

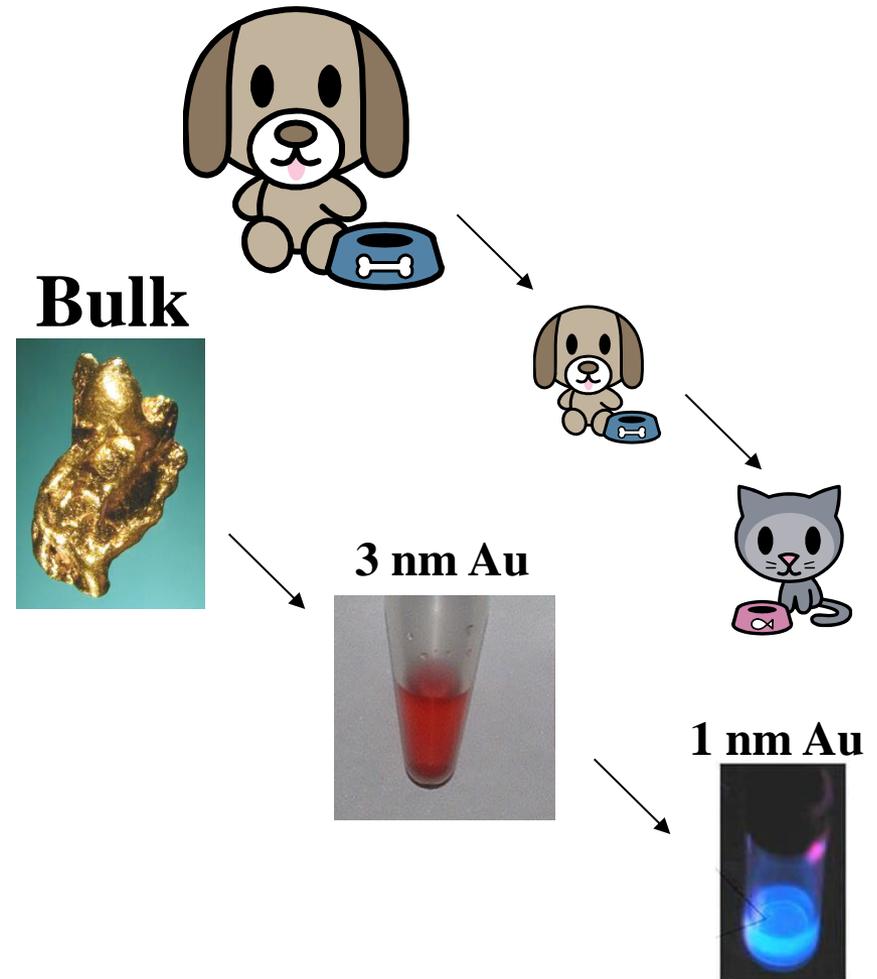
Nanotechnologies and the Precautionary Principle

Steffen Foss Hansen



Why is NT so fantastic?

- Nanotechnology (NT) enables us to manipulate with matter at the nanoscale
- At the nanoscale materials differ in fundamental and valuable ways from the individual atoms, molecules or bulk



The Future is Now!



- 1 - Organic Light Emitting Diodes (OLEDs) for displays
- 2 - Photovoltaic film that converts light into electricity
- 3 - Scratch-proof coated windows that clean themselves with UV
- 4 - Fabrics coated to resist stains and control temperature
- 5 - Intelligent clothing measures pulse and respiration
- 6 - Bucky-tubeframe is light but very strong
- 7 - Hip-joint made from biocompatible materials
- 8 - Nano-particle paint to prevent corrosion
- 9 - Thermo-chromic glass to regulate light
- 10 - Magnetic layers for compact data memory
- 11 - Carbon nanotube fuel cells to power electronics and vehicles
- 12 - Nano-engineered cochlear implant

**- As pervasive in
our society as
electricity is today!**

Concerns has been raised

In Study, Researchers Find Nanotubes May Pose Health Risks Similar to Asbestos

By KENNETH CHANG
Published: May 21, 2009

Nanotubes, one of the wonder materials of the nanotechnology revolution, may carry a health risk similar to asbestos, researchers say.

C&EN
CHEMICAL & ENGINEERING NEWS

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Related Web Links
Carbon Nanotubes into the Air
Mice Show Pathogenic (Nature)

Toxic Socks

Silver nanoparticles intended to kill bacteria on socks, researchers say.

Arizona State University researchers say silver nanoparticles when washed. This study raises concerns about silver nanoparticles.

ScienceNews
MAGAZINE OF THE SOCIETY FOR SCIENCE & THE PUBLIC

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NANOSILVER DISINFECTS — BUT AT WHAT PRICE?

By Janet Raloff
Web edition: Sunday, November 30th, 2009

A broad array of consumer products employ billions of silver nanoparticles as an antimicrobial agent. A study now suggests that silver nanoparticles get into the immune system. Do they occur at very low levels as minute as even, sometimes, one or two (i.e. parts per billion) particles per liter?

nanowerk

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Posted: Feb 26, 2018

Nanomaterials: what are the environmental and health risks?

Nanoparticles can travel from lungs to blood, possibly explaining risks to heart

April 26, 2017, American Chemical Society

ChemicalWatch
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Inhaling nano-titanium dioxide could have epigenetic effects in foetus

Study is 'highly relevant to the worker population'

18 January 2018 / American Chemical Society

If pregnant women are exposed to nanoparticles during pregnancy, it could lead to epigenetic changes in the foetus, according to a study published in the journal *Environmental Health Perspectives*.

Epigenetics describes changes in gene expression without changing the DNA sequence. Researchers from the University of California, San Diego, found significant epigenetic changes in the foetus of pregnant rats that were exposed to nanoparticles during pregnancy.

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Echa says it cannot verify if nanomaterials are being used safely

18 January 2018 / Nanomaterials, REACH

Six years after the European Commission declared that the REACH Regulation set "the best possible framework" for checking if nanomaterials are used safely, the European Commission has found that it cannot verify if nanomaterials are being used safely.

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Posted: July 28, 2008

Nanoparticles in sewage could escape into the environment

(*Nanowork News*) In a conventional sewage works, nanoparticles should really be bound in the sludge and should not represent a major problem in the aqueous effluent. This is not true, however, as shown by a new study of the ceramic model material cerium dioxide. An astonishing amount was able to leave an experimental sewage works and thus could possibly enter bodies of water.

The industry needs large amounts of cerium dioxide (CeO₂) to grind computer components and mobile phone camera lenses or the lasers in CD players. Thousands of tons of this substance are used throughout the world. But what happens when this or other nano-substances get into the environment, especially sewage, and thereby enter sewage works? Is the problem solved because nanoparticles largely agglomerate, i.e. clump together?

Particles survive unbound

FOOD

EFSA raises red flag for silicon dioxide safety over nanoparticles

By Niamh Noonan
19 Jan 2018 - Last updated on 18 Jan 2018 at 13:38 GMT

The European Food Safety Authority (EFSA) cannot give food additive silicon dioxide the safety all-clear because it may contain nano-sized particles, and has urged the Commission to change the specifications.

Nanoproducts: France recommends the precautionary principle

Too few studies and scientific data exist concerning exposure of consumers, workers and environment to nanoproducts, said the French agency in charge of environmental safety. Considering these scientific uncertainties, it recommended applying the precautionary principle and, in some cases, prohibiting the use of certain nano products.

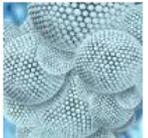
Calls for the application of the Precautionary Principle



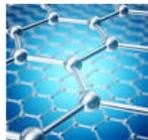
[ClientEarth files complaint over EU cosmetics nano inventory](#)
[Chemical Watch \(subscription\)](#) - 2 Aug 2017
 ClientEarth files complaint over EU cosmetics **nano** inventory ... says, and the government should instead apply the **precautionary principle**.



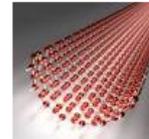
['Nano Foods': There's No Proof Some Of The Tiny Things You're ...](#)
[New Matilda](#) - 28 Jul 2017
 This **nano**-scale ingredient is currently prohibited on the basis that it has accordance with the **precautionary principle**, as well as a reluctance ...



[NGOs urge labelling, restriction of nanomaterials in French ...](#)
[Chemical Watch \(subscription\)](#) - 24 Jul 2017
 ... the **precautionary principle** to protect the public as soon as possible. ... They are calling for the mandatory **nano**-labelling of all consumer ...



[Tiny particles have big hazard potential](#)
[Canadian Occupational Safety](#) - 5 Jun 2017
 Today, however, the terms "**nano**" and "nanotechnology" have seriously ... to risk management is referred to as the **precautionary principle**.



[Germany launches 2020 nanomaterials action plan](#)
[Chemical Watch \(subscription\)](#) - 27 Oct 2016
 ... nanomaterials is a public website (**nano** observatory) listing existing ... the **precautionary principle**, scientific development of legislation and ...



[Laundry detergent eats smog \(but is it a good idea?\)](#)
[Mother Nature Network](#) - 24 Sep 2014
 Catlytic Clothing's own FAQ suggests that any **nano** titanium dioxide that ... it seems fair to suggest that the **precautionary principle** should be ...

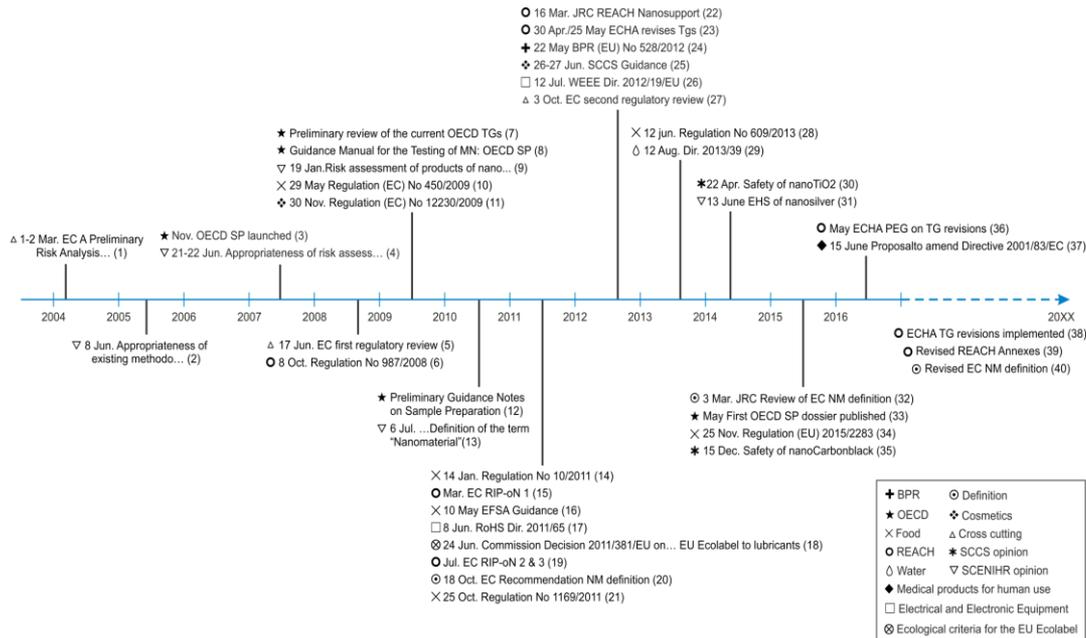


[Company's about-face on nano-free sunscreen claims](#)
[ABC Online](#) - 3 Mar 2013
 The company has admitted its product is a **nano**-material despite ... thing is to use the **precautionary principle** and to use non-**nano** sunscreen.



[Behind the Label: nanosilver](#)
[The Ecologist](#) - 20 Oct 2009
Nano - Can be suspended in water or embedded into fabrics. ... The **precautionary principle** would demand that we stop buying these products ...

Regulatory developments



In summary

- Expert opinions
- Launch of research programmes
- Regulatory reviews
- Guidance revisions
- Some NM specific legal revisions

REACH

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Small things are finally in REACH

Regulatory gaps about nanomaterials are about to be addressed in Europe

Global Business Briefing, June 2018 / Europe, Nanomaterials, REACH

Eleven years ago REACH started its quest for data in the chemicals universe with a massive telescope. Following on from the three volume-related registrations of 2010, 2013 and 2018, nanomaterials are now under examination. This is something industry stakeholders have been waiting four years for.

June, 2018



comment

The ten decrees of nanomaterials regulations

The new revisions of the Annexes of the European Union's chemical legislation with regards to nanomaterials will provide more structure and clarity, but they will also force manufacturers, importers and downstream users to put substantial effort into understanding the details of what should and should not be done.

Lauge Peter Westergaard Clausen and Steffen Foss Hansen

In April 2018, European member states approved the European Commission's draft regulation revising the Annexes of the European Union's chemical legislation with regard to nanomaterials¹. The chemical legislation currently includes 17 Annexes that specify many of the technical and scientific details of the legislation and the criteria for when, how and what different actions such as manufacturers, importers, downstream users and regulatory authorities have to do – and not do – with regard to registration and chemical safety assessment. Hence, the Annexes play a significant role in the practical implementation of the legal prerequisites outlined in the main legal text. The draft regulation was released for public consultation to the autumn of 2017 and has now been adopted by the European Commission after a three-month scrutiny review by the European Parliament and Council². The Annex revisions, which aim to clarify registration duties for nanomaterials, come after years of discussion between the European Commission, EU member states and other stakeholders.

In this Comment, we introduce and discuss the new obligations that manufacturers, importers and downstream users "shall" comply with before this regulation applies from 1 January 2020.

Thou shall register
In essence, we summarize the new Annex revisions into ten decrees aiming at making manufacturers, importers and downstream users register 'nanomaterials' and demonstrate safety of all their uses (see Table 1). Under the EU chemical legislation, manufacturers and importers have to register their substances if produced in quantities of 1 tonne or more per year. According to the new regulation, specific minimum characterization information, such as number-based particle number size distribution, shall be provided by the registrant for nanomaterials, as these characteristics may influence their (eco)toxicological profile and environmental exposure.

Nanomaterials are defined as a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or agglomerate, where for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1–100 nm (ref.7). The information provided by the registrant may be applicable to an individual nanomaterial or to a set of similar nanomaterials, and grouping of nanomaterials is possible if justification is provided. Notably, molecular structural similarities alone cannot serve as a justification for grouping.

For general registration purposes, the revised Annexes require that information on manufacture and use provided in the registration for regular substances shall also apply to nanomaterials or sets of similar nanomaterials. Such information includes storage used, concentration range used, quantities in articles, human and environmental exposure and waste quantities and composition³. When registrants of nanomaterials submit joint registration dossiers, they shall justify why information provided is relevant for nanomaterials, or they may submit relevant information separately⁴.

Thou shall demonstrate safety
The number of decrees and use of the word "shall" is no mere coincidence in the revised Annexes (see in sections related to the Chemical Safety Report that has to be provided for substances manufactured or imported in a quantity of 10 tonnes or more per year. According to the new Annexes, the Chemical Safety Report shall first specify whether and which different nanomaterials have been characterized as part of the registration, and whether they are covered by the Chemical Safety Assessment. Interestingly, this also applies to producers and importers of articles that are required to prepare a Chemical Safety Assessment as part of their registration⁵. Second, registrants shall describe how information is compiled, adequately document control of risks associated with the uses of their nanomaterials and ensure that justifications and conclusions are relevant to these nanomaterials along the life-cycle of the substance.

As a general requirement, the nanomaterial tested shall be appropriately characterized and test conditions documented to allow for adequate assessment of the relevance of any physicochemical, toxicological and ecotoxicological information provided for the different nanomaterials⁶. In case the nanomaterials of a substance fulfil the criteria for dangerous or hazardous substances, an exposure assessment and risk characterization shall be completed using an appropriate metric, and preferably a multiple-metric presentation of the results shall be considered. It is furthermore repeatedly mentioned as a general requirement with regard to classification and labelling that registrants shall indicate and justify actions or decisions taken if information is inadequate to classify a substance and nanomaterials thereof as belonging to a particular hazard class or category⁷.

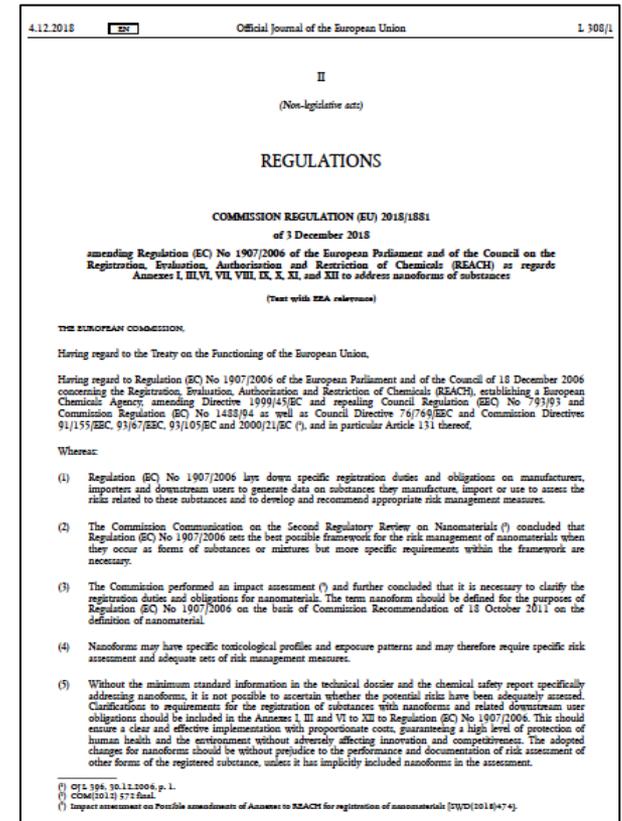
When it comes to fulfilling specific information requirements as part of the Chemical Safety Assessment, the revised Annexes criteria a number of very specific decrees. For instance, for nanomaterials that are not soluble nor have high dissolution rates, further degradation tests shall consider morphological transformation, for example, irreversible changes in particle size, shape, surface properties, loss of coating, chemical transformation and other abiotic degradation^{8,9}. A range of studies do not need to be conducted depending on the specific circumstances, for example, dustiness does not need to be reported if exposure to a granular form of the substance during its life-cycle can be excluded¹⁰. It is important that registrants note that high insolubility in water cannot serve as a justification for waiving a number of information requirements related to the environment, for example, short-term toxicity testing on invertebrates and growth inhibition studies of aquatic plants.

In some aspects, the Annex revisions are very inclusive. In the assessment of persistence, bioaccumulation and toxicity,

Clausen, L.W.P., Hansen, S.F. 2018. Nature Nanotechnology 13(9): 766-768

Basic info

- Aim: Clarify registration duties for nanomaterials
- Applies from 1 January 2020
- 20 pages
- 134 "shall"
- 44 "should"



Reminds you a little of...



The Devil is in the Detail



- 'The devil is in the details' only came into common use in the 1990s... earliest citation of it is in Richard Mayne's **explanation of the workings of the European Union** - *The Community of Europe*, 1963
- **"The phrase might have been tailor-made** for negotiations between European Union countries, which are renowned for their labyrinthine and hair-splitting attention to detail."
- Source: <https://www.phrases.org.uk/meanings/the-devil-is-in-the-details.html>

Thou shalt register nanoforms

- Registration of substances required if produced in quantities of ≥ 1 tonne per year
- Different nanoforms have to be registered individually or as groups
- Manufactures and importers **have to decide whether** they have nanoforms that need to be registered
- But not clear in the Annexes **how?**



The Ten Decrees of the new Annexes

1. Thou shalt **register** nanoforms.

2. Thou shalt **provide information** on particle size distribution, functionalization, shape and specific surface area.

3. Thou shalt **not use molecular structural similarities** alone as a justification for grouping different nanoforms.

4. Thou shalt **document safety for all registered nanoforms** along the life-cycle.

5. Thou shalt **justify why safety information provided** is relevant for all registered nanoforms.

Clausen, L.W.P., Hansen, S.F. 2018. Nature Nanotechnology 13(9): 766-768

How do you measure size distribution?



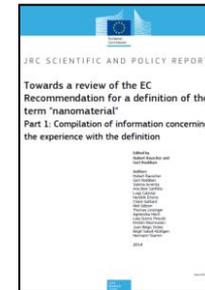
Table 4.1: Main characteristics of particle size methods relevant to the nanomaterial definition

Method name (abbreviation)	Measurement range and medium (limiting factors)	Type of size distribution of raw data	Can deal with challenges of particular types of nanomaterials? (scale: ++, +, 0, -, --)*				Standards for use of method for size analysis available?
			poly-dispersity	non-spherical particles long: + flat: -	low-density materials	aggregates	
Electron microscopy (EM)	1 nm and higher; dry (dynamic range)	number-based	+	-	-	-	yes
Dynamic light scattering (DLS)	5 nm to 500 nm; suspension (sedimentation, scattering intensity)	(no distribution, or scattering-intensity-based)	--	--	+	--	yes
Centrifugal liquid sedimentation (CLS)	20 nm and higher; suspension (particle density)	extinction-intensity-based	+	--	-	--	yes
Small-angle X-ray scattering (SAXS)	5 nm and higher; suspension (dynamic range)	scattering-intensity-based	0	-	0	--	yes
Field flow fractionation (FFF)	1 nm to 200 nm; suspension (dynamic range)	(depends on detector)	+	-	+	--	no
Particle tracking analysis (PTA)	25 nm and higher; suspension (scattering intensity)	number-based	+	--	0	--	no
Atomic force microscopy (AFM)	1 nm and higher; dry (dynamic range)	number-based	+	long: + flat: +	0	-	yes
X-ray diffraction (XRD)	1 nm and higher; dry (only for crystalline materials)	(no distribution measured)	--	--	-	+	yes

* scale: ++ = very well, + = well, 0 = moderately, - = not well, -- = not at all.

How do you measure size distribution?

- Different methods yield different results within and outside the "nanorange"



- Which method(s) to use?
- Potential (ethical/technical) dilemma for importers and producers

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Small-angle X-ray scattering (SAXS)	5 nm and higher; suspension (dynamic range)	scattering-intensity-based	0	-	0	--	yes
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* scale: ++ = very well, + = well, 0 = moderately, - = not well, -- = not at all.

Thou shalt demonstrate safety

- Explain which different nanoforms have been characterized
- Adequately document control of risks associated with uses of all nanoforms
-  **Does anyone in the world know how to do this?**
- **Good news – in 3 months registrants will have done it**
- **Good news – in 3 months registrants will have done it**
t On, for instance,
- Irreversible transformations in particle size, shape, surface properties and loss of coating considering all stages of life-cycle
- Characterization of possible degradation, transformation, reaction processes, dissolution rate, particle aggregation and agglomeration and changes in particle surface chemistry wrt environmental distribution and fate

Setting Ambitious Goals is Not New

Apollo 11 first manned moon landing



Brooklyn Bridge



World's first steel-wire suspension bridge

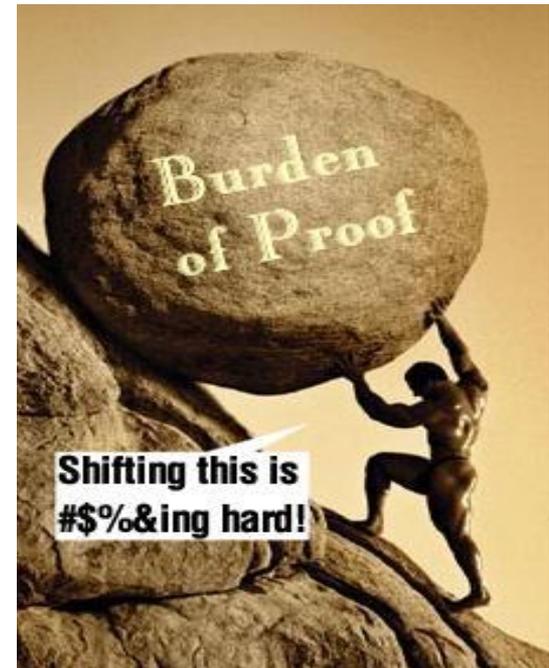
Industry Not Happy



- Testing methods still under development at OECD level and will not be ready on time
 - ECHA guidance on Human Health and Environment for nanomaterials will first be known to industry by Nov., 2019
 - IT tools to register the nanomaterials is due by 31st Oct. 2019
- = Demands placed on ECHA and the resources put at their disposal are out of sync**

The Burden of Proof Having to develop Guidance

- REACH: Responsibility of demonstrating safety on registrants
- ECHA “responsible” to providing guidance wrt practical implementation
- No entity can do this alone



Building Learning Alliances



Mistra
Environmental
NanoSafety
Phase II

- **MISTRA = Swedish Foundation for Strategic Environmental Research**
- Lead: Tommy Cedervall, Lund U
- Total: 62.5 m SEK
- DTU, Gothenburg, Chalmers, Karolinska, KTH, TetraPak, Höganäs Nouryoun (former AkzoNobel)

Total Quality Management, 2014
Vol. 25, No. 9, 1054–1071, <http://dx.doi.org/10.1080/14783363.2013.807680>

A learning alliance for robust design in product development: the case of Volvo 3P and Chalmers University of Technology
Azadeh Fazl Mashhadi^{a,b}, Sverker Alänge^{a*} and Lars-Uno Roos^c

^aDepartment of Technology Management and Economics, Division of Quality Sciences, Chalmers University of Technology, SE-412 96 Gothenburg, Sweden; ^bVolvo Pentia AB, Gothenburg, Sweden; ^cVolvo Technology AB, Gothenburg, Sweden

Although the use of rob potential, its practical ap earlier less-successful in successful in making rob This initiative was cond Chalmers University of The aim of this paper is gathered through formal informal meetings and t broader robust design c creation of local learning The company–university different levels. First, e engineers and master–st learning. Second, the le Chalmers interacting with as well as reflection-in- interaction also supporte practices for organisati

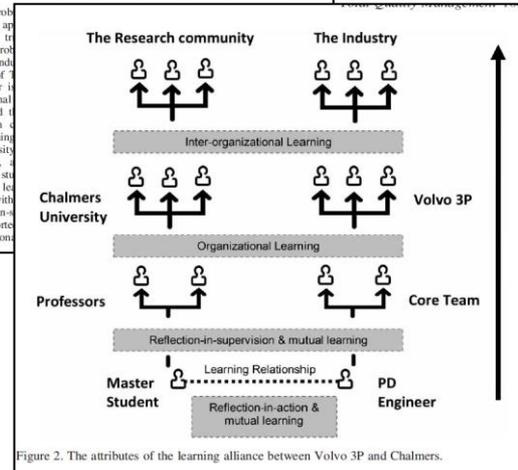
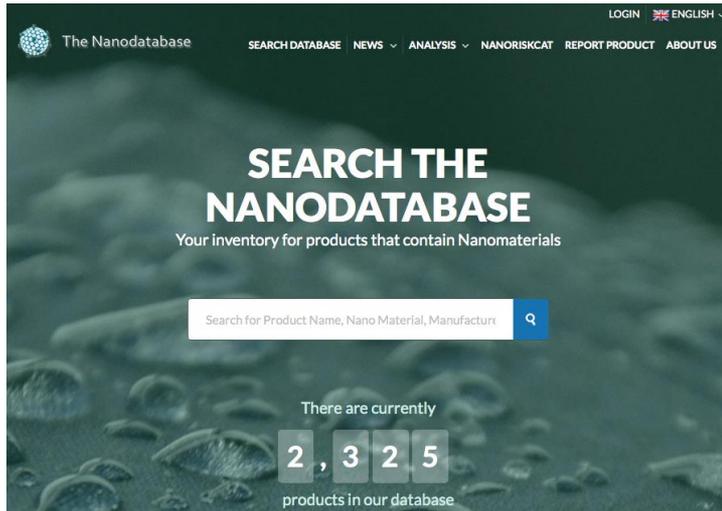


Figure 2. The attributes of the learning alliance between Volvo 3P and Chalmers.

And taking a step back - Tons of “Useless Products”



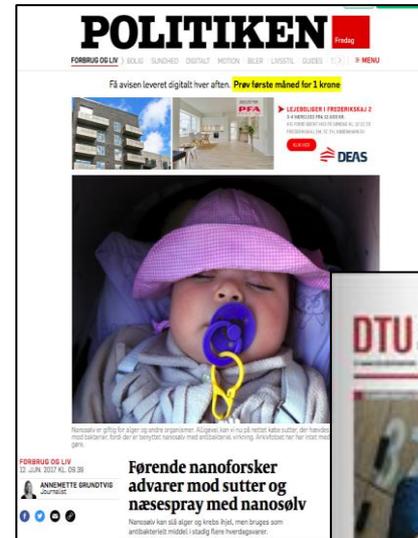
www.nanodb.dk



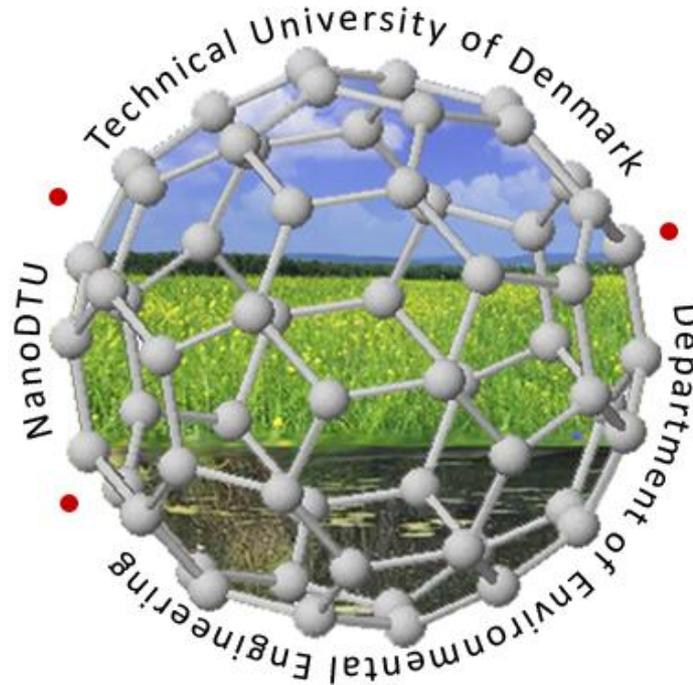
Principle of Necessity

“In cases where there is a **potentially widespread use** of a chemical, material or technology, care should be taken not only to ensure environment and health and safety, **but also** to determine whether this use is **absolutely necessary and unavoidable**”

Hansen et al. *In prep.*



Thank U 😊 & ?'s



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