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Risk assessment of food packaging containing nanoparticles

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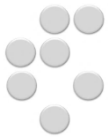
NIJZ Nacionalni inštitut za javno zdravje



Ecobiocap, Montpellier 26.02.2015

- Theoretical case study: plastic box containing nano particles

EFSA document

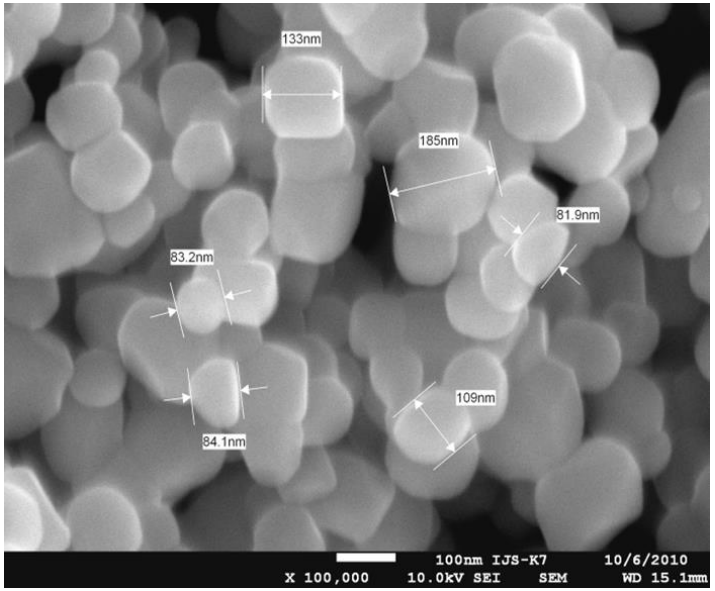
Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain

EFSA Journal 2011;9(5):2140

efsa
European Food Safety Authority

Is packaging ENM (under scope of the Guidelines)?

EC recommendation on the definition of nanomaterial (2011/696/EU):



TiO_2 nanoparticles

(Jožef Stefan Institute, Department for Nanostructured Materials)

'Nanomaterial' means 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.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

Characterisation of ENM

Selection of parameters/methods on case-by-case basis (types of ENMs, measurement environment):

- Particle size
- Chemical composition
- Physical form and morphology
- Surface chemistry
- Surface charge
- Redox potential
- Solubility and partition properties
- Chemical reactivity/catalytic activity…

Different sizes /shapes/… of ENMs of the same chemical composition may have different toxicities!

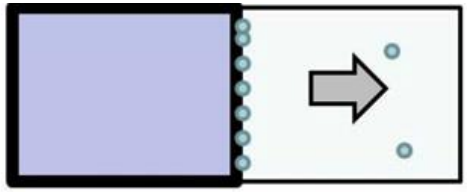
Issues:

- recommendation: size 100 nm ?, solubility
- characterisation: equipment, staff, cost,
- routine work?
- results representative and relevant?

Is (oral) exposure likely?

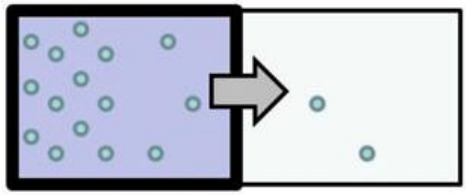
DESORPTION: Weak bonding to surface

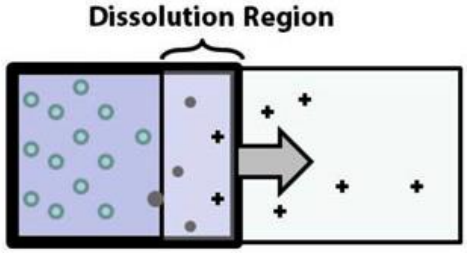
- Agitation
- Surfactants / detergents
- pH
- Temperature



DIFFUSION: Migration to low concentration

- Concentration gradient
- Surface treatment
- Size and shape
- Polymer properties



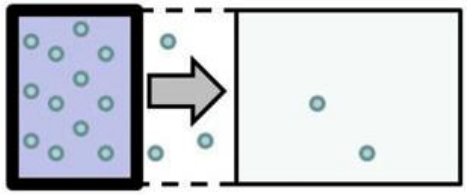


DISSOLUTION: Ions released into product

- pH
- Ionic strength
- Size and shape
- Concentration

DEGRADATION of MATRIX: Loss of polymer

- Mechanical abrasion
- UV exposure
- Material fatigue
- Hydrolysis / swelling



Noonan et al. Comprehensive Revievs in Foof Science and Food Safety 2015

Issues:

- difficult analysis (matrix, low concentrations, equipment, method validation, combination of methods for detection and characterisation)
- reference materials?
- „classical“ migration test appropriate?

Hazard identification & evaluation

Information on non-nanoform not available

Nano form persists in foods and GI fluids:

Provide data according to EFSA guidance for FCM:

- high migration (5 - 60 mg/kg food), an extensive data set (3 mutagenicity studies *in vitro*, repeated dose 90-day oral toxicity studies (in two species), ADME studies, studies on reproduction in one species, and developmental toxicity in two species)
- migration between 0.05 – 5 mg/kg food, a reduced* data set (3 mutagenicity studies *in vitro*, repeated dose 90-day oral toxicity studies (in two species), data to demonstrate the absence of potential for accumulation in man
- low migration (<0.05 mg/kg food), a limited* data set (3 mutagenicity studies *in vitro*)

Not appropriate for nano FCM

Hazard identification & evaluation
Information on non-nanoform <u>available</u>

- Nano form <u>persists</u> in foods and GI fluids?

toxicity testing:

comparison of non-nano and nano data on ADME, toxicity and genotoxicity, repeated dose 90-day oral toxicity study to identify major differences
if differences indicate increased hazard – **more toxicity testing is needed**

Issues:

- lack of tox. data (especially for oral exposure) e.g. no TDI for bulk or nano TiO_2

(JECFA, 1970) "decided not to establish a limit on intake of titanium dioxide since the evidence indicates that it is free from toxic effects on account of its insolubility and inertness". Nano TiO_2 is different

- Insufficient characterisation of NMs in tox.tests
- High administred doses

Exposure assessment

The same as for non-nanoform materials

Possibility - if no exposure data or not possible to determine nanoform in food – assumption that all added ENM is present, ingested and absorbed in nanoform

Issues:

- Determination of amount and characterisation of ENM present in food
- Available consumption data?

Risk characterisation

Characterised risk = Estimated exposure/Reference value

Issues:

- Uncertaintes in estimated exposure
- No reference values

Summary and conclusions

- Definition of ENM (strict size? solubility?)
- Characterisation of ENMs is difficult
- Lack of toxicological data for oral exposure
- Exposure (migration? Consumption data?)

RA of ENMs is very complex task

Interdisciplinary approach needed – materials science, analytical chemistry, toxicology

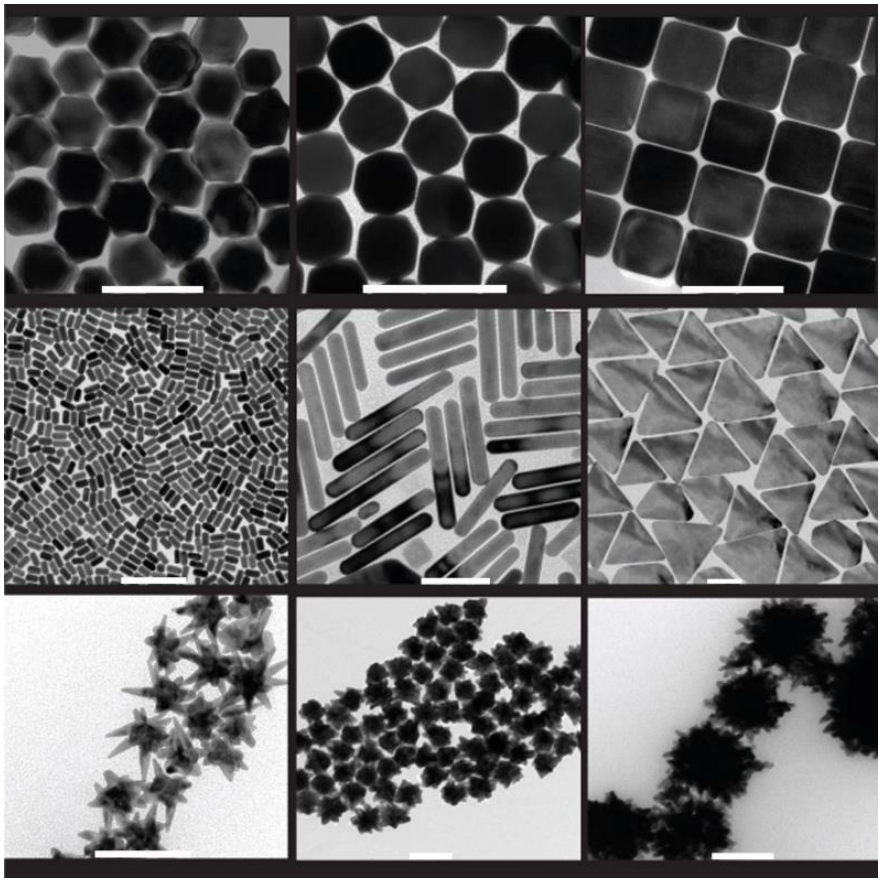


Figure 1. From top left: nano-trisoctahedra, faceted gold nanorods (top view), nanocubes **Science for Environment Policy Issue 48, February 2015**
From Library of anisotropic gold nanoparticles: Transmission Electron Microscopy (TEM) micrographs by Dr Željka Krpetic, Qi Cai and Jennifer Cookman (CBNI, UCD).

Thank you for your attention