



Danish Ministry of the Environment  
Environmental Protection Agency

# Registration of nanoproducts in Denmark – current situation and planned activities

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# Overview

- Handling of the nano-issue in Denmark
  - Political debate
  - Initiatives addressing political and public concern
- Initiatives under the National budget in Denmark (2012-15)
- National database for nanomaterials

# The Danish Parliament and nanomaterials



## Questions to the ministers (2006-2011)

- 20-25 questions (§20 or ordinary questions)
- To the Ministers of the Environment, Research, Labour, etc.
- Main themes:
  - The use of the precautionary measures (principle)
  - Increased research
  - Registration of nanomaterials
  - Regulation of nanomaterials (REACH etc.)
  - Nanosilver



# The Danish Parliament and nanomaterials

## Decision proposals

- The use of “an enhanced precautionary principle” (2007+2008) and more funding of research (2008)
  - Precautionary principle can not be used broadly on NMs – only on specific cases.
  - No need for specific Danish regulation
  - Nanomaterials should be regulation internationally via REACH and with OECD-methods
  - Research was at that time sufficiently funded
- On the use of nanosilver in consumer-products



# Action plan for chemicals (2010-2013)

- Total budget: 173 mio Dkr (+ additions to nano and ED for 2012-13)
- Cross cutting issues:
  - REACH, consumer products, international actions, Increased control of products, (Q)SAR
- Focus on specific substances / subst. groups
  - endocrine disruptors & combination effects, allergy, chemical sensitivity, biocides, Nanomaterials
- 2 mill. DKr [~260.000€] to nano (2010-2011)
- 2 mill. DKr [~260.000€] to nano (2012-2013)



# Nanomaterials in the Danish Action plan for chemicals

- Collection of existing knowledge
- Danish contribution to international regulation (OECD and EU)
- Dialogue and information about NM (consumers and businesses)
- Development of methods for risk-screening of specific uses of NM



# Selected Danish reports on nanomaterials

- **Report ”Nanoteknologi og Sundhed” published by the Ministry of Interior and Health, Dec 2007:**  
Survey of existing legislation in DK, covering environment, chemicals, medicine, food, occupational environment
- **Survey of nanotechnological consumer products** (Survey of Chemical Substances in Consumer Products, No. 81 2007, DK-EPA)
- **Nanotechnology in the Danish Industry** (Environmental Project No. 1206 2007, DK-EPA)
- **NanoRiskCat - A Conceptual Decision Support Tool for Nanomaterials** (Environmental Project No. 1372 2011, DK-EPA)
- **Survey on basic knowledge about exposure and potential environmental and health risks for selected nanomaterials** (Environmental Project 1370, 2011, DK-EPA)
- Reports on CNT and nanosilver in textile in pipeline (DK-EPA)

# Agreement of the National Budget, DK 2012-15

- New government in Denmark, 3. October 2011
  - Two actions related to chemicals in the agreement of the national budget, November 2011
1. Strengthened actions against chemicals  
(48 mio Dkr ~ 6.4 mio €)
  2. Better control of nanomaterials and their safety  
(24 mio Dkr ~ 3.2 mio €)
    - Subproject 1.  
Knowledge building with focus on exposure pathways and implications for consumers and the environment through the use of nanomaterials (approx. 2/3 of budget).
    - Subproject 2.  
Development of a nano-product database in cooperation with other countries (approx. 1/3 of budget ~ 1.1 mio €).
    - Coordination with the Center for Nano Safety under the Ministry of Employment (Budget for 2012-2014, 30 mio Dkr ~ 4 mio €).





# **Sub-project 1: Knowledge on exposure of nanomaterials and consequences for consumers and environment (~ 0.5 mio €/year in 2012-2015)**

- Objective: to build the knowledge needed to clarify regulatory issues related to consumer and environmental aspects of nanomaterials
- Coordination with center for nanosafety (under the Danish Working Environment Research Fund)
- Timeframe
  - Stakeholder dialogue (March-April 2012)
  - Submission of tender for project-proposals (May-July 2012)
  - Initiation of project(s) (August 2012 - ) oriented at concrete regulatory decisions in relation to safety for consumers and environment

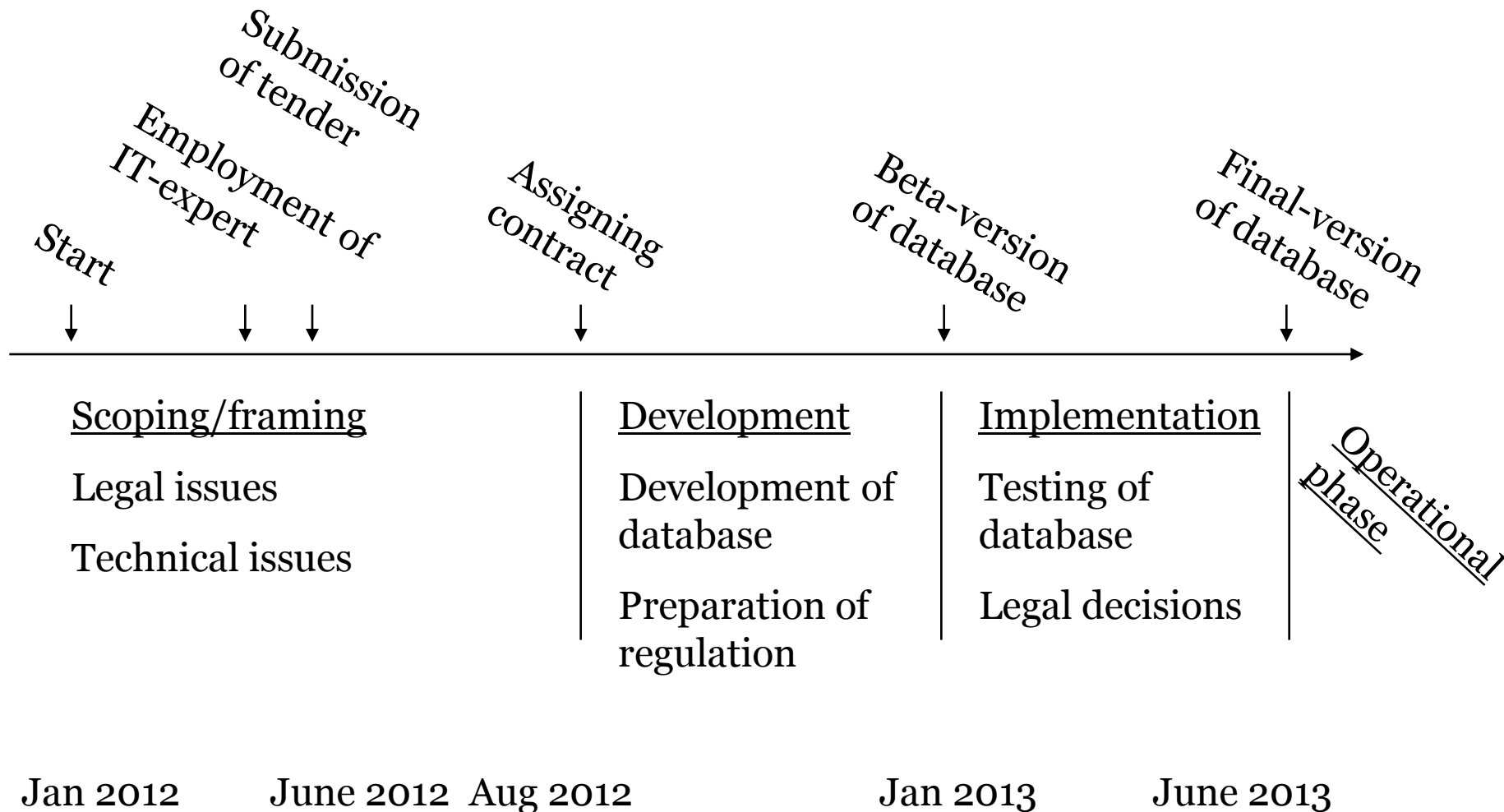
# Center for Nanosafety (~4 mio €)

- Funded by the Danish Working Environment Research Fund (under the **Ministry of Employment**)
- Deadline for application: 1. November 2011
- Expected to be granted within a few weeks from now (21 st. febr.).
- Center oriented at research in the working environment and nanomaterials (e.g. , nanotoxicology, exposure and risk assessment).

# Subproject 2: Nano-database (~ 0.25 mio €/year in 2012-2015).

- From the text explaining the national budget:  
“The enhanced efforts in the nano field include development of a nanoproduct database in cooperation with other countries. The possibility of making it mandatory to submit information to the database should be considered.” (translated from Danish)
- Objective (formulated by the DK-EPA):  
To provide overview of the nanomaterials that are on the Danish marked, the extent of use and the purposes they are used for. In addition the purpose is to put pressure on the EU-system to come up with an EU-covering solution. The database should be provide information to sub-project 1 (knowledge building) as much as possible.
- Timeframe: 2012-2015

# Tentative optimistic timeframe (nanodatabase)



# Framing of the database (Current tentative propositions in brackets)

- Both products and articles will be included.
- What types of nanomaterials should be included?  
[all nanomaterials that should be regulated as chemicals, incl. biocides, pesticides. Unresolved whether food, medicinal equipment, pharmaceuticals, cosmetics, toys, research, etc. should be included]
- What is a nanoarticle?  
[articles as defined under REACH with possible release of NM]
- Who should populate the database?  
[Importers, producers, wholesalers, supermarkets...]
- How is the database oriented towards future EU-initiatives?  
[Collaboration with FR, BE, IT and ECHA]

# Legal issues

- Is there legal authority in DK to demand mandatory registration in the database?
- Is there a need for new regulation?
- When and how should a statutory order be prepared?
- Is a Danish nanodatabase against EU-law?

# Technical Issues

- What type of IT-system should be used?  
[www-interface for input-output of data that feeds to a IUCLID-database. All linked to a national web-portal for public-legal support to businesses (<http://virk.dk>)]
- What data-fields should be available and should they all be mandatory (i.e. registrant, registration time, use, users, particle size, size distribution, aggregation/agglomeration, shape, specific surface area, chemical composition, charge, crystal structure)?  
[We are currently collaborating with FR]
- How is possible future EU-initiatives included?  
[Dialogue with FR/BE/IT and ECHA]