GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT

Bundesinstitut für Risikobewertung

BfR activities on printing inks and paper and board

Stefan Merkel

Germany

- Resolution of the Council of Europe with its adopted parts exists in parallel with national law.
- BfR-Recommendation XXXVI paper and board for food contact.

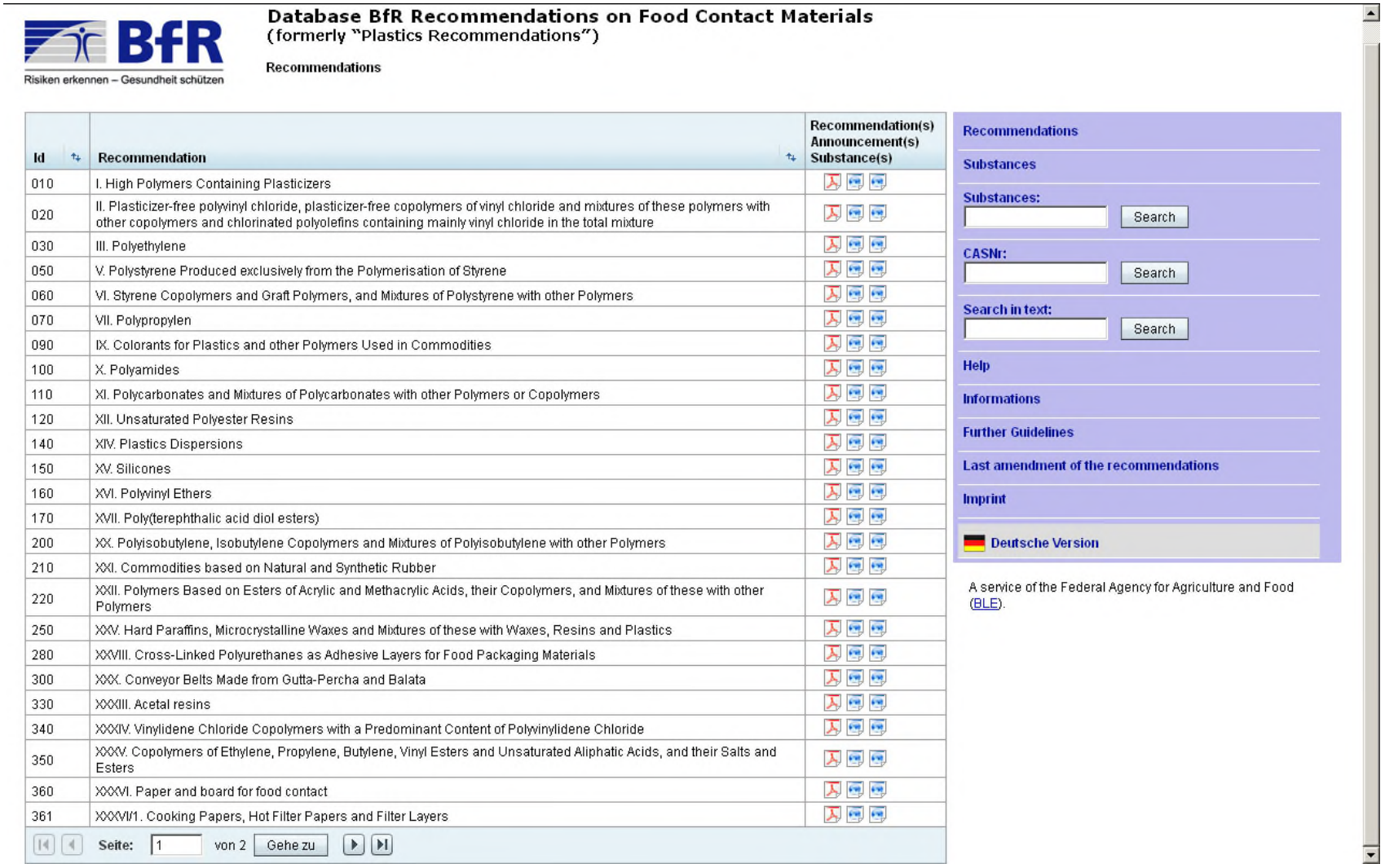
  Issued by BfR since 1958 (“Plastic Recommendations”)

  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
  (http://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp)



Risiken erkennen – Gesundheit schützen

Database BfR Recommendations on Food Contact Materials
(formerly "Plastics Recommendations")

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. Polypropylen	
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. Plastics 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	
220	XXII. Polymers Based on Esters of Acrylic and Methacrylic Acids, their Copolymers, and Mixtures of these with other Polymers	
250	XXV. Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics	
280	XXVIII. Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials	
300	XXX. Conveyor Belts Made from Gutta-Percha and Balata	
330	XXXIII. Acetal resins	
340	XXXIV. Vinylidene Chloride Copolymers with a Predominant Content of Polyvinylidene Chloride	
350	XXXV. Copolymers of Ethylene, Propylene, Butylene, Vinyl Esters and Unsaturated Aliphatic Acids, and their Salts and Esters	
360	XXXVI. Paper and board for food contact	
361	XXXVI/1. Cooking Papers, Hot Filter Papers and Filter Layers	

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Recommendations
Substances
Substances: Search
CASNr: Search
Search in text: Search
Help
Informations
Further Guidelines
Last amendment of the recommendations
Imprint
Deutsche Version

A service of the Federal Agency for Agriculture and Food (BLE).

BfR-Recommendations XXXVI

These Recommendations apply to

- Raw materials, production aids, and special paper refining agents used in the production process for paper, paperboard and board that comes into contact with foodstuffs
- Preservatives that are used to prevent microbial spoilage of formulations and slimicides

These Recommendations do not apply to

- Substances are used to keep manufacturing devices clean and to protect them from corrosion
- Substances that are used for manufacturing of paper raw materials or substances that are used for formulation of active ingredients (e.g. emulsifiers, solvents, set-up chemicals, stabilizer, pH modifiers)

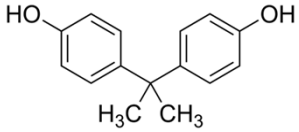
For these substances the manufacturer or distributor of the paper is responsible to comply to food regulations (especially Regulation (EU) No. 1935/2004).

Recent changes

Current risk assessment – Paper and board
Bisphenol A

Bisphenol A

- Not listed in BfR Recommendations XXXVI for use in paper production
- Used in thermal paper as reactant acid



recyled fibres / recyled paper

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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

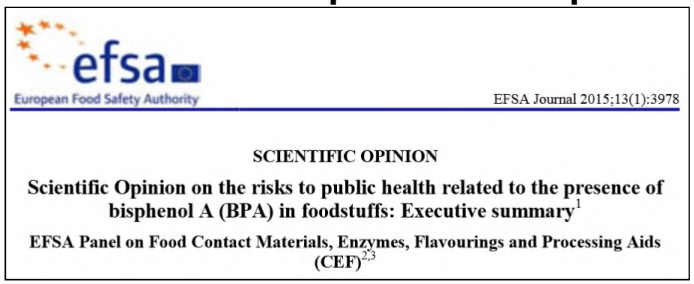
→ Finished article have to comply with the requirements of the Annex to recommendation XXXVI

<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]

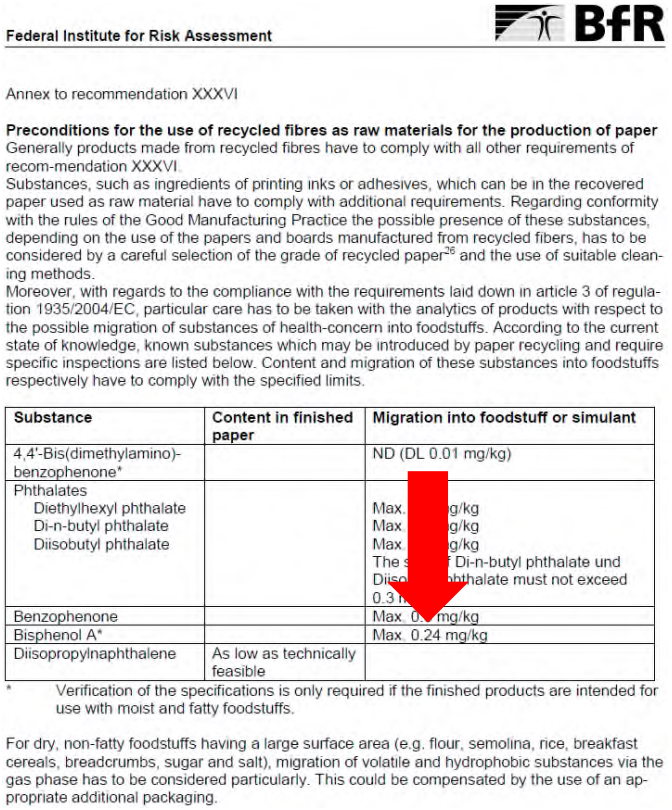
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)[2,3]

→ 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.

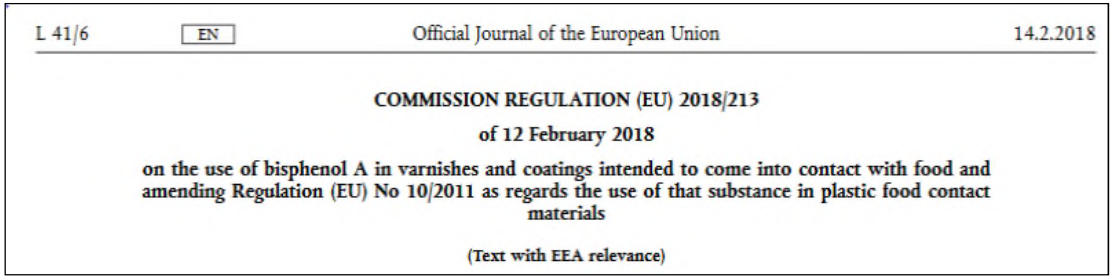
Substance	Content in finished paper	Migration into foodstuff or simulant
4,4'-Bis(dimethylamino)-benzophenone*		ND (DL 0.01 mg/kg)
Phthalates Diethylhexyl phthalate Di-n-butyl phthalate Diisobutyl phthalate		Max. [illegible] g/kg Max. [illegible] g/kg Max. [illegible] g/kg The s[illegible] Di-n-butyl phthalate und Diiso[illegible]phthalate must not exceed 0.3 [illegible]
Benzophenone		Max. 0.[illegible] mg/kg
Bisphenol A*		Max. 0.24 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.

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

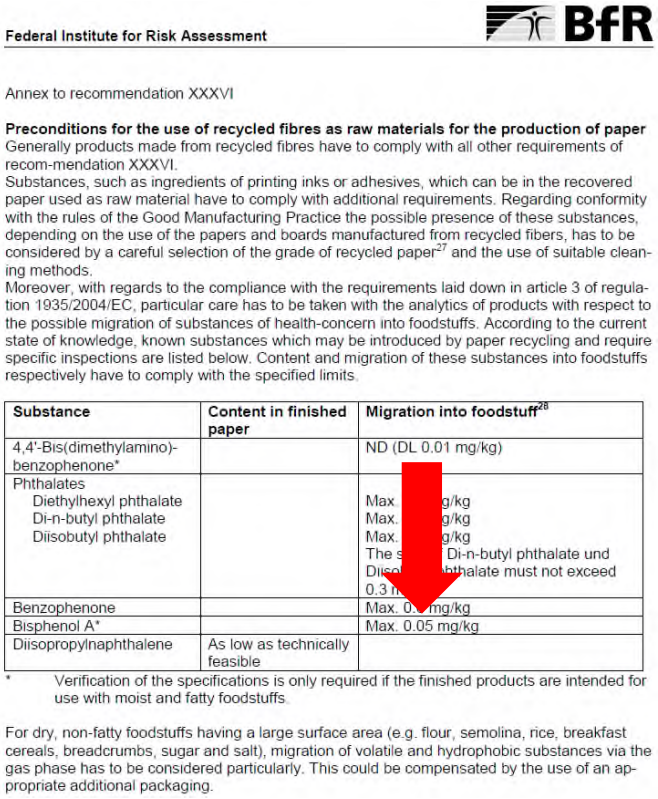
(Text with EEA relevance)

→ 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



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Annex to recommendation XXXVI

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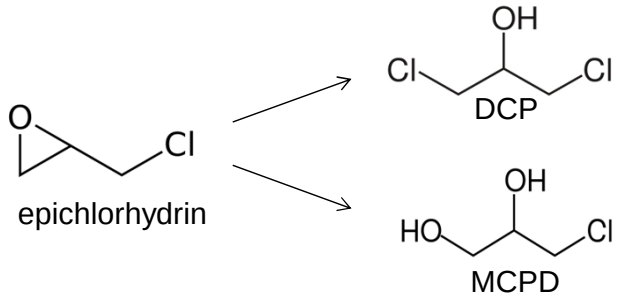
Substance	Content in finished paper	Migration into foodstuff[28]
4,4'-Bis(dimethylamino)-benzophenone*		ND (DL 0.01 mg/kg)
Phthalates Diethylhexyl phthalate Di-n-butyl phthalate Diisobutyl phthalate		Max. [illegible] g/kg Max. [illegible] g/kg Max. [illegible] g/kg The s[illegible] Di-n-butyl phthalate und Diiso[illegible]phthalate must not exceed 0.3 [illegible]
Benzophenone		Max. 0.[illegible] 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.

*Will be published in the journal „Bundesgesundheitsblatt“ in December 2019

Current risk assessment – Paper and board
Chloropropanols



Limit for chloropropanols in Recommendations XXXVI and XXXVI/2

- For substances produced with epichlorhydrin such as sizing agents, retention agents, wet-strength agents

- Footnote:

"1,3-Dichloro-2-propanol [DCP] must not be detectable in **cold water extract** / **hot water extract** from the finished product

Recommendation XXXVI

Recommendation XXXVI/2

(detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol [MCPD] into the hot water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case."

Cold water extract: EN 645 (24 hours, room temperature)

Hot water extract: EN 647 (2 hours, 80°C)

Current risk assessment – Paper and board
Chloropropanols

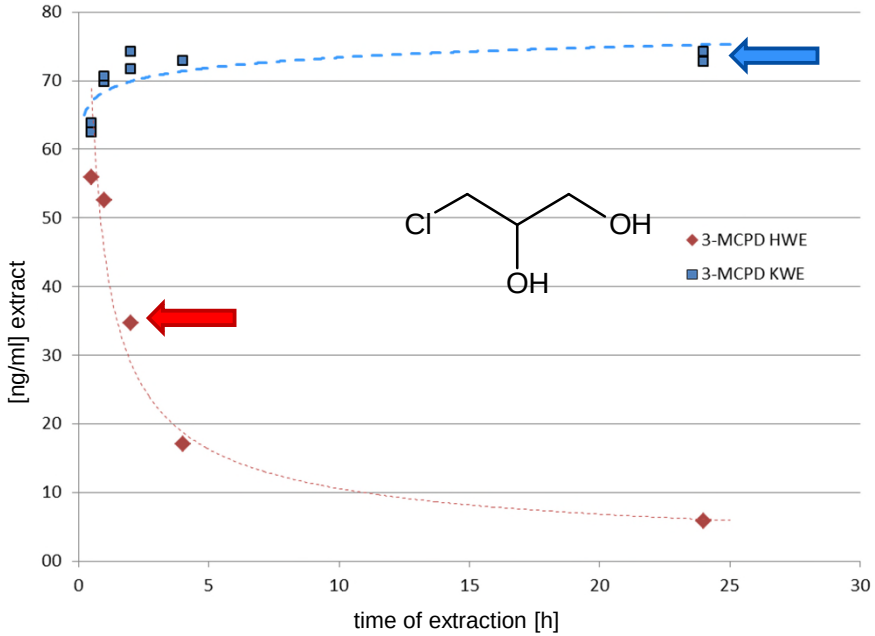
Extracts 3-MCPD	CWE [µg/l]	HWE [µg/l]
LOD (with matrix)	0.4	
Cup cake wrapper 1	67.0	50.5
Cup cake wrapper 2	11.4	11.5
Baking paper 1	9.4	11.5
Baking paper 2	<LOD	<LOD
Drinking straws 1	73.4	34.7
Drinking straws 2	23.8	8.7
Cake paper 1	18.5	6.4
Cake paper 2	5.6	1.9
Poultry cuffs	12.1	4.5

Results in HWE lower than in CWE

Current risk assessment – Paper and board
Chloropropanols

Kinetics for 3-MCPD

→ Comparison hot and cold water extract for 24 hours



Sample: drinking straw

- HWE: exponential decrease
- KWE: plateau
- Extraktion according to EN 645 and EN 647 for 3-MCDP at different points of the kinetic!
- Worst case?

→ Amendment of preamble in Recommendation XXXVI/2 in 2019*:

“The limit values for 1,3-dichloro-2-propanol and 3-monochloro-1,2-propanediol need to be determined in the cold water extracts of paper products despite intended use.”

*Will be published in the journal „Bundesgesundheitsblatt“ in December 2019

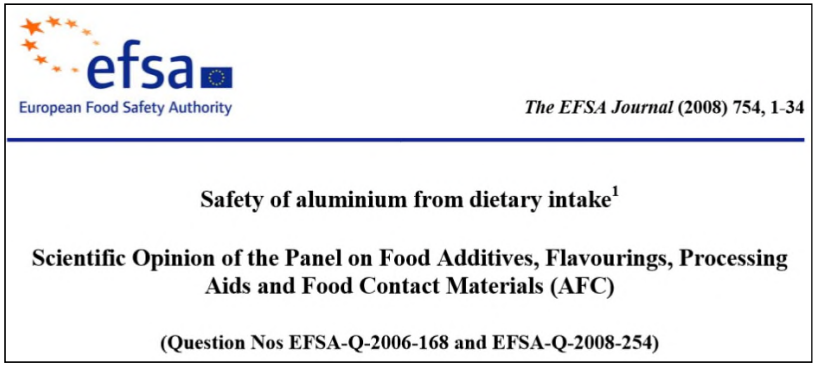
Current risk assessment – Paper and board
Aluminium

Aluminium is used for paper production and listed in BfR-Recommendations XXXVI as:

- Fillers,
- Precipitating, fixing and parchmentisation agents,
- Surface refining and coating agents
- Auxiliary agents
- Neutralising and precipitating agents
- Fibres based on aluminium oxide
- Surface refining agents for the food-contact surface

2008: EFSA Scientific Opinion on AluminiumBisphenol A

→ Tolerable Weekly Intake (TWI) of 1 mg/kg bw per day


efsa
European Food Safety Authority

The EFSA Journal (2008) 754, 1-34

Safety of aluminium from dietary intake[1]

Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC)

(Question Nos EFSA-Q-2006-168 and EFSA-Q-2008-254)

Current risk assessment – Paper and board
Aluminium

2016: Amendment of Regulation (EU) No. 10/2011 for Plastic Food Contact Materials:

8,6 mg/kg food. The opinion however notes that the current dietary exposure of a significant part of the Union's population likely exceeds this level. Therefore, it is appropriate to limit the contribution from exposure by food contact materials to the overall exposure by applying an allocation factor of 10 % to the conventionally derived migration limit. Therefore, a migration limit for aluminium of 1 mg/kg food is considered appropriate for food contact materials.

[Calculation: TWI 1 mg/kg bw per week → for a 60 kg person: 60 mg/person per week
→ 8,6 mg/person per day → 10% allocation and consumption of 1 kg food per day: ~1 mg/kg food]

Discussion in Expert Panel for Paper and Board in BfR started in 2015

Is a migration value of 1 mg/kg food technically possible for paper?

→ Measurement of paper sample from the market in 2017 via German Monitoring Program
52 samples for cold water extract, 112 samples for hot water extract

Current risk assessment – Paper and board
Aluminium

→ Measurement of paper samples from the German market in 2017 via German Monitoring Programm
52 samples for cold water extract, 112 samples for hot water extract

Monitoring Results: 81% (cold water extract) and 83% (hot water extract) of the samples from the market showed lower results than 1 mg/L

2019: Amendment* of BfR Paper Recommendations:

"No more than 10 µg/l lead, 5 µg/l cadmium and 1000 µg/l aluminium must be detectable in the cold water extract of the finished product.[3]"

[3]Testing is not necessary for paper and paperboard intended for contact with dry and at the same time non-fatty foodstuffs (e.g. flour, semolina, rice, breakfast cereals, breadcrumbs, sugar and salt).

*Will be published in the journal „Bundesgesundheitsblatt" in December 2019

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Thank you for your attention

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