

# Nanomaterials on the Market What Regulators Need to Know

Brussels - 9 October 2009

## Conference Report

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## **Background Note**

This Report summarizes the presentations and discussions at the Stakeholder Conference on Nanomaterials on the Market: What Regulators Need to Know that took place on 9<sup>th</sup> October 2009 in Brussels: The Conference was co-sponsored by the Swedish Presidency of the European Union and the European Commission (DG Environment). It was organised by the consultancies Milieu and Risk & Policy Analysts in the context of a study for the European Commission (DG Environment) aimed at assessing whether the reporting requirements under the REACH Regulation are adequate for gathering the necessary information to address potential risks associated with nanomaterials on the EU market today in order to ensure safe use. The agenda of the conference and list of participants are included as annexes to this Report.

## **Session 1: Introduction to the issues**

**Agneta Falk-Filipsson**, Swedish Chemicals Agency (KEMI), opened the conference. She introduced the Conference rapporteur, **David Gee**, European Environment Agency (EEA), who mentioned the need for early warning with regards to the potential risks from new technologies such as nanomaterials. Mr Gee welcomed the conference's participatory approach towards addressing the issue.

Chair Falk-Filipsson introduced the first speakers, Ethel Forsberg, Director General of KEMI, speaking for the Swedish Presidency; Commissioner Stavros Dimas, and Mr Rob Visser, Organisation for Economic Cooperation and Development (OECD).

**Ethel Forsberg** emphasised the role of stakeholders in maximising the benefits of nanomaterials whilst ensuring the protection of human health and the environment. She stressed the 'precautionary principle' and noted that (i) the knowledge gap regarding uses and risks must be closed with new research; (ii) new test guidelines are required to increase knowledge about properties and effects of nanomaterials; and (iii) the right balance of regulation needs to be established. She noted in particular that REACH does not offer the right balance of regulation for nanomaterials because (i) registration thresholds are based on tonnage; (ii) properties of substances change when in nano form as compared to bulk; and (iii) low tonnage chemicals will only be registered by 2018.

Mrs Forsberg expressed approval of the fact that during the conference several countries would be able to share their experiences of addressing the various issues arising in relation to nanomaterials in their respective systems of chemical control. She stated that experience to date demonstrates that voluntary reporting regimes have not shown great success.

She noted that regulators need to know what to regulate and to what extent, and that discussions during the conference would provide useful input with regard to the upcoming review of REACH. The CASG Nano subgroup needs to maintain contact with other areas, such as cosmetics and novel foods and there is also a need to keep abreast of international developments.

Warning signals motivating the present discussions include the possibility of nanomaterials passing the blood-brain barriers and the similarity of the effects of certain carbon nanotubes to those of asbestos fibres. These, and similar findings, must be taken into consideration when developing EU regulation on nanomaterials.

**Commissioner Stavros Dimas** explained that nanomaterials may be found in many products already on the market. He highlighted the promises of nanomaterials in terms of the competitiveness of EU industry and noted that the EU had boosted R&D investment in this field under the FP7. A key question that arises is whether REACH is the right tool for addressing nanomaterials. Commissioner Dimas noted that nanotechnology provides an example of how innovation can challenge existing regulatory frameworks and that a balance between risks and benefits must be struck. Key to this is the setting of the tonnage threshold.

Commissioner Dimas identified the need to understand the number of nanomaterials produced today and future predictions. He referred to the lack of both a single register of nanomaterials and a definition of nanomaterials. He also raised the question of when to intervene (in 2010 or at the end of the REACH regulatory cycle in 2018), and whether there are some nanomaterials that will not be registered under REACH. Commissioner Dimas referred to the resolution of the European Parliament as an important intervention and the significant lack of knowledge and information that is highlighted therein. In response, the Commission will review all relevant legislation over a two year period in order to assess how nanomaterials are regulated. Commissioner Dimas stressed that these issues must be addressed in accordance with the precautionary principle and the highest level of protection for citizens and the environment ensured.

**Rob Visser**, OECD, highlighted the opportunities of nanomaterials and the current lack, from a regulator's perspective, of knowledge about potential health and environmental risks. He outlined the history of nanomaterials and various products in which they are used, and stated that the projections of the value of the nano-markets move into billions of US dollars. He noted that nanotechnology is expected to create two million jobs by 2015 and is set to impact on many industries.

With regard to current knowledge about potential health and environmental risks from nanomaterials, Mr Visser considered the suitability of existing testing methods for nanomaterials and whether the comparability of testing can be confirmed.

He noted that use of OECD test guidelines on physicochemical properties, effects on the biotic systems, etc., together with OECD principles such as good laboratory practice were aimed at ensuring the mutual recognition of results.

The OECD Working Group on Nanomaterials had reviewed the OECD test guidelines and had concluded that most, but not all, of the OECD test guidelines are appropriate for nanomaterials. However, new test guidelines specifically tailored for nanomaterials are needed in two areas:

- Sample preparation and dosimetry (top priority); and
- The need to compare instillation versus inhalation studies

He noted that the WPMN was working on both of these issues. Additionally, a sponsorship programme is currently being implemented in relation to the testing of nanomaterials, which will happen in two stages: (i) the creation of a list of nanomaterials and a list of endpoints for which they should be tested and (ii) the development of a sponsorship programme for testing of nanomaterials. Mr Visser went on to describe the next steps of the WPMN projects.

He concluded by noting that this is a global challenge but that there is time to address it in an inclusive way. He pointed out that UNITAR, OECD and IOMC are engaged in addressing the challenges in developing countries and that nanomaterials are included within discussions under SAICM.

### **Key points of Discussion:**

- There is time between now and the exponential growth that is predicted to address the global challenges presented by nanomaterials. Much research is currently being conducted in relation to safety aspects.
- The development of knowledge and testing protocols on the one hand and of going to regulation on the other will happen in parallel, rather than one after the other.
- Approximately 5%-10% of R&D is dedicated to health and safety. This percentage should be higher.

### **Session 2: Which information do we have?**

**Philippe Martin**, European Commission, chaired the session. He stressed the importance of learning in order to progress and highlighted various questions with respect to information on nanomaterials (what we have; from whom; the quality of the information; who can access it, etc). He stressed the need for balance between the risks and benefits of nanomaterials.

**Pete Floyd**, RPA, presented the findings of the project's Task 1 - to investigate nanomaterials currently on the market and how much information would be gathered under REACH. He described the methods used and conclusions drawn during the completion of the study. He then highlighted the lack of information and knowledge, in particular in relation to nanomaterials that are under development, those available on other markets, for example in Asia, and parent substances.

Referring to the REACH and CLP Regulations, Mr Floyd surmised that in most cases information on impacts of nanomaterials will be submitted during the REACH registration process in the dossiers for their parent substances. He stressed the need for the dossiers to consider all of the nanoforms for a parent substance that might be placed on the market and the ways in which they can reasonably be expected to be used. He then went on to address the specifics of registration requirements, which include chemical safety and hazard assessments for substances over certain tonnage thresholds.

The fact that nanomaterials are scarcely mentioned in REACH, CLP and ECHA guidance was considered a drawback. Inspection of the substances pre-registered with ECHA reveals only five specific entries for substances which are described specifically as nanomaterials and some nanomaterials on the market or under development are forms of substances not covered by REACH, for example polymers and biopolymers. Some may not be registered at all because the bulk substance will fall under the one tonne threshold. Additionally, some nanomaterials used in certain applications are covered by other legislation (*e.g.* biocides, food packaging and cosmetics).

**Lena Perenius**, CEFIC, reiterated the need for a balance between risks and benefits and considered that this challenge could be beaten. She noted that some materials have been on the market a long time and stated that there is knowledge and experience available for companies to take risk management measures in a responsible way.

She drew attention to the findings of a CEFIC survey which correspond with OECD's findings. The survey confirms that there is a limited number of parent substances as being the main ones on the market. She agreed with the RPA finding that only a few will fall below the tonnage threshold for reporting under REACH and that nearly all of them are pre-registered for the 2010 REACH deadline.

Furthermore, she pointed out that groups of substances like polymers that are not subject to REACH registration are covered by other REACH provisions. Finally; she highlighted a discrepancy between the conclusions of two of the project reports. The Task 1 report had concluded that nanomaterials can be adequately covered by REACH, while the Task 2 report had reached a different conclusion.

**Chiara Giovannini**, ANEC, introduced an ANEC/BEUC inventory of products containing nanomaterials that consumers can readily purchase. She noted that consumers are uncertain about the risks and benefits of nanomaterials and about which products contain them. ANEC considered there was not enough reliable information on which policy makers can base decisions. A clear definition for nanomaterials was required for a solid regulatory basis and an extensive publicly available inventory of nanomaterials will provide a strong basis for a reporting scheme. More progress in relation to testing methodologies would be useful as increasing scientific evidence demonstrates that nano-sized materials can be dangerous for human health and the environment. Unfortunately, traditional risk assessment methodologies are not adequate for taking account of all characteristics of nanomaterials. ANEC also calls for the establishment of a mandatory reporting scheme. Regulating nanotechnologies is a question of how to regulate uncertainties (definitions, properties, safety assessment methodologies, risks exposure, etc) and when to regulate.

**Philippe Martin** noted areas of common ground in relation to the duty of care, information requirements, limited numbers of parent products and concerns about progress in developing an internationally agreed definition and the additional testing protocols needed for gathering reliable information on hazards posed by nanomaterials.

#### **Key points of Discussion:**

- In relation to the CEFIC survey, and the risk management measures being taken, reference was made to an OSHA report in relation to issues of worker safety and emerging technologies. Worker safety guidelines for dealing with powders were described as already being in place.
- The ECHA will shortly receive its first registrations and then it will be possible to see whether industry will in fact report adequate information on nanomaterials, *e.g.*, whether the registration dossier for graphite will include all of the information needed for the various forms of carbon nanotubes.
- A commonly agreed definition must be science based and should be adaptable. It should be broad to begin with and then narrowed based on experience.
- A two-tier definition was suggested: the first level would consider size, and the second level whether the functionality of the nanomaterial differed from that of the parent substance.
- The question of threshold was also considered important; instead of the tonnage threshold used for bulk substances, a more relevant threshold might consider a combination of the particle size and the specific surface area. It was pointed out that the threshold problem is relevant mostly for those materials available only in nano form.

### Session 3: Is REACH sufficient?

**Wolf-Michael Catenhusen**, head of Germany's NanoKommission, chaired the session.

**Martin Fuehr**, University of Darmstadt and member of the ECHA Management Board, addressed the questions of whether REACH provides the necessary answers and what is and what is not covered by REACH. He noted that regulation of nanomaterials must take into account their extreme surface energy and the potential for new effects on human health and the environment. Under REACH, the burden is on industry to ensure that these are not adversely affected. He considered REACH in its current form as not adequate for gathering the information needed to assess the potential risks from nanomaterials and he put forward a number of recommendations:

- Nanoforms should be handled separately from the bulk substance, and in some cases different nano-forms of the same bulk substance should also be handled separately.
- Phase-in substances should only include those nanomaterials already listed as in EINECS.
- There should be a return to the 10kg threshold of the old Dangerous Substances Directive.
- Nano-specific information requirements should be introduced.
- Industry should be obliged to undertake nano-specific testing and nano-specific approaches to self-responsibility.
- A nanomaterials chapter should be added to REACH.

**Carl Schlyter**, Member of the European Parliament, noted that the usefulness of nanomaterials lies in the changes in their characteristics and functionalities in comparison to their parent substances. He considered REACH as insufficient for gathering information on these new characteristics. He pointed out that if the hazards are not known, neither are the risks. He observed that some 480 of the first 600 dossiers submitted to ECHA had been returned because the data was considered inadequate, and there had been no specific requests for nano-related information.

Because of the "not knows", he stressed the need for an adaptable system of governance and called for a science, rather than market, based approach, as well as the creation of a compulsory register and a labelling system for consumers. He agreed that a definition of nanomaterials should be initially broad and subsequently narrowed and should address properties and not just size. He recommended notification requirements for all nanomaterials placed on the market whether on their own, in preparations or in articles, irrespective of tonnage and concentration thresholds. He also called for chemical safety reports with exposure assessments for all registered nanomaterials, irrespective of hazard identification.

**Steffi Friedrichs**, Nanotechnologies Industries Association (NIA), considered REACH as fully adequate to cover nanomaterials. They are to be registered along with the bulk form of the substance, if produced in amounts of one tonne or more per year. She observed that CASG Nano had arrived at a similar conclusion. Moreover, additional data could be supplied without a specific registration for nanomaterials and the ECHA could ask for further information at any time. She noted that any registrant can generate additional data should they deem it necessary. She considered the voluntary reporting systems sufficient at this point and said that industry supported these:

### Key Points of Discussion:

- Tonnage threshold issues can arise where different entities import the bulk and the nanomaterial, since the one tonne threshold only applies to the legal entity, not necessarily the company as such. However, if there was a SEIF, it was the responsibility of all companies concerned to come together to provide information:
- Industry could support an EU-level reporting scheme, but a science based definition is needed before moving to a mandatory option.
- Competent authorities cannot give guidance on the nature of nanomaterials due to a lack of information. Due to this lack of information, the properties of nanomaterials cannot yet be properly assessed. REACH will thus not provide the answers.
- Annex 6 of REACH refers to 'all' available information, so if there is more information, industry is obliged to provide it.

Chair **Wolf-Michael Catenhusen** drew out the key point that not only a scientific definition was needed but also a legal definition in order to practice regulations, and noted that this issue needs to be solved quickly. The issue is not whether REACH is sufficient, but whether the information is sufficient for risk management.

## Session 4: Need for strengthening information reporting?

### Part 1 – Experiences to date with voluntary and mandatory reporting

The session was chaired by **Anthony Wilson**, European Chemicals Agency (ECHA).

**Kristan Markey**, US EPA, explained the current US regulatory approaches for existing chemicals with nanoscale forms and new nanoscale chemicals focusing specifically on carbon nanotubes. From publicly available data, USEPA estimated that currently more than 60 chemicals with nanoscale forms are likely to be used commercially in the United States beyond the 73 that have been reported as new chemicals to USEPA, while another 200 are under R&D. USEPA estimates that over 3000 chemicals on the TSCA inventory could be produced with nanoscale forms. He described the US experience with its voluntary Nanoscale Materials Stewardship Programme (NMSP), which had two components: the Basic Programme and the In-Depth Programme. He explained that USEPA estimates 90% of nanomaterials have not been reported, that there is uncertainty as to whether companies that have submitted have provided information on all the nanomaterials that they produce and that companies are not inclined to voluntarily test their nanomaterials. Mr Markey concluded by noting that the ongoing programmes at US EPA had greatly enhanced in-house expertise, and this experience contributed significantly to improving the regulatory approaches on nanomaterials currently under development. A productive policy discussion on broad nanomaterial regulations without this direct experience might be challenging. USEPA's voluntary programme was not sufficient to fill in data gaps, and the Agency was therefore planning to move forward with a mandatory reporting regulations.

**Steve Morgan**, DEFRA, explained that the UK is developing its first nanotechnology strategy. He described the UK's voluntary reporting scheme for manufactured nanomaterials, which was the first of such schemes, and noted the lack of focus of the scheme in light of its numerous objectives. Factors affecting participation included resource implications, uncertainty as to application of the scheme and the lack of incentive to participate. Despite the deficiency in participation, the scheme was not considered to have failed *per se* and has provided useful research data. He called for a more international approach.

**Catherine Mir**, Ministère de l'Ecologie, noted that the French government was seeking more information on nanomaterials and of the products containing them. Many stakeholders were consulted during an Environment Roundtable in 2007, and the working group on environment made a commitment with respect to nanotechnologies to (i) ensure public debate, (ii) establish compulsory reporting, (iii) consider the cost/ benefit balance and (iv) ensure the protection of workers. These commitments were to be implemented through two separate laws, one of which is still in the Parliamentary process. The reporting scheme will include the identity of the nanomaterial, the quantity that is put on the market and the uses of this nanomaterial. She reiterated that a definition is urgently needed; that the OECD has provided a working definition and that other definitions have been adopted in other specific regulations. A definition will soon be adopted in France and, given that the French initiative is not unique, there needs to be a move to harmonisation. She concluded by stating that the application of REACH, alone does not sufficiently address many issues relating to nanomaterials. Compulsory reporting would anticipate, complement and help better application of REACH.

#### **Key Points of Discussion:**

- The French scheme will include only substances and not articles.
- Predictions as to the number of submissions required to make the French scheme work were deemed irrelevant. Only through compulsory reporting could the number of producers and importers be established.

Regarding timelines for a move to a mandatory system:

- The US expects to establish a mandatory system in 2010/2011, with an inventory update to follow every four years.
- No decision has yet been made in the UK regarding a move to a mandatory system.
- The legislative process in France is underway and should be completed by 2010.

#### **Part 2 – Do we need an additional reporting scheme and what might it look like?**

**Catherine Ganzleben**, Milieu, described the building blocks of a EU reporting scheme and what information is needed, taking into account the willingness of participants. This included what is on the market, the intrinsic properties and hazards of various substances, how the products are used and risk management measures. She explained who could provide the information and how it could be used, and concluded by addressing the various drawbacks of a reporting scheme, both for industry and for regulators.

In response, **Andreas Herrman**, Ökoinstitut, representing the German Ministry of the Environment, recommended that a product register (i) requires a working definition; (ii) should cover products ('end' and 'intermediate') as well as substances; (iii) should also cover distributors; and (iv) should be managed by a national authority. End-of-life issues should be taken into consideration, as should the freedom of movement of goods at the European level.

**Wouter Ghyoot**, Umicore, on behalf of Eurometaux, expressed uncertainty as to whether an additional reporting system is necessary. He considered REACH and the OECD programmes would yield a lot of information on a series of nanomaterials. He acknowledged that there are gaps in REACH, *e.g.*, the tonnage threshold, but one should wait for REACH to deliver registration files and then evaluate. Also he observed that the OECD programmes still needed to be concluded and this would take time. The advantage of a voluntary system was that it allowed businesses to show leadership, but there was a need for other stakeholders to be

involved as well. He noted that a mandatory system would require an internationally agreed definition.

**David Azoulay**, CIEL, noted that in relation to information gathering, the need for ecotoxicological data and for basic market data had been confused. In fact, the two types of data are very different and used for very different purposes. He stated that ecotoxicological uncertainty will remain for years to come and that accordingly, the priority is to address the issue of how authorities govern in the face of uncertainty. The first step in this direction is to collect all market data to document all possible exposure pathways and enable proactive risk management measures. This can only be done through a nano specific, basic but compulsory reporting scheme. He reiterated the idea of a wider initial definition that would be narrowed as new knowledge was accumulated.

**Steffen Foss Hansen**, DTU, noted that the window for voluntary reporting is closing and that, in any event, it has failed everywhere. A mandatory system is needed and it should require the reporting of all information needed for a full risk assessment. New threshold values need to be established and a broad catchall definition should be formulated to begin with. He noted that risk assessment does not work for nanomaterials because the technical guidance documents are inadequate. In his view, industry could help in this respect by communicating the problems that they face. He called for the creation of a new independent regulatory entity – a NanoCA – and for the sharing of costs between industry and governments for producing the information needed for risk management. Finally; he recommended that the relevant information should be publicly available so that academics and others can validate it.

#### **Key points of Discussion:**

- In the absence of ecotoxicological data, market data can provide enough information on exposure and exposure pathways to enable initial risk management measures. Voluntary systems were not a complete failure because even the most basic market data acquired is of use.
- The costs of compliance with a mandatory regime should not be prohibitive so as to ensure participation even for SMEs.
- The fact that industry has expressed the will to co-operate with a voluntary regime but is not in favour of a mandatory regime is confusing to other stakeholders. Experience shows that if industry is not obliged to submit information, it is unlikely to do so.
- The ISO will agree a definition in a couple of months. The burden should then be on industry to conduct risk assessments if their nanoforms are different.
- The necessity for additional reporting will become clearer following the submission of the first REACH registration dossiers end of November 2009.
- The problems experienced in using technical guidance documents should be reported in the dossiers.

### **Part 3 – Should future additional EU reporting be voluntary or mandatory?**

**Gretta Goldenman**, Milieu, considered the legal options for a reporting scheme, the first option being the amendment of REACH and the second, the establishment of an additional reporting scheme. She went on to explain how a voluntary system could work and the advantages and drawbacks of self-regulation. She then examined the options, drawbacks and advantages of an additional mandatory reporting scheme. Ms Goldenman noted that experience with voluntary agreements to date is disappointing, for example, the agreements with the car industry on CO<sub>2</sub> emissions resulted in a binding instrument that took eleven years to put into place.

**Gerhard Schmid**, Munich Re, noted, in relation to a mandatory regime, that if there is no pressure, registration is unlikely. With regard to a voluntary regime, the issues are the 'awareness' and 'sensitisation' of companies that are expected to deliver. He moved on to discuss how the reinsurance industry manages the risks from nanomaterials. A recommendation was made for an EU driven insurance nano pool solution (INPS), which would help to address problems in information gathering by restricting participation to only those companies willing to supply the data needed for risk assessment.

#### **Key points of Discussion:**

- Perhaps it is too early to decide if the regime should be voluntary or mandatory. By the end of 2010, 90% of nanomaterials will be registered and on this basis, the decision can be made as to whether new additional information is required.
- It was observed that CLP addresses the key concerns that have been aired (no threshold and operational within one and a half years), and thus the value of additional reporting would be limited.
- However, it was also pointed out that CLP works only if it is known what hazards to look for. The tests are not tailored to nanomaterials and, moreover, classification will not provide relevant information on nanomaterials in articles.
- Resources need to be channelled effectively. As voluntary schemes have failed in several countries, it was important to consider how best to use available resources.
- The European Parliament's call for an inventory of products and safety information and the implementation of a 'no data, no market' approach by 2011 would seem to indicate a need for a mandatory system now.

#### **Session 5: Closure and next steps**

**David Gee** provided the report of the meeting.

He began by reiterating the point that by sharing information we learn from it, which allows us to move forward; a point made by Philippe Martin, European Commission, earlier in the day. Reference was made to what can be called the '*Danish dilemma*'; "to know and not to know, to act and not to act", a quote from the front of the 2001 EEA report "Late Lessons from Early Warnings: the Precautionary Principle 1896-2000".

Mr Gee summarised his response to the discussions and to some of the main issues raised during the conference via nine key points which he thought might be useful. He pointed out that he was not someone familiar with nano issues in particular but he had looked intensively at how societies had handled similar issues in the past.

1. He stressed the need to learn from the lessons of the asbestos experience. Asbestos, previously regarded as a magic substance, is now regarded as a 'malevolent mineral'. The first early warning about the dangers of asbestos fibres came in 1898. In 1934 the Chief Medical Inspector of Factories in the UK said that looking back, the opportunity to save a lot of harm to human health was missed. This point of view had been repeated many times both before and since the eventual EU ban on asbestos in 1999.

2. The CLP and REACH regulations are not designed for nanomaterials. Amending REACH to bring in nano-specific criteria would open the door to much other tinkering with REACH. As nanotechnology is so new and has particular characteristics, it might be better not to adapt

existing systems, but to develop new and targeted systems for information retrieval that are specifically designed for nanomaterials.

3. Good consumer labelling is useful. Labelling often provides safe-use guidelines and provides consumers with the information necessary to make informed choices.

4. With regard to information gathering, two goals seemed to be confused (*i.e.* the need for reliable ecotoxicological data, on the one hand, and market data, on the other). Data about what is currently on the market and related use and exposure data are urgently needed.

5. Experience has shown that voluntary systems for collecting information and risk management do not work. Companies have little incentive to comply with them and they are not taken seriously by the targeted community. A mandatory system would therefore provide a better option. Progressive companies have long seen the benefits of the level playing field that such a system provides. A mandatory system would also impede free-riders.

6. Our scientific knowledge of nanomaterials is very limited and there are many questions that still need to be answered. As was the case in the WTO US-EU Beef Hormones case, much more information is required in order to conduct robust risk assessments.

7. An inadequate proportion of resources are devoted to health, safety and environment (HSE) research with respect to nanomaterials. Only 5-10% of current research goes into HSE implications, according to the OECD estimate heard earlier in the meeting, whereas approximately 90% of research is devoted to commercial applications. The pertinent question here is what the correct proportion should be? More money needs to be put into HSE research in order to secure confidence in the field. Dividing research 50/50, between commercial applications and HSE implications, would seem to be an acceptable option that is probably broadly in line with new pharmaceutical or pesticide product research. This would make commercial sense at this point in nanotechnology history as it would better guarantee long term markets.

8. By analogy to asbestos and beryllium, there are lessons that can be learnt in terms of causation that seem to be relevant to nano:

- Weight versus fibre characteristics for determining exposure – these were interpreted incorrectly in relation to asbestos for over 50 years. It is the fibre characteristics (dimension; bio-physical properties) that are relevant and not the weight.
- Air versus skin exposure – for over 30 years it was thought that the inhalation of beryllium was the most relevant means of entry into the body. It was then realised that skin is the dominant conduit.
- Most harm will come not from manufacturing exposures but from use (bystander and downstream) and from disposal.

9. Finally, we need to establish systems of governance of innovation and not just of risk, as was pointed out in the report from the UK Royal Commission on Environmental Pollution. This needs to happen concurrently with the gathering of information, which has been the focus of today. Both the DG Research report on Risk and Governance and that from the National Academy of Sciences in the US on Risk and Science are relevant.

**Ethel Forsberg**, KEMI, provided positive feedback on the conference and the participatory process and made closing statements:

- A definition is needed, test guidelines developed, and information collected from the market in order to move forward. If the process does not move fast enough we will end up with several definitions.
- There are different perspectives on how fully REACH addresses nano applications; however the tendency is to consider the requirements as currently inadequate.
- The Commission needs to take a strong leadership role and to initiate the process of the adjustment of REACH.
- Voluntary initiatives have been discussed and are often a way to prepare a future action. In this case, however; a voluntary initiative does not appear to be an alternative.

**Gustaaf Borchardt**, DG Environment, stated that the path forward should include a thorough assessment of what we know, the creation of a common and pragmatic definition and an in-depth review of REACH. The lack of knowledge has potentially negative consequences in relation to human health and the environment. Additionally, if the expectations of consumers are not met, nanotechnology could be stigmatised. He underlined that at this stage the Commission has no plans to introduce an additional reporting system. He noted that it must be ensured that actions at national level fit within the internal market and measures to generate additional information would benefit from being undertaken in a coordinated manner.

CLOSE OF CONFERENCE



## Annex I: Conference Agenda

### Nanomaterials on the market: What regulators need to know

Brussels, 9<sup>th</sup> October 2009

Residence Palace, Rue de la Loi 155, 1040 Brussels, Belgium

08:30 – 09:00 Registration

Rapporteur: David Gee, European Environment Agency (EEA)

#### Session 1: Introduction to the issues

Chair: Agneta Falk-Filipsson, Swedish Chemicals Agency (KEMI)

09:05 Opening remarks: Ethel Forsberg, Director-General KEMI, for the Swedish Presidency

09:15 Keynote Address: Commissioner Stavros Dimas

09:30 Opportunities of nanomaterials and current state of knowledge about potential health & environmental risks from nanomaterials - what regulators need to know: Rob Visser, Organisation for Economic Co-operation and Development (OECD)

10:00 Discussion

#### Session 2: Which information do we have?

Chair: Philippe Martin, DG Health and Consumers, European Commission

10:20 Introduction to the project and its findings, *i.e.*, what we know and do not know about what is on the market today: Pete Floyd, Risk & Policy Analysts Ltd. (RPA)

10:35 Responses

- Lena Perenius, European Chemical Industry Council (CEFIC)
- Chiara Giovannini, European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC)

10:45 Discussion

11:15 Coffee break

### Session 3: Is REACH sufficient?

- Chair: Wolf-Michael Catenhusen, Head NanoKommission, Germany
- 11:40 Does REACH provide the necessary answers? What is and is not covered by REACH: Martin Führ, University of Applied Sciences, Darmstadt
- 11:55 Responses
- Carl Schlyter, Member of the European Parliament
  - Steffi Friedrichs, Nanotechnologies Industries Association (NIA)
- 12:15 Discussion
- 12:45 Lunch break

### Session 4: Need for strengthening information reporting?

- Chair: Anthony Wilson, European Chemicals Agency (ECHA)
- 13:45 Panel on experiences to date with voluntary & mandatory reporting
- The US experience: Kristan Markey, US Environmental Protection Agency (US EPA)
  - The UK experience: Steve Morgan, UK Department for Environment, Food and Rural Affairs (DEFRA)
  - The French Approach: Catherine Mir, Ministère de l'Ecologie
- 14:15 Discussion
- 14:45 Do we need an additional reporting scheme and what might it look like? Catherine Ganzleben, Milieu Ltd.
- 14:55 Responses
- Andreas Hermann, Ökoinstitut for the German Ministry of the Environment
  - Wouter Ghyoot, Umicore, on behalf of Eurometaux
  - David Azoulay, Centre for International Environmental Law (CIEL)
  - Steffen Foss Hansen, Danish Technical University (DTU)
- 15:15 Discussion
- 15:45 Coffee break
- 16:00 Should any possible future additional EU information reporting be voluntary or mandatory? If voluntary, how could participation be encouraged?
- Introduction by Greta Goldenman, Milieu Ltd.
  - Comments by Gerhard Schmid, Munich Re
- 16:20 Discussion

**Session 5: Closure and next steps**

16:45 Report back from David Gee, Rapporteur

17:00 Closing statements:

- Ethel Forsberg, KEMI, for the Swedish Presidency
- Gustaaf Borchart, DG Environment, European Commission

17:30 Close of conference



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