



# Nanomaterials Regulations and Measurement Implications

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# Government Chemist Advisory Function



- Main concern is with the link between Regulation/Legislation and Analytical Measurement
- UK) and EU Regulation covered
- Covers all areas except food, medicines and agriculture (these are covered by the Statutory Function)
- Major areas of interest include REACH, CLP, **Nanomaterials**, Environment, Transport (fuels)

# Advisory Function Tasks

- Monitor new and proposed legislation
- Respond to appropriate consultations
  - UK Government
  - Devolved Administrations
  - Agencies
  - European Commission
- Interaction with stakeholders
  - Meetings
  - Presentations
  - Seminars

# Nanomaterials Legislation (EU)

- Very little EU-wide legislation covering nanomaterials
- REACH does not specifically refer to Nanomaterials but does cover specific substances
- EU Cosmetic Regulation (1223/2009) mandates labelling of all nanomaterials ingredients from July 2013
  - Definition is ‘an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm’.
  - Labelling to be e.g. “titanium dioxide (nano)”

# REACH

- REACH does not, at present, specifically cover nanomaterials
- Nanomaterials are covered under the “normal” form of the substance
  - Substance evaluation for specific nanomaterials individually identified as being of concern
    - $\text{SiO}_2$  - evaluated 2012 by the Netherlands
    - Silver;  $\text{TiO}_2$  – to be evaluated in 2015 (NL, FR)
- Safety assessments must be carried out as for all substances

# EU Nanomaterial Definition

- Current EU Definition of a Nanomaterial is still only a recommendation
- A nanomaterial is defined as:
  - a natural, incidental or manufactured material
  - containing particles, in an unbound state or as an aggregate or as an agglomerate
  - and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm.

# EU Nanomaterial Definition

- Final definition expected to be available very shortly
- Expected to be no different from the recommended definition
- Not identical to Cosmetic Regulation definition
- Other countries (e.g. USA) use 1-100nm as “nano” range
- Is enforceable and measurable *in theory*
- Better than definition based upon function not form, favoured by some (but which is not objectively measurable)



# National Regulations in the EU

- 3 Member States have elected to establish their own Nanomaterials Register:
  - Belgium
  - France
  - Denmark
- These differ in scope and application

# Belgian Nanomaterials Register

- Covers:
  - manufactured nanomaterials (from 1.1.16)
  - Preparations containing manufactured nanomaterials (from 1.1.17)
- Exclusions include cosmetics, biocides, medicines, foodstuffs, animal feeds and pigments
- Nanomaterial definition is the same as current European Commission Draft



# Danish Nanomaterials Register

- Uses the same approach as REACH for registering substances and recording information
- Exclusions include: food, feed, medical devices, medicines, pesticides, waste and article where the nanomaterial substance is listed in Annex IV of REACH
- Based on lower tonnage bands to reflect trade in nanomaterials

# French Nanomaterials Registry

- Most comprehensive of the three national systems
- Exceptions where  $< 100$  g/year produced or imported
- R&D materials at  $< 1$  tonne/year
- Very much based on precautionary principle and a lack of knowledge about nanoparticles behaviour

# Possible EU-wide Register

- Consultations have been taking place regarding an EU-wide register. Options vary significantly.
- Exercise is ongoing. UK position is no EU-wide regulation, nor a “nanomaterials observatory” which would read details from all national systems in place
- Indications from consultants show that UK position may be adopted, but Commission yet to make any statement



# Government Chemist Position

- Regulation of nanomaterials should be preceded by an agreed technical definition AND validated measurement methods to underpin it
- Assumption that all nanomaterials are inherent hazardous is flawed – we need proper risk assessments
- REACH could be adapted to cover nano specifically, to reduce regulatory burden and have consistency for industry

# Future Issues

- REACH Annexes to be revised to cover nanomaterials
  - Due to be agreed/published summer 2015
- Definition of a nanomaterial to be agreed
  - Report from JRC (IRMM) expected soon
- Methods of measurement and characterisation to be further funded?

# Conclusions

- Regulation of nanomaterials is inconsistent across sectors and countries
- Presumption that all nanomaterials are intrinsically hazardous
- Agreed definition and validated measurement methods needed before regulation
- Greater dialogue between scientists and regulators?