

Opening Remarks by Rob Visser, Deputy Director for Environment, OECD

I am very honoured to speak at this opening session of the “Dialogue on the Evaluation of Synthetic Nanoparticles in Work and Environmental Areas.” I am also very pleased that Germany has taken the initiative to open up this Dialogue to other countries through OECD’s Chemicals Committee.

The rapid progress made with nanotechnology and the rapidly increasing use of manufactured nanomaterials, as we call these products in the OECD context, are indeed very important developments in the science of chemistry. These developments present a number of opportunities and a number of challenges. Any new technology has in principle a lot of promises for improving the quality of life, for introducing efficiencies in production processes of all kinds of products and for enhancing economic growth.

One of the challenges is that safety aspects would have to be dealt with in a satisfactory way in order to ensure that this new technology is accepted by the public. This means that it should be unambiguously assessed if the technology can be applied on a large scale in a way which, also in the long term, does not harm the environment and the health of workers and the general population. In this respect I would like to point to what happened with the introduction of biotechnology and the acceptance of genetically modified crops. Without taking a position in this still ongoing debate about the risks and benefits of biotechnology, I think that the reason that discussions on this are still ongoing, mainly is the result of the fact that an early and satisfactory public discussion about the possible risks associated with genetically modified organisms, took place only relatively late in the process of development of this technology.

I hope that for nanotechnology we can avoid this situation and that introduction of the technology will be accompanied by an adequate process for consideration of the safety issues. If the outcome of such a process is taken into account in management actions, if these are necessary, it can inspire confidence with a very large majority of the population that a wide and safe use of this technology is possible. This Dialogue is therefore very timely and I am sure that the outcomes of the discussions which will be held here today and tomorrow, will make an important contribution to such a process.

When talking about the risks and benefits of nanotechnology, I would like to focus on manufactured nanomaterials, rather than on nanotechnology as a whole. Using the experience of OECD with developing instruments and tools related to chemical safety, we have taken the lead to start an international discussion on the safety aspects of manufactured nanomaterials.

OECD is indeed a very good forum to assist in setting up such an international discussion and in co-ordinating follow-up of necessary international actions. As you may know, OECD represents the 30 most industrialised countries in Europe, North America and the Asia-Pacific region. We have, in the area of chemical safety, a quite advanced system in place to help countries with implementing national, regional and international regulations. The OECD work aims to deliver good quality tools for the protection of human health and the environment, while at the same time ensuring that such protection can be delivered in the most efficient way possible. We can achieve this through harmonisation activities and assisting countries in finding ways to share work. Such work sharing is of course again facilitated if the methods used by countries are similar.

The regulatory chain includes as main elements testing, assessment and management. OECD has made a variety of tools available to address these elements. These tools cover the field of testing

in the form of the OECD Guidelines for Testing of Chemicals and Good Laboratory Practice. A Mutual Acceptance of Data is then achieved through a legally binding arrangement among countries. This arrangement involves that one test done by industry in an OECD member country (and now also in some non-members) will be accepted by all OECD governments, if these two OECD tools have been used. This saves industry as much as €60 million per year by avoiding duplicative testing. In the field of risk assessment we have developed a lot of guidance material. This guidance brings together the collective experience of the best experts from across OECD governments, industry, trade unions and civil society NGOs, and helps to let assessment methods across OECD converge. With respect to risk management we bring countries together to exchange experiences, compare best practices and improve mutual understanding.

The work of OECD therefore helps to improve efficiencies, to avoid non tariff barriers to trade, to avoid delays in marketing and to promote the creation of a level playing field. The OECD work represents a win/win/win situation for governments, industry and civil society. It is an efficient and effective way to ensure the best scientific input from across OECD to contribute to the development of common instruments. Governments are sure to get good quality, harmonised test data and a better understanding of each other's testing and assessment methods so that they can easily share work. Industry makes savings by avoiding duplicative testing and it benefits from the minimisation of non tariff trade barriers. Civil society has a clear interest in good quality safety data and in a transparent process for development of methods and guidance.

In summary, when looking at the regulatory chain of testing, assessment and management, it is clear that international co-operation in OECD has great benefits. However, the level of international harmonisation is different for each of the elements of the regulatory chain. In the field of testing, legally binding arrangements have been agreed. With respect to the interpretation of the testing, some national or regional specifics come into play, but guidance can be developed

to avoid that conclusions made in the various countries with respect to the test data and the exposure information, diverge too much. Risk management is an area which countries consider to be a national prerogative and international risk management systems are therefore difficult to harmonise. Of course every country is interested in learning about each other's experiences and establishing best practices.

OECD has started the consideration of the safety of manufactured nanomaterials at a Special Session of our Chemicals Committee in June this year. A number of high level experts from across OECD informed the meeting about various aspects related to the use and safety of nanomaterials. The Committee agreed that there are a number of areas where further work might be needed. They considered that an open information exchange on a number of issues should be initiated before decisions on further steps can be made. This will be done at a workshop which is being organised on 7-9 December this year in the US in Washington DC. The recommendations coming out of this workshop will be reported back to the Chemicals Committee in February 2006, and then a decision will be made about what could usefully be done in the future in OECD concerning the safety aspects of manufactured nanomaterials. The issues that will be discussed at the Washington Workshop fall into four categories:

-First, there are Definition questions - For example how can nanomaterials be characterised in ways that can best address regulatory needs? Whatever is undertaken in organisations like IUPAC and ISO will of course be considered.

-Second, the Hazard identification - For example what are the potential environmental and health hazards? What are the hazard end points that should be looked at? Are new test methods needed? How can nanomaterials be measured in the environment?

-Third, the Hazard and Exposure assessment - For example, what is the persistence of nanomaterials? Can potential exposure routes be adequately characterised? Which assumptions with respect to hazard and exposure should be made in the absence of adequate information?

-Fourth, the Regulatory Framework - For example, are nanomaterials 'new or 'existing' chemicals? To what extent can regulatory frameworks deal with nanomaterials? Are these frameworks able to cover the wide and expanding array of actual and potential uses? How can we measure the effectiveness of possible management measures and controls?

Of course open communication with and the involvement of all stakeholders in addressing these issues at the Workshop is of utmost importance. In order to prepare for the Workshop we have sent out a survey to the OECD countries, asking them to identify which activities they have ongoing with respect to addressing the potential implications of manufactured nanomaterials for human health and environmental safety. We hope that the responses will give us valuable overview material to allow the Workshop to assess the state of the art in OECD countries. The countries will also be asked if, and if so which, role they see for the OECD Chemicals Programme in addressing the issues in this field. From the responses received so far, all see indeed issues which could well be dealt with in OECD.

With this workshop OECD has set a further step in addressing the safety aspects of nanotechnology and starting a meaningful international discussion on risk assessment. We want to base such a discussion on good quality data and on sound science, and engage in a process which is open, transparent and inclusive. Based on solid testing and assessment methodologies and learning from each other's experiences, I am sure that all stakeholders will be able to find, possibly co-operating within the OECD framework, a good way to address the risk assessment and management aspects of nanomaterials. Public confidence in the handling of the safety of nanomaterials can then be built and this will only support its further development.

As I mentioned, OECD has indeed a wide experience in finding common ground at the international level in testing and assessment methods. For risk management I would suggest that it would be most effective to leave this to countries, or to the EU in case of Europe, to see how the current regulatory frameworks for managing the safety of chemicals can deal with nanomaterials. In all OECD countries chemicals management systems exist and countries are best placed to determine how these systems can deal with nanomaterials in a way which is most adapted to national needs and how they can be amended most appropriately if needed. Looking for a “one size fits all” international solution to the management issue might be very time consuming, and it might not be the most efficient and effective way forward. If the management systems are based on common testing and assessment methodologies, the various management decisions in countries will most probably not differ too much.

I hope that I have provided some useful starting points from the international perspective for the discussion at this Dialogue. I would congratulate all who are involved with the organisation of this Dialogue, with having had the idea to hold it now. Looking at the programme for today and tomorrow, I am sure that the outcomes of the discussions here will be very helpful in the process of realising the opportunities which the use of manufactured nanomaterials foreshadows, while at the same time the challenges it could potentially pose for human health and environmental safety are being addressed at an early stage. And I am also certain that the outcomes will be important input into the upcoming OECD workshop.

I wish us all a very productive dialogue.