GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT

Bundesinstitut für Risikobewertung

FCM safety assessment at the German BfR

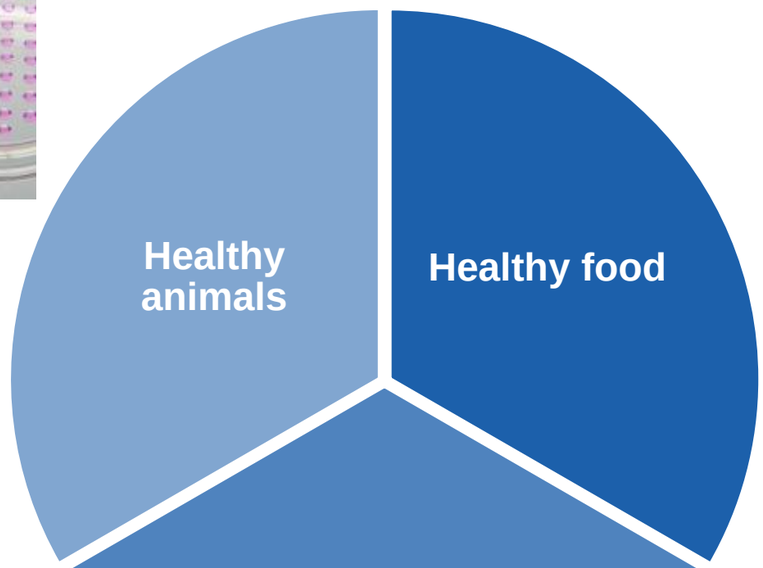
Stefan Merkel

BfR: Three locations in Berlin

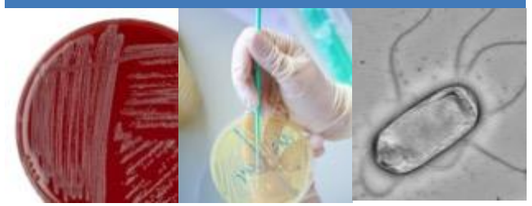
BfR: Fields of Competence

Food safety

Experimental toxicology



Biological safety



Safety of consumer products

Safety of substances and preparations

Risk communication

Chemicals and Product Safety: Areas of Concern

Regulation of Food Contact Materials
Europe

REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 October 2004

on materials and articles intended to come into contact with food

EU-Regulation 1935/2004

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.

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
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics → Regulation (EU) No 10/2011

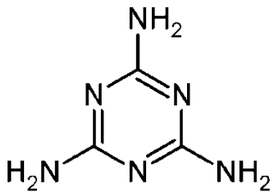
   List of authorised substances for manufacture of plastic with **S**pecific **M**igration **L**imits
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles

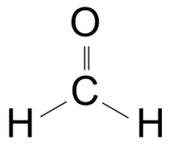
Melamine-Formaldehyde Resin

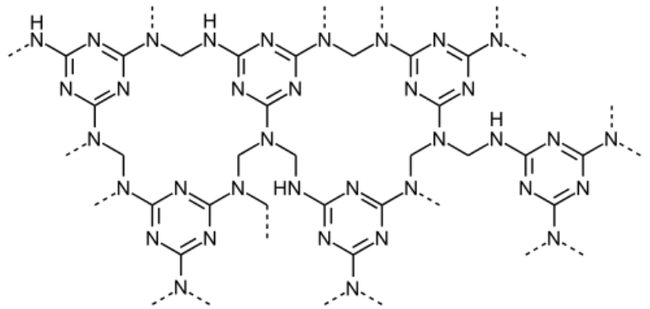
„Melaware“

„Bambooware“

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







Melamine-Formaldehyde Resin

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;

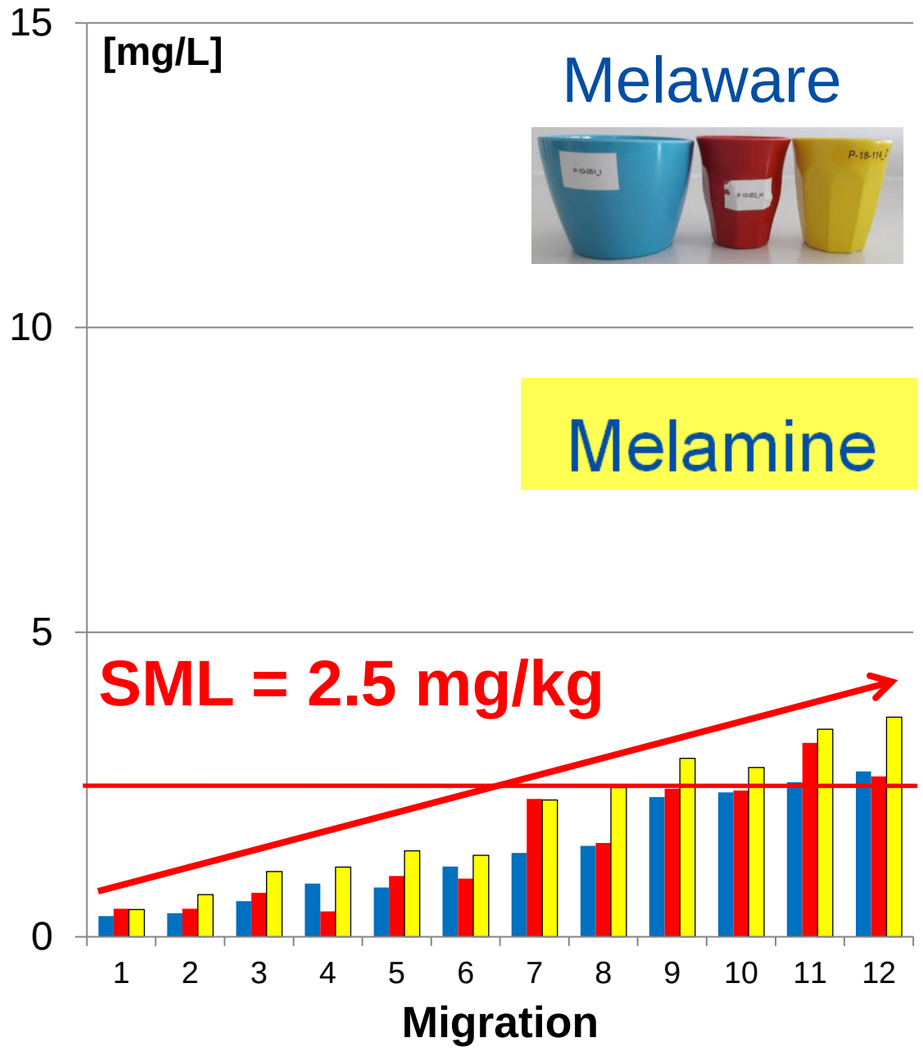
b) the overall migration ...;

c) the restrictions and specifications ...;

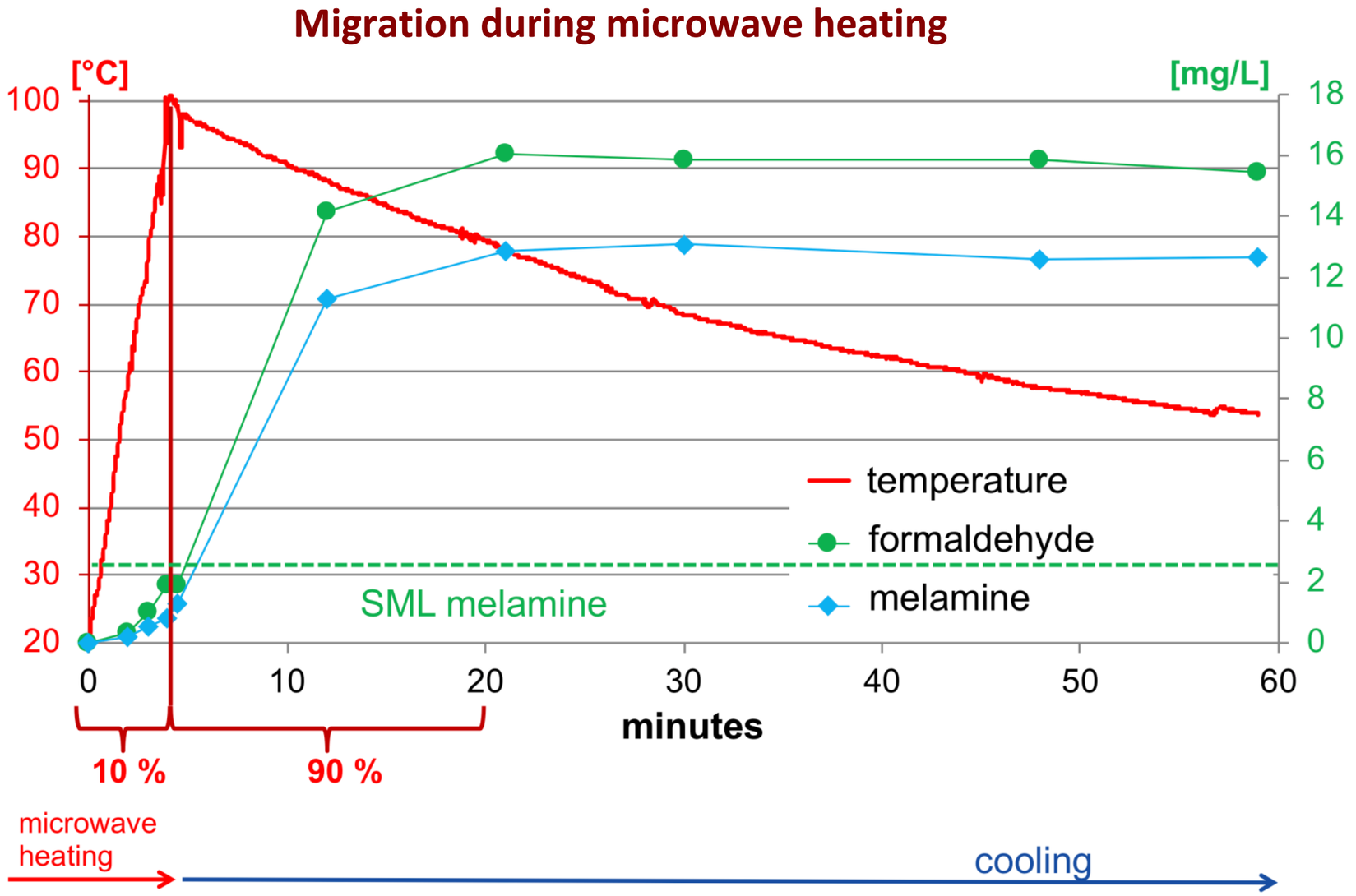
d) ...

	Specific migration limit
Formaldehyde	15 mg/kg food(-simulant)
Melamine	2.5 mg/kg food(-simulant)

Repeated Use: Comparison „Melaware“ vs. „Bambooware“



Melamine-Formaldehyde Resin: Microwave Heating



Melamine-Formaldehyde Resin

- BfR opinion on melamin-formaldehyde resin tableware

  → can be used to consume foodstuffs at room temperature

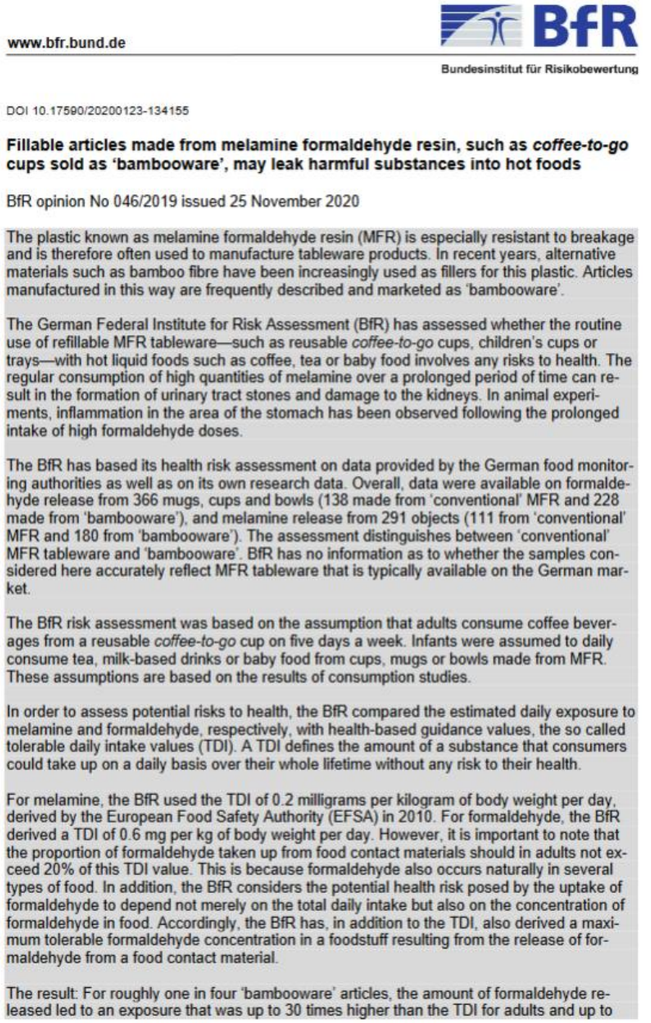
  Material is degraded and damaged by contact with hot liquids

  → 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

https://www.bfr.bund.de/cm/349/fillable-articles-made-from-melamine-formaldehyde-resin.pdf



www.bfr.bund.de

BfR
Bundesinstitut für Risikobewertung

DOI 10.17590/20200123-134155

Fillable articles made from melamine formaldehyde resin, such as *coffee-to-go* cups sold as 'bambooware', may leak harmful substances into hot foods

BfR opinion No 046/2019 issued 25 November 2020

The plastic known as melamine formaldehyde resin (MFR) is especially resistant to breakage and is therefore often used to manufacture tableware products. In recent years, alternative materials such as bamboo fibre have been increasingly used as fillers for this plastic. Articles manufactured in this way are frequently described and marketed as 'bambooware'.

The German Federal Institute for Risk Assessment (BfR) has assessed whether the routine use of refillable MFR tableware—such as reusable *coffee-to-go* cups, children's cups or trays—with hot liquid foods such as coffee, tea or baby food involves any risks to health. The regular consumption of high quantities of melamine over a prolonged period of time can result in the formation of urinary tract stones and damage to the kidneys. In animal experiments, inflammation in the area of the stomach has been observed following the prolonged intake of high formaldehyde doses.

The BfR has based its health risk assessment on data provided by the German food monitoring authorities as well as on its own research data. Overall, data were available on formaldehyde release from 366 mugs, cups and bowls (138 made from 'conventional' MFR and 228 made from 'bambooware'), and melamine release from 291 objects (111 from 'conventional' MFR and 180 from 'bambooware'). The assessment distinguishes between 'conventional' MFR tableware and 'bambooware'. BfR has no information as to whether the samples considered here accurately reflect MFR tableware that is typically available on the German market.

The BfR risk assessment was based on the assumption that adults consume coffee beverages from a reusable *coffee-to-go* cup on five days a week. Infants were assumed to daily consume tea, milk-based drinks or baby food from cups, mugs or bowls made from MFR. These assumptions are based on the results of consumption studies.

In order to assess potential risks to health, the BfR compared the estimated daily exposure to melamine and formaldehyde, respectively, with health-based guidance values, the so called tolerable daily intake values (TDI). A TDI defines the amount of a substance that consumers could take up on a daily basis over their whole lifetime without any risk to their health.

For melamine, the BfR used the TDI of 0.2 milligrams per kilogram of body weight per day, derived by the European Food Safety Authority (EFSA) in 2010. For formaldehyde, the BfR derived a TDI of 0.6 mg per kg of body weight per day. However, it is important to note that the proportion of formaldehyde taken up from food contact materials should in adults not exceed 20% of this TDI value. This is because formaldehyde also occurs naturally in several types of food. In addition, the BfR considers the potential health risk posed by the uptake of formaldehyde to depend not merely on the total daily intake but also on the concentration of formaldehyde in food. Accordingly, the BfR has, in addition to the TDI, also derived a maximum tolerable formaldehyde concentration in a foodstuff resulting from the release of formaldehyde from a food contact material.

The result: For roughly one in four 'bambooware' articles, the amount of formaldehyde released led to an exposure that was up to 30 times higher than the TDI for adults and up to

EU-Regulation 1935/2004

Article 5 – Specific measures for groups of materials and articles

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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

EU-Regulation 1935/2004

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.

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

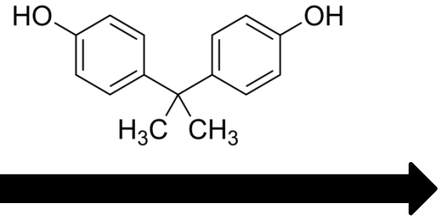
→ They represent the current state of the scientific and technical knowledge

→ 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



recyled fibres / recyled paper

Federal Institute for Risk Assessment BfR

A. Raw materials[5]

The following raw materials may be used:

I. Fibrous materials:

1. Natural and synthetic cellulose fibres, bleached or unbleached.
2. Fibres of synthetic high polymers, provided they comply with the prevailing requirements of food law.
3. Wood pulp, bleached or unbleached.
4. Recycled fibres made from paper or paperboard provided that the finished articles comply with the requirements in the annex of this Recommendation.

- Recycled fibres can be used as raw material but

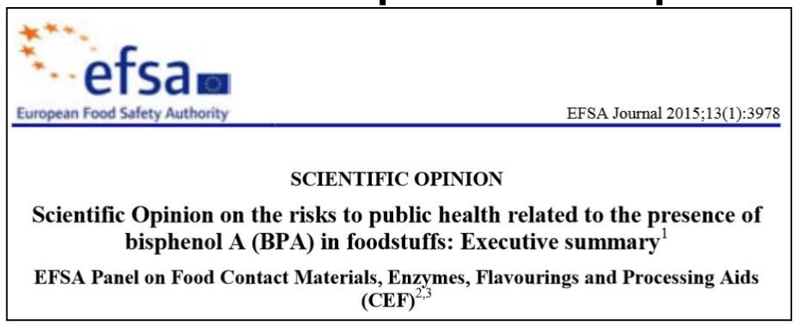
→ Finished article have to comply with the requirements of the Annex to Recommendation XXXVI

<u>Preconditions for the use of recycled fibres as raw materials for the production of paper</u>

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

Current risk assessment – Paper and board
Bisphenol A

2015: EFSA Scientific Opinion on Bisphenol A



efsa
European Food Safety Authority
EFSA Journal 2015;13(1):3978

SCIENTIFIC OPINION

Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: Executive summary[1]

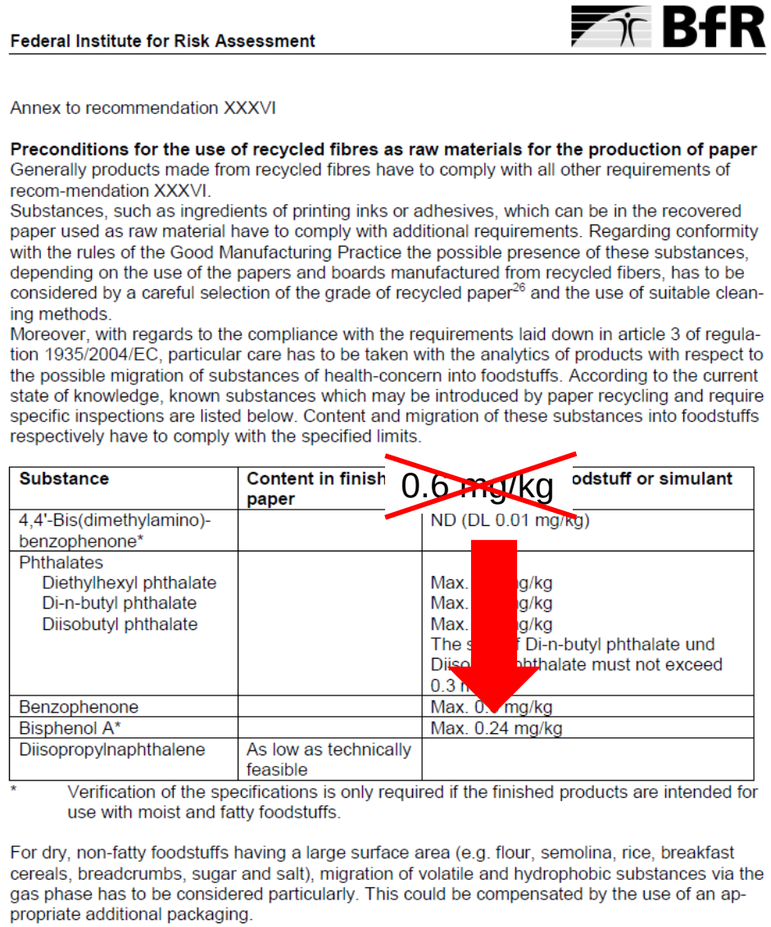
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)[2,3]

→ 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



Federal Institute for Risk Assessment

BfR

Annex to recommendation XXXVI

Preconditions for the use of recycled fibres as raw materials for the production of paper
Generally products made from recycled fibres have to comply with all other requirements of recom-mendation XXXVI.
Substances, such as ingredients of printing inks or adhesives, which can be in the recovered paper used as raw material have to comply with additional requirements. Regarding conformity with the rules of the Good Manufacturing Practice the possible presence of these substances, depending on the use of the papers and boards manufactured from recycled fibers, has to be considered by a careful selection of the grade of recycled paper[26] and the use of suitable clean-ing methods.
Moreover, with regards to the compliance with the requirements laid down in article 3 of regula-tion 1935/2004/EC, particular care has to be taken with the analytics of products with respect to the possible migration of substances of health-concern into foodstuffs. According to the current state of knowledge, known substances which may be introduced by paper recycling and require specific inspections are listed below. Content and migration of these substances into foodstuffs respectively have to comply with the specified limits.

Substance	Content in finish paper	odstuff or simulant
4,4'-Bis(dimethylamino)-benzophenone*		ND (DL 0.01 mg/kg)
Phthalates Diethylhexyl phthalate Di-n-butyl phthalate Diisobutyl phthalate		Max. g/kg Max. g/kg Max. g/kg The s f Di-n-butyl phthalate und Diiso phthalate must not exceed 0.3 m
Benzophenone		Max. 0. mg/kg
Bisphenol A*		Max. 0.24 mg/kg
Diisopropylnaphthalene	As low as technically feasible	

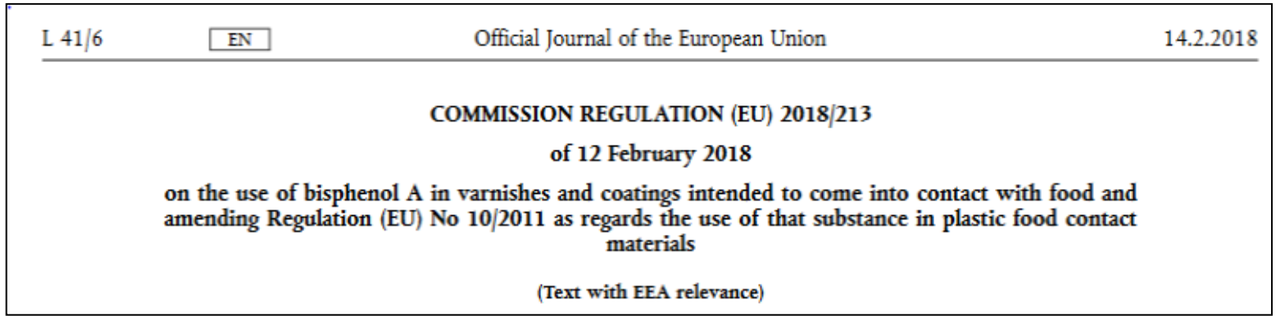
0.6 mg/kg

* Verification of the specifications is only required if the finished products are intended for use with moist and fatty foodstuffs.

For dry, non-fatty foodstuffs having a large surface area (e.g. flour, semolina, rice, breakfast cereals, breadcrumbs, sugar and salt), migration of volatile and hydrophobic substances via the gas phase has to be considered particularly. This could be compensated by the use of an ap-propriate additional packaging.

Current risk assessment – Paper and board
Bisphenol A

2018: Amendment of Regulation (EU) No 10/2011 for Plastic Food Contact Materials



L 41/6 EN Official Journal of the European Union 14.2.2018

COMMISSION REGULATION (EU) 2018/213

of 12 February 2018

on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials

(Text with EEA relevance)

→ 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

Federal Institute for Risk Assessment BfR

Annex to recommendation XXXVI

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Generally products made from recycled fibres have to comply with all other requirements of recom-mendation XXXVI.
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Substance	Content in finished paper	Migration into foodstuff[28]
4,4'-Bis(dimethylamino)-benzophenone*		ND (DL 0.01 mg/kg)
Phthalates Diethylhexyl phthalate Di-n-butyl phthalate Diisobutyl phthalate		Max. g/kg Max. g/kg Max. g/kg The s Di-n-butyl phthalate und Diiso hthalate must not exceed 0.3 m
Benzophenone		Max. 0. mg/kg
Bisphenol A*		Max. 0.05 mg/kg
Diisopropylnaphthalene	As low as technically feasible	

* Verification of the specifications is only required if the finished products are intended for use with moist and fatty foodstuffs.

For dry, non-fatty foodstuffs having a large surface area (e.g. flour, semolina, rice, breakfast cereals, breadcrumbs, sugar and salt), migration of volatile and hydrophobic substances via the gas phase has to be considered particularly. This could be compensated by the use of an ap-propriate additional packaging.

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Thank you for your attention

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