FCM safety assessment at the German BfR

Stefan Merkel
BfR: Three locations in Berlin
Experimental toxicology

Food safety

Biological safety

Safety of consumer products

Healthy animals

Healthy food

Healthy people

Risk communication

Safety of substances and preparations

BfR: Fields of Competence

Stefan Merkel, 21 October 2020, Food Packaging Forum
Chemicals and Product Safety: Areas of Concern
of 27 October 2004
on materials and articles intended to come into contact with food
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.
2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.
**EU-Regulation 1935/2004**

**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 | 8. Metals and alloys |
| 5. Rubbers | 12. Regenerated cellulose |

Regulation (EU) No 10/2011

List of authorised substances for manufacture of plastic with **Specific Migration Limits**
Melamine-Formaldehyde Resin

„Melaware“

2,4,6-Triamino-1,3,5-triazine (Melamine) + Formaldehyde → Resin

„Bambooware“
Specific requirements on substances (*Article 9*)

Substances used in the manufacture of plastic layers in plastic materials and articles shall be subject to the following restrictions and specifications:

a) the *specific migration limit* set out in Article 11;
b) the overall migration ...;
c) the restrictions and specifications ...;
d) ...

<table>
<thead>
<tr>
<th>Substance</th>
<th>Specific migration limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>15 mg/kg food(-simulant)</td>
</tr>
<tr>
<td>Melamine</td>
<td>2.5 mg/kg food(-simulant)</td>
</tr>
</tbody>
</table>
Repeated Use: Comparison „Melaware“ vs. „Bambooware“

Melaware

Melamine

SML = 2.5 mg/kg
Melamine-Formaldehyde Resin: Microwave Heating

Migration during microwave heating

- Temperature
- Formaldehyde
- Melamine

SML melamine

minutes

[°C]
[mg/L]

microwave heating ➔ cooling

10 % 90 %
Melamine-Formaldehyde Resin

- BFR opinion on melamin-formaldehyde resin tableware
  - can be used to consume foodstuffs at room temperature
  - Material is degraded and damaged by contact with hot liquids
  - not for use in microwave ovens
  - not to consume hot meals or beverages from melamine-formaldehyde resin tableware
  - not suited for repeated usage in contact with hot liquid foodstuffs

**Article 5 – Specific measures for groups of materials and articles**

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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.
Germany: Paper and board

- National specific measures shall continue to apply. In Germany:

  **BfR-Recommendation XXXVI paper and board for food contact**

  → They are not legal norms
  → They are based on German and European law
  → They represent the current state of the scientific and technical knowledge
  → Access via the BfR website is free of charge
  (https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp?)
Current risk assessment – Paper and board
Bisphenol A

Bisphenol A
• Not listed in BfR Recommendations XXXVI for use in paper production
• Was used in thermal paper as reactant acid till end of 2019

• Recycled fibres can be used as raw material but
→ Finished article have to comply with the requirements of the
Annex to Recommendation XXXVI

Preconditions for the use of recycled fibres as raw materials for the production of paper

→ Max. value for migration of Bisphenol A into food is listed in the Annex

Stefan Merkel, 21 October 2020, Food Packaging Forum
Current risk assessment – Paper and board
Bisphenol A

2015: EFSA Scientific Opinion on Bisphenol A

→ Temporary Tolerable Daily Intake (t-TDI) of 4 µg/kg bw per day
→ For a 60 kg person that consumes 1 kg of food per day: 240 µg/kg food

2016: Annex to recommendation XXXVI for recycled fibres as raw material for paper

→ Migration value lowered from 600 µg/kg food to 240 µg/kg food
Current risk assessment – Paper and board

Bisphenol A


→ An allocation factor of 20% is used – the overall exposure does not exceed the t-TDI but there are sources other than FCM
→ Specific migration limit for Bisphenol A for plastic FCMs is lowered to 50 µg/kg food

2019*: Amendment of the Annex to recommendation XXXVI for recycled fibres as raw material for paper
→ Migration value will be lowered from 240 µg/kg food to 50 µg/kg food

*Bundesgesundheitsbl 2019 · 62:1546–1550
Thank you for your attention

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