

Contribution from the Danish EPA

- **Further dialogue between authorities / industry and other stakeholders**
- **Further research initiatives**
- **Future projects regarding information and possible administrative measures**

Please identify work completed, underway or planned in your country or organisation, which relates to activities in the chemicals regulatory area on health and environmental safety aspects of manufactured nanomaterials:

- 1. Any national regulatory developments on human health and environmental safety including recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance materials;**

At present there is no regulation specifically addressing nanomaterials in Denmark.

In Denmark, the Ministry of the Interior and Health has, in 2006, initiated a survey examining whether the existing regulation in the different sectors (environment-sector; chemical sector, food-sector, pharmaceutical-sector, occupational environment sector, and health sector) would also cover risk related issues in connection with handling and use of nanomaterials. The work is almost completed (expected to be published at the end of 2007). The regulation in the different sectors covers in general situations where nanomaterials are handled or used although there are no specific mentioning of nanomaterials as such. It is recognised, however, that in order to address aspects specifically related to nanomaterials there may be a need for adjustments in the regulation.

In general, there seems to be no need for a new and a broad trans-sector regulation on nanotechnology but rather to focus on identification on areas in the present regulations where updating or adaptations may be required in order to consider specific aspects of nanomaterials.

In summer 2006, the Danish Board of Technology published a report concerning environmental and health aspect of nanotechnology (http://www.tekno.dk/pdf/projekter/p06_nanoteknologi_rapport.pdf - summary in English). The authors behind the report concluded that the existing regulation has to be further developed to specifically address the potential risks from nanomaterials. In the present chemical regulation and in REACH the tonnage levels for data requirement have to be reassessed because of the low weight of nanomaterials. Furthermore industrial use of nanomaterials should be subjected to approval from the authorities and it is proposed that the authorities provide specific risk assessment guidance and that obligatory risk assessment should be required from industry in case of possible environmental or human exposure to nanomaterials.

The different proposals in this report are under discussion by the relevant authorities.

In March 2007, the Danish parliament has debated a regulatory proposal concerning the use of an enhanced precautionary principle in connection with regulation of nanotechnological products and processes. The bill was rejected most of all because the proposal only addressed some general and overall concern and could not identify or verify specific situations of concern in which the precautionary principle would apply.

The Danish EPA together with the Danish Working Environment Authority has initiated work in order to examine the possibility to include nanomaterials in the mandatory notifications to the Danish Product Register in which hazardous chemical products and their content is registered.

The Danish EPA has sent out a call for a project to examine, describe and possibility to develop a declaration guide or standards on chemical products and articles containing nanomaterials.

2. Developments related to voluntary or stewardship schemes;

At present there are no specific initiatives in relation to voluntary or stewardship schemes in DK.

3. Information on any risk assessment decisions;

No risk assessments on specific nanomaterials have been conducted in Denmark and no specific risk assessment decisions have been taken in relation to nanomaterials.

4. Information on any developments related to good practice documents;

In Denmark we are not yet at a stage to develop good practice documents as more specific knowledge concerning nanomaterials and situations for guidance-request are needed. However future project (se below item 5) may give further valuable input in order to further evaluate the need and the areas/ situations where guidance or good practice documents may be relevant.

The Nordic Council of Ministers has issued a project aimed at "Evaluation and control of occupational health risks from nanoparticles". The project report was finalized in November 2007; see <http://norden.org/pub/miljo/miljo/sk/TN2007581.pdf>

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;

There is no specific overall research programmes or strategies in this area, however several governmental research institutions and university institutes have now issued a series of projects addressing aspects concerning health and environmental risks in relation of nanomaterials. Especially the testing of nanomaterials both in existing and alternative ecotoxicological and toxicological test systems is in focus in these projects. In relation to the occupational environment an important and extensive contribution to this research is carried out by the National Research Centre of Working Environment (the former National Institute of Occupational Health) where a research group was established in 2005 with focus on health risks associated with fabrication and use of nanoparticles and nanoparticle products (see <http://www.arbejdsmiljoforskning.dk/Forskningsresultater/Nye%20teknologier.aspx>). Also research concerning human health and use of nanomaterials in food packing materials is in progress.

The Danish EPA continues its network for risk assessment and risk management of nanomaterials. The network includes authorities from different sectors and scientific institutions experienced in chemical testing and risk assessment. The network is meant to support national coordination and the Danish work in relation to risk assessment and risk management in EU and OECD.

Knowledge about use and exposure is as important as knowledge about the intrinsic properties of nanomaterials. In spring 2007 the Danish EPA finalized a project in which the presence of nanomaterials in consumer products in Denmark was identified. About 250 different articles and chemical products were identified which were claimed to contain nanomaterials. Nearly all products containing nanomaterials were imported and the majority of the products were only available via the internet. For most products, however, it was not possible to get documentation/ verification regarding the content and an identification of the nanomaterial. For those products/ articles where the nanomaterials could be verified it was well-known substances such as titanium dioxide, zinc oxide, silver, fullerenes, carbon nanotubes. (See

http://www2.mst.dk/common/Udgivramme/Frame.asp?pg=http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-536-7/html/default_eng.htm , in English).

Currently the Danish EPA are finalising two projects concerning automobile care products and textile impregnation products, respectively. Both projects have analysed the content of several products including products claiming to contain nanomaterials and risk assessments is attempted

In November 2007 the Danish EPA finalized a project in collaboration with industry with the aim to identify industrial branches in which nanomaterials is used; how they are used, and how aspects concerning environment and human health is considered. The project was conducted by the use of a combination of questionnaires and interviews of the relevant industries. (See http://www2.mst.dk/common/Udgivramme/Frame.asp?pg=http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-648-7/html/default_eng.htm , in English)

Although not fully established yet the Danish EPA consider that knowledge exchange and cooperation with industry and research laboratories is important in order to obtain relevant knowledge for targeting the work concerning risk assessment and risk management of nanomaterials.

6. Information on any public/ stakeholder consultation.

Danish Standards Association has started a network group for nanomaterials with various stakeholders (authorities, industry, universities, advisors etc) in relation to the standardization work concerning nanomaterials in ISO and CEN.

The Danish EPA has just started a project with the aim of analyzing the information need with regard to use of nanomaterials and knowledge about nanomaterials and to propose a strategy how information from the authorities should be coordinated and made public available.

In November 2007, the Danish EPA together with the Confederation of Danish Industries industry were hosting a public conference/workshop for industry, NGOs and other stakeholders concerning a responsible development of nanotechnology with the focus on nanomaterials and issues in relation to use, handling and risk management. An information booklet was published in connection with the conference (see <http://www2.mst.dk/common/Udgivramme/Frame.asp?pg=http://www2.mst.dk/Udgiv/publikationer/2007/978-87-7052-647-0/html/default.htm>, in Danish only)

In relation to the conference two focus groups had been held and their discussions have been analysed in order to describe the public perception of nanotechnology. The analysis was performed by Information center for Environment and health (see <http://www.miljoeogsundhed.dk/filarkiv/NanorapportWeb.pdf>, in Danish only). The report showed that in general the public do not feel that they know very much about nanotechnology and nanomaterials.

Additional Information

Delegations may wish to provide any additional related information, e.g., any consideration of the benefits of nanotechnologies and consideration of ethical implications.

In general there is awareness in worker organizations, in NGOs some parts of the public; in the media and in the political system in DK concerning nanotechnological products and processes in relation to potential environmental and health risks. In relation to further development in this area the Danish authorities support and refer to the work and the strategic approach by the OECD, as we consider a global and collaborative effort as crucial in order to gain more knowledge as quick as possible and to achieve a common understanding for an administrative/ regulatory approach for handling nanomaterials.