Update on nanomaterials in food contact materials

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Outline

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2. How are nanomaterials regulated in the field of fcm
   1. EU-regulations
   2. BfR-Recommendations
3. Migration-ways of substances from fcm into the food
4. Example: Microfibrillated cellulose (MFC)

picture:https://chemtrust.org/food-contact-materials/
1. The Unit of food contact materials in the BfR

Chemicals and Product Safety: Areas of Concern

1) Assessment of Chemicals under REACH and CLP
2) Safety of Consumer Products including
   - Packaging of food
     - Cosmetics, Perfumes
     - Cleaning agents and detergents
     - Textiles
     - Toys, Tattoos, Tobacco products
     - Other commodities
3) Research Activities to substantiate risk assessment
4) National Reference Laboratory for Food Contact Materials
2. How are nanomaterials regulated in the field of FCM?


Article 1 – subject matter
2. This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, which in their finished state:
(a) are intended to be brought into contact with food;
or
(b) are already in contact with food and were intended for that purpose;
or
(c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.
2.1 EU-Regulations


Article 3 – General requirements
1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
   (a) endanger human health;
   or
   (b) bring about an unacceptable change in the composition of the food;
   or
   (c) bring about a deterioration in the organoleptic characteristics thereof.

  No specific reference to nanomaterials
2.1 EU-Regulations


Article 5 – Specific measures for groups of materials and articles
ANNEX I - List of groups of materials and articles which may be covered by specific measures

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
   4. Cork
   5. Rubbers
   6. Glass
   7. Ion-exchange resins

8. Metals and alloys
9. Paper and board
10. Plastics
   11. Printing inks
12. Regenerated cellulose
   13. Silicones
   14. Textiles
2.1 EU-Regulations


• Specific regulation on plastics
• List of specific substances with migration limits, rules on testing,…
• Adding a substance by application

• Specific regulations on nanomaterials in plastics:
  • „Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I”
  • e.g. titanium nitride, nanoparticles

Restriction: “No migration of titanium nitride nanoparticles. Only to be used in polyethylene terephthalate (PET) up to 20 mg/kg. In the PET, the agglomerates have a diameter of 100-500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm.”
2.1 EU-Regulations


Article 6 – National specific measures
In the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty.

For substances for which there are no harmonised EU regulations:
• Plastics:
  - aids to polymerization (catalysts and initiators) and
  - polymerisation production aids (emulsifiers)
• Rubber
• Silicones
• Paper and board
• Artificial Sausage Casings
• Fillers
• Temperature Resistant Polymer Coating Systems
• …
2.2 BfR-Recommendations

- are not legal norms
- are based on German and European law
- access via the BfR website is free of charge

• represent the current state of the scientific and technical knowledge on the conditions under which Art. 3 of EU-Regulation 1935/2004 is met
3. Migration-ways of substances from fcm into the food

1. Direct food contact (migration)

2. Via gasphase
   (in particular dry foods with a high specific surface)

3. Via set-off
   (during storage upon reels or in piles)

4. Hydrolysis / Oxidation

5. Abrasion (especially Nanomaterials)

Influencing factors:
- Concentration of the substance
- Layer thickness
- Material (diffusion properties)
- Type of substance (molecule size)
- Time and temperature conditions
- Partition coefficient of the substance between material and food
- Food
- Ratio between surface area and filling volume
3. Migration-ways of substances from fcm into the food

Specific Regulations/Recommendations on nanoparticles in FCM

- Framework Regulation (EC 1935/2004) does not specifically address nanoparticles
- Plastics Regulation (EC 10/2011): nanoparticles are allowed if explicitly authorized

BfR-Recomm.: “Unless otherwise indicated the listing is based on the risk assessment of the substances in conventional particle size and does not cover engineered nanoparticles.”

- Other ways of protection: multi-layer FCM containing functional barrier layers
- EFSA guidance: for toxicological assessment – read-across may be used

By now: all nanomaterials used in FCM have been evaluated within a case-by-case decision
4. **Example: Microfibrillated cellulose (MFC)**

- Natural material, produced in different ways from wood fibres
- properties:
  - light weight
  - thermal stability
  - high optical transparency
  - high strength and modulus
  - …

- Broad range of applications:
  - Textiles, hygiene and absorbent products, automotive industry, pigments and paints,…
  - In FCM e.g., paper coatings and films, paper strength additive

  ➡️ Replacement of plastic packaging product and plastic films
4. Example: Microfibrillated cellulose (MFC)

- Process:
  1. Mechanical treatments (Homogenizer, Microfluidizer, Grinding, Cryocrushing, …)
  2. Pre- or Post-treatments (Enzymatic, TEMPO-mediated, Carboxymethylation, …)

Picture: most applied mechanical processes and the most frequently applied pre-treatments used for MFC (Bras et. al., Carbohyd. Polym. 2012, 90, 735-764)
4. Example: Microfibrillated cellulose (MFC)

Analytical problems and solutions during the assessment:

- Problem: Micro- vs. Nanofibrillated cellulose
  - Solution: MFC embedded between two layers
- Problem: Migration of Nanoparticles
  - Solution: no migration via AF4 + MALS analysis or less than in conventional cellulose (SEM)

Toxicological assessment difficult:

- for inclusion into the BfR-Recomm. at least genotox-tests (Ames- and micronucleus-test)
  - Ames-Test not suitable
- Best case: no migration or functional barrier

- Inclusion of MFC in the recomm. 36 (Paper and Board for Food Contact) and 36.2 (Paper and Paperboard for Baking Purposes) in 2017
Thank you for your attention

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