



**Nanomaterials
and safe food production
Point of view
of the Austrian Ministry of
Health, Family and Youth**





Nanotechnology in food- a regulatory challenge



- “Engineered nanoparticles can have very different properties and effects which may entail new health risks for humans and other species never encountered before”
(European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) 2007)
- Food shall not be placed on the market if it is unsafe
(General Food Law, Article 14)



„The regulatory challenge is to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained „
(Commission Communication of 17 June 2008 on "Regulatory aspects of nanomaterials")



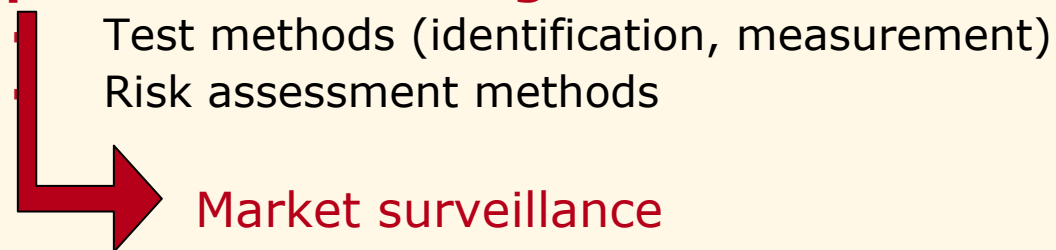
Ensuring Food Safety-prerequisites



1. Legislation

- Products which are subject to a pre-market control or pre-market notification (novel food, food additives)
- products which can be placed on the market without specific pre-market procedural requirements (food in general)

2. Implementation of Legislation





Definitions



SCCP (Scientific Committee on Consumer Products, 2008):

- A **nanoparticle** is a particle with one or more dimensions at the nanoscale and is defined as a particle with at least one dimension $<100\text{nm}$.
- A **nanomaterial** is a material with one or more external dimensions, or an internal structure, on the nanoscale, which could exhibit novel characteristics compared to the same material without nanoscale features.

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks, 2007):

- A **nanostucture** is any structure that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less.
- A **nanomaterial** is any form of a material that is composed of discrete functional parts, many of which have one or more dimensions of the order of 100 nm or less.
- An **engineered nanomaterial** is any material that is deliberately created such that it is composed of discrete functional parts, either internally or at the surface, many of which will have one or more dimensions of the order of 100 nm or less.



SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR) 2006



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



Commission Communication of 17 June 2008 on "Regulatory aspects of nanomaterials" (1)



Conclusions and recommendations:

- **Current legislation covers the potential health risks in relation to nanomaterials.**
- **The protection of health needs to be enhanced by improving implementation of current legislation.**
- **Member States should**
 - "carefully monitor the market and use Community market intervention mechanisms"
 - "exchange information or intervene when products present a risk, even where they conform with legal requirements"
- **Concerted actions for market surveillance.**



Safeguard clauses



Regulation 178/2002, Article 14(8)

Competent authorities take appropriate measures to impose restrictions despite conformity, if justified suspicion that food is unsafe.

Regulation 1935/2004, Article 18(1)

When use of a material or article endangers human health, although it complies with the relevant specific provisions, C.A. may temporarily suspend or restrict application of the provisions



Commission Communication of 17 June 2008 on "Regulatory aspects of nanomaterials" (2)



Food contact materials

- Special provisions can be adopted for active and intelligent food contact materials and articles
- EFSA guidelines need to be adapted to require identifications of possible compounds present in "nano form".
- The risk assessment need to be adapted to take into account specific risk arising from the use of substances in "nano-form".



Commission Communication of 17 June 2008 on "Regulatory aspects of nanomaterials" (3)



- Where the full extent of a risk is unknown, but concerns are so high that risk management measures are considered necessary, as is currently the case for nanomaterials, measures must be based on the precautionary principle.
- **Suggested activities:**
 - Improving the knowledge base
 - Improving the implementation of legislation
 - Information to users
 - Market surveillance and intervention mechanisms (exchange of information via RASFF)



Precautionary principle (General Food Law, Article 7)



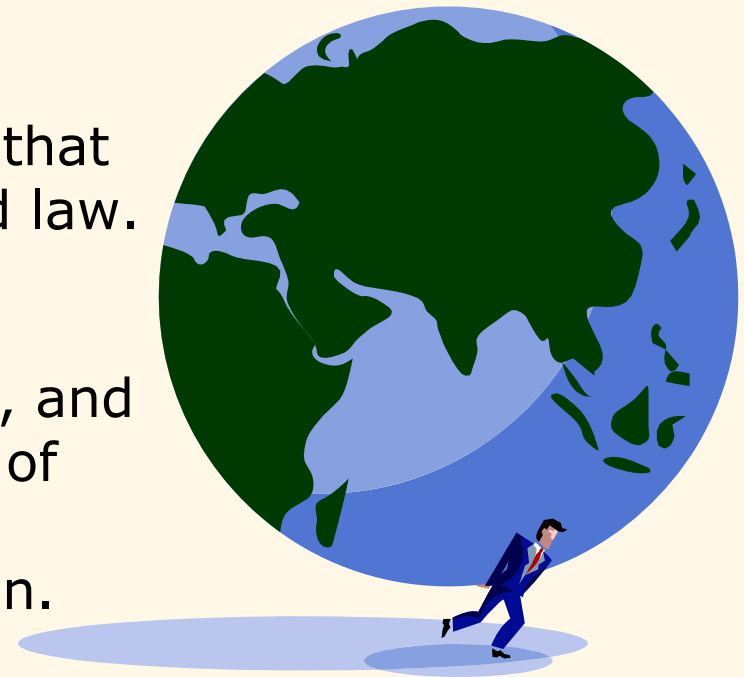
1. In specific circumstances where the possibility of harmful effects on health is identified but scientific uncertainty persists, **provisional risk management** measures may be adopted
2. Measures shall be
 - proportionate
 - regard to technical and economic feasibility and other legitimate factors
 - review



Responsibilities (General Food Law, Article 17)




1. Food business operators shall ensure that foods satisfy the requirements of food law.
2. Member States shall enforce food law, and monitor and verify that requirements of food law are fulfilled at all stages of production, processing and distribution.





Commission recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research



- Given the deficit of knowledge **Member States** should apply the **precautionary principle** in order to protect consumers.
- Application of the precautionary principle should include reducing the gaps in scientific knowledge
- As long as risk assessment studies on long-term safety are not available, **research involving deliberate inclusion in food** (especially in food for babies) **should be avoided.** 



Forthcoming amendments of EC regulations with specific provisions for nanomaterials



Main driving force in the regulatory process = EP

- Proposal for a Regulation of the European Parliament and of the Council on food additives
- Proposal for a Regulation of the European Parliament and of the Council on novel foods
- Proposal for a Regulation of the European Parliament and of the Council on cosmetic products



Proposal for a Regulation of the EP and of the Council on food additives-Outcome of the European Parliament's second reading



Food additives can be approved only provided that:

- they present no hazard to the health of the consumer
- there is a reasonable technological need and
- they do not mislead the consumer

Article 12

When there is a significant change in

- the production methods
- the starting materials
- in particle size (e.g. **nanotechnology**),

a new entry in the Community lists or change in the specifications



Proposal for a Regulation of the EP and of the Council on food additives- outcome of the EP 's second reading



Centralised Community authorisation on the
basis of a scientific opinion by EFSA

Article 14

The **specifications** of food additives relating, in particular, to origin, purity criteria and **any other necessary information**, shall be adopted when the food additive is included in the Community lists.



Proposal for a Regulation of the EP and the Council on novel foods (Review of Regulation (EC) No 258/97)



- centralised **Community authorisation** on the basis of a scientific opinion by EFSA.
- For every authorised novel food a specification, **labelling, conditions of use** and a requirement of **post-market monitoring** may be laid down;
- Novel foods once authorised are kept under **continuous observation and re-evaluated** wherever necessary.
Producers of novel foods will be obliged to inform the Commission of any new information which may affect the safety assessment of the novel food;



Proposal for a Regulation of the EP and the Council on novel foods (Review of Regulation (EC) No 258/97)



Article 3 lit 2a

„novel food" means:

- (iii) „food to which is applied a new production process, not used before 15 May 1997, where that production process gives rise to **significant changes in the composition or structure** of the food which affect its nutritional value, metabolism or level of undesirable substances.“
- **Austrian proposal:**
new additional provision (iv)
Foods produced using nanotechnology and nanoscience



Summary of Austrian views Regulatory gaps (1)



- Nanoparticles may exhibit different properties to those in the macroscopic form, these effects may be potentially hazardous
- No internationally recognized set of (legal) definitions
- No sufficient consideration of nanomaterials in current food legislation
- Ingredients authorized in the bulk form but utilized in nanoparticulate form
 - Food additives, flavourings
 - Ingredients of FCM (eg „intelligent“ packaging materials)
- Processing aids (?!)
- No obligatory declaration of nanomaterials in the labelling (list of ingredients)



Summary of Austrian views (2)



- Concern at the lack of progress regarding understanding of the potential health and environmental impacts of nanomaterials.
- As first priority these knowledge gaps have to be addressed in close collaboration with industry (**research priorities**)
 - methods for measurement and detection of nanoparticles
 - and methods for assessment of the potential risks associated with their use
- If nanotechnology and nanoscience is used, the resulting food products should be considered as novel foods (pre-market authorization).
- Precautionary principle should be applied until methods for identification and risk assessment have been developed (Moratorium within an European context)



Summary of Austrian views (3)



- Manufactured nanoparticles contained in food should be identified as such on lists of ingredients
- Stakeholder dialogue on nanotechnology to respond to public concerns related to ethical, social, health, safety and environmental issues.
- Collaboration between industry and governments to facilitate legislation and control for nanotech in food
- Consideration of a nanotechnology-specific horizontal EC regulation

**Thank you
for your
attention**