German Federal Institute for Risk Assessment

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XXXVI/1. Cooking Papers, Hot Filter Papers and Filter Layers[1]

As of 01.08.2024

Preamble

This Recommendation applies to overall raw materials (section I), overall production aids (section II), and special raw materials and production aids (section III) used in the production process for paper, paperboard and board that comes into contact with foodstuffs. Moreover, in the paper production process substances are used to keep manufacturing devices clean and to protect them from corrosion. This Recommendation shall not apply for these substances. The manufacturer or distributor of the paper is responsible to comply to food regulations (especially Regulation (EU) No. 1935/2004) for these substances[2]. However, substances listed in this Recommendation subject to the above stated applications were listed before 2013.
Substances that are used for manufacturing of paper raw materials listed in section I or substances that are used for formulation of active ingredients listed in section II and III (e.g. emulsifiers, solvents, set-up chemicals, stabilizer, pH modifiers) are not subject to this BfR-Recommendation. For their application requirements of article 3 of the Regulation (EU) No. 1935/2004 shall be used[2]. However, substances listed in this Recommendation subject to the above stated applications were listed before 2013. Preservatives that are used to prevent microbial spoilage of formulations and slimicides are still covered by this Recommendation.
No more than 10 µg/l lead and 5 µg/l cadmium must be detectable in the hot water extract of the finished product.
The migration of aluminium into foodstuffs must not exceed 1 mg/kg.[3,4] Compliance with this requirement can be checked in the hot water extract.[5]
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.
There are no objections to the use of papers for the purpose of hot extraction (e.g. boil-in-bag packagages, tea bags, hot filter papers) or the use of filter layers whose intended purpose involves them being subjected to extraction (filtration), as commodities in the sense of § 2, Para. 6, No 1 of the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch), provided they are suitable for their intended purpose and comply with the following conditions:

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[1] This Recommendation only applies to paper that comes into contact with aqueous foodstuffs.

[2] For guidance on compliance of the manufacturer's responsibility the following guidelines and assessments of substances may be used exemplarily: other Recommendations of the BfR, assessments of the European Food Safety Authority or the Scientific Committee on Food (SCF), Regulation (EU) No. 10/2011, European rules on food additives and drinking water. Moreover, an assessment can be made by the manufacturer on his own responsibility.

[3] Testing is not necessary for paper and paperboard intended for contact with exclusively fatty foodstuffs, such as butter or vegetable fats, as well as for foodstuffs which, according to Table 2 of Regulation (EU) No 10/2011, are to be tested exclusively with food simulant E.

[4] If the actual use is not known, migration into food shall be tested with a surface area to packed food ratio of 13.3 dm^2/kg food under the worst foreseeable conditions of use regarding type and duration of contact, contact temperature and food.

[5] For additional information on the determination of aluminium in water extract, see: Method collection paper and paperboard (https://www.bfr.bund.de/de/methodensammlung_papier__karton_und_pappe-32620.html).

I. Overall raw materials[6]

A. Fibrous materials:

1. Natural and synthetic fibres based on wood pulp[7] and cellulose derivates, unbleached or bleached
2. Synthetic fibres made of
   a) plasticizer-free copolymer of vinyl chloride and vinyl acetate
   b) Polyethylene
   c) Polypropylene
   d) Polyester
   provided they comply with the prevailing requirements of food law.[8, 9]
3. Cellulosic fibres, phosphorylated, carbamidated[10]

B. Auxiliary agents

1. Silicon dioxide
2. Silicates or mixed silicates of aluminium, calcium, magnesium and sodium, including kaolin and talcum (free from asbestos fibres)
3. Calcium sulfate
4. Titanium dioxide
5. Calcium and magnesium carbonate
6. Aluminium oxide
7. Aluminium chloride hydroxide

The substances listed above must comply with the purity requirements stipulated under No 3 of Recommendation LII. "Fillers".

8. Activated carbon[11]
9. Tetrasodium iminodisuccinate, max. 0.17 %, based on the dry fibres weight.

II. Overall production aids[6]

A. Slimicides:

a) Enzymatic agents
   Fructose polysaccharide (levan)-hydrolase, 12.5 mg dry substance per kg paper. No more than one unit of levanase activity per gram paper must be detectable.

b) Antimicrobially active substances
   1. Chlorine dioxide
   2. Hydrogen peroxide
   3. Alkali-stabilised solution of hypobromite, max. 0.07 %, based on the dry fibres weight.
      The sodium hypobromite content of the solution is max. 10 % and the sodium sulfa-mate content is max. 12 %.

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[6] Raw materials and production aids that are suitable for all applications of this Recommendation.

[7] Compare DIN 6730 "Paper and board - Vocabulary ".

[8] If other auxiliary agents, for example for fibre preparation, are necessary, they must be submitted for approval.

[9] Going beyond the requirements laid down in Recommendation III, in the manufacture of polyethylene, polyvinyl alcohol may also be used as a protective colloid. Viscosity of 4 % aqueous solution of the polyvinyl alcohol at 20 °C, min. 5 mPa·s.

[10] These fibres have ion exchanging properties. Substances added to foodstuffs by their use are subjected to the requirements of the food additives law.

[11] Purity requirements for E 153 established by Regulation (EU) No. 231/2012.

4. Active bromine generated from hydrogen bromide, sodium hypochlorite and urea, max. 0.02 % (active substance determined as chlorine), based on the dry fibers weight.
5. Performic acid, max. 0.064 %, based on the dry fibres weight

The following substances must not be detectable in the hot water extract of the finished articles[12]:

6. 1,2-Benzisothiazolin-3-one (detection limit of analysis method 10 µg/dm²)
7. Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in the ratio of 3:1, max. 4 mg/kg (detection limit of analysis method 0.5 µg/dm² for the sum of the mentioned isothiazolinones)
8. Ammonium bromide/sodium hypochlorite adduct, max. 0.02 % (active substance determined as chlorine), based on the dry fibre.
9. 2-Bromo-2-nitropropane-1,3-diol, max. 0.003 %, based on the dry fibres weight.
10. 2-Methyl-4-isothiazolin-3-one (detection limit of analysis method 1µg/dm²)
11. Peroxyacetic acid, max. 0.1 %, based on dry fibres weight
12. Sodium hypochlorite, max. 0.028 %, based on dry fibres weight

B. Paper-refining agents

1. Polyacrylamide, provided it contains no more than 0.1 % monomeric acrylamide, max. 0.015 %
2. Copolymer of acrylamide and (2-(methacryloyloxy)ethyl)trimethylammonium chloride, max. 0.1 %, provided it contains no more than 0.1 % residual acrylamide and no more than 0.5 % residual (2-(methacryloyloxy)ethyl)trimethylammonium chloride
3. Copolymer of acrylamide and (2-(acryloyloxy)ethyl)trimethylammonium chloride, max. 0.1 %, provided it contains no more than 0.1 % residual acrylamide and no more than 0.5 % residual (2-(acryloyloxy)ethyl)trimethylammonium chloride
4. Cross-linked, cationic polyalkylene amines[13], i.e.
   a) Polyamine-epichlorohydrin resin, produced from epichlorohydrin and diaminopropyl methylamine
   b) Polyamide-epichlorohydrin resin, produced from epichlorohydrin and adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine
   c) Polyamide-epichlorohydrin resin, produced from adipic acid, diethylenetriamine and epichlorohydrin or from a mixture of epichlorohydrin and ammonia
   d) Polyamide-polyamine-epichlorohydrin resin, produced from epichlorohydrin, adipic acid, dimethyl ester and diethylenetriamine
   e) Polyamide-epichlorohydrin resin, produced from epichlorohydrin, diethylenetriamine, adipic acid and ethyleneimine[14], max. 0.3 %
   f) Polyamide-epichlorohydrin resin, produced from adipic acid, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine, max. 0.1 %[15]
   g) Polyamide-epichlorohydrin resin, produced from diethylenetriamine, adipic acid, glutaric acid, succinic acid and epichlorohydrin, max. 4.0 %

[12] Methods for testing commodities (materials and articles) made of paper or paperboard are available under http://www.bfr.bund.de/de/methodensammlung_papier__karton_und_pappe-32620.html.

[13] 1,3-Dichloro-2-propanol must not be detectable in aqueous extract from the finished product (detection limit: 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the 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.

[14] Ethyleneimine must not be detectable in the resin (detection limit: 0.1 mg/kg).

[15] Dimethylamine must not be detectable in the aqueous extract (detection limit: 0.002 mg/dm²).

h) Polyamide-epichlorohydrin resin, produced from diethylenetriamine, triethylenetetramine, adipic acid and epichlorohydrin, max. 4.0 %
i) Polyamide-epichlorohydrin resin, produced from adipic acid, diethylenetriamine, aminoethylpiperazine and epichlorohydrin, max. 1.0 %. In the resin the proportion of aminoethylpiperazine in relation to adipic acid must not exceed 10 mol%.

Of the wet-strength agents named above (II B 4a) to i)), in total max. 4 %, based on dry fibre in the finished product, may be used.

5. Copolymer of vinyl formamide and vinyl amine, max. 1.0 %
6. Polyethyleneimine, modified with ethylene glycol and epichlorohydrin, max. 0.2 %[13]
7. Polyhexamethylene-1,6-diisocyanate, modified with ethylene glycol monomethyl ether, max. 1.2 %
8. Polyhexamethylene-1,6-diisocyanate, modified with ethylene glycol monomethyl ether and N,N-dimethylaminoethanol, max. 1.2 %
9. Galactomannan, max. 0.5 %
10. Copolymer of styrene, butylacrylate and methylmethacrylate, max. 5.0 %
11. Copolymer of acrylamide and acrylic acid, cross-linked with N-methylene-bis(acrylamide), max. 1.0 %
12. Melamine-formaldehyde resin, max. 3 %
    No more than 1 mg formaldehyde/dm² must be detectable in extract from finished product.
13. Polyethyleneimine, max. 0.05 %[14]
14. Copolymer of acrylamide, (2-(methacryloyloxy)ethyl)trimethylammonium chloride, N,N'-methylene-bis-acrylamide and itaconic acid, max. 1.0 %, based on the dry fibre.
15. Copolymer of acryamide, (2-(methacryloyloxy)ethyl)trimethylammonium chloride, N,N'-methylene-bis-acrylamide, itaconic acid and glyoxal, max. 1.0 %, based on the dry fibre.
16. Copolymer of hexamethylenediamine and epichlorohydrin, max. 2.0 %[13, 14]
17. Copolymer of diethylenetriamine, adipic acid, 2-aminoethanol and epichlorohydrin[13], max. 0.1 %, based on the dry fibres weight
18. Copolymer of vinylformamide and acrylic acid, max. 1 %, based on the dry fibres weight
19. Copolymer of vinylformamide, vinylamine and acrylic acid, max. 1 %, based on the dry fibres weight
20. Galactomannane phosphoric acid ester, max. 0.25 % based on dry fibres weight
21. Sodium salt of carboxymethyl cellulose, cross-linked, produced from 3 parts carboxymethyl cellulose sodium salt, 2 parts citric acid and 1 part sodium dihydrogen phosphate, max. 3 %[16].
22. Copolymer of acrylamide and diallylamine, max. 1.0 % based on the dry fibres weight
23. Starch[13], treated with 3-chloro-2-hydroxypropyl trimethyl ammonium chloride or glycidyl trimethyl ammonium chloride (specification of starch: nitrogen, max. 4.0 %).
24. Copolymer of styrene, n-butylacrylate and acrylic acid, max. 6.1 %, based on dry fibre.

C. Preservatives

Sorbic acid
2,2'-dithiobis[N-methylbenzamide][17].
2-methyl-1,2-benzothiazol-3(2H)-one[17], max. 15 µg/dm².

[16] As far as the mentioned substances comply with the purity requirements of Regulation (EU) No. 1333/2008 and meet the following purity requirements: Arsenic, max. 3 mg/kg; lead, max. 10 mg/kg; zinc, max. 25 mg/kg; copper and zinc combined, max. 50 mg/kg.

[17] The sum of 2,2'-dithiobis[N-methylbenzamide] and its hydrolysis products 2-methyl-1,2-benzothiazol-3(2H)-one and 2-mercapto-N-methylbenzamide must not exceed 30 µg/dm², determined in dimethyl sulfoxide extract of the finished product.

2-bromo-2-nitropropane-1,3-diol, max. 0.003 %, based on dry fibres weight. This substance must not be detectable in the hot water extract of the finished product.
The listed preservatives must only be used in amounts necessary to protect the raw materials and processing aids listed under I, II and III from deterioration and decay.

D. Dewatering accelerators

Lignosulfonic acid
Water-glass, stabilised with 0.42 % sodium tetraborate, based on the formulation.
Cellulase[18]

E. Dispersing agents

Calcium stearate, max. 0.4 %
1-Amino-2-propanol. The substance may not contain more than 10 % of 2-amino-1-propanol. The transfer into foodstuff may in sum not exceed 5 mg/kg.

F. Defoamers

a) 2,4,7,9-tetramethyl-5-decyne-4,7-diol
b) 3,6-dimethyl-4-octyne-3,6-diol
c) 2,5,8,11-tetramethyl-6-dodecyne-5,8-diol
The transfer of these three substances (a-c) from the final product (in)to foodstuff may not exceed 0.05 mg/kg foodstuff (sum of the three substances).
N,N'-ethylene-bis-stearamide
Linear primary alkan-1-oles/alken-1-oles with 8-26 carbon-units (fatty alcohols), also in emulsified form[19]
Distillation residue from the alcohol production of linear long-chain alcohols

a) according to the Ziegler process by oligomerisation of ethene and subsequent oxidation. The product consists of linear alcohols C_{18}-C_{30} (70-85%, thereof C_{20} 30-45%, C_{22} 21-39%, C_{24} 4-12%, C_{26} 1-7%), branched alcohols C_{18}-C_{30} (3-12%), paraffins C_{20}-C_{32} (0.7-2.5%), esters C_{20}-C_{40} (4-9%) and ethers C_{22}-C_{40} (1-6%) (synonym: ethene, homopolymer, oxidized, hydrolyzed, distillation residues, from C16-18 alcohols manuf.). The distillation residue must not contain more than 0.1% steranes of plant origin (e.g. stigmastane),
b) according to the Ziegler process by oligomerisation of ethene and subsequent oxidation. The product consists of linear alcohols C_{18}-C_{30} (50-70%, thereof C_{20} 25-35%, C_{22} 10-20%, C_{24} 4-12%, C_{26} 1-7%), branched alcohols C_{18}-C_{30} (12-20%), paraffins C_{20}-C_{32} (1-4%), esters C_{20}-C_{40} (6-12%) and ethers C_{22}-C_{40} (0.5-4%) (synonym: ethene, homopolymer, oxidized, hydrolyzed, distillation residues, from C16-18 alcohols manuf.),
c) based on natural fatty acids. The product consists of linear alcohols C_{16}-C_{26} (10-60%), esters C_{24}-C_{46} (30-80%), ethers C_{24}-C_{46} (1-10%), paraffins C_{16}-C_{40} (0-2%), aldehydes C_{16}-C_{26} (0-3%) and steranes of plant origin (e.g. stigmastane, 0-5%) (synonyms: alcohols, C16-18, distn. residues and alcohols, C18-22, distn. residues). The product may only be used in a mixture with distillation residues from the alcohol production of linear long-chain alcohols according to the Ziegler process [substances a) and b)] up to a maximum of 20% of the corresponding products.

[18] There must be no detectable residual activity of this enzyme in the finished product.
[19] Max. 2 % paraffin and max. 2 % alkyl and alkyaryloxethylates and their esters with sulfuric acid (as emulsifiers) may be added to 20-25 % aqueous solution of this antifoam agent. The liquid paraffins must comply with the "Purity requirements for liquid paraffins" in the 155th Communication of Bundesgesundheitsblatt 25 (1982) 192)

The sum of substances a) - c) shall not exceed 0.0225%, based on the dry fibres weight. The transfer into foodstuff must not exceed 5 mg/kg.

Requirements for the finished products

The cooking and hot-filter papers and filter pads must cause no inhibition zone[20]. Only colourants which are listed in this recommendation must be used.

III. Special raw materials and production aids

A. for cook-in-bag packages

1. Parchmentisation agents
   Sulfuric acid
2. Neutralising and precipitating agents
   a) Ammonia
   b) Sodium carbonate
   c) Sodium hydrogen carbonate
   d) Aluminium sulfate
   e) Sodium aluminate
3. Binding agents
   Dispersion of vinylidene chloride/acrylic acid methyl ester copolymer, provided it complies with amended Recommendation XIV. "Plastics Dispersions", Part A, max. 15.0 %

B. For tea bags

Surface refining and coating agents

1. Sodium salt of carboxymethyl cellulose, purity at least 98 %[16]
2. Methyl cellulose[16]
3. Hydroxyethyl cellulose[16]
4. Xanthane[16]
5. Sodium di-(2-ethylhexyl) sulfosuccinate, max. 0.04 %, based on the dry fibres weight
6. Polyamide-epichlorohydrin resin, produced from adipic acid, diethylenetriamine, aminoethylpiperazine and epichlorohydrin[13], max. 1.5 %. In the resin the proportion of aminoethylpiperazine in relation to adipic acid must not exceed 10 mol%.

C. For hot filter papers and filter layers[21] for hot filtration

1. Special fibres
   inorganic fibres based on aluminium oxide
2. Precipitating agents
   a) Aluminium sulfate
   b) Sodium aluminate

Special requirements for III A - III C:

[20] Determination of transfer of antimicrobial constituents after DIN EN 1104
[21] "Filter layers" refers to products with a thickness of 500 g/m² or more.

The total dry residue of the extract with hot water[12] must not exceed 10 mg/dm² resp. 10 mg/g for filter layers with a maximum total nitrogen content (determined after Kjeldahl) of 0.1 mg/dm² resp. 0.1 mg N/g for filter layers[22].

D. Filter layers[21] for cold filtration

1. Special fibres
   a) Fibres based on aluminium oxide
   b) Carbon fibres
   c) Fibres, produced from simple or mixed silicates (e.g. glass fibres)
   d) Polyoxymethylene fibres according to Recommendation XXXIII
2. Precipitating agents
   a) Aluminium sulfate
   b) Sodium aluminate
3. Binding and wet-strength agents
   a) Polyethylene dispersion according to Recommendation XIV, max. 4.0 %
   b) Neutral resins based on abietic acid (colophony)/maleic acid/fumaric acid according to Recommendation XXXVI, max. 4.0 %
   c) Polyethyleneimine, max. 0.5 %[14]
   d) Anionic polyacrylamide according to Recommendation XXXVI, max. 0.3 %

   Of the binding and wet-strength agents listed under D. 3., in total, max. 4.0 %, based on dry fibre in the finished product, may be used.
4. Special aids
   Polyvinyl polypyrrolidone

Special requirements for III D:

Total dry residue of the cold water extract[12] must not exceed 5 mg/g filter layer, with inorganic components of max. 3 mg/g. Total nitrogen content of the extract (determined after Kjeldahl) must not exceed 3 mg/g filter layer. Formaldehyde must not exceed 0.3 mg/g.

[22] Determination of total nitrogen should not be conducted immediately following paper production, but only after about 8 days or after the paper has been placed on the market. Since wet strengthening with cationic polyalkylene amines is only complete after 8 days, it is possible that extract from paper tested within this period will have a total nitrogen content greater than 0.1 mg/dm².