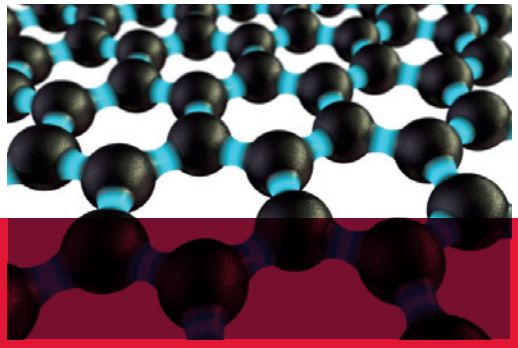


Nanomaterials
Call-for-Action

The Danish Ecological Council

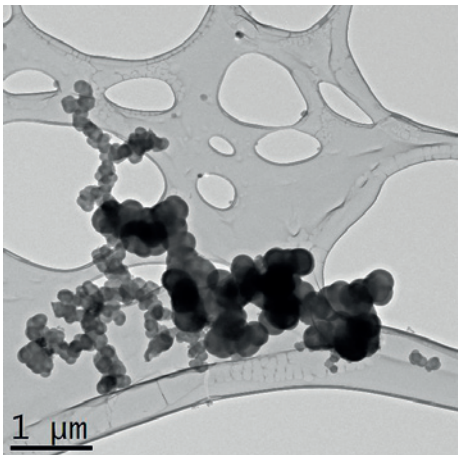
August 2012

The Ecological Council
Tomorrows environment is created today

Nanomaterials Call-for-action

The Danish Ecological Council calls upon the EU to:

- **Adopt the definition of a 'nanomaterial' proposed by the Scientific Committee on Emerging and Newly Identified Health Risks**: The European Commission has recently proposed a new definition of nanomaterials which goes against the recommendations of the Commission's own scientific experts (SCENIHR 2010) and furthermore obviously needs to be revised as it does not cover all the nanomaterials in commerce. We recommend that SCENIHRs definition of a nanomaterial is adopted, which would mean that a material is considered to be a nanomaterial when > 0.15% of the particle number size distribution is < 100 nm or for dry materials that the volume specific surface area is > 60 m^2/cm^3.



- **Register all nanomaterials commercialized in Europe**: Independent of the volume/mass manufactured and/or imported, all nanomaterials should be registered under REACH. Furthermore, all nanomaterials should undergo a safety assessment prior to being commercialized. As a general rule the safety assessments should follow similar guidelines as those established by European Food Safety Agency for nanofood (EFSA 2011). EFSA requires a full physico-chemical characterization of the nanomaterial (followed by a full description of the analytical methods used for particle characterization) as well as *in vitro* and *in vivo* hazard tests.

With current legislation this implementation is not possible, but with the adoption of a stand-alone nano patch to close the REACH loopholes, it could be possible.

For nanomaterials already in commerce, manufacturers should be required to provide nanospecific environmental-, health- and safety information within six months.

- **Ensure thorough evaluation of all nanomaterial dossiers**: Given the emerging scientific field of nano(eco)toxicology and safety assessment, all nanomaterial dossiers should undergo thorough scrutiny. Any prioritization in regard to the need for further evaluation should furthermore be hazard-based and not risk-based. Current exposure information, including monitoring methodologies and estimation models developed for bulk chemicals are pitiable when it comes to assessing exposure of nanomaterials.
- **Implement authorisation of nanomaterials**: For nanomaterials, for which human and/or environmental exposure is to be expected, authorisation should be demanded when they fulfill the conditions described in Appendix 1.

- **Establish an independent public nanomaterial and nanoproduct inventory**: Based on the registration of all nanomaterials in commerce, a European nanomaterial and nanoproduct inventory, that has information on basic production and uses of nanomaterials, is urgently needed. This includes information about who produces what, why and how much. As a general rule, all information concerning nanomaterial identity and uses as well as environmental-, health- and safety (EHS) information, should be accessible for the public. On a case-by-case basis, industry can apply for having elements of this information restricted.
- **Restrict dispersive uses of nanomaterials**: Restrictions on use should be implemented for nanomaterials that fulfill the criteria for authorization and for which dispersive uses that cannot be ruled out throughout the life-cycle of the nanomaterials exist. Authorisation without restrictions on use should only be given in cases where it can be shown that the nanomaterial in question is non-dispersive and it can be shown that exposure is non-existing at all stages of the life-cycle e.g. if the nanomaterials is produced under closed conditions, used as suspended in solid matrix and recycled and retrieved after ended use.
- **Product declaration**: The presence of nanomaterials should be clearly indicated on all commercialized products either on the product itself or in the list of ingredients by the name of the nanomaterials followed by the word 'nano' in brackets (e.g. TiO_2 [nano], silver [nano]). This is similar to the implementation in e.g. the Cosmetic Regulation (EC) No 1223/2009.
- **Establish a Nano Agency**: In order to support industry in fulfilling the nanospecific requirements proposed here, a partly industry and partly Government Nano Agency should be established. In function and structure, this agency would be very similar to the current European Medicines Agency and it should especially provide support to small and medium size enterprises in regard to establishing nanomaterial identity and characterization, environmental-, health- and safety data generation as well as best practices in regard to risk management procedures. The agency should furthermore be responsible for providing independent EHS research and funding opportunities.

The development of nanotechnology and nanomaterials is a great example of how small is beautiful and that extremely small is absolutely fantastic!

Huge investments are being made in Europe in the development of nanotechnology and nanomaterials. It is however a historical fact that there are no free lunches[1] and it seems inevitable that there will be some health and environmental risks associated with the use of nanomaterials although we do not know the exact nature of these risks yet (RS & RAE 2003, RCEP 2008). Some nanomaterials have been associated with pulmonary inflammation, induction of oxidative stress and histological changes in target organs as well as reproductive effects. It is furthermore well-established that, for instance, nanosilver is environmentally toxic[2]. However, specific knowledge about the possible risks of nanomaterials is still scarce.

Currently, nanomaterials are regulated by a patchwork of existing pieces of European legislation but all have limitations when it comes to dealing effectively with nanomaterials and only a few have been recasted in order to make nanospecific revisions[3]. In regard to regulation of nanomaterials, the European Union (EU) Regulation on Registration, Evaluation, Authorization and Restriction of CHemicals (REACH) is probably the single most important piece of legislation in Europe.

Unfortunately, REACH has been found to have a number of limitations when it comes to nanomaterials, including:

1. **Unclear terminology**: The terminology and definitions used in REACH are so broad that it is not clear whether a nanomaterial with different physicochemical and (eco)toxicological properties should be considered different from the bulk form of a given material.
2. **Inadequate registration**: REACH registration and health and environmental information requirements are guided by rules relating to 'existing substances' and further triggered by annual production tonnage levels, which might not be relevant for nanomaterials: These thresholds would hardly be reached for many nanomaterials and the current 'existing substance' provisions would exclude registration of most nanomaterials before 2018, if registered at all. There is a general lack of knowledge about who produces what, why and how much as well as specific characteristics of the nanoparticles available on the European marked.

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1 EEA. 2001. Late Lessons from Early Warnings: The Precautionary Principle 1896–2000. Copenhagen: European Environmental Agency

2 Mikkelsen, S.H., Hansen, E., Christensen, T.B., Baun, A., Hansen, S.F., Binderup, M.L. 2011. Survey on basic knowledge about exposure and potential environmental and health risks for selected nanomaterials. Environmental Project 1370. Danish Ministry of the Environment Danish Protection Agency; Stone, V, Hankin, S, Aitken, R, Baun, A, Christensen, F, Fernandes, T, Hansen, SF, Hartmann, NB, Hutchison, G, Johnston, H, Micheletti, C, Peters, S, Ross, B, Sokull- Klüttgen, B, Stark, D & Tran, L. 2009, Engineered nanoparticles: Review of health and environmental safety, Final report of FP7 Coordination and Support Action. Grant Agreement number: 218433, **http://ihcp.jrc.ec.europa.eu/whats-new/enhres-final-report** (Accessed February 1, 2010)

3 Hansen et al. 2012, Review of recent Policy initiatives affecting European regulation of nanomaterials Limitations and future Recommendations in relation to REACH revisions, forthcoming

3. Deleterious risk assessment: The risk assessment procedures that producers have to adhere to under REACH have a number of limitations when it comes to nanomaterials as current test and safety assessment guidelines are based on conventional methodologies for assessing chemical risks and may not be appropriate for assessing risks associated with nanomaterials.

Good news is that REACH is up for review in 2012 and 2013, which provides European decision-makers with a unique chance to implement much-needed nanospecific environmental, health and safety provisions.

However, it is clear that a REACH review with changes only to the annexes and guidelines is insufficient to close the legal gaps in REACH and handle the potential nano hazards. Modification in the REACH text itself (a REACH revision) or a specific stand-alone regulation closing those gaps (i.e.: a nano patch) is therefore necessary; for example to alter the tonnage thresholds when it concerns the registration of nanomaterials[4].

[4] D. Azoulay, 2012: "Just out of REACH: How REACH is failing to regulate nanomaterials and how it can be fixed". Available at http://www.ciel.org/Publications/Nano_Reach_Study_Feb2012.pdf

APPENDIX I

Authorisation of nanomaterials: For nanomaterials for which human exposure is to be expected, authorisation should be required for nanomaterials that either fulfill the High-Aspect Ratio Nanoparticles (HARN) -paradigm[i], are acute toxic or have been associated with mutagenic-, genotoxic-, carcinogenic-, respiratory-, cardiovascular, neurotoxic or reprotoxic effects in humans and/or laboratory animals. For nanomaterials for which environmental exposure is to be expected authorization should furthermore be required for nanomaterials that have a 1) Lethal Concentration (LC) or Effect Concentration $(EC)_{50}$ < 10 mg/l; 2) LC or EC_{50} < 100 mg/l plus along with either a half-life ($T_{½}$) > 40 days or an bioaccumulation factor (BCF) of > 50; or 3) $T_{½}$ > 40 days and a BCF of > 50. These threshold limits correspond to the cut-off values that trigger a red color code in the *NanoRiskCategorization* framework proposed by Danish experts[ii].

Authorisation of nanomaterials based on bulk information: European Regulation (EC) No 1272/2008 lays down the rules for Classification, Labelling and Packaging (CLP) of Substances and Mixtures. Authorisation should be required for nanomaterials, where the bulk form of the material has a CLP classification different from skin corrosion/irritation category 2, specific target organ toxicity-single exposure category 3, and serious eye damage/irritation category 2. In regard to the environment, authorisation should furthermore be required for nanomaterials, where the bulk form of the material has a CLP classification of Acute 1, Chronic 1 or Chronic 2. For nanomaterials where the bulk form of the material has a CLP classification of CLP Chronic 3 or 4, authorisation should be required for any nanomaterial that has either a LC or EC_{50} < 100 mg/l or a $T_{½}$ > 40 days or a BCF of > 50[iii].

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[i] HARN refers to High Aspect Ratio Nanoparticles indicating that the nanoparticles have a length to diameter aspect ratio greater than 10 to 1. Furthermore, it is required that: 1) The diameter of the fibres must be thin enough to reach past ciliated airways; 2) the length must be long enough to initiate the onset of e.g. frustrated phagocytosis and other inflammatory pathways; and 3) the nanomaterials must be biopersistent (Tran CL, SM Hankin, B Ross, RJ Aitken, AD Jones, K Donaldson, V Stone, R Tantra, 2008, 'An outline scoping study to determine whether high aspect ratio nanoparticles (HARN) should raise the same concerns as do asbestos fibres', Report on DEFRA project CB0406)

[ii] Hansen, S.F., Jensen, K.A., Baun, A. 2011. NanoRiskCat – a conceptual decision support tool for nanomaterials. Danish Environmental Protection Agency

[iii] *ibid*

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