Risk Assessment of Nanomaterials in Cosmetics and Food Products

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Member Scientific Committee on Consumer Safety (SCCS)
Member EFSA WG on risk assessment of nanotechnologies in food/feed
Over 1000 consumer products already available*  

- Cosmetics and personal care products (~60%)  
- Paints & coatings (~10%)  
- Catalysts & lubricants (~10%)  
- Security printing (~10%)  
- Textiles & sports (~10%)  
- Medical & healthcare (~10%)  
- Food and nutritional supplements (~10%)  
- Food packaging (~10%)  
- Agrochemicals (~10%)  
- Veterinary medicines (~10%)  
- Water decontamination (~10%)  
- Construction materials (~10%)  
- Electrical & electronics (~10%)  
- Fuel cells & batteries (~10%)  
- Paper manufacturing (~10%)  
- Weapons & explosives (~10%)  

*Source: www.nanotechproject.org/inventories/consumer/
Nanomaterials in Cosmetics
Nano-Cosmetics

- A major area of available products containing nanomaterials (mainly outside the EU) in the form of antioxidants, antimicrobials, vitamins/minerals etc.
  - Nanomaterials used include
    - inorganic, organic nanomaterials
    - uncoated, coated, doped
    - particulates, micelles, liposomes
- Only a few products available in the EU member states - mainly sunscreens containing nano metal oxide UV filters.
Europe is leading the way in the development of regulatory frameworks for nanotechnologies

- **Cosmetics** related applications in the EU will be regulated under the Cosmetics Regulation (EC) No 1223/2009;
  - The EC’s Scientific Committee on Consumer Safety (SCCS) will provide opinion on risk assessment;
- **Food** related applications in the EU will be regulated under the frameworks relating to Novel Foods, Food Additives, Food Packaging (currently under revision), and other frameworks*;
  - EFSA will provide opinion on risk assessment;

Any existing or new ingredient in nano form will have to go through a process of safety evaluation and approval in the EU.

*e.g. relating to general food safety, general product safety, chemical safety, water quality, biocides, pesticides, veterinary medicines
The Cosmetics Regulation  
(Regulation (EC) No 1223/2009)

- Provides the first regulatory definition of a nanomaterial*
- Requires:
  - cosmetic products containing nanomaterials to be notified to the Commission 6 months prior to being placed on the market;
  - nanoscale ingredients to be labelled (name of the ingredient, followed by ‘nano’ in brackets);
  - if there are concerns over safety of a nanomaterial, the EC will refer it to the Scientific Committee on Consumer Safety (SCCS) for opinion.

*“nanomaterial” means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.”
Scientific Committee on Consumer Safety (SCCS)

- Composed of Experts from different EU countries, with diverse range of expertise (chemistry, toxicology, medicine, dermatology, allergies, exposure assessment, risk assessment, alternative methods ….)

- Safety of non-food consumer products (cosmetics and personal-care products, textiles, toys, domestic products ….)

- Assessment of safety of cosmetic ingredients under the Cosmetic Regulation
  - Mainly dossier based safety evaluations
  - Mandate includes nanomaterials in cosmetics
The SCCS WG on Nanomaterials:

- assesses the likelihood of risk of nano ingredients to the consumer;
- draws upon expertise from other SCs and external Experts;
- currently considering the very first dossiers on nanomaterials in cosmetics:
  - ETH50 (1,3,5-Triazine, 2,4,6-tris[1,1′-biphenyl]-4-yl-)
  - Titanium dioxide
  - Zinc oxide
- outcome of these assessments is also likely to set a precedent for future assessments;
Challenges

• Many issues and challenges:
  • Agreed definition of a nanomaterial
  • Validated methods for detection/characterisation of nanomaterials – especially in dispersions/final products;
  • Assessment of nanomaterial exposure through dermal, inhalation, and (where applicable) ingestion routes;
  • Validity of the *in vitro* methods currently used for cosmetic ingredients to nanomaterials;
  • Case-by-case risk assessment – can similarities be drawn to group nanomaterials for risk assessment purposes?

• SCCS is addressing the issues through a close collaboration with the industry, and by setting systematic standards for the safety data needed in dossiers.
In 2010, an ICCR Adhoc WG* discussed and agreed on a nanomaterial definition:

“For purposes of the International Cooperation on Cosmetic Regulation, a substance used in a cosmetic is considered a nanomaterial if it is an insoluble ingredient, intentionally manufactured, with one or more dimensions in the realm of 1 to 100 nanometers in the final formulation and is sufficiently stable and persistent in biological media to allow for the potential of interaction with biological systems.”

A new ICCR Joint WG is currently looking into safety assessment of nanomaterials in cosmetics.
Nanomaterials in Food
Food related applications

- Less use of (agro)chemicals
- Safer animal feeds (e.g. detoxification of mycotoxins)
- Hygienic food processing
- Healthy food products (less fat, salt, preservatives)
- Improved bioavailability of nutrients & supplements
- Nano(bio)sensors for detection of pathogens
- Improved, ‘Active’ and ‘Smart’ packaging materials (safety, extended shelf-life)
- Coatings – hydrophobic, antimicrobial, gas barrier
- Water decontamination
Current Status

- Most applications are currently outside the EU - only a few products in Europe so far (mainly supplements, packaging);
- Several applications worldwide:
  - Nano-agrochemicals (mainly R&D stage)
  - Nano-structured foodstuffs (for better taste, flavour, texture)
  - Nano-formulated food additives and supplements (liposomes, encapsulates)
  - Nano metal/oxide additives (e.g. silica, TiO$_2$, silver)
  - Water purification/ desalination, Nano(bio)sensors, barrier coatings
Dekkers et al. (2010 - Nanotoxicology) attempted RA for nanosilica in food products (e.g. soup powders, coffee creamers), and highlighted knowledge gaps and uncertainties:

- Analysed food products with added silica (E551)
- Estimated the likely intake of nanosilica via food
- Considered two scenarios for RA:
  - silica is absorbed as dissolved silica (no expected adverse effects),
  - silica nanoparticles are absorbed from the GI tract (too many uncertainties to allow adequate RA)
- Recommended research on the form silica is absorbed from the GI tract.
Challenges

• Main issues and challenges (similar to nano-cosmetics):
  • definitions, Validated methods for detection/characterisation, hazard/exposure/risk assessment;
• Main safety concerns relate to insoluble, persistent and/or highly reactive nanoparticles.
  • EFSA Draft Scientific Opinion (2011) provides guidance on Risk Assessment
Physico-chemical characterisation
See chapter 3.
Is the material an ENM?

Yes

Determine exposure scenarios
See figure 2

If likely exposure

Is there an approved non-nanoform of the food/feed substance?

Yes

Provide data on the nanoform according to this ENM Guidance

No

Provide data according to appropriate EFSA guidance and perform specific testing taking into account the nanoform according to this ENM Guidance
See table 2 and chapter 5

Hazard identification and hazard characterisation.
See chapter 5

No

Exposure assessment
See chapter 6

Risk characterisation
See chapter 7

The material is outside the scope of this guidance

If evidence demonstrates no exposure there is no need for further testing

Yes

Is the non-nanoform food chemical/material tested according to appropriate EFSA guidance?

No

Yes

No

EFSA Draft Scientific Opinion (2011)
Toxicity Testing

- *In vivo* test
  - ADME
    - 90-day rodent repeat oral toxicity, considering extended endpoints (e.g. endocrine activity and immuno- and reproductive toxicity)
  - *In vitro* tests not yet validated. Provide screening and initial understanding of biological effects.
    - Genotoxicity and mutagenicity tests
    - Additional *in vitro* in *vivo* tests triggered by initial results
    - Limited datasets not considered appropriate
Current Challenges

• Most challenges are not restricted to one sector:
  • Definitions, validated methods for detection, characterisation, toxicological evaluation, exposure assessment, risk assessment;
  • New methods and tools emerging from R&D will be equally applicable to most sectors;
  • A close collaboration between industry, researchers and regulators can address many of the current uncertainties.
Summary

• First examples of nanomaterials in cosmetics are currently undergoing a scrutiny of safety evaluation;

• Current challenges are being addressed by EC’s Scientific Committees and Working Groups in collaboration with industry;

• Regulatory landscape has become clearer in relation to the use of nanomaterials in cosmetics and food;

• Guidance on risk assessment is available;

• Efforts are underway to harmonise risk assessment approaches in different regulatory jurisdictions.
This paper was produced for a meeting organized by Health & Consumers 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 & Consumers 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.