EUROPEAN COMMISSION

Community Health and Consumer Protection

REPORT

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The present report may be found under:
http://ec.europa.eu/health/ph_risk/ev_20071025_en.htm

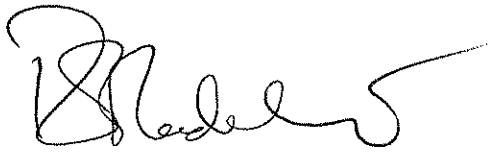
Foreword *by Robert Madelin*

I am pleased to offer here the report of our first Annual Nanotechnology Safety for Success Dialogue Workshop: The Food, Consumer, and Health Policy Perspective" held at the Hotel Sofitel Brussels Europe, Brussels, Belgium, on Thursday, 25 and Friday, 26 October 2007 provided a venue for scientists, risk assessors, industrialists, public authorities, and NGOs to convene, to exchange information, and to confront views by taking part in a structured dialogue. As the reader will appreciate, each stakeholder group walked away from the meeting with tasks to fulfil in support of a safe, integrated, and responsible development of nanotechnologies.

Nanotechnologies constitute the next technological wave after ICT and biotech, but with a much shorter time to maturity. Nanoelectronics have become so pervasive in electronics to the point of becoming invisible. Materials sciences enjoy a rebirth thanks to nanotechnologies as do catalysis and chemistry in general. Consumer products including cosmetics have made their entry in the world market. Energy capture and production, transformation, transmission, and storage, water purification, environmental remediation technologies as well as health applications in imagery and diagnostics, targeted drug delivery, and regenerative medicine emerge as precursors of what should become a steady stream of major developments. Finally, in the agri-food area, manufacturers and distributors make nanotechnology claims on products and technologies as varied as food supplements, extraction, stabilization, monitoring and tracing, packaging, and pesticides. Yet, few of them make claims about foods *per se*. Absence of novel food substances and processes? Lack of common definitions? Marketing and communication choices?

In the event, demonstrating the safety of existing and future applications of nanotechnologies in all domains in the paramount need, not only to meet legal requirements but also to gain the trust of consumers. Understandably, businesses favour a no-nonsense, hard-nosed, strategic approach to IPR to maximize their competitive edge. Let me therefore repeat the encouragement I voiced at last October's Brussels conference, that industry should proceed in a similar fashion to ensure consumer confidence and market uptake.

I look forward to welcoming an even broader group of actors at the "2nd Annual Nanotechnology Safety for Success Dialogue Workshop" to be held at the Hotel Sofitel Brussels Europe, Brussels, Belgium, on Thursday, 2nd and Friday, 3rd October 2008 to take stock and pursue this structured strategic conversation on innovation, safety, and consumer trust.



Robert Madelin

Executive Summary

The Health and Consumer Protection Directorate-General convened the first annual "Safety for Success" dialogue on nanotechnologies in consumer products including foods, cosmetics and medical applications. 120 participants from industry, universities, NGOs and public authorities from the European Union and its international partners discussed the status of commercial applications, risk assessment, risk management and the regulatory framework. In four Break Out Groups, interests, concerns and priorities for dialogue activities were identified by the stakeholders.

Outcome:

- Building public confidence in nano products and players is crucial for innovation and market success in Europe.
- Public authorities and NGOs requested open communication from Industry. Industry underscored its commitment to proactive and open exchange, and emphasised the need for flexibility in relation to the different nanotechnology applications.
- Stakeholders debated the labelling of nano products, without calling for a single, mandatory "Nano Label". All stakeholders agreed on the importance of proper information of the public – including web pages for different levels of knowledge (understandable to the wider public with links to scientific studies).
- Ways of sharing information considering intellectual property rights and reporting formats should be clarified as a matter of urgency.
- Definitions, standard testing and measurement methods (including bioassays) and reference materials are necessary to ensure the development of a common language and comparable results. Stakeholders have the responsibility to suggest preliminary data sets on risk related questions and to provide information about current activities along the value chain.
- More research is needed on toxicity, exposure, environmental safety (including unintended release) and life cycle issues (e.g. aging of products).
- Further dialogue is needed to determine if the regulatory framework (novel food, REACH) is flexible enough to cover nanotechnologies; pre-market evaluation of nanomaterials (especially in food) is requested by public authorities.
- Guidance (with clear lines of authority) and a toolbox for good governance should be developed through collaboration among the stakeholders. Independent oversight is requested by NGOs.
- All stakeholder groups expressed a strong need for a regular, transparent and in-depth dialogue.

"There is a need for speed and for contribution to these sorts of fora for shaping rapid orientations", Robert Madelin said in his final summary of the event and underlined the informational needs of consumers, NGO´s and public authorities.
"I would like companies to tell me very explicitly what they are and are not doing. I also perceive, from my position, that that is what citizens in Europe expect of companies." Therefore he called for an innovative and courageous stakeholder communication approach within Industry and contributions from all stakeholders to the ongoing dialogue.

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Workshop Report

Introduction

Following the Finnish Presidency Conference on "Nanotechnologies – Safety for Success" the Health and Consumer Protection Directorate-General convened a stakeholder dialogue meeting bringing together over 120 participants from industry, public authorities, academia, research institutes, civil society and the media. Ms Paola Testori-Coggi (Deputy Director General DG SANCO) introduced the aims of the workshop, which were to establish a basis for sustained stakeholder dialogue on significant industrial and scientific developments and to examine the state of development of risk assessment and risk management. An open discussion of policy and regulatory dimensions was promoted to identify stakeholders´ interests, concerns, informational needs and priorities for the future dialogue.

Day 1: Presentations and debate[1]

Session 1: Nanotechnologies: today and tomorrow (Chaired by Françoise Roure, OECD)

Food applications of nanoscience and nanotechnologies (Sue O'Hagan, CIAA)
Naturally occurring nanoparticles have always been present in food, for example milk and fruit juice. Nano-emulsions and nano-powders have also been in safe use for many years. Nanomaterials defined as manufactured materials with sub-100nm dimensions and with new properties due to the size of the material are, to the best of CIAA knowledge, hardly in use of food and drink manufacture in Europe at present. It is important to strengthen stakeholder dialogue to support consumer confidence and prevent GMO-type debates. There is no need to have specific nanotechnology legislation but it is important to review the existing regulatory framework and adapt it if necessary. While the food industry wishes to be fully engaged in the process of ensuring consumer confidence and product safety, public authorities must set clear criteria for the specific risk assessment of nanotechnology.

Consumer product applications of nanoscience and nanotechnologies (Michael Holman, Lux Research)
Nanotechnology-enabled products will affect many industries across the value chain. Concerns over environmental, health and safety risks present a challenge to the commercialisation of nanotechnologies. Action is required in relation to risk assessment, public confidence and the regulatory environment. It is important for risk assessments to look at the whole life-cycle of the nanomaterial, from manufacture and use to end of life. Some companies are no longer talking about their product development or have stopped their product development because they are not confident about the regulatory environment and are concerned about consumer perceptions of risk.

[1] Download of the presentations: http://ec.europa.eu/health/ph_risk/ev_20071025_en.htm

Health applications of nanoscience and nanotechnologies (Carole Moquin-Pattey, EMRC)
Nanotechnologies will play an important part in the shift from big markets for medicine to personalised markets and towards preventive and predictive medicine. The many examples of possible treatments include research on porous calcium phosphate cements for bone repair and regeneration with minimally invasive surgery. There is a need to create interdisciplinary research environments and provide long-term funding of large research projects. There is also a need to develop better systems for evidence-based medicine and health technology assessment for recommendations of standard practice in patient care.

Session 1 discussion
The discussion emphasised the specificity of debates about safety and regulation in the food and drink sectors. Questions were raised about labelling, with calls from some NGOs for consideration of statutory labelling of nanotechnology-containing products. Questions were also raised about the responsibility of suppliers to the food industry for testing of food additives that may include nanoparticles.

For medicine and health services, the capacity of authorities to monitor the market is greater than for other areas. Therefore it was suggested to design pre-market authorisation procedures in the food sector. Both Industry and public authorities stressed that for all products there is a general obligation for Industry to put safe products on the market.

There were questions raised about the capacity of smaller companies and also local regulatory agencies in Member States to make appropriate risk assessments concerning nanotechnologies.

Discussion of life cycle analysis raised questions about the current methods for monitoring environmental safety aspects e.g. behaviour of nanoparticles in air and water. More research is needed on these questions. Other risk related questions like occupational health are currently being carried out by NOSH, a research consortium (including 16 international partners such as DuPont, Procter & Gamble, Evonik and the UK Health and Safety Executive).

Session 2: Risk assessment: knowns and unknowns (Chaired by Herman Koeter, EFSA)

Nanoparticle toxicity: scientific state-of-the-art (Ken Donaldson, University of Edinburgh)
Inhaled nanoparticles can cause oxidative stress which may lead to inflammation and a number of disease conditions including Alzheimer and heart disease. An important area of research that requires more work is in the area of toxicokinetics, including questions of size-related effects and the translocation of nanoparticles within the body. It is important to note that toxicology can describe only the possible hazard with high dosage experiments. Risk analysis requires data of real exposure and a better understanding of exposure pathways.

Risk assessment needs (Jim Bridges, SCENIHR)
The risk assessment of nanomaterials is a rapidly developing field. So far, there is no evidence that unique hazardous properties can arise from exposure to substances in the nanoform, but the current risk assessment knowledge is insufficient to 'read across' from one nanomaterial to another with any confidence. In the absence of a sufficient body of knowledge, each substance in a new nanoform needs to be considered individually. Priority for an assessment should be for products where significant human and/or environmental exposure (during manufacture, use and/or disposal) and potential uptake of the nanoform of a substance can be expected.
The SCENIHR has developed a four-stage framework: 1) physico-chemical characterisation; 2) understanding of toxicokinetics and exposure pathways; 3) hazard identification; 4) characterisation of dose-response relationships. In addition, strong international collaboration is important, as is ongoing monitoring of products entering the market.

Session 2 discussion
The importance of harmonising risk assessment approaches was emphasised. This included widely accepted testing methods, reporting formats and the use of standard reference materials. It was suggested that the OECD has a role to play in harmonisation. The discussion on standardisation related to early comments about the need for agreed definitions, in spite of a general acknowledgement of the difficulties in agreeing a standard definition for all contexts.

It was argued that toxicological animal studies to explore dose-response relationships are currently feasible. The SCENIHR advocates the use of an exposure-driven model, which would assess the likelihood of exposure before committing to detailed toxicological tests. There were also calls for having consideration of environmental persistence and bioaccumulation into risk assessment.

It was agreed that more research was required to underpin the work of risk assessment and that this research requires central co-ordination in order to ensure the development of shared standards. It was suggested that DG Research should play a role in research co-ordination, but that it also required a strong voice from the user community. There is also an important role for the Joint Research Centre. In all cases Jim Bridges stressed the importance of ensuring that data be made accessible to risk assessors as soon as reasonably possible. It was also pointed out that in order to gain a complete picture of environmental, health and safety risks it is important that negative results be also published.

Session 3 – Risk management: Ensuring safety (Chaired by Georgette Lalis, DG Enterprise)

The EU perspective on policy and regulatory aspects (Kees Brekelmans, DG Enterprise)

Substances at the nano-scale fall within the scope of existing legislation and their health and environment properties must be assessed following the relevant provisions of current legislation. Implementation of the regulatory framework in many areas is difficult as current methodologies for identifying hazards and evaluating risks may not necessarily fully take into account the specific properties of substances at the nano-scale. The Commission will "examine and, where appropriate, propose adaptations of EU regulations in relevant sectors... " This regulatory review is now under way. Most EU action in relation to nanotechnologies and materials is likely to occur at the level of "supporting documents", within the existing legal framework. Health, safety and environmental protection aspects associated with nanomaterials and nanotechnologies are in principle covered, to different degrees, by current EU regulatory framework. Where the need arises, regulatory change will be proposed.

Nanotechnology and the US Food and Drug Administration: policy and regulatory approaches (Richard Canady, US FDA)

Nano-scale materials can be used in most product types regulated by the FDA. They present challenges similar to other emerging technologies. The fact that safety and efficacy can vary with size can be a challenges. Therefore the FDA has taken an inclusive approach and its Task Force report offered no definition of nanotechnology. In the future it may be useful to tailor definitions to specific product areas. The FDA's authority to obtain information on particle size differs depending on whether products are subject to pre-market authorization. Its authority is comprehensive in cases where pre-market authorization is required but its authority to obtain information on particle size for products not subject to pre-market authorization is more limited. The FDA Task Force report recommends addressing on a product-by-product basis whether labeling must or may contain information on the use of nanomaterials.

The consumer perspective on applications of nanoscience and nanotechnologies (Sue Davies, BEUC)

Consumer groups consider voluntary reporting schemes as inadequate. In the UK, the current reporting scheme has had 14 submissions in a year. Regulators do not know what is on the market and are vague about what is coming up in the future. While defining nanotechnologies for risk and regulatory purposes is difficult, this should not be an excuse for inaction. In addition, labelling should not be a surrogate for safety. Definitions should be agreed and adopted as quickly as possible. Urgent research is needed to address uncertainties around environmental and health risks raised by some nanomaterials. The precautionary principle should be applied for products with potential risks, or where it is not yet possible to assess their safety so that consumers are not put at risk. Transparency of information is seen as key to ensuring openness about the uncertainties in the research underpinning safety assessments and claims. The consumer organisation requested more involvement of the public in meaningful discussions about the development of the technology, priority applications and no-go areas and to address broader social and ethical concerns.

Session 3 discussion
The DG Research code of conduct is addressed to researchers and is currently being drafted after an initial period of public comment. DG Research has also funded public engagement projects.

The discussion on labelling products containing nanomaterials generated a wide range of views. Several argued that a simple indication of the presence of nanoparticles would be misleading as the technology itself is not a significant indicator of risk, whereas others argued it was a matter of consumers' right to choose. Others raised problems of definition arguing that labelling without a standardized definition is not useful. The debate went on about whether labels should be mandatory or voluntary. Two points of agreement emerged. First, that public confidence is important in ensuring the commercial success of nanotechnologies and second, that provision of information to consumers is an important part of maintaining public confidence.

Day 2: Stakeholder Dialogue

Session 4 – Identifying interests, concerns and priorities to map the way ahead

Four stakeholder groups met to identify interests, concerns, and priorities in order to map the way ahead. They talked about objectives of voluntary or regulatory activities, appropriate ways to reach those objectives and about the contributions that their stakeholder group could make towards these objectives. The outputs on nanotechnologies in the food, consumer goods and health product sectors were presented by Rogerio Gaspar and Philippe Hubert (Science & Risk Assessors), Michael Knowles (Industry), Aleksandra Kordecka (NGOs) and Sabine Hoekstra-van den Bosh (Public Authorities)[2].

Session 5 - Taking stock of common ground, differences, and priorities

The results of the Break Out Groups were the focus of the final dialogue session. The frank and constructive tone was set by the Director-General for Health and Consumer Protection, Robert Madelin. He began by highlighting the responsibility of industry to be pro-active in communicating to its consumers about the potential uses of nanotechnologies. He said: "*It is my personal strong conviction that there is much more that corporate players could do for an innovative and courageous communication with their customers around emerging technology issues*." He underscored the importance of public confidence in nano-products and players to create the conditions for an innovative and competitive Europe. Confidence has to be built upon an open exchange of information, he stressed. With a clear request for immediate web-based public information, he closed his opening remarks and handed over to Antje Grobe, the facilitator of session 5.

[2] Download of the results from the Break Out Groups:
http://ec.europa.eu/health/ph_risk/ev_20071025_en.htm

Definition
The response from Industry stakeholders to this challenge from Robert Madelin was that a standard definition is needed to frame what is meant by "nanotechnologies". Food producers were asked to communicate openly about their use of nanomaterials. With the example of titanium dioxide, Industry explained that materials are in use that do not fall under the definition of nanomaterials. The question was asked about the regulatory implications for well known and approved food additives, if they are called a "nanomaterial" today. Additionally, Industry pointed out that public authorities should give a common set of reporting and testing guidelines.
Information was provided by the International Standards Organisation (ISO) about their progress on a definition of nanotechnology, which is due to be finished in spring 2008. Industry, NGO and public authorities pointed out that definitions must extend beyond questions of 1-100nm size range. Considerations of shape, surface chemistry, aggregation and agglomeration of nano-objects should be included. It was also agreed that criteria for risk assessment of nanotechnologies should not be limited to a size-based definition. The importance of developing internationally harmonized criteria for risk assessment was also highlighted.

Regulatory Framework
Then, the discussion turned to the adequacy of the existing regulatory framework. NGOs called for amendments to the current regulatory framework to make explicit reference to nanotechnologies. Stakeholders agreed that further dialogue is needed to determine if the regulatory framework (novel food, REACH) is adequate and flexible enough to cover nanotechnologies. Pre-market evaluation of nanomaterials when the novel foods legislation applies was requested by public authorities.
Prompted by a response from Industry, stakeholders agreed to invest in more dialogues to explore how to implement the current framework. Guidance (with clear lines of authority) and a toolbox for good governance should be developed through collaboration among the stakeholders. Independent oversight was requested by NGOs. In terms of interpreting and implementing current regulations, it was agreed that more effort is required to develop common testing and reporting formats. Efforts should also be made to harmonize standards worldwide. It was also agreed that more and better co-ordinated research is needed on life-cycles, end of product life and environmental impacts.

Informational needs and labelling
The discussion then focused on labelling, corporate openness about nanotechnology developments, and ways of informing and educating the wider public. Robert Madelin argued that companies have to be proactive and could not wait for the right conditions to communicate with the wider public. Consumers are interested in the functionality and safety of products. NGOs endorse the importance of providing information about nanotechnologies in consumer products. They agreed that product labels would not necessarily be the best way to communicate. For consumer information and education public web pages in a commonly understandable language were requested with links to scientific studies and independent tests.
Beside public information well-elaborated material safety data sheets should be accessible for communication along the value chain and with public authorities. Replying to Robert Madelin's request for more information, Industry encouraged a debate on ways of sharing information that protects intellectual property rights and uses shared reporting formats.

Future Dialogue
Finally the discussion took up the question of future dialogue activities. Industry stakeholders underscored their willingness to provide information and engage in stakeholder dialogues. A commitment to regular, transparent and ongoing dialogue was expressed by all stakeholder groups. In this context, Mr Madelin announced the creation of a stakeholder forum as well as the dates and venue for the 2nd Annual Nano Safety for Success Dialogue workshop on 2nd – 3rd October 2008, in Brussels, Belgium.

Robert Madelin closed the session by emphasizing "the need for speed" to avoid a public backlash as seen in the case of GMOs. He said that "*there is no excuse for a 'wait and see' attitude by researchers, producers and retailers*". Inspiring an open and ongoing dialogue process, he encouraged all stakeholders to contribute to the responsible development of these exciting new technologies and to invest in innovative communicational strategies.