

European Committee for Food Contact Materials and Articles (Partial Agreement) (CD-P-MCA)

- 1 **TECHNICAL GUIDE ON PAPER AND BOARD MATERIALS AND ARTICLES FOR**
- 2 **FOOD CONTACT**
- 3 *Draft*

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34 1. Scope and Definitions

35 1.1 Scope

36 This Technical Guide supplements Resolution CM/Res (2020) X and lays down additional requirements
37 for materials and articles, under its scope, made from paper and board. The provisions of this guideline
38 are without prejudice to the specific requirements for active and intelligent materials and articles under
39 the scope of Regulation (EC) No 450/2009.

40 The scope includes materials and articles for all types of food contact applications (e.g. plates, cups,
41 baking and filter papers, food packaging, kitchen towels, napkins, etc.). Paper and board materials and
42 articles addressed in this Technical Guide are made predominantly from cellulose-based fresh and/or
43 recycled fibres. They may also contain additives, synthetic fibres, adsorbents, treatment agents,
44 colorants, and may be coated, glued, printed, or be composed of several layers.

45 Additional requirements for other materials, such as adhesives, printing inks or plastics are not subject
46 of this Technical Guide. However, the migration limits set in this Technical Guide for some well-known
47 constituents or contaminants also apply to the final article.

48 In a multi-layer or coated material or article, each layer made of paper or board must comply with the
49 requirements laid down in this Technical Guide, unless a functional barrier reduces migration into food
50 during the time of contact below the applicable threshold of toxicological concern and provided there is
51 no set-off when the paper or board is stacked or reeled.

52 1.2 Definitions

53 **Functional adsorbents:** additives introduced into the paper or board that adsorb migrants, reduce
54 migration and ensure that the final material or article in use complies with Article 3 of Regulation (EC)
55 No 1935/2004, Resolution CM/Res (2020) X and with the requirements of this Technical Guide.

56 **Functional barrier:** a barrier to migrants consisting of one or more layers of any type of material that
57 ensures that the final material or article in use complies with Article 3 of Regulation (EC) No 1935/2004,
58 Resolution CM/Res (2020) X and with the requirements of this Technical Guide.

59 **Recycled paper or board:** Materials containing recycled cellulose-based fibres.
60 Cellulose-based fibres obtained from production off-cuts and/or process scraps, which have not been
61 used, printed, coated etc., and which were produced from fresh fibres only and in accordance with this
62 Guideline, are not considered recycled fibres.

63 2. Requirements

64 2.1 General requirements

65 The general requirements of Resolution CM/Res (2020) X (Appendix, Section 3) apply to substances
66 used in the manufacture of paper and board materials and articles for food contact.

67 In case of packaging applications the whole system (direct or indirect contact) has to be assessed, i.e. all
68 paper and board that can reasonably be expected to transfer constituents to food under normal or
69 foreseeable conditions of use.

70 Relevant national regulations and official recommendations applicable to food contact materials and
71 articles made from paper and board are stated in this Technical Guide in ANNEX I. Additionally, paper
72 and board materials and articles for food contact applications must meet the following criteria in their
73 final state:

74 2.1.1 The specific migration limits for the substances listed in Table 1 of ANNEX II apply. Tests
75 may be omitted for non-printed, non-coated paper and board made from fresh only fibres,
76 with the exception of testing for lead.

77 2.1.2 The intensity of any taste or odour imparted from the food contact material or article to the
78 food has to be less than 3 according to the testing method mentioned in chapter 3.6.

79 2.1.3 Paper and board must be of suitable microbiological purity. Criteria have to be set taking
80 into account the intended use and the specific hygiene requirements in order to comply with
81 Regulation (EG) No. 852/2004.

82 2.1.4 Paper and board in contact with hydrophilic or lipophilic food must not release fluorescent
83 whiteners or dye using the methods mentioned in chapter 3.5. A score of 5 is required.

84 2.1.5 As a criterion for inertness, overall gas phase migration does not exceed 10 mg/dm² into
85 food simulant E (modified polyphenylene oxide) according to ÖNORM A 1123 (see Annex
86 III: Standardised Methods).

87 **2.2 Specific requirements for the use of recycled paper and board**

88 Recycled cellulose fibres may be used provided that the paper and board is manufactured in accordance
89 with good manufacturing practices in compliance with the general requirements of 2.1. Risks in recycled
90 paper and board may originate from several substances present in recycled fibres from:

- 91 - non-food grade paper and board;
- 92 - printed materials, adhesives or coatings of the input paper or board that is being recycled;
- 93 - the recycling process (e.g. technical aids or additives used in the process);
- 94 - the previous use of the input paper and board that is being recycled (e.g. residuals, etc.);
- 95 - the degradation products and impurities of the chemicals introduced at the various steps.

96 To demonstrate compliance with the requirements of this Technical Guide, it has to be ensured that the
97 migration of all constituents and all possible impurities is below the limits applicable to them. When
98 using recycled cellulose fibres, precautionary considerations and measures are needed to fulfil the
99 general requirements of 2.1.

100 The use of input materials of suitable quality and the application of a cleaning process are necessary.
101 Relevant quality criteria have to be always specified and checked. Additional measures such as the use
102 of functional barriers (on the paper or board or as an internal bag) or functional adsorbents (added to the
103 recycled material to retain substances in the paper or board) might be needed.

104 The measures implemented, relevant quality criteria and applicable restrictions in use of the finished
105 paper or board material or article have to be described in the Declaration of Compliance and have to be
106 supported by data for their effectiveness in the compliance documentation.

107 Functional barriers and functional adsorbents

108 The ability of the barrier or adsorbent to keep the migration of all constituents and all potential impurities
109 below the applicable limits has to be documented in the compliance documentation. All foreseeable
110 conditions of the intended use have to be taken into account.

111 Some barrier materials are known to either completely block migration, e.g. aluminium foils of sufficient
112 thickness and quality, or to reduce it to negligible levels even for a long time, e.g. low diffusivity plastics
113 or multilayers with low permeability. Supporting data have to be provided in the compliance
114 documentation in such cases.

115 **3. Compliance Testing**

116 Results of specific migration determined in food prevail over results obtained by other methods.

117 **3.1 Determination of specific migration into food**

118 Analytical methods for the quantification of migrants in food have to be chosen in accordance with
119 Article 34 of Regulation (EU) 2017/625 and their performance criteria as listed in ANNEX III of the
120 Regulation have to be fit for purpose. Compliance with the applicable limits must be verified as
121 prescribed in the Resolution CM/Res (2020) X (Appendix, Section 9).

122 **Conditions of testing**

123 The worst reasonably foreseeable conditions of contact of the test specimen (paper or board material or
124 article) with food are chosen for testing.

125 In the case of testing packaging material, the food shall be stored during testing as indicated on the food
126 packaging label or under adequate conditions if no instructions are given. Migration must not exceed
127 the specified limits at least up to the end of the shelf life of the product. At the end of the shelf life, the
128 food shall be removed from contact with the material or article.

129 If the food is to be cooked or otherwise prepared in the package, it shall be treated in accordance with
130 the instructions on the package. Parts of the food that are not intended to be eaten shall be removed and
131 the remainder homogenised.

132 **3.2 Screening and simulated migration tests for paper and board not yet in contact**
133 **with food**

134 The commonly used approaches for testing compliance include:

- 135 • Non-targeted screening analysis for the detection and identification of potential migrants has
136 to be performed for materials and articles made from recycled paper and board but also to
137 identify additives and NIAS in fresh paper and board. Such tests, generally based on extraction
138 are reported in the literature (e.g. [23-27]). Bioassays, e.g. on cytotoxicity according to EN
139 15845, may provide additional information for the hazard identification/assessment of
140 migrants.
- 141 • Worst case migration calculated from the amount of substance added to or determined in the
142 paper or board, assuming complete transfer to food. If restrictions are not exceeded, no further
143 testing is necessary. Physico-chemical considerations, such as solubility and volatility of

- 144 potential migrants and validated mathematical modelling [16], may refine this approach, but
145 are not developed to the extent as for plastics.
- 146 • Cold water extraction according to EN 645 to estimate the potential release of water-soluble
147 or hydrophilic substances into hydrophilic food (e.g. PAA, formaldehyde or chloropropanols).
148 It is proposed for contact at ambient or lower temperature.
 - 149 • Hot water extraction according to EN 647 to estimate the release of water-soluble or
150 hydrophilic substances into hydrophilic food at temperatures above room temperature (e.g. for
151 tea and coffee filter papers or technical filters).
 - 152 • Simulating migration with 3% acetic acid to estimate the release of metals into acidic (pH < 4.5)
153 foods. Selection of contact time and temperature according to the JRC Guidelines on testing
154 conditions for articles on contact with foodstuffs. [1].
 - 155 • Extraction with isooctane and/or 95% ethanol according to EN 15519 to estimate potential
156 migration of fat-soluble and hydrophobic substances (e.g. phthalates, benzophenones, DIPN,
157 PAH, mineral oils, bisphenol A) into lipophilic food.
 - 158 • Simulating migration tests as described for plastics in Regulation (EU) No 10/2011, for paper
159 and board with a plastic layer in food contact (e.g. cups, plates, bottles, board with a barrier
160 layer).
 - 161 • Migration tests using modified polyphenylene oxide (MPPO) as adsorbent, (EN 14338,
162 ÖNORM A 1123) for the migration of volatile or semi-volatile substances into food [28]. Paper
163 and board materials or articles for baking applications are tested with MPPO for 2 hours at
164 220°C; those for microwave oven use for 30 minutes at 150 °C [29].

165 Annex III lists standardised methods for compliance testing.

166 For the calculation of the migration into food, the real ratio of food contact surface to amount of food
167 must be used. If the intended use of paper and board is unknown, the result of EN 645 and EN 647 must
168 be directly compared with the SML. This corresponds to a ratio of 13.3 dm²/kg food if the weight of
169 paper or board is assumed to be 300 g/m² [18].

170 3.3 Testing of barrier and adsorbent effectiveness

171 The required barrier or adsorbent properties depend on the quality of the recycled material or article and
172 the demands of the application. For example, barriers or adsorbents that keep the migration of substances
173 below 1% of their content in the board up to the end of the shelf life of the product [9, 10] ensure that,
174 for all substances falling under CM/Res (2020) X Appendix, Section 3.1 C, migration is below the
175 acceptable detection limit [0.01 mg/kg], based on the following assumptions:

- 176 - the packaging-to-food mass ratio is equal or less than 1:10
- 177 - the concentration of any such substance is less than 10 mg/kg material (measured e.g. by
178 GC/FID of the extract).

179 Analogous considerations can be made based on the applicable assumptions.

180 3.3.1 Experimental testing with surrogate substances

181 The effectiveness of functional barriers or adsorbents can be determined either using target substance(s)
 182 or surrogate substances representing potential migrants, such as *n*-heptadecane, 4-methyl benzophenone
 183 and dipropyl phthalate [9, 10]. For the targeted determination of functional barrier effectiveness, various
 184 permeation tests with a broader range of model substances have been developed [11-13]. Methods have
 185 to be adequately supported and validated.

186 *Testing of functional barrier effectiveness of internal bags*

187 For the determination of the functional barrier effectiveness of internal bags used in boxes of recycled
 188 paperboard, recycled paperboard spiked with surrogate substances (donor) can be placed on one side of
 189 the barrier layer and a receptor simulating food, such as silicone paper, on the other [10]. Periodically a
 190 sample of the receptor is analysed for the permeated surrogate substances. Data from an interlaboratory
 191 comparison using this approach were published [19].

192 Since packaged foods may have shelf lives of up to several years, tests must allow extrapolation to long
 193 periods. They may be accelerated by increased temperature, but care is required not to reduce the barrier
 194 effectiveness through physical changes of the barrier material.

195 *Testing of effectiveness of functional barriers placed onto the paperboard and functional adsorbents*

196 For testing the effectiveness of a functional barrier that is already placed on paper or board, a similar
 197 method may be applied. A donor paper or board spiked with exactly known quantities of the surrogate
 198 substances can be used if direct spiking of the test specimen is experimentally challenging. Then their
 199 migration into the receptor (e.g. silicone paper) can be determined as described above.

200 Alternatively, permeation tests can be carried out by establishing at the donor (non-food contact) side
 201 appropriate concentrations of surrogates in the gas phase and collecting permeated substances on the
 202 receptor (food-contact) side in a trap for quantitative analysis of permeated surrogate substances [11-
 203 13] and subsequent data evaluation as mentioned below in 3.3.2.

204 For functional barrier layers placed onto the paperboard it has to be taken into account that migration
 205 into the functional barrier starts already at the production of the material or article, which may be long
 206 before the food contact application.

207 An approach using surrogate substances is described in [21] for testing functional adsorbents. The
 208 surrogate substances may serve for the determination of migration as well as for testing the sorption
 209 capacity by dosing varied amounts.

210 Caution must be paid to the fact that functional adsorbents, such as activated carbon, adsorb substances
 211 from the food itself and from other sources and may thus become saturated and lose their effectiveness.
 212 They must therefore show sufficient capacity not only for the sorption of substances in the paperboard,
 213 but also for those released from all other sources. Sorption starts already at the production of the material
 214 or article, which may be long before the food contact application.

215 *Testing for set-off*

216 Set-off, i.e. transfer from the non-food contact side of the paper or board to the barrier on the food
 217 contact side during storage in stacks or reels, may be simulated by bringing the food contact surface into
 218 contact with a donor and measuring the transferred surrogate substances [20].

219 *Testing migration from the flaps of closures*

220 If barriers are applied to the paper or board, migration from flaps of closures reaching into the internal
221 room of the box may be relevant, depending on the type of closure. It can be determined with real packs
222 made of paperboard spiked with surrogates and filled with a food representative for the intended use.

223 3.3.2 Modelling

224 The permeability of a barrier polymer by chemicals is typically characterised by the lag time (i.e. the
225 time of the breakthrough of the chemical) and the permeation rate (i.e. the mass of permeated chemical
226 per area and time). Both can be determined analogously to 3.3.1. [11,12,14,15]. Then the performance
227 of the functional barrier can be calculated for any food contact conditions, barrier thicknesses and food-
228 package contact time. Only validated mathematical modelling may be applied.

229 **3.4 Antimicrobial activity**

230 In case of applications involving hydrophilic or lipophilic food, antimicrobial substances in paper and
231 board shall be tested according to EN 1104. No inhibition zones shall be observable.

232 **3.5 Release of colourants or fluorescent whiteners**

233 In case of applications involving hydrophilic or lipophilic food, the release of colourants or fluorescent
234 whiteners shall be determined in accordance with EN 646 and EN 648.

235 **3.6 Sensory/organoleptic testing**

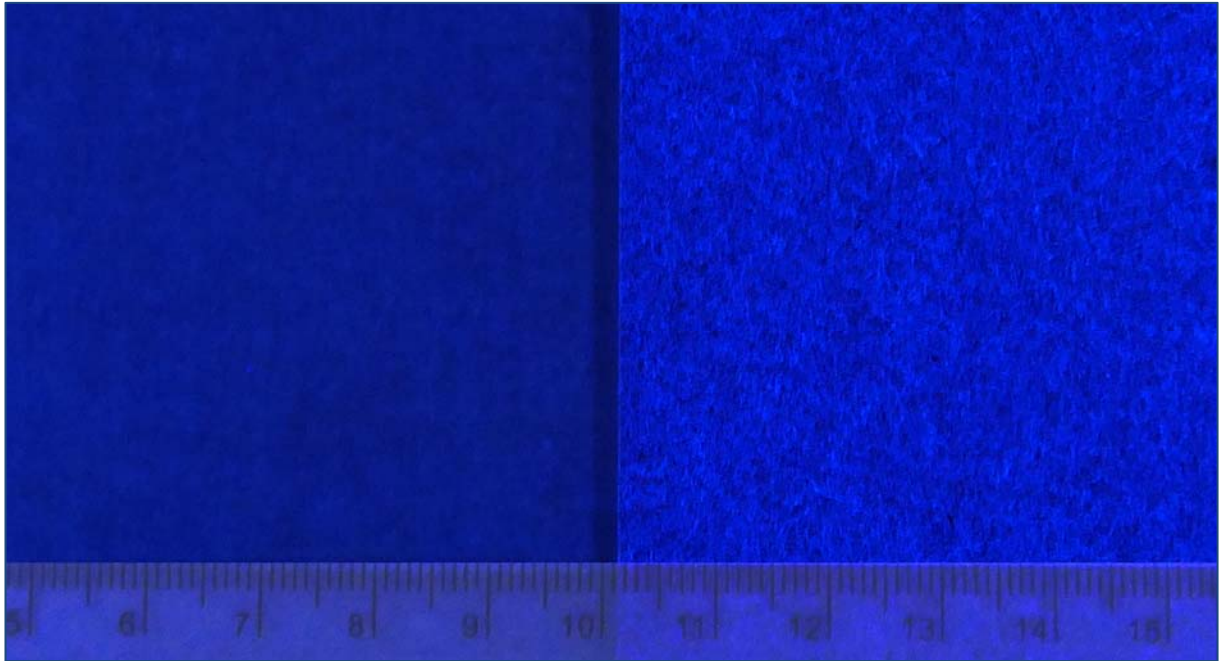
236 Methods for testing potential sensorial effects of paper and board on foods are described by EN 1230-1
237 and EN 1230-2.

238 **4. Detection of Recycled Fibres**

239 For the reliable determination of recycled material in paper or board, more than one of the following
240 methods may be needed. As the top layer of recycled paperboard may consist of fresh fibre or highly
241 purified material, the structure may need to be opened.

242 **4.1 Identification by UV illumination**

243 Under UV illumination at 366 nm, an irregular pattern of spots of whitened or fluorescent particles is
244 observed (Fig. 1).

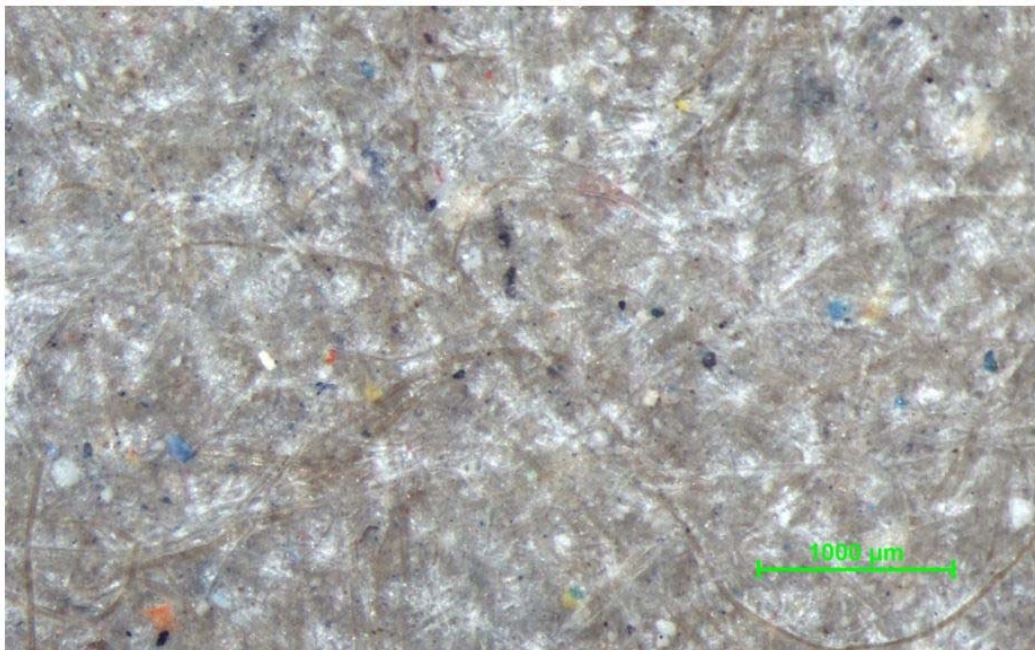


245

246 *Figure 1: Paperboard under UV illumination: left, fresh fibre material; right, recycled fibre content,*
247 *scale in cm*

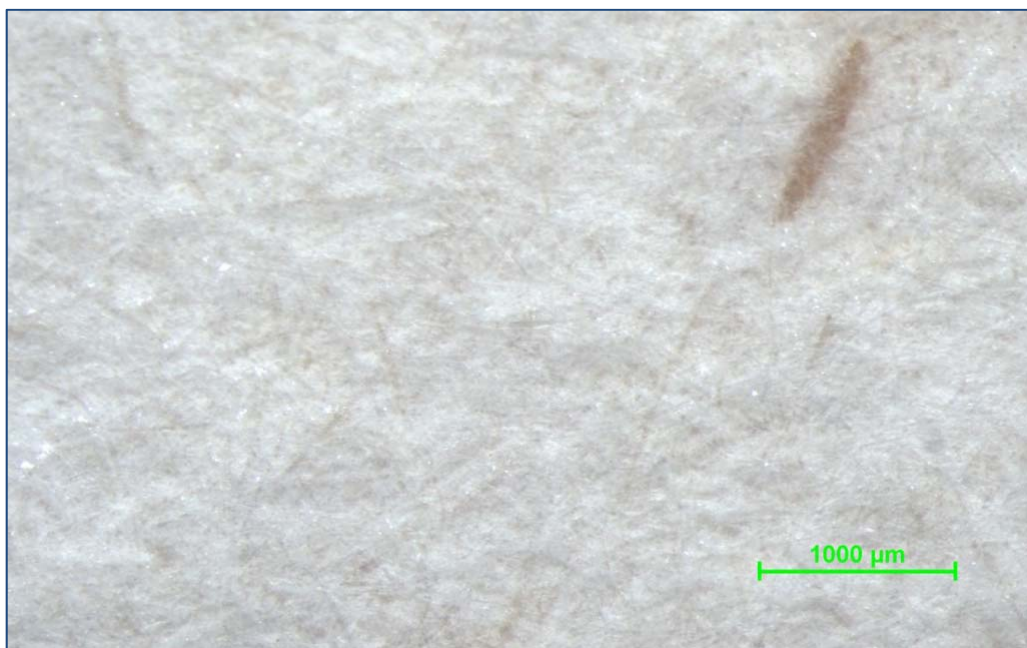
248 **4.2 Identification by light microscopy**

249 Particles of coloured paper and plastic can be detected by reflection or transmission light microscopy
250 (Fig. 2).



251

Figure 2: Recycled board under transmission light microscopy



252

Figure 3: Fresh fibre board under transmission light microscopy

253 **4.3 Marker substances for recycled material**

254 Diisopropyl naphthalenes (DIPN) are commonly used as solvents for dyes in carbonless copy paper.
255 The DIPN may be detected in solvent extracts of paper and board according to EN 14719. Very low
256 levels of DIPN have been reported in fresh fibre paper and board as a result of cross-contamination from
257 recycled paper. Recycled fibres may not contain DIPN.

258 Bisphenol A is used in thermal paper, e.g. in cash register receipts. It may be measured in paper and
259 board according to EN 15519 by solvent extraction with 95% of ethanol or methanol.

260 Other sources of marker substances may be printing ink components.

261 **5. Compliance Documentation and Declaration of Compliance**

262 The Resolution CM/Res (2020) X (Appendix, Section 8) sets out the general principles of the
263 documentation on the compliance work (compliance documentation) and the communication throughout
264 the chain of business operators (declaration of compliance).

265 **5.1 Compliance documentation**

266 In addition to information common to all food contact materials and articles and stemming from the
267 general requirements laid down in the Resolution CM/Res (2020) X (Appendix Section 8.1), the
268 compliance documentation of food contact materials and articles made from paper and board (including
269 the intermediate products) needs to include the following information (as applicable):

- 270 1. for fresh fibre paper and board: source of the fibres and description of the process(es) applied to
271 obtain the fibres;
- 272 2. process(es) applied for bleaching;
- 273 3. percentage of recycled fibre in the paper or board material or article;

- 274 4. grade of the material being recycled based on EN 643 (Paper and board - European list of standard
275 grades of paper and board for recycling);
- 276 5. cleaning and sorting procedure applied during recycling for recycled paper and board, criteria set
277 and data supporting conformity with the criteria;
- 278 6. if a barrier layer on the food contact surface of recycled paper or board is used to reduce migration
279 into food: description of the barrier, process to apply the barrier, the criterion used for determining
280 its effectiveness, the method of testing and the resulting data;
- 281 7. if recycled material is used with a functional adsorbent to reduce migration into food, the criterion
282 used for determining its effectiveness, the method of testing, data on the adsorption capacity and
283 its interpretation for the range of applications it is suitable for.
- 284 8. if no measure is taken to reduce the migration from the recycled paper and board, the restrictions
285 in use and data supporting lack of migration.

286 **5.2 Declaration of compliance**

287 In addition to the requirements laid down in Resolution CM/Res (2020) X (Appendix, Section 8.2), the
288 Declaration of Compliance of food contact materials and articles from paper and board (including their
289 intermediates) must include the following information (as applicable):

- 290 1. type of material, such as fresh and/or recycled material, in all layers;
- 291 2. measures taken to render recycled material or article compliant with Resolution CM/Res (2020)
292 X and this Technical Guide;
- 293 3. type of functional barrier or functional adsorbent;
- 294 4. for recycled paper and board with a functional barrier applied to the food contact surface: data on
295 the effectiveness of the barrier, the proposed expiry date, taking into account the period before
296 being in food contact and requirements on closure design;
- 297 5. for recycled paper and board incorporating functional adsorbents: data on the effectiveness,
298 restrictions on printing and food types for which the functional adsorbent has sufficient sorption
299 capacity;
- 300 6. storage conditions for the material or article, e.g. related to barrier/adsorbent effectiveness or set-
301 off;
- 302 7. percentage of recycled fibres in the paper or board; quality of the recycled material; cleaning
303 process.

304 6. References

305 Please note that standardised methods are stated in Annex III.

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388 der Verwendung verbotener Azofarbstoffe auf gefärbten textilen Bedarfsgegenständen"
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390 Bedarfsgegenständegesetz, Methode L 00-00-6: Bestimmung von primären aromatischen Aminen in
391 wässrigen Lebensmittelsimulanzien. (Official Collection of Methods of Analysis under § 35 of the
392 Foods and Other Commodities Act, Method No. L 00-00.6: Determination of primary aromatic amines
393 in aqueous food simulants).

394 ANNEX I References/Links to national regulations or 395 recommendations

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397 XXXVI. Paper and board for food contact
398 <https://bfr.ble.de/kse/faces/resources/pdf/360.pdf> (english translation:
399 <https://bfr.ble.de/kse/faces/resources/pdf/360-english.pdf>)
- 400 XXXVI/1. Cooking Papers, Hot Filter Papers and Filter Layers
401 <https://bfr.ble.de/kse/faces/resources/pdf/361.pdf> (english translation:
402 <https://bfr.ble.de/kse/faces/resources/pdf/361-english.pdf>)
- 403 XXXVI/2. Paper and Paperboard for Baking Purposes
404 <https://bfr.ble.de/kse/faces/resources/pdf/362.pdf> (english translation:
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407 <https://wetten.overheid.nl/BWBR0034991/2017-01-01>. The positive list for paper and board
408 (in Dutch) is found in Chapter II, of Annex-part A of this Regulation (Bijlage deel A,
409 Hoofdstuk II). Translations of the complete version as it was notified in 2013 can be found in
410 the TRIS database:
411 <http://ec.europa.eu/growth/toolsdatabases/tris/en/search/?trisaction=search.detail&year=2013>
412 [&num=407](http://ec.europa.eu/growth/toolsdatabases/tris/en/search/?trisaction=search.detail&year=2013). Amendment since then contains updates on positive lists of several materials, and
413 was notified in 2016. The text of the amendment (so, not a consolidated version) is available
414 in TRIS:
415 [http://ec.europa.eu/growth/tools-](http://ec.europa.eu/growth/toolsdatabases/tris/en/search/?trisaction=search.detail&year=2016&num=208)
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420 [mentare&menu=chimica](http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1173&area=sicurezzaAlimentare&menu=chimica)
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422 <https://www.economie.gouv.fr/dgccrf/Materiaux-au-contact-des-denrees-alimentaires>. For
423 organic materials based on vegetable fibres
424 [https://www.economie.gouv.fr/files/files/directions_services/dgccrf/securite/produits_alimen](https://www.economie.gouv.fr/files/files/directions_services/dgccrf/securite/produits_alimentaires/materiaux_contact/doc_pdf/Fiches-materiaux-organiques-fibres-vegetales-v02.pdf)
425 [taires/materiaux_contact/doc_pdf/Fiches-materiaux-organiques-fibres-vegetales-v02.pdf](https://www.economie.gouv.fr/files/files/directions_services/dgccrf/securite/produits_alimentaires/materiaux_contact/doc_pdf/Fiches-materiaux-organiques-fibres-vegetales-v02.pdf)

426 **ANNEX II Specific migration limits (SML) for some**
 427 **constituents or known contaminants**

 428 **Table 1**

Substance	CAS-No.	SML (mg/kg in food/food simulant)	Comments	Reference and explanations
4,4'-Bis(dimethylamino) benzophenone (Michler's ketone)	90-93-7	0.01	1	Technical document No. 3, Paper and board materials and articles made from recycled fibres intended to come into contact with foodstuffs, Version 2, 10.06.2004, CoE
Bisphenol A	80-05-7	0.05	1	EFSA Journal 2015;13(1):3978 t-TDI 4 µg/kg bw per day, average body weight 60 kg, allocation factor 20% Regulation (EU) No 2018/213
		0.01	1	Regulation (EU) No 2018/213: applications for infants and young children as referred to in Regulation (EU) No 609/2013
Sum of benzo(a) pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene	50-32-8 56-55-3 205-99-2 218-01-9	0.001	1	Regulation (EC) No 1881/2006
Mineral oil hydrocarbons MOH	—	under discussion	2	
Sum of benzophenone, 2-methyl benzophenone, 3-methyl benzophenone and 4-methyl benzophenone	119-61-9 131-58-8 643-65-2 2134-84-9	0.6	1,6	Regulation (EC) 10/2011, EFSA Journal (2009) 1104, 1-30 TDI 0.01 mg/kg bw per day average body weight 60 kg, no allocation factor Swiss Ordinance (SR 817.023.21) Annex 10
2-methyl benzophenone, 3-methyl benzophenone, 4-methyl benzophenone	131-58-8 643-65-2 134-84-9	0.05	1	This limit applies to each individual substance and to their sum. Swiss Ordinance (SR 817.023.21) Annex 10
Sum of dibutylphthalate (DBP) and diisobutylphthalate (DiBP)	84-74-2 84-69-5	0.3	1, 6	Regulation (EC) 10/2011 EFSA Journal (2005) 242, 1-17 TDI for DBP: 0.01 mg/kg bw per day DiBP: comparable structure
Di(2-ethylhexyl)phthalate (DEHP)	117-81-7	1.5	1, 6	Regulation (EC) 10/2011 EFSA Journal (2005) 243, 1-20 TDI 0.05 mg/kg per day
Benzylbutylphthalate (BBP)	85-68-7	30	1, 6	Regulation (EC) 10/2011 EFSA Journal (2005) 241, 1-14 TDI 0.5 mg/kg bw per day
Primary aromatic amines (PAAs)		0.01	1, 3, 6	Sum of all primary aromatic amines (see Annex IV).
Lead (Pb)	7439-92-1	0.003	4	EFSA Scientific Opinion on Lead in Food (2013) BMDL ₀₁ : 0.5 µg/kg per day
PFAS (Per- and polyfluoroalkyl substances)		under discussion	5	

429

430 Comment 1: Entry sources may be printing inks, adhesives, organic coatings and recycled fibres.

- 431 Comment 2: Until a specific migration limit or other restrictions based on the evaluation of the latest
432 available scientific evidence can be established, producers or other operators
433 responsible for the placing on the market of food contact materials and articles are
434 recommended to keep migration of MOH as low as technically unavoidable and to
435 ensure that migration of MOAH does not occur.
- 436 Comment 3: PAAs that are classified as carcinogens of class 1A and 1B according to section 3.6 of
437 Annex I of Regulation (EC) No 1272/2008, may not be detectable in food or food
438 simulant with a detection limit of 0.002 mg/kg.
- 439 Comment 4: Entry sources for lead may be recycled fibres or intentionally added minerals.
- 440 Comment 5: The substances are currently under evaluation by EFSA. National restrictions or
441 restrictions under REACH may apply to one or more of these substances.
- 442 Comment 6: Limits and groups will be adapted pending on relative amendments of Regulation (EU)
443 No 10/2011.

444 **ANNEX III List of currently available standard methods for**
445 **testing compliance**

446 Generally analytical methods shall be selected in accordance with the requirements of Article 34 of
447 Regulation (EU) 2017/625.

- 448 • EN 645: Paper and board intended to come into contact with foodstuffs. Preparation of a cold
449 water extract;
- 450 • EN 647: Paper and board intended to come into contact with foodstuffs. Preparation of a hot water
451 extract;
- 452 • EN 648: Paper and board intended to come into contact with foodstuffs. Determination of the
453 fastness of fluorescent whitened paper and board;
- 454 • EN 646: Paper and board intended to come into contact with foodstuffs. Determination of colour
455 fastness of dyed paper and board;
- 456 • EN 15519: Paper and board intended to come into contact with foodstuffs. Preparation of an
457 organic solvent extract (isooctane / 95% ethanol);
- 458 • EN 14338: Paper and board intended to come into contact with foodstuffs. Conditions for
459 determination of migration from paper and board using modified polyphenylene oxide (MPPO)
460 as a simulant;
- 461 • ÖNORM A 1123: Paper and board intended to come into contact with foodstuffs – Determination
462 of overall gas phase migration of paper and board using modified polyphenylene oxide (MPPO)
463 as a simulant;
- 464 • EN 16453: Pulp, paper and board. Determination of phthalates in extracts from paper and
465 paperboard;
- 466 • EN 15845: Paper and board – Determination of the cytotoxicity of aqueous extracts;
- 467 • EN 1230-1: Sensory analysis. Part 1;
- 468 • EN 1230-2: Sensory analysis. Part 2: Off flavour (taint);
- 469 • ISO 8784-1: Pulp, paper and board – Microbiological examination – Part 1: Enumeration of
470 bacteria and bacterial spores based on disintegration;
- 471 • EN 1541: Determination of formaldehyde in an extract;
- 472 • EN 14719: Determination of the diisopropylnaphthalene (DIPN) content by solvent extraction;
- 473 • CEN/TS 13130-13: Plastics substances subject to limitation – Determination of 2,2-bis(4-
474 hydroxyphenyl)propane (Bisphenol A) in food simulants;
- 475 • EN 1104: Determination of antimicrobial constituents;
- 476 • DIN 54600-1: Prüfung von Papier und Pappe; Prüfung auf antimikrobielle Zusatzstoffe;
477 Bestimmung des Gehaltes an Tetramethylthiuramdisulfid (TMTD);
- 478 • DIN 54600-8: Prüfung von Papier und Pappe; Prüfung auf antimikrobielle Zusatzstoffe;
479 Bestimmung des Gehaltes an Methylen-bis-thiocyanat;
- 480 • EN 14479: Flexible packaging material – Determination of residual solvents by dynamic
481 headspace gas chromatography;

- 482 • EN 17163: Pulp, paper and board – Determination of primary aromatic amines (PAA) in a water
483 extract by a LC/MS/MS method;

Draft for consultation

484 **ANNEX IV Primary aromatic amines (PAAs) that have been found in napkins and other food contact**
 485 **materials and articles.**

Primary Aromatic Amines	CAS-No.	EC No 1272/2008 Classification	EURL GUIDE for PA (2011) ¹	EURL GUIDE for PA (2011) - Recommendation	CoE Resolution AP (89) 1	RASFF (2013-2016/ may be incomplete)	BfR from Isocyanates (2014)	Napkins Annual Report (EuRL-2013) ²	Napkins Annual Report (EuRL-2013) Detection Frequency
Aniline (ANL)	62-53-3	Carc.2, Muta 2	X	X		X	X	X	17
o-Anisidine (o-ASD)	90-04-0	Carc 1B, Muta 2	X			X	X	X	9
2,4-Dimethylaniline (2,4-DMA)	95-68-1		X				X	X	9
o-Toluidine (o-T)	95-53-4	Carc 1B	X			X	X	X	9
3-amino-4-methoxybenzanilidine (3A-4MOB)	120-35-4						X	X	9
2-methoxy-4-nitroaniline (2,4- MONA)	97-52-9						X	X	7

¹ C. Simoneau, E. Hoekstra, E. Bradley, J. Bustos, V. Golja, O. Kappenstein, D. Kalsbe, J. Keegan, M.R. Milana, K. Cwiek-Ludwicka, J. Petersen, M. Polz, P. Sauvegrain, F. Vanhee; Technical guidelines on testing the migration of primary aromatic amines from polyamide kitchenware and of formaldehyde from melamine kitchenware; 1st edition 2011 <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC64903/lbna24815enn.pdf>

² Oguzhan Yavuz, Sandro Valzacchi, Eddo Hoekstra & Catherine Simoneau (2016) Determination of primary aromatic amines in cold water extract of coloured paper napkin samples by liquid chromatography-tandem mass spectrometry, Food Additives & Contaminants: Part A, 33:6, 1072-1079, DOI: 10.1080/19440049.2016.1184493

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Primary Aromatic Amines	CAS-No.	EC No 1272/2008 Classification	EURL GUIDE for PA (2011) ¹	EURL GUIDE for PA (2011) - Recommendation	CoE Resolution AP (89) 1	RASFF (2013-2016/ may be incomplete)	BfR from Isocyanates (2014)	Napkins Annual Report (EuRL-2013) ²	Napkins Annual Report (EuRL-2013) Detection Frequency
4-aminoazobenzene (4-AAB)	60-09-3	Carc 1B						X	6
4-Chloro-Aniline (4-CA)	106-47-8	Carc 1B	X					X	5
4-chloro-2,5-dimethoxyaniline (4,2,5-CDMA)	6358-64-1							X	5
3-chloroaniline (3-CA)	108-42-9							X	4
4,4'-Methylenedi-o-toluidine (4,4'-MDoT) (4,4Mb-2MA)	838-88-0	Carc 1B	X					X	3
m-Phenylenediamine (m-PDA)	108-45-2	Muta 2	X					X	3
Benzidine (BNZ)	92-87-5	Carc 1A	X		X	X		X	2
2,4 Toluenediamine (2,4 TDA)	95-80-7	Carc 1B, Muta 2	X	X		X	X	X	2
4-Aminobiphenyl (4-ABP)	92-67-1	Carc 1A	X		X			X	1
4,4'-Diaminodiphenylether (4,4'-DPE)	101-80-4	Carc 1B, Muta 1B	X				X	X	1
3-anisidine (m-ANS)	536-90-3							X	1

Primary Aromatic Amines	CAS-No.	EC No 1272/2008 Classification	EURL GUIDE for PA (2011) ¹	EURL GUIDE for PA (2011) - Recommendation	CoE Resolution AP (89) 1	RASFF (2013-2016/ may be incomplete)	BfR from Isocyanates (2014)	Napkins Annual Report (EuRL-2013) ²	Napkins Annual Report (EuRL-2013) Detection Frequency
2-methyl-4-nitroaniline (2-M-4-NA)	99-52-5							X	1
4,4'-Methylenedianiline (4,4'-MDA)	101-77-9	Carc 1B, Muta 2	X	X		X	X	X	
3,3 Dimethylbenzidine (3,3 DMB)	119-93-7	Carc 1B	X			X	X	X	
β-Naphthylamine (B-NpA)	91-59-8	Carc 1A			X	X		X	
4,4'-methylen-bis-(2-chloraniline)	101-14-4	Carc 1B				X			
1,5-diaminonaphthalene (1,5-DAN)	2243-62-1	Carc 2				X		X	
2,5 dichloroaniline	95-82-9					X			
4-Chloro-o-Toluidine (4-CoT) (4-C-2-MA)	95-69-2	Carc 1B, Muta 2	X					X	
2,6-Dimethylaniline (2,6-DMA)	87-62-7	Carc 2	X					X	
2-Methoxy-5-Methylaniline (2-M-5-MA)	120-71-8	Carc 1B	X					X	
p-Phenylenediamine (p-PDA)	106-50-3		X						

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Primary Aromatic Amines	CAS-No.	EC No 1272/2008 Classification	EURL GUIDE for PA (2011) ¹	EURL GUIDE for PA (2011) - Recommendation	CoE Resolution AP (89) 1	RASFF (2013-2016/ may be incomplete)	BfR from Isocyanates (2014)	Napkins Annual Report (EuRL-2013) ²	Napkins Annual Report (EuRL-2013) Detection Frequency
4-Methoxy-m-phenylenediamine (4-M-m-PDA)	615-05-4	Carc 1B, Muta 2	X						
2,6 Toluenediamine (2,6 TDA)	823-40-5	Muta 2	X					X	
2,4,5 Trimethylaniline (2,4,5 TMA)	137-17-7	Carc 1B	X						
2-aminobiphenyl (2-AMP)	90-41-5	Carc 2						X	
2-methyl-5-nitroaniline (2-M-5-NA)	99-55-8	Carc 2						X	
2,4-diaminoanisole (2,4-DAS)	615-05-4	Carc 1B, Muta 2						X	
4-ethoxyaniline (4-EA)	156-43-4	Muta 2						X	
5-amino-6-methyl-benzimidazolone (5A-6MB)	67014-36-2							X	
3-amino-4-methylbenzamide(3A-4MB)	1946-86-1							X	
5-chloro-2-methylaniline HCl (5C-2MA)	95-79-4							X	

Primary Aromatic Amines	CAS-No.	EC No 1272/2008 Classification	EURL GUIDE for PA (2011) ¹	EURL GUIDE for PA (2011) - Recommendation	CoE Resolution AP (89) 1	RASFF (2013-2016/ may be incomplete)	BfR from Isocyanates (2014)	Napkins Annual Report (EuRL-2013) ²	Napkins Annual Report (EuRL-2013) Detection Frequency
o-phenitidine (2-Ethoxyaniline) (o-PHE)	94-70-2							X	
4-aminobenzamide (4-AB)	2835-68-9							X	
2-chloraniline (2-CA)	95-51-2							X	

487