

2nd Annual
nano 

BRUSSELS, 2nd-3rd October 2008
SAFETY FOR SUCCESS DIALOGUE

Workshop Report

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The present report may be found under:

http://ec.europa.eu/health/ph_risk/ev_20081002_en.htm

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Foreword by *Robert Madelin*

The “2nd Annual Nanotechnology Safety for Success Dialogue Workshop” held at the Hotel Sofitel Brussels Europe, Brussels, Belgium, on Thursday, 2nd and Friday, 3rd October 2008 offered an opportunity to take stock and pursue the structured strategic conversation on innovation, safety, and consumer trust that we started in 2007.

This 2nd Nano Dialogue proved extremely instructive albeit frustrating at times. Indeed, some unquestionably useful exchanges of information did take place. Yet, we also witnessed instances where discussants were talking past each other for lack of common ground and a common language. Moreover, we all noted significant advances in our scientific understanding of nanoscience and the nanotechnologies as well as encouraging progress in the area of the risk assessment of nanomaterials. However, most of us would agree that we would like to know more about the characteristics of nanomaterials and about a broader range of materials today, when we can only reasonably expect public research programs and international efforts to deliver in five to fifteen years. Stakeholders, citizens and their representatives in particular, also stressed the need for market intelligence about existing and likely products of nanoscience and the nanotechnologies.

In recognition of this state of affairs, I indicated during the closing session of the workshop that I would ask my services to pin down five to ten priority actions to be undertaken by Easter to address key points raised during this 2nd Nano Dialogue. Ten actions were identified on the basis of the conference material, notes, and the present report. They concern “Dialogue and Governance”, “Market intelligence”, and “Scientific knowledge gap-filling, risk assessment and guidance”. They will shortly be communicated to all participants and published on the conference web site.

I look forward to the “3rd Annual Nanotechnology Safety for Success Dialogue Workshop” to be held in Brussels, Belgium, on Tuesday, 3rd and Wednesday, 4th November 2009 to assess how far we were able to progress, in particular with respect to addressing the three, generic priorities identified this year, namely, engaging all stakeholders and developing shared references, developing trustworthy and trusted information on products and their safety, and providing useful risk assessment and regulatory guidance.

Robert Madelin

Executive Summary

Stakeholders attending the second annual “Safety for Success” dialogue agreed that while many activities had taken place during the past year towards the responsible development and regulation of nanotechnologies more effort was needed. Discussion highlighted three areas that require coordinated effort from all parties:

1. Developing trustworthy information on products containing nanomaterials that are on or near the market, and on how they are tested.
2. Meaningful public engagement on the basis of shared definitions of nanotechnologies.
3. Ongoing regulatory reviews to provide clear guidance to industry on how to interpret regulatory frameworks, and clear indications to the public about action being taken in cases where relevant risk data is limited or uncertain.

In addition, the meeting identified a number of key points that need to be addressed in order to meet these three priorities.

Further research on nanotechnology risks remains a significant priority. This work should include developing practical methodologies for testing nanomaterials. For example, more work is required to make reliable comparisons of *in vitro* and *in vivo* toxicology studies. Further work is needed on exposure routes and effects of long-term exposures to low dosages. In addition, more knowledge is needed about nanomaterials in the environment, including questions of aggregation and disaggregation, accumulation, and interactions with other chemicals.

In the area of regulation, further clarification is requested regarding the adequacy of current regulation given uncertainties about the characterization and biological properties of nanomaterials. The meeting discussed developing regulatory options for pre-market intervention (assessment and authorisation processes) including the question of considering nanomaterials as ‘new’ substances. Finally, work is required on the introduction of post-market monitoring systems and consideration of the question of labelling.

The meeting requested that industry make information on safety aspects of nanotechnology containing products more accessible to regulators and consumers. While industry has engaged in several public dialogue processes in recent years further effort is needed to ensure that these are visible, well co-ordinated and lead to meaningful action.

Many participants agreed that positive steps had been taken during the past year. However, the overarching question remained how to ensure public confidence in efforts by all stakeholders to provide relevant information, develop appropriate testing methods, deal with remaining questions of uncertainty over risks, and appropriately implement regulatory frameworks.

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Workshop Report

Introduction

On the 2nd and 3rd October 2008 over 200 stakeholders met in Brussels to exchange information and discuss key issues in the safe development, regulation and commercialisation of nanotechnologies. Building on the first Nanotechnology Safety for Success Dialogue, nearly double the number of participants discussed progress during the past year and charted priorities for further work.

The meeting was opened by Commissioner for Health Androulla Vassiliou, who noted the great potential promised by nanosciences and nanotechnologies in the fields of healthcare, energy, electronics and other consumer goods. However, she also noted the importance of ensuring the safety of nanotechnology applications and working to promote innovation that meets the aspirations of citizens and consumers.

Commissioner Vassiliou drew attention to the European Union (EU) Action Plan that sets a path for the safe, integrated and responsible development of nanotechnologies. In this context she welcomed the Safety for Success Dialogue as an opportunity to:

- exchange information on science, risk assessment and regulation, as well as societal awareness, aspirations and concerns;
- discuss the adequacy of existing frameworks; and
- formulate recommendations to promote safe innovation.

Ms. Sophie Delaporte (Deputy Director General, French Ministry of Health) then opened the conference on behalf of the French Presidency. She too noted the great economic potential of nanomaterials and the critical questions that must be addressed to ensure public acceptance of nanotechnologies. Ms Delaporte welcomed the research being carried out in Europe on the safety of nanomaterials, and called for further research and greater effort in applying the lessons learned to risk management. Ms Delaporte called on participants to not only exchange information, but also to develop consensus positions on the next steps required to promote the responsible development of nanotechnologies.

Day 1: Presentations and debate¹

Session 1: Science and risk assessment

Chaired by Professor Jim Bridges, Chair of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the European Commission

Developments in Nanotoxicology: Some old and new concepts (Professor Günter Oberdörster, University of Rochester)

Nanotoxicology provides information for risk assessment, risk management and risk communication. When evaluating the safety of nanomaterials, there is an urgent need to develop and validate non *in vivo* testing methods like cell-free and cellular assays or computational models to predict *in vivo* responses. Oberdörster discussed a set of risk assessment criteria like surface area, particle size, dose, the exposure route, questions of translocation and excretion for different nanomaterials. But the problem remains how to compare doses and responses from *in vitro* and *in vivo* studies and therefore he called for a concept of an equivalent dose and response metric. Other limitations are that current studies only relate to acute toxicity and do not assess more realistic scenarios of long-term exposure to lower doses. Some new findings were presented showing that adsorption patterns and translocation of nanomaterials depended on specific coatings. Oberdörster argued that size, surface coating and the portal of entry will affect particle biodistribution.

High aspect ratio nanoparticles: Length-dependent pathogenic behaviour mimics that of asbestos in a mesothelial response model (Professor Ken Donaldson, University of Edinburgh)

The focus of Donaldson's presentation was the question whether the aspect ratio (length / diameter) of a fibre will provide an 'extra hazard' factor in the toxicity of nanoparticles. He showed different studies of the effects of fibre length on toxicity, including the results of a study of carbon nanotubes from 2008, published with Poland et al. This study tested the hypothesis that carbon nanotubes have similar length-dependent pathogenicity as asbestos. In the study, short and tangled nanotubes (500 nm and 5 µm) were compared with long straight samples (20 µm). Both acute and chronic inflammation was observed in the peritoneal cavity for long, straight fibres. These were shown to cause a significant amount of granulomas, an early indicator of fibrosis. For the short, the short-tangled, and the long-tangled carbon nanotubes, complete phagocytosis by macrophages was observed. For these materials no inflammatory effects occurred. Donaldson showed rapid inflammatory and fibrogenic effects in a model of direct mesothelial exposure for Nickel-wires and concluded that other biopersistent (insoluble) materials could probably behave like asbestos if they are straight and long enough (>about 20mm).

¹ Presentations available: http://ec.europa.eu/health/ph_risk/ev_20081002_en.htm

Assessing the Risk of Nanofoods (Professor Staffan Skerfving, Lund University, Chair of the European Food Safety Authority Scientific Committee Working Group on Nanotechnology)

The European Food Safety Authority (EFSA) was requested by the EU Commission to produce a scientific opinion addressing the specific need for risk assessments in the area of nanotechnologies in food and feed. The scope of the evaluation only covers engineered nanomaterials that have at least one dimension smaller than 100nm. EFSA is not aware of current uses of nanomaterials added to food or feed. A survey carried out by EFSA did not result in any information about current applications. Currently, the EFSA analysis faces challenges of detecting nanomaterials and their toxicokinetics. Little information is accessible for the oral exposure route, about absorption and translocation or circulation in the body. Skerfving argued that a case-by-case risk assessment approach to nanomaterials should be followed when considering their bio-distribution and accumulation in organs and tissue. He called for a better consideration of possible changes of bioavailability through engineered nanomaterials, to strengthen research on accumulation and behavior in the tissue and to invest in long-term assessments. Additionally he recommended building up *in vitro* assays for toxicity tests.

Responsible Development of Nanotechnology: What about safety? Is there a risk? (Dr. Wim de Jong, Dutch National Institute for Public Health and the Environment)

Several consumer products are currently on the market that claim to utilize nanotechnologies. The two largest product areas are health and fitness followed by food and beverage. De Jong drew the full picture of risk assessment including substance identification, hazard characterization, information about dose response effects (no effect level) and an exposure assessment. He stressed that risk is a combination of likelihood of occurrence of harm to health and the severity of that harm. That means, if there is no exposure, there is no risk and without reliable information about the concrete use of nanomaterials in a product, risk assessment has to remain incomplete. Additionally for the risk assessment of nanomaterials several problems were described. The example of rutile, anatase, and brookite titanium dioxide showed that nanomaterials can differ even in the same chemical composition; nanomaterials behave differently according to the used dispersion. There is less knowledge about absorption and possible changes of protein coronas; and there is less knowledge about the dose metric and the no-effect levels. De Jong concluded that a proper characterization is necessary – respecting that the characteristics of materials may differ between manufacturers. It should be taken into account that nanomaterials may change depending on test conditions.

Session 1 discussion

Several questions were raised about the adequacy of current regulation given the significant uncertainties about the characterization and biological properties of nanomaterials. In the context of the asbestos experience, NGOs requested that regulators oblige industry not to deal with long straight fibres. One of the speakers answered that the question should not be about prohibition, but rather about requiring the safe handling of toxic substances. He argued that there is the possibility of a “Design for Safety” if short or tangled types of carbon nanotubes are used. Other questions were raised about potential long-term neurotoxicity of nanoparticles and a possible links to Alzheimer’s diseases. It was mentioned that there are studies which

showed a link between air pollution and Alzheimer's (in Mexico City), but that there is no information about nanomaterials in this context.

EFSA's statement that there is no nanotechnology in food was questioned. EFSA clarified that no use in food had been reported to them by industry. Several comments called for better information about effects of increased bioavailability of certain nutrients resulting from the use of nanoscaled carriers.

A proposal for more stringent application of the 'no data, no market' principle was put forward. It was proposed that industry should be required to provide details of the nanomaterials used in products, and evidence that safety tests have been carried out. In response, regulators suggested that in the absence of knowledge about the general properties of nanomaterials, case-by-case risk assessment and toxicological studies were appropriate. However reliability of test methods and long-term assessments were questioned.

Questions were raised about definitions of nanomaterials. It was suggested that definitions that focused on length scales were inadequate for regulatory purposes, and more attention should be paid to the emergence of novel properties.

Investigating the Effects of Nanomaterials on the Environment: Current knowledge and future research needs (Professor Teresa Fernandes, Napier University)

Professor Fernandes stressed the necessity of integrating toxicity and ecotoxicity since more studies have been completed on environmental effects. For both, toxicological and ecotoxicological questions, the following parameters are highly relevant:

(i) Physical and chemical characteristics:

- Size, surface area, dimensions;
- Solubility (biopersistence, durability);
- Aggregation / clumping, contaminants, composition.

(ii) Toxicological mechanisms:

- Free radical and reactive oxygen species production;
- Oxidative stress, inflammation, toxicokinetics;
- Absorption, distribution, metabolism and excretion.

Routes of release and exposure have to be detected as well as interactions of nanomaterials in the environment, including questions of aggregation and disaggregation.

Additionally, information has to be gathered about the stability of the materials and a possible increase or decrease of uptake of nanomaterials. Fernandes introduced a conceptual model of sources, media, transport processes and exposure pathways. A review of over 30 studies relevant to environmental safety with different nanomaterials showed effects on microbes, including bactericide and viricide effects, reactive oxygen species production, oxidative damage, cell membrane damage, inhibited growth and cytotoxic effects. Another model illustrated mechanisms for toxicity. The "unknowns" are: uptake and translocation, excretion, accumulation and

food chain effects, interactions with other chemicals and procedural approaches, including protocols and characterization (e.g. in soil systems).

The European Commitment to Nano Safety Research (Ms. Pilar Aguar, DG Research, European Commission)

Several milestones have been reached in order to support the safe, integrated, and responsible development of nanotechnologies. The EU has provided more funding than any other funding body to the study of the environmental, health and safety impacts of nanomaterials, and the amount of money devoted to this aim is increasing. The funding of safety research for the first year of the Framework Programme (FP) 7 is 25 Million Euro, which is as large as the funding for the whole FP 6 period. Currently there are several projects running under the 6th Framework Programme, including CELLNANOTOX, DIPNA, IMPART, NANOINTERACT, NANOSH, PARTICLE-RISK, NANOSAFE 2, SAPHIR and NANOCAP. For questions on standardization and metrology NANO-STRAND and NANOTRANSPORT are set up. Under the new 7th Framework Programme NanoImpactnet, Nanommune, NANOTEST and ENRHES are just started. Another four projects are being negotiated.

With a total amount of 79 Million Euro, the 14 EU projects and other 92 projects of EU Member States are building up information in the field of health and environmental impacts of nanomaterials.

Session 2: Regulation

Chaired by the Honorable Member Ms. Dorette Corbey, European Parliament, Member of the Committee on the Environment, Public Health and Food Safety

Regulatory Challenges of Nanotechnologies (Professor Graeme Hodge, Monash University)

Three different languages used to talk about nanotechnologies were defined. First, 'nanotechnology as a phenomenon' encompasses the many complex developments that can be classified under the umbrella of nanotechnology. The connotations of nanotechnology include promise for the future as well as potential risks and pitfalls. Next, 'nanotechnology as a science frontier' presents some of the problems with trying to define what exactly nanotechnology is and how it should be regulated. This leads to the final language of 'regulation,' which itself is evolving. With multiple disciplines represented, the mechanisms and tools for regulation are more widely spread than before. To create a new regulatory approach for nanotechnology, existing models can be utilized and expanded. However, many challenges will need to be overcome, including language games, scientific gaps, regulatory gaps/triggers, balancing regulation, evaluating what works, transparency for trust, education and engagement.

Regulatory Aspects of Nanotechnologies in the EU (Mr. Cornelis Brekelmans, DG Enterprise, European Commission)

The European Commission has outlined its approach to nanotechnology in several communications over the past years. The overall paradigm is to take a safe, integrated, and responsible approach which is technology neutral. The concept of "no data, no market" is applied and there is an obligation to continually update the technical information files and authorisations. These commitments provide tools for member

states and their regulators. Brekelmans emphasized the great amount of work to be done on developing implementing rules, standards, guidance, testing methods, risk assessment models and data gathering. He mentioned options for premarket intervention, access to information, the question of labelling, as issues of high priority to work on.

On an ongoing basis, a review process within three years should ensure the adequacy of regulations, and their implementation and enforcement. Research and development priorities are the creation of common nomenclature, amalgamation of data on human health and environmental effects along with exposure assessment, and standardization of measurement, characterization and analytical tools. Currently, work is being done to cover the fields of cosmetics, medical devices, medicinal products, food and chemicals. In concert with this work, there needs to be a European-wide dialogue with citizens and relevant stakeholders. Trust and transparency are keys to success. Many member states and industry sectors have already created platforms for dialogue. These should be augmented by coordination at the European Level.

Nanotechnology: A societal perspective on regulation (Ms. Laura Degallaix, BEUC – the EU Consumers' Organisation)

BEUC made clear that the current regulatory approach is not sufficient from their perspective. They identified regulatory gaps such as a lack of clarity over how general requirements for safety are to be applied. Degallaix gave examples where regulatory measures might fail:

- where use of a substance is restricted by % weight or volume
- where thresholds are set for permitted concentrations in products
- where authorization is based on whether substances are 'equivalent' to ones regulated and understood.

Consumer surveys carried out by the British consumer organization "Which?" indicate a general lack of information regarding nanotechnologies, and that consumers' concerns include safety, lack of regulation, lack of information, accessibility, and environmental safety. Consumer organisations would appreciate definitions in order to help develop regulatory requirements. The definitions should refer to nanoparticles and aggregates, avoiding limiting the size to 100nm. The precautionary principle should be adhered to when implementing a pre-market assessment and authorization process. This approach would consider nanoparticles as 'new' substances and introduce post-market monitoring systems. Overall, consumers would like more information about nanotechnologies, a transparent approach to safety assessment, and better engagement, including public debate. Therefore, Degallaix requested that the European Commission urge industry to provide the necessary information.

Session 2 discussion

In response to the discussion of public engagement in the regulatory process, it was stressed that engagement had to be meaningful rather than 'just talk'. Public engagement should be able to influence decisions, and public participants should have the right to 'say no' to specific proposals.

The adequacy of the legislative framework was discussed. It was suggested that there were significant gaps in the current regulatory framework as far as novel properties of

nanomaterials were concerned. Premarket risk assessment and approval was requested. The counter position was that there are gaps in necessary data, and gaps in the implementation of regulations, but that the primary legislation is adequate. Others gave comments that it is difficult to implement regulation if there is no information about materials that are already in use.

Questions were raised about what was meant by a ‘case-by-case’ approach to regulation. It was stated that important questions about the application of a case-by-case approach need to be debated, e.g., what counts as a ‘case’—a new material, a new use of a material, or each specific product. And what studies are required under this approach.

A questioner asked about the legal status of products on the market where there was evidence that nanomaterials were coming into contact with food (including packaging and bottles), or are in cosmetics, in cases where there are open questions about the biological activity of the nanomaterials.

The question of enforcement was also raised. A particular concern was how smaller companies can cope with requirements to compile adequate data on the nanomaterials they use.

Session 3: International developments

Chaired by Dr. Françoise Roure, French Ministry of Industry, Deputy Chair of the Organisation for Economic Co-operation and Development (OECD) Working Party on Nanotechnology

OECD Working Party on Manufactured Nanomaterials (Dr. Jim Willis, US Environmental Protection Agency, Chair of the OECD Working Party on Manufactured Nanomaterials)

The OECD Working Party on Manufactured Nanomaterials was established in September 2006 to promote international co-operation in health and environment safety aspects of manufactured nanomaterials, in order to assist in their safe development. The Working Party is engaged in eight projects including the development of a database of safety research; research strategies on manufactured nanomaterials; safety testing of a representative set of manufactured nanomaterials; developing test guidelines; and co-operation on voluntary schemes and regulatory programs; co-operation on risk assessment, research on alternative methods in nano toxicology; and exposure measurement and exposure mitigation.

A current priority is a testing programme of representative manufactured nanomaterials. More details can be found at: www.oecd.org/env/nanosafety.

Monitoring International Nanotechnology Activities (Dr. Robert Rudnitsky, US State Department, Chair of the OECD Working Party on Nanotechnology)

The OECD Working Party on Nanotechnology, established in March 2007, aims to promote global dialogue on best practice in nanotechnology policy. The Working Party has a particular focus on policies to support the development and application of nanotechnologies. Its projects include the development of indicators and statistics for more robust and comparative data on nanotechnology innovation; the study of the business environments for the commercialisation of nanotechnology; sharing best practice in public engagement with nanotechnology policy making; and a case study

in the development of nanotechnologies to tackle the global challenge of clean water provision. More information can be found at: www.oecd.org/sti/nano .

Standardization in Support of Safe and Successful Nanotechnologies (Dr. Peter Hatto, IonBond Ltd, Chair of International Organisation for Standardization (ISO) Technical Committee (TC) 229)

The International Organization for Standardization (ISO) works to provide legitimacy for standards through a systematic process whereby standards are proposed by members of the international community, developed by nominated experts, and finally approved through consensus. Nanotechnology presents particular challenges due to the diverse range of disciplines affected, its global impact, and rapid speed of developments. Critical areas are:

- The coordination and harmonization across standards developers and stakeholders
- Terminology
- Measurement and characterization
- Health, safety and environment effects
- Material specifications.

The ISO technical committee on nanotechnologies (ISO/TC 229) was established in June 2005 with 40 members and further 16 liaisons to other technical committees or external bodies. ISO/TC 229 coordinates different horizontal activities including standards for terminology and nomenclature, measurement and characterization, and health, safety and environment assessment. A second committee, the International Electrotechnical Commission (IEC) Technical Committee 113 – “Nanotechnology standardization for electrical and electronic products and systems” was established in 2006.

Session 3 discussion

A question was raised about the discrepancy between the large estimations of markets for nanotechnologies and the limited range of products that have been subject to risk assessment. The questioner called for clarity about what nanotechnology enhanced products are on the market, and for manufacturers to publish information on the safety of the nanomaterials they use.

One answer given to the apparent discrepancy was that risk assessment is carried out on 14 nanomaterials at the OECD level, and each of them has multiple applications in a wide range of products. But it was agreed that an important priority is to work towards trusted sources of information on what nanomaterials are on the market and what safety tests have been done. Market surveillance and a shared definition of the investigated subjects were therefore described as key steps for developing more trustful relations among stakeholders.

The opportunity for the OECD and the ISO to work together was discussed, and it was pointed out that some members sit on both committees. One speaker pointed out that there is an informal working understanding that the two bodies will coordinate their efforts.

A concern was raised about the perception of ISO as being mainly influenced by industry with a narrow focus on industrialised countries. It was stated that experts who sit on standards committees are generally perceived not to have a particular bias, and that all countries participate not only in the expert nomination process, but also in the standards acceptance procedure.

Session 4: Risk governance, communication, and perception

Chaired by Professor Rolf F. Hertel, German Federal Institute for Risk Assessment

Nanotechnology: Risk governance (Professor Ortwin Renn, University of Stuttgart)

The International Risk Governance Council (IRGC) framework links a phase of issues framing (Pre-Assessment Phase) with physical risk assessment and concern assessment in the Risk Appraisal Phase. If this is done, a Tolerability and Judgement Phase has to prepare concrete action of the Risk Management Phase. Risk communication is the centre of such a risk governance framework. Renn mentioned the high relevance of the social, the cultural and the economic frames for risk perception, risk management and risk communication processes. They determine boundaries of what is included and excluded in the focus of the public debate as well as the focus of risk assessment. For the debate on nanotechnologies, two major frames have to be reflected. Frame one refers to passive nanostructures, for example in easy-to-clean surfaces, paints or in cosmetics. Frame two refers to active nanostructures and molecular systems which could be able to interact actively or could be understood as evolutionary biosystems which change their properties in an autonomous process. Renn recommended distinguishing between Frame 1 and Frame 2; to standardise nomenclature, measuring and handling systems to ensure that the same frames could be used; to increase proportion of public and private funding devoted to dealing with risks and to improve data sharing. Renn recommended industry and public authorities improve communication strategies to engage the public and make this participation effective.

Risk communication (Dr. Jørgen Schlundt, World Health Organisation)

In risk analysis, risk assessment must be science-based while risk management must be policy-based. Risk communication should therefore encompass both risk assessment and risk management, and it should foster the exchange of information and opinions concerning risks. Risk perception is based on experience and knowledge, and is shaped by values, beliefs, confidence and trust. When describing risk, scientists tend to ignore the public's reaction, while consumers tend to pay too little attention to actual risks. With nanotechnologies, potential hazards are mentioned, but the risks are difficult to evaluate. Results reflecting hazard and exposure in an effective way for nanotechnologies are rare; the knowledge base for risk assessment is insufficient. Schlundt commented that the World Health Organisation (WHO) would need more funding if it were to prepare sufficient knowledge about the risks of nanotechnologies. Additionally, public risk perception is influenced by scientific statements, press amplification, political involvement, and regulatory action. Poor risk communication leads to a perception of greater risk. Therefore Schlundt recommended that all stakeholders should improve their communication strategies.

Risk perception (Professor James Hammitt, Harvard School of Public Health)

Although the general public often accepts expert evaluations, lay people may perceive risks to be either greater or smaller than expert assessments. These disagreements can be based on ideology, mistrust, or dual rationalities. Different psychometric factors influence perception. High public estimations of risk may be due to ‘dread’, where a technology is perceived as uncontrollable, involuntary, catastrophic, and inequitable, if there is no balanced distribution of benefits, or if it affects future generations. Uncertainty will increase if a technology is perceived as unobservable, if it is not understood scientifically, if there could be delayed consequences, or if it is newly recognized. Experts and public sometimes perceive risk differently, James Hammitt concluded. Core issues for risk communication would be: What explains the occurrence of disagreement and what are likely directions of disagreement? For the future, Hammitt expects that both the salience and distribution of benefits and harms will be critical for the development of nanotechnologies.

Session 4 discussion

All the participants in the discussion emphasized the importance of improving communication. There was general agreement that scientists must shift their paradigm that public perception can be easily persuaded by facts alone. The difficulty in burdening scientists with the task of public communication was recognized, and alternative solutions were discussed. A concern was raised that scientists could be seen to be talking down to the public. People expect meaningful, balanced and trustworthy information, including transparency about uncertainty. If all relevant information is given to the public, they can evaluate it and make their own decisions. It was suggested that appropriate institutions should be established fostering genuine dialogue rather than ‘one-way’ communication.

Another question was the appropriate role for industry. It was suggested that industry should take responsibility to communicate more openly about the technologies it is developing. But the problem of public trust in industry was also raised. A common understanding of nanomaterials used in consumer products (question of definition) was identified again as an important basis for trust in this part of the discussion.

One expressed his concern that the biggest risk associated nanotechnology could be the missing participation of consumers. The appropriate goal should be to democratise discussions about risk and technology. It was suggested that a broader definition of risk is needed. Debate should also include discussion of non-quantifiable risks, such as social and spiritual risks. Public discussion should also include consideration of the public value of technologies.

Session 5: Communication with the customer

Chaired by Dr. Georg Karlaganis, Swiss Federal Office for the Environment (BAFU)

Enabling Responsible Innovations of Nanotechnologies: European chemical industry's strategy on nanomaterials and nanotechnologies (Mrs. Jenny Holmqvist, European Chemical Industry Council (CEFIC))

Holmqvist introduced CEFIC's core principles of safety, innovation and transparency for sustainable nanomaterials and nanotechnologies. The aims of European Chemical Industries are to achieve technology leadership, harmonized global standards, safety for workers, consumers and the environment, engagement with policy makers, regulators and stakeholders, and to do that in a transparent way. One important part of the current work is industry's support for the OECD programmes on nanotechnologies in order to improve the characterization of 14 selected nanomaterials as well as the work on exposure and mitigation. CEFIC has launched two long-range research initiatives: one to develop tiered testing strategies for nanomaterials; the second on the environmental fate of nanomaterials and strategies of exposure assessment. Additionally member companies are involved in national or European research projects such as NanoCare and TRACER, which focus on questions of testing procedures and measurement. Holmqvist stressed the possibilities of innovation. She mentioned examples in the field of environmental technologies including solar cells (coatings), thermal insulation of houses (nanoporous materials), LEDs, light weight, stiff materials for cars or wind mill rotors (carbon nanotubes in polymers). Other examples of surface enhancement or coatings for water purification were covered. Transparency is key in closing the gap between what industries communicate and what stakeholders want to know, she stated. CEFIC is working to improve this by providing more safety information about nanomaterials, proactively participating in regulatory working groups, and engaging in national and international stakeholder events. In 2008 CEFIC started its Stakeholder Engagement Process which will be continued with small workshop groups on issues agreed upon in advance and a larger stakeholder dialogue workshop in the second half of 2009.

Communicating Business-to-Business Product Information (Dr. Markus Pridöhl, Evonik)

EVONIK contributes to the OECD Working Group of Nanomaterials. Pridöhl explained the Responsible Care® Programme, a voluntary code of conduct for the chemical industry, which is a framework of responsible research, production and communication. This code addresses also nanomaterials and nanotechnologies. EVONIK supported the German Chemical Industry Association (VCI) in developing a suite of documents on the implementation of the Responsible Care Principles; the implementation of REACH; three guidance documents on the tiered gathering of information for risk assessment; for the safe use and handling of nanomaterials; and on passing information along the value chain using material safety data sheets (MSDS). All these documents are available in English (<http://www.vci.de/default~cmd~shd~docnr~122306~lastDokNr~116417.htm>).

Current legal requirements include a risk assessment for all uses, classification and labelling of each product, and the provision of information in the supply chain according to the REACH framework. Pridöhl emphasised that these legal requirements apply without volume thresholds and independent of registration timelines (see the VCI recommendations). Further recommendations beyond legal

requirements include stakeholder dialogues; intensifying safety research in dedicated projects; and in specific cases the gathering of health, safety and environmental information beyond REACH Annex VII (i.e. from Annex VIII, IX, X). The VCI further recommends:

- to minimise exposure at the workplace until specific limit values are laid down for nanoparticles or certain nanomaterials; publication of MSDSs by companies on a regular basis,
- to complete MSDS for all substances/preparations, also for those not classified as dangerous and
- to gather additional physicochemical information on top of REACH requirements for risk assessment.

Some examples of freely available MSDS for nanomaterials were introduced and it was stressed that almost all relevant manufactured nanomaterials from the OECD list have to be registered under REACH due to their high production volumes.

Session 5 discussion part 1

One questioner indicated some contradictions between the scientific presentations in the morning about knowledge gaps and problems concerning the detection, measurement and assessment of nanomaterials on the one hand; and the industry's statements of proactive assessments and a responsible use of nanomaterials on the other hand. How is it possible that industry tests can be appraised when the science remains uncertain? Industry stated that a lack of generic scientific understanding does not impede a proper risk assessment of a given product. But this lack prevents from generalisation and therefore requires an assessment on case-by-case basis. To answer these general scientific questions is much more difficult.

Communicating Business-to-Consumers Product Information (Ms. Carolin Kranz, BASF)

As a producer of nanomaterials (e.g. organic and inorganic particles) or components (e.g. thermoplastics or formulations) BASF is mainly involved in the beginning of the value chain for nanotechnology products. In these cases, communication is focussed on the value chain, not towards consumers. Therefore chemical industry would be not the best partner to discuss labelling issues from a consumer perspective. However there are some examples of nano-enabled products on the market which are clearly labelled as such. Kranz presented several examples of quality labels or descriptions of product functionality. A nanodispersion that equips textiles with a self-cleaning effect has been awarded a label by the German Institutes for Textile and Fibre Research, Denkendorf. This label indicates the material's hydrophobic properties, its nanostructured surfaces, dirt resistance, and stability. A second product is a binder for paints which is labelled by the customer of BASF as "Herbol Nanotec". A third example is a range of joint grout and insulating compounds, where the term Nano is used in the product name. Inside there are no nanomaterials in the narrow sense, but nanostructures are formed during hardening. The products are sold to industry and to do-it-yourself stores. Therefore BASF offers product information, Material Safety Data Sheets, test certificates and information on applications and handling. Information about each of their materials can be found on the BASF website. Furthermore, Kranz discussed proposals for a nano hazard label similar to the well-

known orange hazard symbols. These symbols must be self-explanatory to the consumer about the hazard, and they must indicate what safety measures the consumer could take to minimize the hazard. A hazard symbol “nano” would be useless, according to Kranz because a nanomaterial is not *per se* a risk. What consumers really want to know and how they could get access to the desired information should be developed in sector specific stakeholder dialogues.

Engineered Nanomaterials: Consumer expectations on product information (Dr. Michael Hansen, Consumers Union)

Hansen stated that the US based Consumers Union views consumer choice to be critical for creating a free and fair marketplace. He mentioned the United Nations Guidelines for Consumer Protection “Access of consumers to adequate information to enable them to make informed choices according to individual wishes and needs” (II 3(c)), and the Codex Alimentarius which indicates food labelling “for the health protection of consumers and for the promotion of fair practices in food trade”. The US Food and Drug Administration rules recognise the importance of disclosing “material facts”. Consumers have a right to information about the unique physical and chemical properties of nanomaterials, including safety and quality concerns as well as waste management issues. In order to achieve proper risk management, there must be disclosure of nanomaterials in products. This disclosure will allow traceability that can assist in possible recalls, unforeseen life cycle issues, product quality problems, cumulative exposure information, and increasing the understanding of nanomaterials. Risk-relevant nanoscale characteristics not only include the material composition, but also size, shape, crystal structure, and charge. Hansen emphasized the necessity of adequate nomenclature and definition regarding these properties. Consumers expect to be informed of the effects of nanomaterials on the body and in the environment. They require that products on the market are demonstrated to be safe, their ingredients are disclosed, and that manufactures and governments can respond quickly to recall unsafe products. Freedom of choice should be guaranteed so that consumers can take precautions in the face of uncertainty, and take other legitimate factors (e.g. religion, ethics, and environmental safety) into consideration when purchasing goods.

In some cases, these expectations are perceived to have not been met with nanomaterials. Hansen mentioned sunscreens, fire and explosion risks from lithium batteries; silver exposure from socks; dietary supplements; fullerenes in face cream; and easy mail-order access to dangerous nanomaterials, e.g. carbon nanotubes. He concluded by arguing that consumers need labelling of nanomaterials, premarket safety testing, regulations limiting use in exposure-intensive applications, life cycle assessments, and ongoing public dialogue.

Session 5 discussion part 2

Attention was drawn to the fact that safety information is provided by industry. Some mentioned that the quality of safety data might vary between companies. One response was that industry associations at national and European levels could provide assistance to companies. An example in Germany was given where the authorities worked with the Chemical Industry Association (VCI) to fill the gaps in safety information and to assist smaller companies with their own assessments. A questioner stated that information on safety assessments can only be as good as the state of the art methodology, therefore we have to invest in research and standardisation on safety measurement before products are marketed.

Day 2: Presentations, debate and stakeholder dialogue

Session 6: Highlights from the participant survey on communication, legislation, and its implementation

(Dr. Antje Grobe, University of Stuttgart, and Dr. Robert Doubleday, Cambridge University)

Session 6 discussion

Participants in the Second Annual Safety for Success dialogue were asked to respond to a four-question survey as part of the registration process. The questions were written by the Directorate-General for Health and Consumers and addressed topics of communication and regulation:

1. Which aspect of communication would you like to see improved?
2. Who should do what, where, and when on this aspect of communication?
3. Which aspect of the regulatory framework or issue with the implementation of the existing regulatory framework would you like to see improved?
4. Who should do what, where and when on this aspect of the regulatory framework or issue with the implementation of the existing regulatory framework?

The purpose of the survey was to inform the break-out group discussions by illustrating participants' prior views. The sample of survey respondents is not representative of the wider public or stakeholder community. The results of the survey should therefore be taken to provide only a 'snap-shot' of views of the self-selecting range of participants in the "Safety for Success" meeting.

The survey shows that participants believed that there are three priorities for improvements in communication. These are the provision of information about safety issues; information about products on the market; and developing forms of communication appropriate for consumers. The majority of participants viewed improvements in communication to be either the responsibility of all stakeholders or primarily the European Commission. Respondents identified this as an area of immediate concern.

On regulation and its implementation, there was strong agreement that further work needed to be done to apply the regulatory framework. A majority of participants viewed the European Commission as playing an important role in this process. Four priority areas were identified: the development of guidance documents; processes for the implementation and surveillance of regulations; work on risk characterisation and risk assessment methodologies; and the development of agreed and workable definitions.

Session 7: Introduction to the discussion and implementation of the existing legislation: Examples from the chemical, medical, and food areas

Chaired by Dr. Richard Canady, US Food and Drug Administration

Nano in REACH Implementation and Guidance (Dr. Peter van der Zandt, DG Environment, European Commission)

Nanomaterials are covered under the regulation of the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH). The goals of REACH are to ensure a high level of protection of human health and the environment, promote alternative test methods, facilitate free circulation of substances on the internal market, and enhance competitiveness and innovation. The basic principle is to ensure that manufactured, used or marketed substances do not cause any adverse effects on human health or the environment. Although there are no specific provisions for nanomaterials, REACH requirements apply. Key elements of REACH include the registration of substances used in quantities greater than one tonne per year, increased communication throughout the supply chain, evaluation of some substances of concern, authorization for substances of very high concern, restrictions of some substances, and public access to relevant information. By registering chemicals in volumes of 1 tonne or more per year, all relevant information will be collected and safety has to be ensured for the substances in whatever size or form and for all identified uses. Chemical Safety Reports (CSRs) are required at volumes of 10 tonnes or more per year. A CSR includes an assessment of specific properties, hazards (characterisation and labelling), risks and risk management measures (exposure assessment). Different European institutions and committees like Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR, European Chemicals Agency (ECHA), and the REACH Competent Authorities Group on Nanomaterials address the issues of REACH's applicability to nanomaterials. Collaboration is needed from the Member States and on international level with the OECD.

Guidance in the medical area (Dr. Marisa Papaluca Amati, Deputy Head of Sector, Safety, and Efficacy of Medicines, EMEA)

The European Medicines Agency was established to coordinate the existing scientific resources of EU member states. Nanomaterials or the use of nanotechnologies are covered by Art. 3(2) of Regulation (EC) No 726/2004 as "New Active Substances" or "Significant Innovation" in the broad sense of therapeutic, scientific or technical innovation.

There are several examples of medicinal products that contain nanotechnology on the market. Each nanomedicine is evaluated for its benefits and risks. Areas in which nanotechnologies are affecting pharmaceuticals are new manufacturing systems and new drug delivery methods. There is also the potential to see novel applications for *in vivo* diagnostics, regenerative medicine, intelligent multifunctional monitoring systems, and *in vivo* theranostics. Nanomedicines present unique scientific and regulatory challenges. As regards quality, there is a need for not only accurately characterizing size, size distribution, purity, chemical composition, stability, and solubility, but also the need to consider other characteristics including surface area,

surface chemistry, porosity, surface functionality and aggregation ability. Novel properties of nanomaterials may also require non-standard characterization methods. As regards safety, existing methodologies seem to be adequate for most, but not all, potential hazards.

Nanoparticle behaviour in diverse biological systems will need to be studied as well as the distribution, persistence and the subsequent effects of nanoparticles in humans and the environment. Although there is an adequate system in place for current toxicological screens of nanoscale materials, the potential for novel, unanticipated reactions might require new testing methods and models. These must be able to address concerns about efficacy, administration method and dose, and biodistribution to create a safety profile for risk management and minimization. Nanomedicines also present regulatory challenges due to the complexity of regulatory boundaries and gaps in scientific knowledge. The appropriate regulatory framework has to be clarified early in development process since there are different regulatory requirements, for example, a medicinal product compared to a medical device. Papaluca highlighted the importance of learning across regulatory frameworks.

Guidance in the Food Area: An introduction to the issues from EFSA (Dr. David Carlander, European Food Safety Authority (EFSA))

The European Food Safety Authority is compiling new proposed guidance for nanotechnologies in food. Current guidance does not specifically address engineered nanomaterials. Under the new proposed guidance, many parameters will need to be provided for a nanomaterial, including size, size distribution, mass, surface area, specific surface area, number, shape, chemical composition including impurities and processing chemicals, surface properties such as coating and charge, and solubility. Because of the difficulty in analyzing final food and feed products for nanomaterials, a prudent approach is taken to assume that all engineered nanomaterials added to the product exists in the nanoform. In some cases, nanomaterial may be examined as its bulk form. However, if nanostructures are found to persist in the gastrointestinal tract, there is a need for *in vivo* toxicokinetic data. The bioavailability of the nanoparticles should also address the consequences of possible changes. Since the experience with engineered nanoparticles in regulatory framework is limited, the adequacy of existing testing methods is yet to be established. As more information becomes available, a more thorough risk assessment can be performed on nanomaterials in food and feed.

Session 7 discussion

Several questions about boundaries between regulatory regimes were raised. For example which authorities take the lead in regulating products at the borderline between food and medicines; between cosmetics and medicines; or between medicines and medical products?

Clarification was requested regarding the necessity to evaluate nanomedicines on a case-by-case basis. The current paradigm dictates that companies must provide all data obtained at every step of the development process. In tandem, there is an examination by the agency to evaluate each company's ability to adequately address the safety concerns. There is a distinction between nanomaterials that are found in the final product and those that are utilized only in the manufacturing process. Any new material, even ones that are similar to existing materials, must be tested and evaluated on its own merits.

There was a discrepancy between the guidance required from regulators and the information available to them. Although there is a need for revised guidance, it has to be done with the available knowledge. Regulators therefore need as much information from industry as possible.

The tonnage limit for registering chemicals was questioned for its ability to accommodate several different forms of the same substance. However, it was explained that the tonnage barrier applied to the substance, but that if different forms of the same substance exhibited different properties, they must be registered separately, regardless of the weight.

The French Health Ministry last year developed a new set of regulatory guidelines for nanotechnologies in health products. These guidelines were sent to EMEA. EMEA received contributions from all national Competent Authorities. As national CA play a role in regulating research they often have more information on innovative healthcare technologies than EMEA, therefore good communication between regulators is important.

Session 8: Identification in break-out groups

of means to improve (i) communication and (ii) the implementation of the existing legislation in the chemical, medical, products, and food areas (priorities and next steps, for whom and when)

Four thematic groups met to identify interests, concerns, and priorities in order to improve communication and the implementation of the existing legislation. The four groups focused on the areas of nanotechnologies in chemicals, medicines, products and foods.

Session 9: Presentation in plenary of recommendations to improve communication and implementation

Chaired by Mr. Robert Madelin, Director General, European Commission, DG Health and Consumers

Summary of the four breakout sessions:

Break-out group 1. Chemicals: Chair: Dr. Agneta Falk-Filipsson, Swedish Chemicals Agency (KemI); Co-Chair: Ms. Maila Puolamaa, European Commission, DG Enterprise

The group identified a range of divergent views around the adequacy and implementation of REACH. It noted differences among criteria and processes for developing definitions; and it called attention to the significance of substance identification under REACH. The total volume approach was considered to be sufficient by different stakeholders. But additional concerns were raised about small volumes.

Different perceptions of the current situation of existing information and transparency were considered. Many asked for more information. However, differences between what is meant by 'information' within the group became visible. Industry pointed out that information is available on company homepages, on the OECD High Production Volume Chemicals Programme and via the voluntary commitment of individual

companies. The group talked about the current dialogue initiative from CEFIC and several national dialogues and sector-by-sector dialogues. They acknowledged the need to build trust for further progress in dialogues. They concluded that multi-level communication needs to be developed and managed.

Break-out group 2. Medicines: Chair: Professor Ruth Duncan, Centre for Polymer Therapeutics, Welsh School of Pharmacy, Cardiff University; Co-Chair: Dr. Hermann Stamm, European Commission Joint Research Centre, Institute for Health and Consumer Protection (Ispra)

The Medicines Breakout Group covered two principle aspects of communication that should be improved. Aspect 1 is the communication from experts to the general public; Aspect 2 is the communication amongst the expert community. Concrete action was required from the regulatory agencies to build up an information Website with the following criteria: readability in lay language; possibility to interact and to give feedback to the information provider; follow-up by regulatory agencies on the feedback from the public. Nanodialogues and Nanojuries should enable a feedback for policy makers. For Aspect 2, the communication across scientific disciplines, the Safety for Success Conference is one example. Another approach are Strategic Advisory Teams from Member State governments. Other ideas could be:

ESF Research Conferences or Summer Schools Workshops. The group recommended using existing communication lines for nano-specific information.

Break-out group 3. Products: Chair: Dr. Andrew Maynard, Project on Emerging

Nanotechnologies, Woodrow Wilson International Center for Scholars; Co-Chair: Mr Manfred Kohler, European Commission, DG Enterprise

The highest priority identified by the Products Breakout Group is trust that is created by a multi-stakeholder approach visible to the general public (not a focused nano organisation). The Group stressed the necessity of making information relevant to nanomaterials available on the internet and to build up such platforms independently from the outcome of the discussion on labelling. They recommended industry and authorities first to learn how to communicate and to draw existing information to public attention. Some major questions were discussed such as:

What happens when you cannot measure exposure? How to regulate under conditions where methods to measure risk are not fully developed? How to handle the issues democratically? How to sort-out what is really new in nanomaterials and what is not new? What is meaningful information for consumers?

For the improvement of regulation the Breakout Group recommended the development of methodologies for market surveillance and to work on sector specific safety criteria and their implementation.

Break-out group 4. Food: Chair: Professor William Dab, French National Institute for Science, Technology, and Management (CNAM); Co-Chair: Dr. Sirkku Heinimaa, European Commission, DG Health and Consumers

The Food Group drew up a set of considerations for developing communication strategies. But first they drew attention on the great expectations towards the EU and that a strong involvement is required. The means to improve communication are: Transparency; honesty about uncertainty; the need to reach appropriate audience

(multi-national approach); a framework for communication (EU assistance for local authorities), and a common understanding and use of a consistent definitions. The group highlighted the necessity for all stakeholders to define a common language as a basis for regulatory or voluntary activities. The recommended a worldwide inventory to achieve greater transparency and predictability by the inclusion of different perspectives. They discussed options for positive lists (allowed materials) versus mandatory registration, the issue of classification of supplements and the challenges of food supplements. Additionally they stated that these approaches and issues have to be discussed openly not only between the EU and the US.

Robert Madelin concluded the session by referring to regulator's paradigm of equally balancing the triangle of innovation, growth and sustainability. Transparency on all three aspects is key to gaining the confidence of consumers. But the situation is not like this ideal model. The lack of agreed working definitions for nanomaterials, even after last year's dialogue, has provided some disappointment amongst stakeholders and there is still uncertainty as to what is on the market. Now the ball is in the industry's and provider's court to share this information. Facing the current lag of transparency, a company's reputation is not a sufficient reason for consumer confidence in nanotechnologies. Although a multitude of data is available, it is often not conveyed in a meaningful way to the general public. The great challenge of dealing with nanotechnologies in the next months will be: identifying responsibilities of communication (who has to provide what kind of information) and the ways of best practice to do so. This is not only an industry task, Robert Madelin closed: any policy that is developed without proper communication will not be effective. Therefore it appears that the most urgent piece of work is to close this communication gap for both industry and public authorities.

Session 10: Plenary discussion on communication, legislation, and its implementation

In the final plenary discussion five main topics were raised:

1. Questions of definitions
2. Preparation of guidance documents
3. Positive regulatory actions under conditions of uncertainty
4. Providing trustworthy information
5. Strengthening stakeholder dialogue

The question of how nanomaterials should be defined for regulatory purposes was a major topic of last year's *Nano Safety for Success Dialogue*. It was noted that during the past year considerable effort has been spent in developing definitions. Some participants argued that it was now the responsibility of the European Commission to define nanomaterials for risk regulatory purposes. Others argued that more work needed to be done to develop shared understandings among stakeholders. The example of the food industry definition of nanotechnologies was given, which some participants felt was so narrow as to limit any meaningful discussion.

There were some participants who felt that writing guidance documents for risk assessors should be a priority for the European Commission. These documents would make clear how the risk assessment of nanomaterials should be handled. According to

this view, the major issue at stake is the application of standard risk assessment models. However, against this view two arguments were put forward. First, uncertainty over the detection of nanomaterials and the characterisation of their effects means that risk assessment will not provide all the answers. Second, that public confidence in handling of nanomaterials by regulators and industry relates to a wider set of questions than those dealt with by risk assessment.

Several participants from environmental NGOs and consumers groups called for more active response by regulators given uncertainties about nanomaterials. Examples of the proposals put forward included adopting a more precautionary approach (no-data, no market); and, for example in the cosmetics area, having a 'positive list' of materials that are approved for use.

The majority of the discussion focused on practical questions of how to develop trustworthy information and stakeholder dialogue.

Many participants agreed that a priority should be to work towards the provision of information on the risk assessment, regulation, and commercial application of nanomaterials. The argument was made that in order for such information to have the confidence of citizens it should be developed by a multi-stakeholder process. It was assumed that such information would best be communicated via websites. Several examples of websites were considered:

- EMEA use formal dialogue processes with patient groups and other key audiences to develop meaningful information: www.emea.europa.eu
- CEFIC: www.cefic.be/
- BASF: <http://www.basf.com/group/corporate/en/content/innovations/events-presentations/nanotechnology/index>
- "Nano&Me" website is currently being developed by the UK-based Responsible Nano Forum as a platform for consumers: <http://www.responsiblenanoforum.org>
- It was suggested that the US-based Health Effects Institute provides a mode of how credibility can be built through multi-stakeholder partnerships. Significantly there is a 'hard wall' between funding, some of which comes from industry, and decision making. Health Effects Institute: www.healtheffects.org

The greatest attention during the final plenary discussion was focused on practical questions of developing dialogue. While it was pointed out that there have been several stakeholder dialogue activities it was felt that there was scope to improve the dialogues.

Many participants from civil society argued that it was crucial that any dialogue process should have consequences. There was a danger that too many dialogues in the past appeared to some participants to be 'inauthentic', which served to undermine rather than enhance mutual trust.

Several important points were made. Dialogues should involve a wide range of stakeholders, and there should be agreement on the 'rules of the game'. All

participants in the dialogue should collectively agree the agenda and purposes of dialogue, and the dialogue process should be carried out by independent bodies.

As next steps for an improvement, sector specific dialogues were suggested as well as better communication about dialogue results. During the meeting several participants agreed to work towards a dialogue process on nano and food. This process would not assume any prior definition of nano as related to food, but would work through specific materials of concern raised by the dialogue process itself.

Robert Madelin recommended industry – especially the food industry – work with a common definition of nanomaterials and not limit discussions to narrow definitions. A clarification of their approach would be a first step for the further exchange of information. All stakeholders are invited to come up with concrete examples and to initialise a process of mutual learning how to develop the right set of questions and appropriate ways to provide information. For the next steps a strong stakeholder approach within small working groups is needed to work on sector-by-sector differences.

In addition the Directorate-General will map the full range of dialogue processes currently underway. This map will be made public with the intention of facilitating meaningful participation of relevant stakeholders.

Robert Madelin, Director-General for Health and Consumers, committed to publishing a list of the top ten questions to be answered in order to make progress on points raised during the workshop. DG for Health and Consumers will work with all relevant stakeholders to provide answers by Easter 2009.