

Nano Safety for Success Dialogue – March 2011

Risk Assessment of Nanomaterials in Cosmetics and Food Products

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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.

Risk Assessment/ Regulation

- **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.

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 biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.⁶

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

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.

Global Initiative

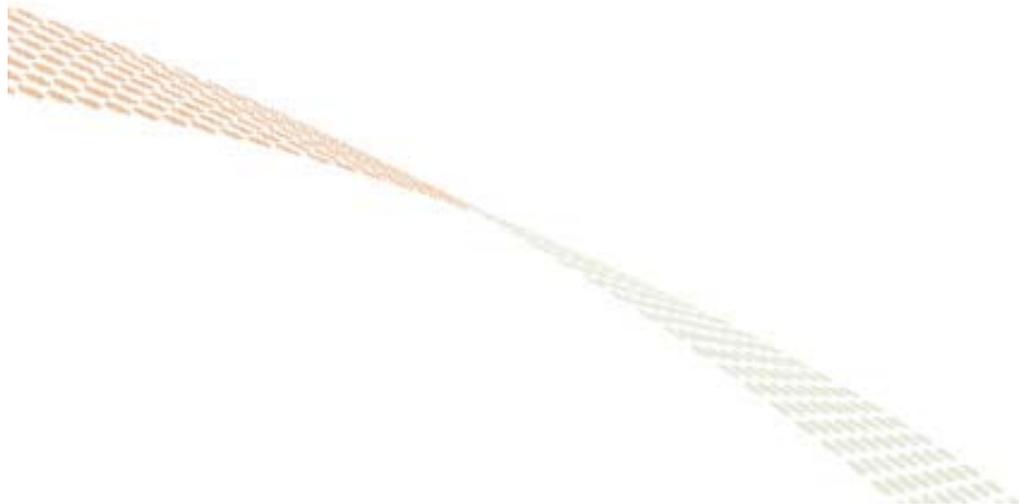
International Collaboration on Cosmetics Regulation (ICCR)

- In 2010, an ICCR Adhoc WG* discussed and agreed on a nanomaterial definition:

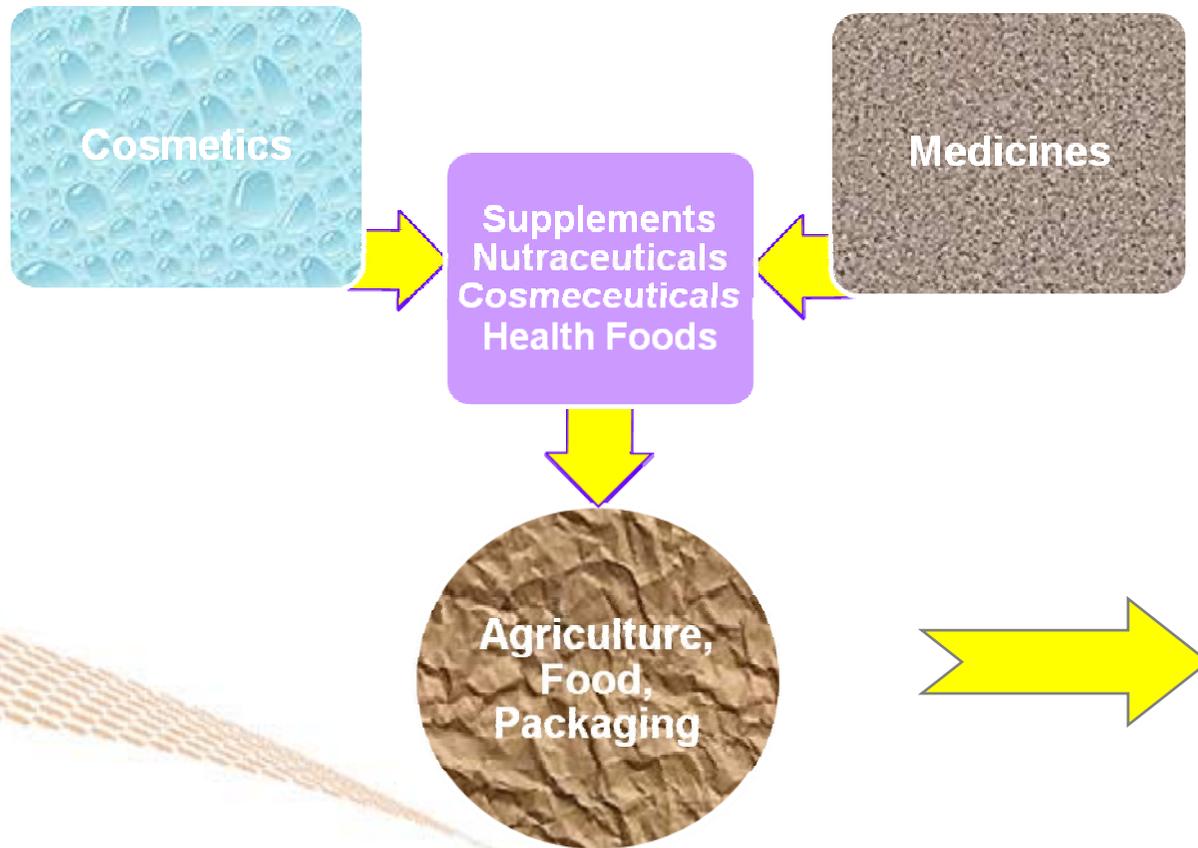
'For purposes of the International Cooperation on Cosmetic Regulation, a substance used in a cosmetic is considered a nanomaterial if it is an insoluble ingredient, intentionally manufactured, with one or more dimensions in the realm of 1 to 100 nanometers in the final formulation and is sufficiently 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, TiO₂, silver)
 - Nano-polymer composites for improved, 'Active', 'Intelligent', 'Smart' food packaging
 - Water purification/ desalination, Nano(bio)sensors, barrier coatings

Risk Assessment Challenges

Dekkers et al. (2010 - Nanotoxicology) attempted RA for nanosilica in food products (e.g. soup powders, coffee creamers), and highlighted knowledge gaps and uncertainties, :

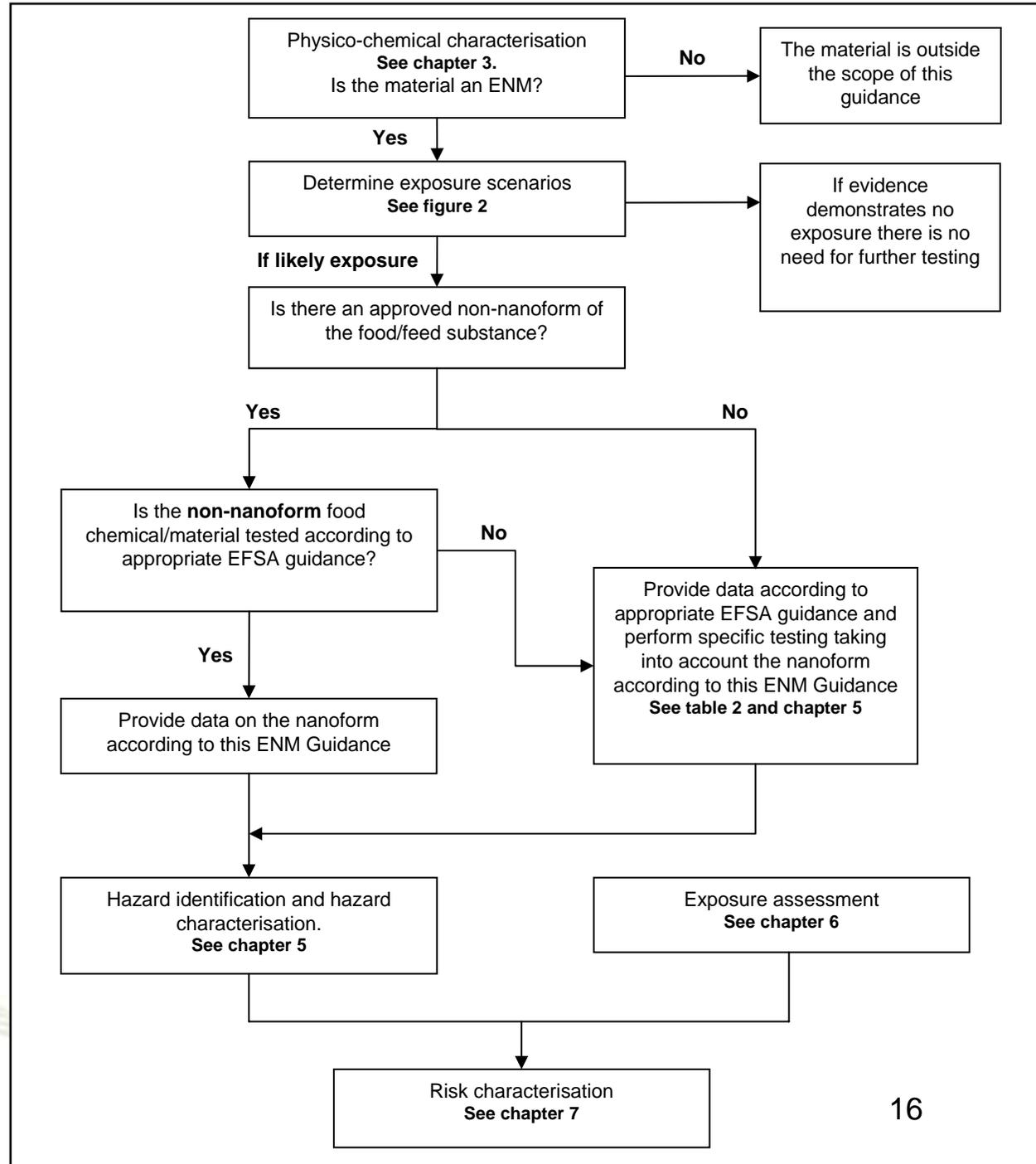
- Analysed food products with added silica (E551)
- Estimated the likely intake of nanosilica via food
- Considered two scenarios for RA:
 - silica is absorbed as dissolved silica (no expected adverse effects),
 - silica nanoparticles are absorbed from the GI tract (too many uncertainties to allow adequate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



EFSA Draft Scientific Opinion (2011)



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.

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