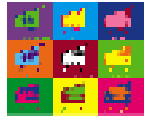


Nano Safety for success  
dialogue – 2-3 Oct 2008

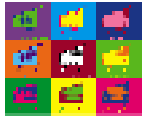
# Nanotechnology: A societal perspective on regulation

Laura Degallaix  
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BEUC, the EU Consumers' Organisation



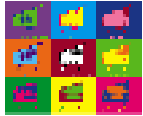
# What applications for nanotechnologies





## Existing uncertainties, unanswered questions

- At present, limited understanding of the potential effects
- Numerous warnings:
  - ✓ UK Royal society and Royal Academy of Engineering (2004)
  - ✓ SCENIHR (2006)
  - ✓ UK Council for Science and Technology (2007)
  - ✓ SCCP (2007)
  - ✓ + DG Enterprise recent letter to cosmetics sector



## What definitions for nano?

Definitions are needed but problem with size limit:  
between 1 and 100nm, typically around 100nm,  
≥ 100, up to 200nm, up to 300nm, up to 1000...

### *Examples:*

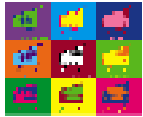
In the US,

- US FDA 2006: less than 1000nm
- NNI: 100nm
- US FDA July 2007: no size-based definition

In Australia, CSIRO scientists: up to 1000nm

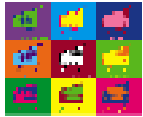
At international level, ISO, ASTM, OECD...

In the EU, EU Commission, SCENHIR, SCCP, UK Royal Society, DEFRA, BSI...



## Identified regulatory gaps

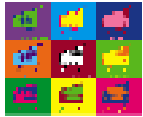
- Current approach not sufficient
- Lack of clarity over how general requirements for safety are to be applied
- Identified instances where regulatory measures might fail e.g. :
  - ✓ where use of substance restricted by %, weight or volume
  - ✓ where thresholds are set for permitted concentrations in products
  - ✓ where authorisation is based on whether substances are 'equivalent' to ones regulated and understood



# What consumers know

Consumers know very little. E.g.:

- Which? Consumer survey : 61% of people had never heard of nanotechnologies
- Which? Consumer panel (with rep. steering group): consumers raised the following key issues:
  - ✓ Safety
  - ✓ Lack of regulation to deal with the risks + no international action
  - ✓ Lack of information
  - ✓ Accessibility
  - ✓ Environment



# **Addressing nanotechnologies in regulation: the consumer perspective**

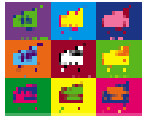


## Definitions in order to help develop regulatory requirements

In existing EU product specific legislation (Cosmetics Regulation, Novel Food Regulation...):

- Introduce definitions (for nanoparticles, avoiding limiting the size to 100nm, and aggregates)
- Allow for changes to be made to the definitions (via Comitology with scrutiny)
- Require the EU Commission to seek for an international agreement





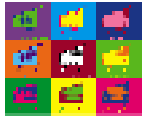
## Applying a precautionary approach

- Urge industry to provide the necessary data
- Apply the precautionary principle
- Introduce strict and effective pre-market assessment and authorisation processes
- Consider nanoparticles as 'new' substances
- Ensure adequacy and harmonisation of safety evaluation methodologies
- Introduce post market monitoring systems



## Ensure transparency, information and public engagement

- Understand what products are and will come on the market (e.g. mandatory reporting scheme)
- Transparency about uncertainties, safety assessment and uses
- Information about where nanoparticles are used (e.g. in list of ingredients) and ensure claims are true
- Public engagement with meaningful public debate



“If you once forfeit the confidence of your fellow citizens,  
you can never regain their respect and esteem.”

*Abraham Lincoln*

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**This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.**