particular when used in cosmetics. Second, and at a more abstract level, individuals engage themselves differently as citizens and consumers. Third, people need trustworthy, understandable information in order to formulate an opinion. Fourth, entities perceived as neutral by the public therefore have a major role to play. Fifth, when trustworthy, understandable information is available, people tend to formulate their opinion either on some rough, first-order risk/benefit (or cost/benefit) analysis or some decision heuristic. In the latter case, perceived benefits, exposure, and possibility of penetration into the body emerge as decisive criteria concerning the acceptance of nanoproducts. Sixth, when trustworthy, understandable information is available, people tend to rely on emotions. Seventh and finally, a sustained dialogue seems essential.

Presidency conclusions

The conference confirmed nanotechnologies as a very divers array of promising technologies. Indeed, nanotechnologies will revolutionize areas as different as electronics, material sciences, medicine, agriculture and food, etc. In that sense, they potentially qualify either as "lead markets" in their own right—as with nanomedicines—or as "lead market enablers"—as in electronics. Thus, nanotechnology is a vivid example of the innovative knowledge based and demand driven economy envisaged by the Lisbon strategy.

However, major gaps remain concerning the hazard and exposure—and therefore risk—associated with nanomaterials. Representatives of the civil society made it clear that they want demonstrably safe products. Therefore, filling the gaps regarding the characterization, toxicology, and ecotoxicology of nanomaterials is a prerequisite for maximizing market uptake and minimizing the downside financial risk of investors and insurers.

This calls for the accelerated development in the characterization of nanomaterials, of appropriate risk assessment methodologies, of adequate, operational instrumentation, of reference materials and processes, and of international guidelines and standards. It also necessitates sharing existing data to the greatest extent possible, establishing archives to store and make accessible comprehensive, consistent, and complementary data, and generating data in the many areas where they are lacking.

The safe, integrated, and responsible development of nanotechnologies, the creation of a sustainable market for nanotechnologies, and the conditions for their economic success need also another set of key measures. These include setting up a predictable, innovation-friendly regulatory framework, defining performance-based standards, designing and implementing a balanced innovation policy approach that combines technology supply with user interests, guaranteeing intellectual property rights that encourage creation, and fostering a culture that welcomes and sustains innovation.

Finally, the EU should promote the definition and adoption of international safety standards applicable and accepted worldwide to establish a level playing field for international trade.

Reaching these objectives makes strengthening coordination and multidisciplinary cooperation within the EU and with its partners a priority. In parallel, the EU should acquire the capacity to observe and monitor scientific, regulatory and economic development in nanosciences and nanotechnologies. This is essential to ensure coherence with preferences, values and norms of the European society. To this end, a new kind of network or virtual body could be put in place. The European Commission is requested to assume a greater leadership in this respect and is asked to produce a document on safety and competitiveness of European nanotechnologies, including a road map defining actions, responsibilities, and timings. Finally, meeting these goals requires establishing *an operational nanotechnologies risk governance regime*. Such a regime explicitly includes engaging all stakeholders in a sustained dialogue.

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