Research in Support of Consumer Protection Legislation

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Research-Based Policy Support

JRC - Robust Science for Policy Making

As a Directorate-General of the European Commission, the JRC provides customer-driven scientific and technical support to Community policy making.

Supporting citizen’s security, health and environmental protection, safety of food and chemicals, alternative energies, nuclear safety, econometrics, prospective technologies...
Consumer Products

- Automotive
- Chemical Industry
- Construction
- Cosmetics
- Electronics
- Energy
- Environment
- Food
- Nanomedicine
- Photonics
- Textiles
- ………….
EU Regulation – Nanotechnology Relevance

<table>
<thead>
<tr>
<th>Horizontal Legislation</th>
<th>Product Legislation</th>
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<tbody>
<tr>
<td>1. Chemicals Legislation (REACH)</td>
<td>• General Safety of Consumer Products</td>
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Safety aspects regarding nanotechnologies are in principle covered.

Need for modification?

| Control                                          | • Cosmetic Products                                  |
|                                                 | • Aerosol Dispensers                                  |
| Major-accidents, Seveso II Directive             | • Medicinal Products                                  |
| Water                                            | • Cars                                               |
| Waste                                            | • Food Legislation                                   |
Position of the European Parliament

RESEARCH NEEDS

• Safety/Risk Assessment

• Detection, Quantification and Characterization of Nanomaterials in Complex Matrices

  – Environment/Health/Safety (EHS) data
  – Labelling of products containing nanomaterials
  – Inventory on types and use of nanomaterials one the EU market
Safety/Risk Assessment

HAZARD IDENTIFICATION

HAZARD CHARACTERIZATION

EXPOSURE ASSESSMENT

RISK CHARACTERIZATION
Exposure

**Potential**
- Liquid, powder or solid?
- Content/concentration?
- Frequency and duration of use?
- Application, e.g.
  - Spraying; e.g. sunscreen
  - Dermal applications, e.g. cosmetics
  - Articles/solid products, exposure due to wear and tear,
  - Accidents?
- Release
- ......

**Estimation**
- Measurement
  - Metric (mass-, surface-, number-, or?)
  - Size distribution
  - Costs vs. quality of information
  - Background & artefact(s)
  - ....
- Modelling
  - Mainly based on mass-metric
  - not validated for NMs
  - do underlying algorithms take account of nano-specific properties?
Hazard Assessment

• Assessment Methodology
  – Definition of Nanomaterial
  – Information requirements
  – Test methods and test strategies
  – Guidelines for safety and risk assessment

• Data
  – Relevant for regulation
  – Harmonized data templates
  – Data storage and availability

• Tools
  – Reference nanomaterials
  – Standards and harmonized methods
  – Protocols for testing
  – Databases
Test Methods and Test Strategies

**NANOMATERIALS**

- Size and shape
- Dispersion state
- Physical and chemical properties
- Surface and Porosity
- Surface Chemistry

**In vivo**

- Biol. Response, Pathogenesis
- Uptake, Accumulation
- Tissue and Cell Response

**In vitro**

Engineered Nanomaterials
There are no provisions in REACH referring specially to nanomaterials, but

REACH addresses chemical **substances**, in whatever size, shape or physical state.*

*** Substances at the nanoscale are covered by REACH and its provisions apply.

* Nanomaterials in REACH (CA/59/2008 rev.1)
REACH Implementation Projects on Nano

• **Substance Identification of nanomaterials**
  – Identification parameters – how to produce information?

• **Information Requirements**
  – What is needed?
    (physicochemical properties, toxicity, environmental fate, ecotoxicity)
  – How to generate?

• **Chemical Safety Assessment**
  – Dose response characterization
  – Exposure scenarios and estimation
  – Metrics

CASE STUDIES ON
• Carbon Nanotubes
• Nano-silver
• Nano-TiO$_2$
• Nano CaCO$_3$
Detection, Quantification and Characterization of Nanomaterials in Complex Matrices

Labelling obligation for ingredients present in the form of nanomaterials,
in the list of ingredients the names of such substances shall be followed by the word 'nano' in brackets:

- No hazard labelling
- only for information
- will allow consumers to make a choice

Titanium Dioxide (nano)
Nanomaterials in Complex Matrices

Detect
- Imaging (SEM, TEM, AFM, ...)

Quantify
- Extraction from matrix
- Separation/fractionation (filtration, centrifugation, chromatography, Field Flow Fractionation, ...)
- Elemental analysis (e.g. ICP-MS)

Characterize
- Size
- State of dispersion
- Physico-chemical properties
- Surface properties

After Lynch and Dawson, Nanotoday 2008, (3) 1-28
Nanoparticles in Matrices

- Sunscreen has been deposited on silicon wafer through Spin-coating
- Samples treated with plasma (Ar:O₂ 6 mins) to eliminate organic compounds

• TiO₂ nanoparticles
• in cosmetic creams

Dimension: 30-50nm
Characterization and Detection Techniques

A number of tools – no best techniques

- All techniques have advantages and drawbacks
- A combination of techniques is needed
- Combination of separation/analysis is particularly promising
- Difficult to make robust analysis without Electron Microscopy
- Most non-imaging methods assume particles with known shape (spherical)

IF TRUE PARTICLE SIZE IS CRITICAL TO YOUR RESEARCH/PRODUCT
DO NOT UNDERESTIMATE THE DIFFICULTIES OF SIZE MEASUREMENT
Standardization Activities

CEN TC 352 Nanotechnology
ISO TC 229 Nanotechnology

OECD Working Party on Manufactured Nanomaterials

- Safety Testing of a Representative Set of Manufactured Nanomaterials
- Manufactured Nanomaterials and Test guidelines
- The Role of Alternative Methods in Nanotoxicology

Reference Nanomaterials

IT Platforms and Databases
Definition of Nanomaterial for Regulatory Purposes

Requirements

– A single definition broadly applicable in EU legislation and policies

– Legally clear and unambiguous, i.e. enforceable

Questions concerning the key elements of a definition

– What is the nanoscale and which size range should it encompass?

– Should other properties which are the consequence of the material being at the nanoscale be included?
OUTLOOK

• Nanomaterials to be assessed following the provisions of current legislation

• Implementation for nanomaterials difficult:
  – Knowledge gaps
  – Current methodology incomplete

• Need for appropriate test methods and new data

• Harmonized test methods and standards required

• Next generation nanomaterials in consumer products

• International cooperation necessary
Nanobiosciences

Thank you for your attention