



Nanotechnology - (non)existing Regulation


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There are many regulations in the European Union to ensure safe food and feed, but none of them respect the particle size. Once a component is registered it can be used independent on its size.

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Regulation 178/2002

Producers of food and feed are responsible that products are safe and in accordance with existing regulations on each level of production.

➔ *no special guidelines concerning particle size*

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Regulation 1935/2004

for all materials contacting food (packaging material)


It is forbidden that the material:

- endanger human health
- influence the composition of the product
- influence the organoleptic properties of the product

Active and intelligent materials have to be labelled in an adequate way (no misleading information!)

➔ *no special guidelines concerning particle size*

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Regulation 76/768


Guidelines for the production of cosmetics

Cosmetics

- have to be safe
- have to guarantee (or even improve) human health
- Each product has to be evaluated concerning its safety data

➔ *no special guidelines concerning particle size*

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Pesticides and Biozides

Active ingredients have to be evaluated based on safety dossiers before registration.

➔ *no special guidelines concerning particle size*

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Hedge clauses

Member states have the possibility of banning products from the market on national level, when there are justified doubts on the safety of a product.

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SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

The Committee points to major gaps in the knowledge necessary for risk assessment :

- nanoparticle characterisation,
- the detection and measurement of nanoparticles,
- the dose-response,
- fate, and persistence of nanoparticles in humans and in the environment and
- all aspects of toxicology and environmental toxicology related to nanoparticles.

Equipment for routine measurements in various media for representative exposure to free nanoparticles is inadequate.


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Gaps in Regulation

- There is no explicit consideration of nanosized particles in applicable Community Law
- Problem with already registered components, when they are used in nanosize
- No obligatory labelling


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Outlook

- EC checks Community Law if Nanotechnology is covered or if amendments are necessary
- EFSA is obliged to give an statement concerning potential risks of nanotechnology in food (?2008)
- EC „Nano Safety for Success Dialogue“ Workshop (October 2008)

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Outlook (EC contracted SCENIHR)

- Provide, recommendations on:
 - improvements of existing test methods and/or on the development of new ones,
 - improvements in exposure assessment (including, amongst others, also relevant information on sampling, detection tests, instrumentation, modelling) OECD !
 - improvements in risk assessment in general
- Recommend further prioritised needs for short, medium and long-term research
- Identify direct or indirect health risks with regard to current and foreseeable applications of nanomaterials based on information related to volume of production in different sectors. For the sector of cosmetics indications from patents should also be taken into account.

Deadline: November 2008

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THANK YOU!

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