

NanoTrust-Conference on “Nanotechnologies – The Present State of Regulation”, Vienna, Sept. 29th, 2008

Rapporteur’s Summary

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For the second consecutive year, the Institute for Technology Assessment at the Austrian Academy of Sciences arranged an international workshop on governance of nanotechnologies. The workshop, “Nanotechnologies – the Present State of Regulation”, took place on September 29 and attracted more than 60 participants. A dozen speakers from various countries were recruited from both foreign and domestic research institutes, authorities, ministries, and international interest organisations. The scope of the workshop was based on the EU legislation within relevant sectors where nanotechnologies and nanomaterials are present. This includes occupational safety, food and feed, consumer products and chemicals. The presentations and discussions related to the over-riding question if current legislation is relevant and sufficient, or if there are additional aspects that need to be taken into account.

Background

In general, the European legislation demands that manufacturers and importers ensure that products that are introduced on the market fulfil safety requirements. When technological development results in creation and introduction of new products, these also have to be assessed so that negative consequences for human health, societal injustice or environmental risks are not introduced. This also applies to nanotechnologies and their products. Thus, the use of nanotechnologies and resulting products must comply with the EU public health, safety and environmental protection measures.

There is a current framework for introduction and implementation of new regulations and legislations. Prior to regulation, appropriate risk assessment has to be performed and risk management tools need to be identified. Regulations should be technology neutral. Furthermore, product introduction has to adhere to the “no data, no market” principle, and also requesting manufacturers and importers to continuously update technical files on technologies and products.

Chemicals regulation of nano-sized substances is covered by REACH, which step by step is replacing a number of directives and regulations. Worker protection is mainly covered by the specific Framework Directive 89/391/EEC. Many groups of products are covered by specific Community legislation, e.g. regarding cosmetics, pharmaceuticals, medical devices, cars etc. Food legislation is found within the General Food Law (Regulation 178/2002), but also more specifically in other regulations covering e.g. novel foods, food contact materials, additives and supplements. This is all relevant for nanomaterials.

A relevant, reliable legislation has to be supported by appropriate research activities. In the case of nanomaterials, there are recognized needs for improvements of measurement methods, increased knowledge regarding reference materials and materials characterisation, as well as development of and validation of test methods for nanomaterial, and their effects on human health, safety, and the environment. In addition, exposure assessment needs to be improved, as well as life cycle analyses of various nanotechnology products.

Workshop presentations

The workshop was divided into a number of sessions on various topics. These included political and societal aspects of regulation; occupational health; food safety; chemicals regulation; perspectives of interest organisations.

Torsten Fleischer from ITAS, Karlsruhe gave an extensive overview of political and societal aspects that are influencing regulation of nanotechnologies. He pointed out that regulatory efforts are influenced by perceptions such as that there are unknown properties of nanoscale materials and their impact on humans and environmental; that nanotechnologies are representative of “risk” technologies in general, and that new nanotechnologies could introduce risk; and that implications of technologies enabled by nanotechnologies has to be considered.

Regarding regulation, he referred also to that there are distinctly different positions in the debate. One position is the “restrictive” one, which stresses that benefits are not permitted to be overshadowed by risks. The “permissive” point of view points to that there are still knowledge gaps, and that regulations will be negative for innovation. Between these two extremes, he found the adaptive position, which proposes that regulatory frameworks make as flexible implementations as possible. Fleischer also stressed that so-called Codes of Conduct may

sometimes precede regulations. They can have various degrees of involvement from external actors and they thus allow for various degrees of stringency.

He concluded that regulators indeed face a number of complex problems, including the multitude of knowledge gaps; that regulation has to consider risks and benefits simultaneously; that legislators must consider self-regulation and “soft law”, and that precautionary approaches should not inhibit innovation.

Michael Nentwich from the organizer ITA, Vienna, discussed that risk governance and technology assessment are foundations for regulatory issues. He went on to shortly describe how the processes can identify technology-induced risks at an early stage and also that these activities may present options of measures for decision makers that can be relevant for subsequent actions.

Aspects regarding occupational health were presented by **Michael Riediker** from IST, Lausanne. His overview started with an overview of characteristics of risk assessment and also classical toxicology and its use of the important dose-response concept. In this context, he also asked two very relevant questions; viz. how one is proceeding from knowledge about exposure to dose? And, what constitutes dose in the case of nanoparticles? This latter question is extremely important, and so far unsatisfactorily answered by toxicologists that are working with nanomaterials. Riediker was referring to a many examples from their own research on occupational aspects of nanotechnology. Thus, he showed a scheme for uptake routes for nanoparticles into the body. In principle, these compounds can enter via inhalation, the gastrointestinal tract, and the skin. For the occupational setting, the most important pathway for powders and aerosols is via the lung. Regarding the mechanisms of nanoparticle hazards, one has to distinguish between toxicological hazards and physico-chemical hazards. An important knowledge gap regarding occupational hazards can be filled by prospective cohort studies of exposed workers. However, such studies are currently problematic to perform due to other knowledge gaps such as in exposure assessment and end-point choice and analyses.

On the national level, the presentation by **Robert Piringer** from AUVA, Vienna indicated one of the problems facing many authorities, namely the lack of relevant exposure limits and guidelines for particles in the nanometer size range. To some extent, extrapolations from limit values regarding larger particles are used, which may or may not be accurate.

The situation regarding food and feed regulations was presented by **Frans Kempers**, Wageningen UR. He stressed that regulatory issues have to overcome many different kinds of problems. Among these, definitions are presently to some extent unclear, and not uniformly accepted and agreed upon. Regarding food issues, it is also problematic to distinguish between what are natural and man-made nanostructures in food. The problem is made complex also by the technical limitations of how to detect and measure nanoparticles in food. Nanotechnologies are furthermore extremely complicated, and relevant dose-response dynamics and kinetics are less well understood. As mentioned also by others, Kempers pointed to lack in exposure assessment knowledge. Finally, regulators have to include environmental issues.

The Austrian Ministry of Health, Family and Youth has identified a number of regulatory gaps in the present EU legislation according to **Alexander Zilberszac**. He pointed to that nanoparticles may confer new properties compared to the same substance in other size ranges and that this is not sufficiently reflected in the current legislation. Other deficits are due to the lack of an international set of legal definitions. He also asked for mandatory labelling of nanoparticle presence, and argued that if nanotechnologies and/or nanoscience in any form were used in the food production, it would imply that that the particular food should be considered as novel food. The domestic stand was also that the precautionary principle should be invoked on research where nanotechnology is used for food formulations. For risk assessment purposes, he also mentioned that there are many knowledge gaps including nanoparticle characterisation, detection and measurement methods, dose-response kinetics, fate and persistence of nanoparticles both in organisms and in the environment, and understanding of toxicological mechanisms.

A very interesting presentation from **Peter Kearns**, OECD, Paris highlighted the activities within an OECD Working Party on Manufactured Nanomaterials. Membership countries in this WP have decided to analyze a number (14) of representative nanomaterials, and 61 different end-points for each material. The data-base that will appear due to this ambitious work has the potential to inform about the impact of manufactured nanomaterials on health and environmental safety. This work will furthermore provide with knowledge that can be used to extrapolate to other nanomaterials when finished. It is likely that several of the knowledge gaps that currently exist can be filled by this work.

Renate Paumann from the Austrian Ministry of Agriculture, Forestry, Environment and Water Management discussed the challenges that REACH is encountering regarding nanomaterials. First

of all, Paumann stressed that REACH covers also nanomaterials, whether they are substances, preparations/mixtures, or even articles. One of the difficulties is that not only the nanoform, but also the bulk form of a substance often exists, and the bulk form may be exempted from REACH. It is then necessary to complement the Chemical Safety Report (CSR) of the substance with specific nano-relevant information. Additional testing and information steps may be needed, and communication of risk management issues in the supply chain has to be developed.

The view points of the industry regarding regulation and legislation was presented by **Steffi Friedrichs** from Nanotechnology Industries Association, Brussels. Her presentation focused on a voluntary Code of Conduct, the Responsible NanoCode which is signed by over 100 industrial members. The Code is voluntary, based on seven principles, and applicable across various sectors. She also stressed that the industry does not see the Code as something which is replacing or superseding current or future regulations. Not surprisingly, she also stated that industry does not see any need for additional regulation regarding nanotechnologies besides what exists currently.

A different view was presented by **Jurek Vengels**, German chapter of Friends of the Earth. His message was that they see a need for regulation/legislation which is specifically aimed for nanomaterials. The regulation should include pre-market safety assessment and allow consumers to have the right to choose whether or not they want to buy products containing nanomaterials. He also opined that REACH is adequate for first generation nanomaterials, but needs adoptions to accommodate the present and coming product generations. He also suggested that particles with a size <300 nm (diameter) should be categorized as nanoparticles.

Conclusions

A common and appropriate language is necessary for processes that are leading to regulations. It was therefore striking that several of the speakers mentioned that definitions of terms and concepts regarding nanotechnologies and nanostructures are inconsequent and insufficient. For the purpose of any nano-specific regulation, it was also apparent that many speakers saw the imminent need to fill several knowledge gaps regarding properties of nanomaterials, as well as their possible effects on human health and the environment. Both these knowledge gaps and insufficiently developed detection methods and exposure assessments make it difficult today to point to specific nano-relevant changes or additions to regulations. We do not know either to what extent, and even if, nanomaterials differ fundamentally in physico-chemical and subsequent

biochemical-toxicological characteristics from substances in bulk-form. These insecurities are the most important ones to overcome before it is appropriate to state that nano-specific regulation is needed. It seems that certain aspects of present regulations regarding nanomaterials are based on extrapolations from the rules set for non-nanomaterials. Whether or not this is relevant remains to be seen.

The main question of the workshop was if current legislation is relevant and sufficient, or if there are additional aspects that need to be taken into account. Although many speakers identified many crucial knowledge gaps, it was somewhat contradictory stated by several presenters that they see a need for regulation besides the existing ones. The form and extent of these new regulations or amendments was however not specified.