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

TECHNICAL GUIDE ON PAPER AND BOARD MATERIALS AND ARTICLES FOR FOOD CONTACT

Draft

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Please use this **comment form** to enter your comments.	
Comments should be sent to: FCM.paper_board@edqm.eu.	

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1. Scope and Definitions

1.1 Scope

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

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

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

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

1.2 Definitions

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

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

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

2. Requirements

2.1 General requirements

The general requirements of Resolution CM/Res (2020) X (Appendix, Section 3) apply to substances used in the manufacture of paper and board materials and articles for food contact.
In case of packaging applications the whole system (direct or indirect contact) has to be assessed, i.e. all paper and board that can reasonably be expected to transfer constituents to food under normal or foreseeable conditions of use.

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

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

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

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

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

2.1.5 As a criterion for inertness, overall gas phase migration does not exceed 10 mg/dm^2 into food simulant E (modified polyphenylene oxide) according to ÖNORM A 1123 (see Annex III: Standardised Methods).

2.2 Specific requirements for the use of recycled paper and board

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

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

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

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

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

Functional barriers and functional adsorbents

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

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

3. Compliance Testing

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

3.1 Determination of specific migration into food

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

Conditions of testing

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

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

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

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

The commonly used approaches for testing compliance include:

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

potential migrants and validated mathematical modelling [16], may refine this approach, but are not developed to the extent as for plastics.

- Cold water extraction according to EN 645 to estimate the potential release of water-soluble or hydrophilic substances into hydrophilic food (e.g. PAA, formaldehyde or chloropropanols). It is proposed for contact at ambient or lower temperature.
- Hot water extraction according to EN 647 to estimate the release of water-soluble or hydrophilic substances into hydrophilic food at temperatures above room temperature (e.g. for tea and coffee filter papers or technical filters).
- Simulating migration with 3% acetic acid to estimate the release of metals into acidic (pH <4.5) foods. Selection of contact time and temperature according to the JRC Guidelines on testing conditions for articles on contact with foodstuffs. [1].
- Extraction with isooctane and/or 95% ethanol according to EN 15519 to estimate potential migration of fat-soluble and hydrophobic substances (e.g. phthalates, benzophenones, DIPN, PAH, mineral oils, bisphenol A) into lipophilic food.
- Simulating migration tests as described for plastics in Regulation (EU) No 10/2011, for paper and board with a plastic layer in food contact (e.g. cups, plates, bottles, board with a barrier layer).
- Migration tests using modified polyphenylene oxide (MPPO) as adsorbent, (EN 14338, ÖNORM A 1123) for the migration of volatile or semi-volatile substances into food [28]. Paper and board materials or articles for baking applications are tested with MPPO for 2 hours at 220°C; those for microwave oven use for 30 minutes at 150 °C [29].

Annex III lists standardised methods for compliance testing.

For the calculation of the migration into food, the real ratio of food contact surface to amount of food must be used. If the intended use of paper and board is unknown, the result of EN 645 and EN 647 must be directly compared with the SML. This corresponds to a ratio of 13.3 dm^2/kg food if the weight of paper or board is assumed to be 300 g/m2 [18].

3.3 Testing of barrier and adsorbent effectiveness

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

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

Analogous considerations can be made based on the applicable assumptions.

3.3.1 Experimental testing with surrogate substances

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

Testing of functional barrier effectiveness of internal bags

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

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

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

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

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

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

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

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

Testing for set-off

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

Testing migration from the flaps of closures

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

3.3.2 Modelling

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

3.4 Antimicrobial activity

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

3.5 Release of colourants or fluorescent whiteners

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

3.6 Sensory/organoleptic testing

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

4. Detection of Recycled Fibres

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

4.1 Identification by UV illumination

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

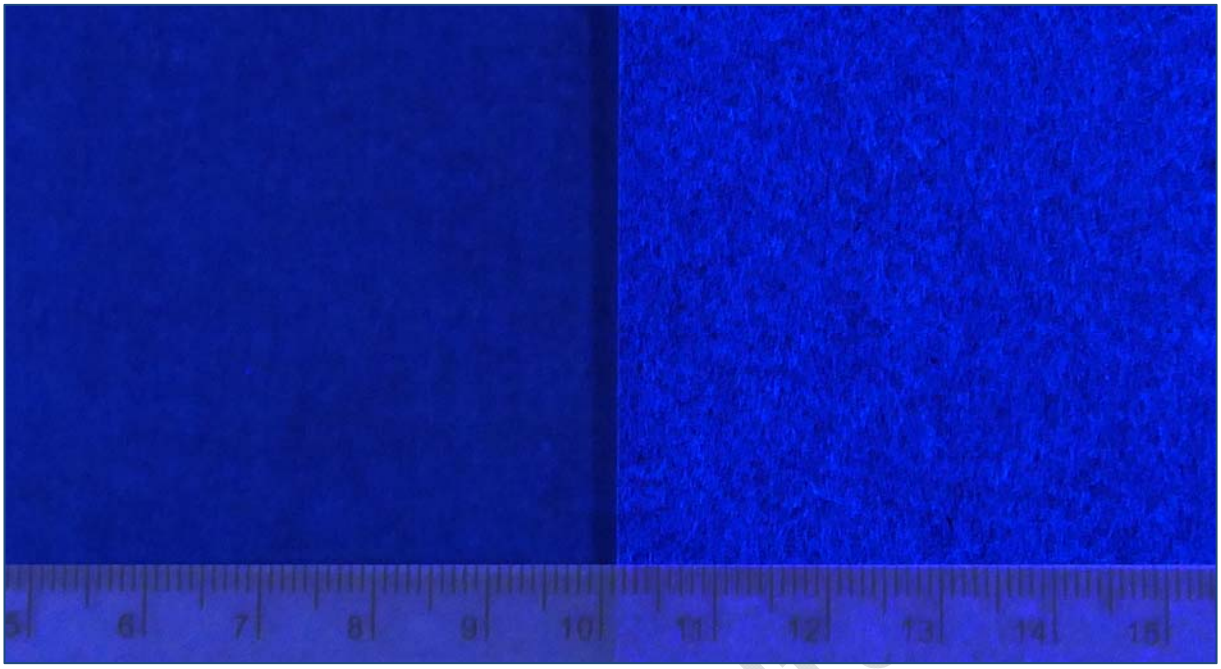

Figure 1: Paperboard under UV illumination: left, fresh fibre material; right, recycled fibre content, scale in cm

4.2 Identification by light microscopy

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

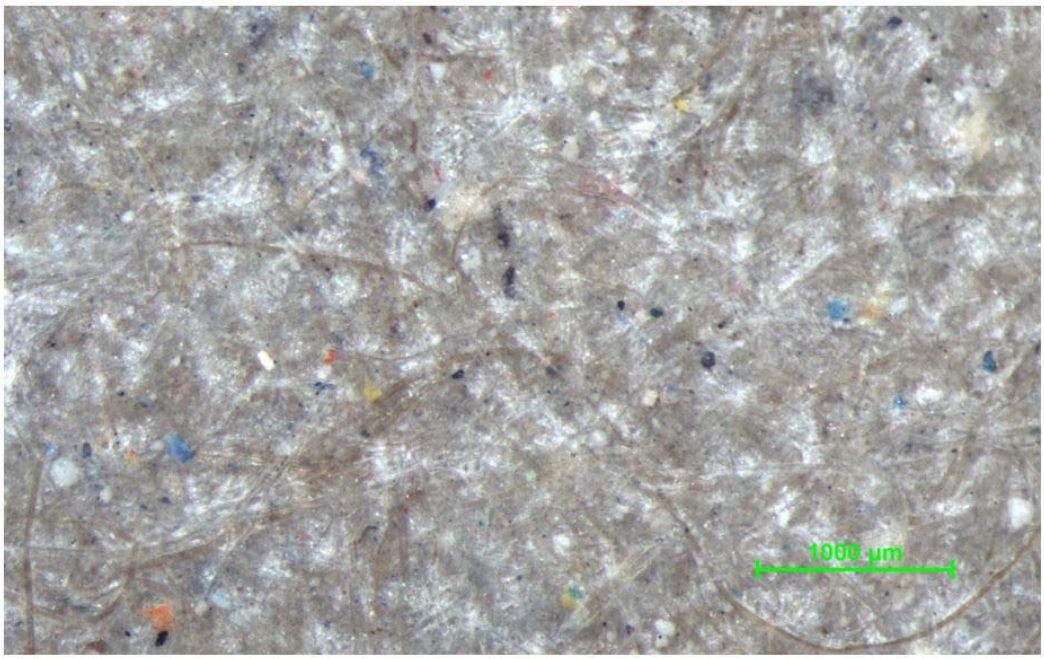

Figure 2: Recycled board under transmission light microscopy

Figure 3: Fresh fibre board under transmission light microscopy

4.3 Marker substances for recycled material

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

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

Other sources of marker substances may be printing ink components.

5. Compliance Documentation and Declaration of Compliance

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

5.1 Compliance documentation

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

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

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

5.2 Declaration of compliance

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

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

6. References

Please note that standardised methods are stated in Annex III.

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[3] Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials, EUR 24105 EN – 1st edition 2009.

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ANNEX I References/Links to national regulations or recommendations

1. BfR Recommendations for paper and board:
   XXXVI. Paper and board for food contact
   https://bfr.ble.de/kse/faces/resources/pdf/360.pdf (english translation:
   https://bfr.ble.de/kse/faces/resources/pdf/360-english.pdf)

   XXXVI/1. Cooking Papers, Hot Filter Papers and Filter Layers
   https://bfr.ble.de/kse/faces/resources/pdf/361.pdf (english translation:
   https://bfr.ble.de/kse/faces/resources/pdf/361-english.pdf)

   XXXVI/2. Paper and Paperboard for Baking Purposes
   https://bfr.ble.de/kse/faces/resources/pdf/362.pdf (english translation:
   https://bfr.ble.de/kse/faces/resources/pdf/362-english.pdf)

2. Dutch legislation on FCM "Warenwetregeling verpakkingen en gebruiksartikelen" https://wetten.overheid.nl/BWBR0034991/2017-01-01. The positive list for paper and board (in Dutch) is found in Chapter II, of Annex-part A of this Regulation (Bijlage deel A, Hoofdstuk II). Translations of the complete version as it was notified in 2013 can be found in the TRIS database: http://ec.europa.eu/growth/toolsdatabases/tris/en/search/?trisaction=search.detail&year=2013&num=407. Amendment since then contains updates on positive lists of several materials, and was notified in 2016. The text of the amendment (so, not a consolidated version) is available in TRIS:
   http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2016&num=208

3. Decreto Ministeriale 21 marzo 1973, consolidated by Decreto 25 settembre 2007, n. 217, lastly amended by Decreto 4 aprile 2012, n.72. Legislation available: http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1173&area=sicurezzaAlimentare&menu=chimica

4. French legislation on FCM: Matériaux au contact des denrées alimentaires https://www.economie.gouv.fr/dgccrf/Materiaux-au-contact-des-denrees-alimentaires. For organic materials based on vegetable fibres https://www.economie.gouv.fr/files/files/directions_services/dgccrf/securite/produits_alimentaires/materiaux_contact/doc_pdf/Fiches-materiaux-organiques-fibres-vegetales-v02.pdf

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

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	119-61-9 131-58-8 643-65-2134-84-9	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	

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

Comment 2: Until a specific migration limit or other restrictions based on the evaluation of the latest available scientific evidence can be established, producers or other operators responsible for the placing on the market of food contact materials and articles are recommended to keep migration of MOH as low as technically unavoidable and to ensure that migration of MOAH does not occur.

Comment 3: PAAs that are classified as carcinogens of class 1A and 1B according to section 3.6 of Annex I of Regulation (EC) No 1272/2008, may not be detectable in food or food simulant with a detection limit of 0.002 mg/kg.

Comment 4: Entry sources for lead may be recycled fibres or intentionally added minerals.

Comment 5: The substances are currently under evaluation by EFSA. National restrictions or restrictions under REACH may apply to one or more of these substances.

Comment 6: Limits and groups will be adapted pending on relative amendments of Regulation (EU) No 10/2011.

ANNEX III List of currently available standard methods for testing compliance

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

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

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

ANNEX IV Primary aromatic amines (PAAs) that have been found in napkins and other food contact 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	17
o-Anisidine (o-ASD)	90-04-0	Carc 1B, Muta 2	X			X		X	9
2,4-Dimethylaniline (2,4-DMA)	95-68-1		X					X	9
o-Toluidine (o-T)	95-53-4	Carc 1B	X			X		X	9
3-amino-4-methoxybenzanilidine (3A-4MOB)	120-35-4							X	9
2-methoxy-4-nitroaniline (2,4- MONA)	97-52-9							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

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-Methylaninline (2-M-5-MA)	120-71-8	Carc 1B	X					X	
p-Phenylenediamine (p-PDA)	106-50-3		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
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	

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