



# **Update on nanomaterials in food contact materials**

Dr. Leonard John

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# Outline

1. The Unit of food contact materials in the BfR
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

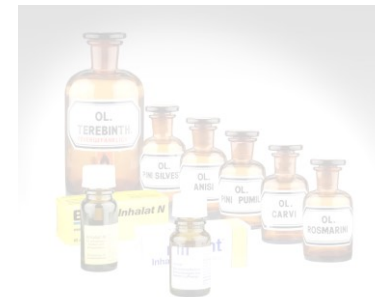
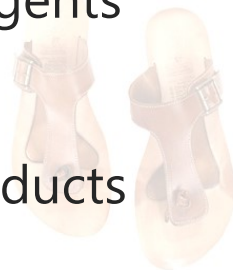
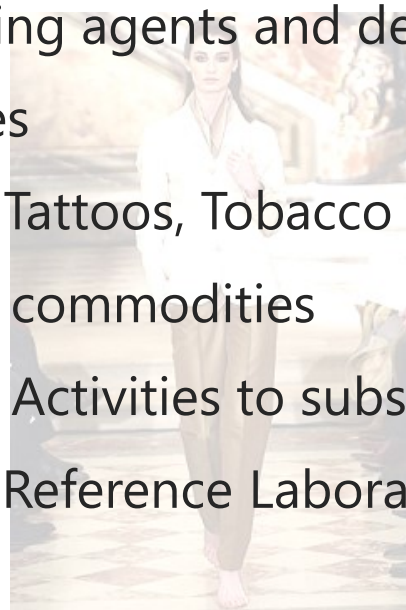
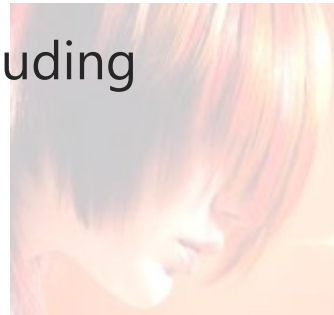
1) Assessment of Chemicals under REACH and CLP

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



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## 2. How are nanomaterials regulated in the field of fcm?

REGULATION (EC) No **1935/2004** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (of 27 October 2004)



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.



Nesic, et al., *molecules* **2020**, 25, 1

## 2.1 EU-Regulations

REGULATION (EC) No **1935/2004** OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL (of 27 October 2004)



### 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

REGULATION (EC) No **1935/2004** OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL (of 27 October 2004)



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

REGULATION (EC) No **10/2011** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (of 14 January 2011)



- 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

REGULATION (EC) No **1935/2004** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (of 27 October 2004)

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



### Database BfR Recommendations on Food Contact Materials Recommendations

Id	Recommendation	Recommendation(s) Announcement(s) Substance(s)
010	I. High Polymers Containing Plasticizers	  
020	II. Plasticizer-free polyvinyl chloride, plasticizer-free copolymers of vinyl chloride and mixtures of these polymers with other copolymers and chlorinated polyolefins containing mainly vinyl chloride in the total mixture	  
030	III. Polyethylene	  
050	V. Polystyrene Produced exclusively from the Polymerisation of Styrene	  
060	VI. Styrene Copolymers and Graft Polymers, and Mixtures of Polystyrene with other Polymers	  
070	VII. Polypropylene	  
090	IX. Colorants for Plastics and other Polymers Used in Commodities	  
100	X. Polyamides	  
110	XI. Polycarbonates and Mixtures of Polycarbonates with other Polymers or Copolymers	  
120	XII. Unsaturated Polyester Resins	  
140	XIV. Polymer Dispersions	  
150	XV. Silicones	  
160	XVI. Polyvinyl Ethers	  
170	XVII. Poly(terephthalic acid diol esters)	  
200	XX. Polyisobutylene, Isobutylene Copolymers and Mixtures of Polyisobutylene with other Polymers	  
210	XXI. Commodities based on Natural and Synthetic Rubber	  

**Recommendations**

**Substances**

**Substances:**

**CASNr:**

**Search in text:**


**Help**

**Information**

**Further Guidelines**

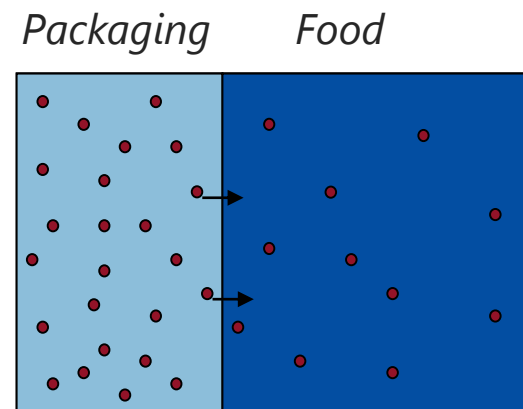
**Last amendment of the recommendations**

**Imprint**

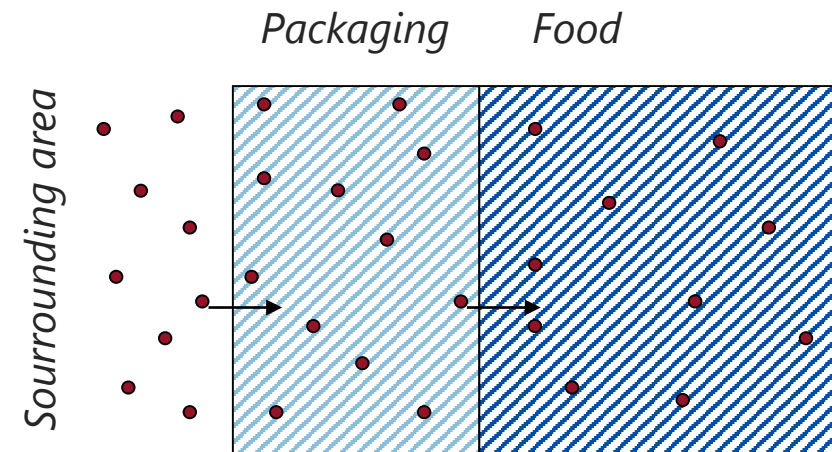
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### 3. Migration-ways of substances from fcm into the food

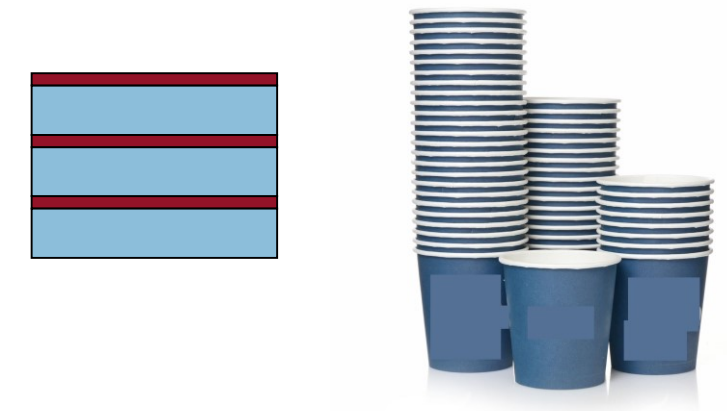
#### 1. Direct food contact (migration)



#### 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

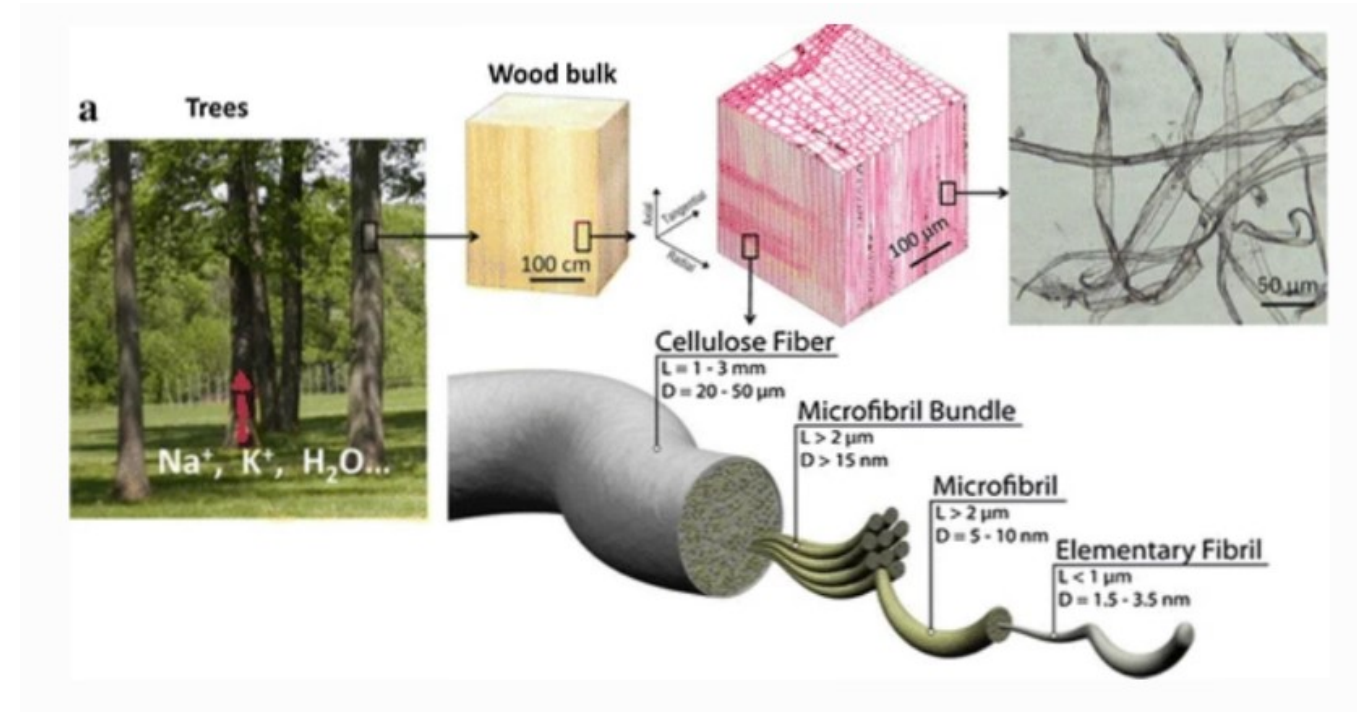
BfR-Comm.: “Unless otherwise indicated the listing is based on **the risk assessment of the substances in conventional particle size** and does not cover engineered nanoparticles.”

- 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
  - ...



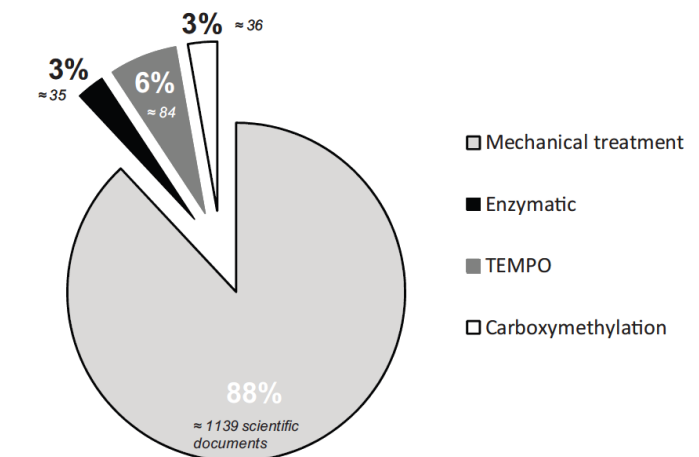
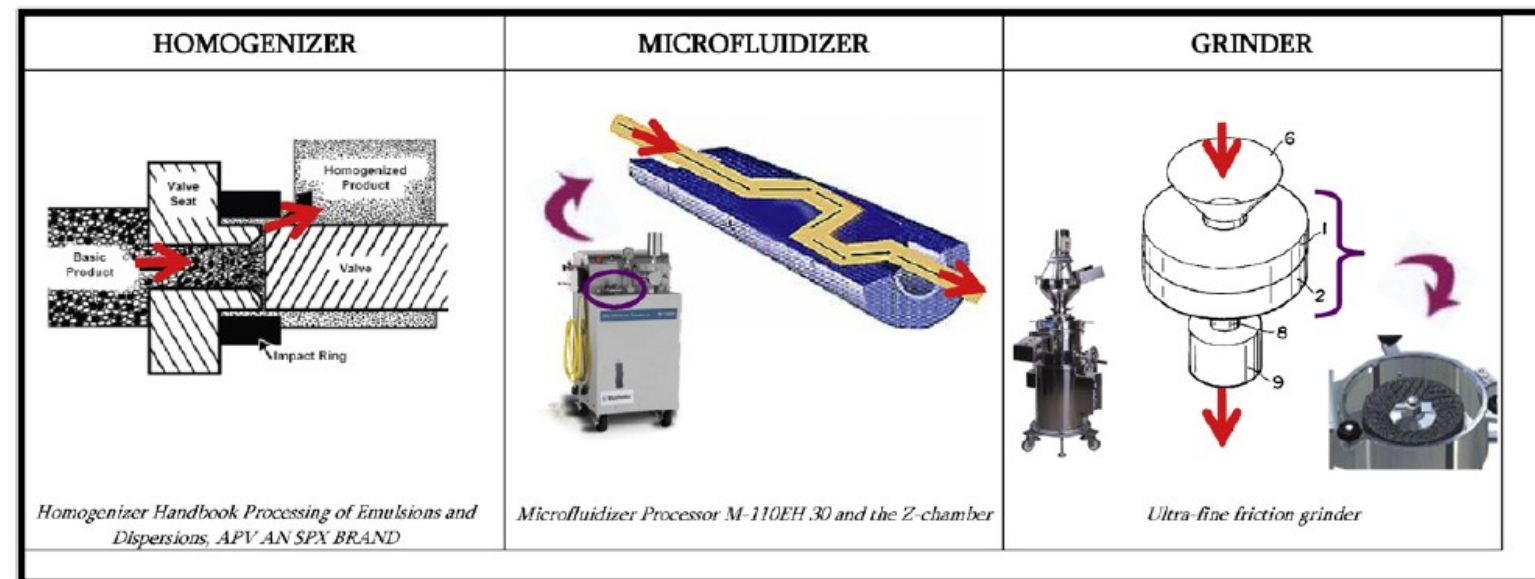
Zhu et. al., *Nano Lett.* **2013**, 7, 3093–3100

- 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,...)

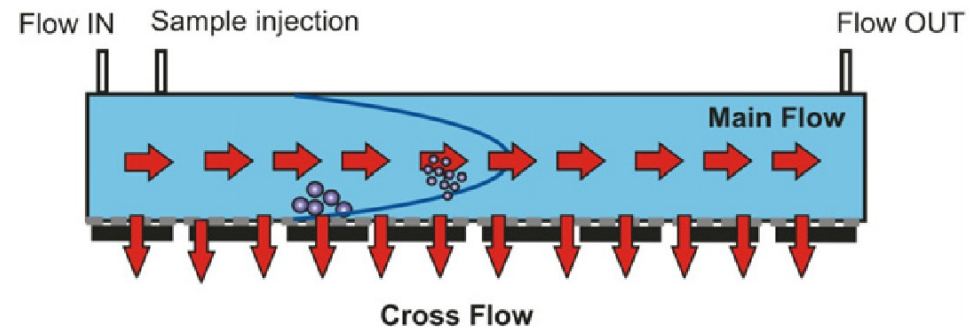


Picture: most applied mechanical processes and the most frequently applied pre-treatments used for MFC (Bras et. al., Carbohydr. Polym. 2012, 90, 735-764)

## 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)



picture: Principle of the AF4 (Dutz *et al Nanotechnology* 2012, 23,355701)

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

### Toxicological assessment difficult:

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



**Thank you for your attention**

Dr. Leonard John  
leonard.john@bfr.bund.de