

PAPER AND BOARD

used in food contact
materials
and articles



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Paper and board used in food contact materials and articles

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Foreword

In October 2020, the Committee of Ministers of the Council of Europe adopted [Resolution CM/Res \(2020\) 9 on the safety and quality of materials and articles for contact with food](#). This instrument is expected to improve the protection of consumers from contaminants (metals, antioxidants, stabilisers, colorants, plasticisers, etc.) potentially released by material in contact with food, such as containers, work surfaces or packaging. The annex to this resolution includes Guiding Principles for the implementation of suitable policies in the member states of the Council of Europe.

Manufacturers of materials, food packers and other businesses benefit from harmonised regulatory measures across Europe and from technical guidance for specific materials, such as paper and board intended for contact with food.

The resolution and technical guidance presented in this publication were prepared under the aegis of the [European Committee for Food Contact Materials and Articles \(CD-P-MCA\)](#) as part of its task to set standards that supplement the relevant European Union and national regulations.

The two documents, Resolution CM/Res (2020) 9 on the safety and quality of materials and articles for contact with food and the supplementary Technical Guide, supersede the Policy statement concerning paper and board materials and articles intended to come into contact with foodstuffs (Version 4 dated 12.02.2009).

Acknowledgements

Great thanks are due to the members of the European Committee for Food Contact Materials and Articles (Partial Agreement) (CD-P-MCA) for their long-term commitment to harmonise specifications, address them in Resolution CM/Res (2020) 9 and provide supplementary guidance to regulators and business operators.

The CD-P-MCA rapporteur from Austria dedicated her time and expertise to the elaboration of these technical guidelines. Drafts had to be prepared, background information gathered and independent specialists and experts from national authorities, control laboratories and industry had to be consulted.

This work would not have been accomplished by the *ad hoc* working group without the full support of the Austrian Agency for Health and Food Safety (AGES). The German Federal Institute for Risk Assessment (BfR) also hosted several meetings of the working group.

Working group members from the public and private sectors joined forces to provide advice on the manufacturing process, the quality of the raw materials, final products and their applications. Their contributions are gratefully recognised and appreciated.

Many helpful comments were also received from the participants in the public consultation and critically reviewed by several CD-P-MCA members. This publication has been made possible by the efforts of the many knowledgeable persons in the field.

The Secretariat of the EDQM co-ordinated the work of the Committee, the working groups and independent experts, translated the contributions and edited the final document. The EDQM team received support from a scientist seconded from the General Chemical State Laboratory of Greece.

Part I. Council of Europe
Resolution CM/Res (2020) 9
on the safety and quality of materials
and articles for contact with food

Adopted by the Committee of Ministers
on 7 October 2020 at the 1385th meeting of the Ministers' Deputies

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia¹ (“the Convention”),

Considering that the aim of the Council of Europe is to achieve greater unity between its member States and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field;

Recalling that protection of health is a social human right and an essential condition for social cohesion and economic stability;

Acknowledging the need to set quality and safety standards to minimise the health risk posed to humans by certain material constituents when released from materials or articles intended for contact with foodstuffs;

Considering that food contact materials and articles are also used in pharmaceutical applications when the said materials are deemed suitable and safe for that purpose;

Having regard to the opportunity to enhance synergies between the food contact materials and articles and pharmaceutical sectors;

Following an approach similar to that published by the European Medicines Agency (EMA) in the “Guideline on Plastic Immediate Packaging Materials”, effective since 1 December 2005, which specifies that the provisions of Community legislation on plastic materials and articles for food contact should be taken into account, in cases indicated in the guideline;

Having regard to Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and specific EU measures for particular groups of food contact materials and articles adopted in accordance with that Regulation, Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, Regulation (EU) 2017/625 of the European Parliament and

¹ States concerned: Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom.

of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin and Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products or relevant national legislation which, although not binding for all of the States Parties to the Convention, should nevertheless be taken into consideration;

Taking into account that the Technical Guides on food contact materials and articles and resolutions are widely recognised and used as a reference for the safety, quality and use of coatings, colorants, cork, glass, metals, paper and board, plastics, printing inks for food contact materials, resins for adsorption and ion exchange and elastomers such as rubber and silicones;

Taking into account that Resolution CM/Res (2013) 9 and the applicable Technical Guide on metals and alloys used in food contact materials and articles are widely recognised and used as a reference for the safety and quality of such materials and articles;

Being convinced that each member State would benefit from harmonised state-of-the-art quality requirements and test procedures, described in the Technical Guides and published under the aegis of the EDQM,

Recommends to the governments of States Parties to the Convention that, in the absence of the specific measures referred to in Article 5 of Regulation (EC) No. 1935/2004, they adopt suitable legislative and other measures aimed at reducing the health risks arising from human exposure to constituents released from materials or articles for contact with food according to the appended “Guiding Principles for food contact materials and articles” and the Technical Guides published under the aegis of the EDQM to supplement this resolution. Likewise, in cases considered appropriate by the national competent authorities, the Committee of Ministers recommends that they apply these principles to materials and containers for pharmaceutical use in the absence of dedicated standards. This resolution shall not prevent governments from maintaining

or adopting national measures that implement stricter or different rules and regulations.

Agrees that the CD-P-MCA, taking into account scientific or regulatory developments or needs, will update, as necessary, the appendix “Guiding Principles for food contact materials and articles” and the Technical Guides, published under the aegis of the EDQM to supplement this Resolution.

Appendix: Guiding principles for food contact materials and articles

1. Purpose and scope

Resolution CM/Res (2020) 9, its Guiding Principles and the supplementary Technical Guides contribute to the protection of human health by ensuring, as defined in relevant European legislation, i.e. Regulation (EC) No. 1935/2004, the safety and quality of food contact materials and articles that are not covered by specific European legal provisions or other measures, e.g. at the European Union (EU) level. The resolution therefore complements European legislation taking into account Council of Europe member States' legislations or recommendations. This appendix provides general guidance, e.g. on the use of substances in the manufacture of food contact materials and articles, labelling of these materials and articles and the need for a declaration of compliance and supporting documentation. It applies to all food contact materials and articles under the scope of the resolution. The Technical Guides specify the requirements (or derogations from the principles stated hereafter) for particular types of materials, such as paper and board or metals, and testing.

2. Definitions

The definitions of Regulation (EC) No. 1935/2004 and, where appropriate, of Regulation (EU) No. 10/2011, apply in the context of the resolution, the Guiding Principles and the applicable Technical Guides.

In addition, the following definitions apply:

- *Food contact*: direct (physical) contact or indirect (through the gas phase or through different packaging components or layers in a multi-layer material) contact of a food contact material or article with a food.
- *Officially evaluated substances*: substances for which risk assessment has been carried out according to the principles stated under section 4, by a competent authority of a Council of Europe member State or a relevant European authority.

- *Overall release limit (ORL)* or *overall migration limit (OML)*:² the maximum permitted amount of non-volatile substances released from a material or article into food simulants.
- *QM*: the maximum permitted quantity of a substance in the final material or article expressed as mass per mass concentration.
- *QMA*: the maximum permitted quantity of a substance in the final material or article expressed as mass per surface area in contact with food.
- *(Quantitative) structure-activity relationship models ((Q)SAR models)*: theoretical models that can be used to quantitatively or qualitatively predict the physicochemical, biological (e.g. an (eco) toxicological endpoint) and environmental fate properties of compounds from the knowledge of their chemical structure.³
- *Specific release limit (SRL)*⁴ or *specific migration limit (SML)*: the maximum permitted amount of a given substance released from a material or article into food or food simulants.

3. General requirements

Food contact materials and articles shall comply with Regulation (EC) No. 1935/2004 and Regulation (EC) No. 2023/2006, or with relevant national legislation. Under normal or foreseeable conditions of use, they shall not transfer their constituents to food in quantities which could:

- a. endanger human health; or
- b. bring about an unacceptable change in the composition of the food; or
- c. bring about a deterioration in the organoleptic characteristics thereof.

2 The term 'OML' is especially used in connection with polymeric materials (e.g. plastics), whereas the term "release" is understood to designate any mechanism of substance transfer from a food contact material and article to food. In the context of these Guiding Principles the general term 'release' is used for substance transfer from food contact materials and articles to food, including polymeric materials.

3 Practical Guide – How to use and report (Q)SARs, ISBN: 978-92-9247-809-4, European Chemicals Agency, 2016. Available online at https://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf.

4 The term 'SRL' was introduced in the context of metals and alloys used in food contact materials. Whereas the more general term 'release' may be applied to various materials, the term 'migration' is especially used in connection with polymeric materials (e.g. plastics), where release is commonly dominated by physical processes such as diffusion.

In addition, food business operators shall ensure that they use food contact materials and articles during food production or preparation, storage and distribution in a way that does not compromise compliance with applicable Council of Europe Technical Guides, EU and member States' legislation or recommendations for food contact materials and articles.

3.1. *Substances used in the manufacture of food contact materials and articles*

In the manufacture of food contact materials and articles, substances may only be used after risk assessment has been performed according to the principles stated hereafter under section 4; assessment includes consideration of impurities, reaction and/or degradation products.

Substances can be used in the manufacture of food contact materials and articles, in compliance with any restrictions applicable to them, if they meet any of the following criteria:

- a. they are approved by competent authorities of the Council of Europe member States concerned, in accordance with the procedures for the elaboration of lists of officially evaluated substances; or
- b. their use is in compliance with material-specific provisions in EU or national legislation or official recommendations, as specified in the applicable Technical Guide; or
- c. absence of their release into food and absence of release into food of their impurities, and known or foreseeable reaction or degradation products can be demonstrated by a method of analysis in accordance with Article 34 of Regulation (EU) No. 2017/625 or relevant national legislation with a limit of detection not higher than 0.01 mg/kg. This limit shall apply to groups of compounds if they are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group.

In the case of substances, their impurities and known or foreseeable reaction or degradation products that belong to any of the following categories and meet criterion 3.1.c, demonstrating absence of release is not sufficient and therefore a specific risk assessment must be performed:

- substances in nano-form;⁵
- substances classified as “mutagenic”, “carcinogenic” or “toxic to reproduction” in accordance with the criteria set out in sections 3.5, 3.6 and 3.7 of Annex I to Regulation (EC) No. 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures;
- substances which are assessed to be genotoxic or predicted to be genotoxic using (Q)SAR models if valid data (e.g. complying with the European Food Safety Authority’s (EFSA) criteria) confirming absence of genotoxicity are not available.

Criterion 3.1.c applies without prejudice to applicable European and national provisions or the provisions set out in the applicable Technical Guide.

d. When none of the criteria *a*, *b* and *c* is met and without prejudice to applicable European and national provisions, or the provisions set out in the applicable Technical Guide, substances may be used in the manufacture of food contact materials and articles, if they are risk-assessed in accordance with section 4 by or on behalf of the responsible business operator and in compliance with Article 3 of Regulation (EC) No. 1935/2004 or relevant national legislation.

3.2. *European Committee for Food Contact Materials and Articles (CD-P-MCA⁶)*

The CD-P-MCA, in accordance with its terms of reference and resources permitting, prepares technical guidance that supplements the Guiding Principles of the resolution. Further to section 3.1.a, the Committee agrees on the procedures for creating, publishing and updating lists of officially evaluated substances.

When new substances are subject to assessment and/or authorisation for use in the manufacture of food contact materials and articles, member States are

5 Nanomaterials as defined in Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterials (OJ L 275, 20.10.2011, p. 38).

6 CD-P-MCA stands for Steering Committee – Partial Agreement – European Committee for Food Contact Materials and Articles (*Comité directeur – Accord partiel – Comité européen sur les matériaux et objets pour contact alimentaire*).

advised to share relevant information with the CD-P-MCA with a view to updating any lists of evaluated substances as indicated in 3.1.a.

3.3. *SML, SRL, OML, ORL, QM and QMA*

1. Food contact materials and articles should not transfer their constituents to foodstuffs or food simulants in quantities exceeding the limits set out in the applicable Technical Guides (i.e. specific or overall release or migration limits or restrictions for the material composition to limit the amount of certain components referred to as “QM” and “QMA”).
2. Unless otherwise specified, a generic SML or SRL of 60 mg/kg applies to those substances listed in the applicable Technical Guide for which no specific release or migration limit or other restrictions are provided.

4. Risk assessment

The safety of substances used in food contact materials and articles shall be evaluated in accordance with internationally recognised scientific principles on risk assessment, and with, where appropriate, EFSA guidance.⁷ The safety evaluations shall also take into account impurities and known or foreseeable reaction and degradation products.

The risk assessment should be reviewed whenever relevant composition or process changes are implemented or new scientific or other data become available.

5. Labelling

Food contact materials and articles not yet in contact with food when placed on the market shall be labelled in accordance with Article 15 of Regulation (EC) No. 1935/2004 or relevant national legislation to ensure safe and appropriate use. The label shall be sufficiently clear to avoid any misuse or misinterpretation. It shall not mislead consumers and not rule out reasonably foreseeable uses of repeated use articles.

⁷ Note for guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.21r>; <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2379>; <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.5113>.

6. Traceability

Traceability of food contact materials and articles shall be ensured at all stages in accordance with Articles 15 and 17 of Regulation (EC) No. 1935/2004 or relevant national legislation.

7. Good manufacturing practice

Food contact materials and articles shall be manufactured in accordance with Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, or with relevant national legislation. If appropriate, guidelines on good manufacturing practice developed by trade and producer associations can also be taken into account without prejudice to any applicable member State legislation.

8. Compliance documents

8.1. *Documents supporting compliance and safety (supporting documentation)*

Appropriate documentation, demonstrating that food contact materials and articles under the scope of the resolution comply with the requirements applicable to them, must be available from each business operator along the supply chain. It should be compiled as “supporting documentation” and provided to the competent authorities on request, without undue delay.

The supporting documentation is a record, especially of:

- the substance(s) used and corresponding risk assessment (including reference to relevant legislation or recommendation), the process(es) applied, and the reaction(s) and treatment(s) performed;
- the safety of released substances, including impurities and reaction and degradation products, and evidence for compliance with the applicable requirements supported with data or other adequate reasoning, taking into account the level of release or migration under the most severe conditions of use;
- if applicable, the conditions and results of migration/release testing, i.e. the description of the applied methods and other relevant information, calcula-

tions (including modelling), toxicological test descriptions and data as well as the reasoning used for the conclusion.

The supporting documentation may be confidential; however, protection of information in the documentation must not compromise the safety of food contact materials and articles and must not prevent a business operator from disclosing safety information related to released substances and conditions of use in the declaration of compliance.

8.2. *Declaration of compliance*

Food contact materials and articles under the scope of the resolution are to be accompanied by a declaration of compliance.

The declaration of compliance means that the manufacturer of the food contact material or article assumes responsibility for the suitability for food contact, including the safety of all released substances or, whenever applicable, explicitly informs the next business operator in the supply chain of the compliance work that needs to be completed. The declaration also specifies the limitations to the applications of the food contact material or article, any further processing and treatments as well as conditions of food contact and is based on the documentation referred to under 8.1.

The declaration of compliance provides all relevant information to enable subsequent business operators along the supply chain to carry out any additional compliance work in order to deliver safe and compliant food contact materials and articles.

A declaration of compliance is issued at all stages of the supply chain. It is available at all marketing stages, other than the retail stage, and includes, at least (if applicable):

- a. the identity and address of the business operator issuing the declaration of compliance;
- b. the date the declaration was issued;
- c. the identity and address of the manufacturer or importer of the food contact material/article;
- d. the identity of the food contact material/article (final or intermediate) or substance intended for the manufacture of the said material/articles (chemical name or description and trade name);

- e. confirmation that the food contact material or article (final or intermediate) or substance intended for the manufacture of any material or article complies with the applicable legal or other relevant provisions and requirements laid down in the Guiding Principles and in the applicable Technical Guide;
- f. specifications and conditions ensuring safe use of the food contact material/article (e.g. types of foods for which it can be used, maximum temperature, duration of contact, repeated or single contact, the highest food contact surface area to volume ratio for which compliance has been verified);
- g. whenever applicable, a statement that the substances used are specified:
 - i. in the corresponding Council of Europe list of officially evaluated substances; or
 - ii. in European or national legislation or official recommendations as referenced in the applicable Technical Guide, providing the exact reference;
- h. whenever applicable, a statement that:
 - i. risk assessment has been performed by or on behalf of the business operator for substances that are detailed in the supporting documentation;
 - ii. the use of these substances does not infringe relevant EU or national legislation or official recommendations;
 - iii. the use of these substances is not in conflict with the provisions set out in the applicable Technical Guide;
- i. adequate information on the substances used, impurities and reaction and degradation products for which restrictions and/or specifications apply;
- j. adequate information on the substances which are subject to a restriction regarding their use in food (dual use additives);
- k. information on substances used, impurities and reaction and degradation products, including those known or foreseen to be generated at later production stages, for which the business operator has identified that further compliance work needs to be conducted at the next stages in the supply chain.

If necessary, additional requirements or derogations for particular types of food contact materials/articles may be specified in the applicable Technical Guides.

The declaration is renewed whenever substantial changes are made to the composition or to the production process that may affect the compliance of materials/articles, or in response to relevant scientific or regulatory developments.

9. Compliance testing

Compliance of the food contact materials and articles with the relevant provisions and restrictions shall be verified by appropriate scientific methods (including modelling or worst case calculations) in accordance with Regulation (EU) No. 2017/625 or relevant national legislation.

Tests on release from the material or article into foodstuffs are carried out under the reasonable worst-case conditions during manufacture, storage, distribution and normal or foreseeable use, with respect to time, temperature and composition of the foodstuff.

When it is not feasible or not practical to test release into foodstuffs, food simulants are used to imitate the respective foodstuffs. The food simulants and conditions of contact are selected in such a way that release is at least as high as into food. Specifications for the choice of simulants and test conditions may be laid down in the relevant Guidelines of the Joint Research Centre (JRC) of the European Commission and the applicable Technical Guides.

For verification of compliance with the SML or SRL, solely release from food contact materials and articles (not contamination from any other sources) is taken into account.

10. Technical guides

The Technical Guides supplementing the resolution⁸ cover specific and detailed material requirements and principles as regards the safety and quality of food contact materials and articles.

Technical Guides may cover the following areas:

- general provisions (especially purpose/scope, additional definitions);

⁸ Technical Guides are available on the EDQM Website.

- specific requirements (or derogations from general principles) related to the particular material, including particular labelling requirements, if applicable;
- if applicable, officially evaluated substances used for the manufacture of the particular type of food contact material or article including relevant restrictions and specifications applicable to them;
- if applicable, material-specific provisions in European or national legislation or official recommendations;
- testing conditions and methods of analysis;
- additional information relating to supporting documentation and declaration of compliance, if applicable.

Technical Guides are published under the aegis of the EDQM and will be regularly updated, as necessary, by the CD-P-MCA.

Part II. Technical guide on paper and board used in food contact materials and articles

Scope

This Technical Guide supplements Resolution CM/Res (2020) 9 and lays down additional requirements for materials and articles, under its scope, made from paper and board. The provisions of this Technical Guide 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 (plates, cups, straws, 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 recovered fibres. They may also contain additives, synthetic fibres, adsorbents, treatment agents and colorants, and may be coated, glued, printed, composed of several layers or combined with other materials.

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

Definitions

Functional adsorbent: additive introduced into the paper or board that adsorbs migrants, reduces migration and ensures that the final material or article in use complies with Article 3 of Regulation (EC) No. 1935/2004, Resolution CM/Res (2020) 9 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) 9 and with the requirements of this Technical Guide. This may be achieved by a layer in or on the paper or board or a separate internal bag.

Recycled paper and board, recycled material: materials containing recovered 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 Technical Guide, are not considered recovered fibres.

General requirements

The general requirements of Resolution CM/Res (2020) 9 (Appendix, Section 3.1) apply to substances used in the manufacture of paper and board materials and articles for food contact.

Relevant national regulations and official recommendations (Resolution CM/Res (2020) 9, Appendix, Section 3.1.b) 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 meet the following criteria in their final state:

- The specific migration limits for the substances listed in Table 1 of Annex II apply.
- The intensity of any taste or odour imparted from the final food contact material or article to the food is less than 3 according to the testing methods mentioned in the next section.
- As a criterion for inertness, overall gas phase migration does not exceed 10 mg/dm² into food simulant E (modified polyphenylene oxide) according to EN 14338 (for paper and board in direct contact with food) or ÖNORM A 1123 (for paper and board not in direct contact with food (see Annex III).
- Paper and board in contact with aqueous, alcoholic or fatty foods do not release fluorescent whiteners or colourants using the methods mentioned in the next section. A score of 5 is required.
- Paper and board are of suitable microbiological purity. Criteria are set taking into account the intended use and the specific hygiene requirements in order to comply with Regulation (EC) No. 853/2004.
- The paper or board must not transfer antimicrobial substances to the food-stuffs with which they come into contact (see next section).

In the case of packaging applications, the whole system (possibly of several parts and with 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.

The effectiveness of the barriers and adsorbents used must be taken into account in the overall packaging concept. Protection against migration may be provided by a combination of packaging layers.

Specific requirements

Recycled paper and board may be used for the manufacture of food contact materials and articles, with the exception of filter paper and cooking and baking paper. Risks in recycled paper and board may originate from several substances present in recovered 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 (contaminants from previous use, 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 recovered cellulose-based fibres, precautionary considerations and measures are needed to fulfil also the *General requirements*.

The use of input materials of suitable quality is necessary and a cleaning process may be applied. These measures are part of the recycling process that should be performed in accordance with good manufacturing practices. Relevant quality criteria always have to be 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 in order to ensure and demonstrate compliance of the final material or article.

The effectiveness of the combination of measures taken to ensure compliance has to be recorded in the supporting documentation. All foreseeable conditions of the intended use have to be taken into account.

Compliance testing

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

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 [1, 2]. Compliance with the applicable limits must be verified as prescribed in Resolution CM/Res (2020) 9 (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 to be chosen for testing.

When testing migration, the food shall be in contact with the materials and articles, as indicated on the label or under adequate conditions if no instructions are given. In the case of packaged food, 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.

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

The appropriate tests should be chosen based on the application. The approaches for testing compliance may include the following:

- Migration tests using modified polyphenylene oxide (MPPO, e.g. Tenax®) as adsorbent, (EN 14338, ÖNORM A 1123) to estimate the migration of volatile or semi-volatile substances into dry food [9]. Paper and board materials or articles for baking applications are tested with MPPO for 2 hours at 175 °C; those for microwave oven use for 30 minutes at 150 °C [10].
- Migration tests as described in the JRC Guidelines on testing conditions [1], for paper and board articles (e.g. cups, plates, bottles, board with a barrier layer, liquid packaging boards) for contact with liquid foods or beverages (usually with a plastic layer in food contact).

- Non-targeted screening analysis for the detection and identification of potential migrants from materials and articles made from paper and board. It can be applied to identify the substances used and their impurities or reaction or degradation products. Such tests, generally based on extraction, are reported in the literature (e.g. [3-7]). Bioassays, for example, on cytotoxicity according to EN 15845, may provide additional information for the hazard identification/assessment of migrants.
- Cold water extraction according to EN 645 to estimate the release of substances into aqueous foods and beverages. It is proposed for all applications except for filter paper for hot applications and baking paper.
- Hot water extraction according to EN 647 to estimate the release of water-soluble or hydrophilic substances into hot foods and beverages in contact with filter or baking papers.
- Migration tests with simulant 3 % acetic acid to estimate the release of metals into acidic ($\text{pH} < 4.5$) foods and beverages. Selection of contact time and temperature according to the JRC Guidelines on testing conditions for articles in contact with foodstuffs [1].
- Extraction with isooctane and/or 95 % ethanol according to EN 15519 to estimate migration of lipophilic substances (e.g. phthalates, benzophenones, DIPNs, PAHs, mineral oils, bisphenol A) into fatty food.
- 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 [8], may refine this approach, but are not developed to the same extent as for plastics.

Annex III lists standard methods for compliance testing.

By convention, the results for EN 645 and EN 647 (in mg/L of water extract) are considered equivalent to migration in mg/kg of food. This corresponds to $13.3 \text{ dm}^2/\text{kg}$ food if the mass of paper or board is 300 g/m^2 [11].

For calculation of migration into food, the real ratio of food contact surface area to amount of food must be used. If the intended use of paper and board is unknown, the ratio of surface area to amount of food up to which compliance is declared should be known and included in the declaration of compliance.

Testing of barrier and adsorbent effectiveness

The required barrier or adsorbent properties depend on the paper or board material and the given application. A standardised test for assessing barrier and adsorbent effectiveness is not available. Various test procedures can be found in peer-reviewed literature.

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 [12, 13] ensure that migration does not exceed a concentration of 0.01 mg/kg food, based on the following assumptions:

- the packaging-to-food mass ratio is equal to or less than 1:10;
- the initial concentration of the above-mentioned substances is less than 10 mg/kg material (measured, for example, by GC/FID of the extract).

Experimental testing with surrogate substances

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 over a long period of time, e.g. low diffusivity plastics or multilayers with low permeability. Supporting data have to be provided in the compliance documentation in such cases.

The effectiveness of functional barriers or adsorbents can be determined either using target substance(s) or surrogate substances representing potential migrants with different chemical properties (polarity, molecular mass or volatility), such as *n*-heptadecane, 4-methyl benzophenone and dipropyl phthalate [8, 9]. For the targeted determination of functional barrier effectiveness, various permeation tests with a broader range of model substances have been developed [14-16]. Approaches have to be justified and methods adequately validated.

Testing of functional barrier effectiveness of internal bags

For the determination of the barrier effectiveness of internal bags used in boxes of paperboard, 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 [13]. Periodically a sample of the receptor

is analysed for the permeated surrogate substances. Data from an interlaboratory comparison using this approach have been published [17].

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 paperboard and of functional adsorbents

To test the effectiveness of a functional barrier that is already placed on paper or board, similar methods may be applied. One approach is to first transfer the surrogate substances to the non-food contact side of the paper or board from a donor paper or board (to avoid spiking with a solution), and then measure the transferred amount. The migration into the receptor (e.g. silicone paper) can then be determined as described above [18]. Another approach is to spray a known amount of the surrogates onto the non-food contact side of the paperboard [19] and then measure their concentration in food.

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 in a trap on the receptor (food contact) side for quantitative analysis of permeated surrogate substances [14-16] and subsequent data evaluation as mentioned for internal bags. For functional barrier layers placed onto the paperboard it has to be taken into account that migration into the functional barrier starts during the production of the material or article, which may be long before the food contact application.

An approach using surrogate substances is described in [20] 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.

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 [21].

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 of the intended use.

Modelling

The permeability of a barrier polymer for 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 using model substances [14, 15, 22, 23]. The performance of the functional barrier can then be calculated for any food contact condition, barrier thickness and food-package contact time. Only validated mathematical modelling may be applied.

Testing of the transfer of antimicrobial substances

In the case of materials and articles in contact with aqueous or fatty foods, antimicrobial activity in paper and board shall be tested according to EN 1104. No transfer of antimicrobial constituents shall be observable.

Testing of release of colourants and fluorescent whiteners

In the case of materials and articles in contact with aqueous, alcoholic or fatty foods, the release of colourants and fluorescent whiteners shall be determined in accordance with EN 646 and EN 648.

Sensory/organoleptic testing

Methods for testing potential sensorial effects of paper and board on foods are described in EN 1230-1, EN 1230-2 and DIN 10955.

Detection of recycled material

The following methods can be used to detect recycled material in paper or board. For reliable detection 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.

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

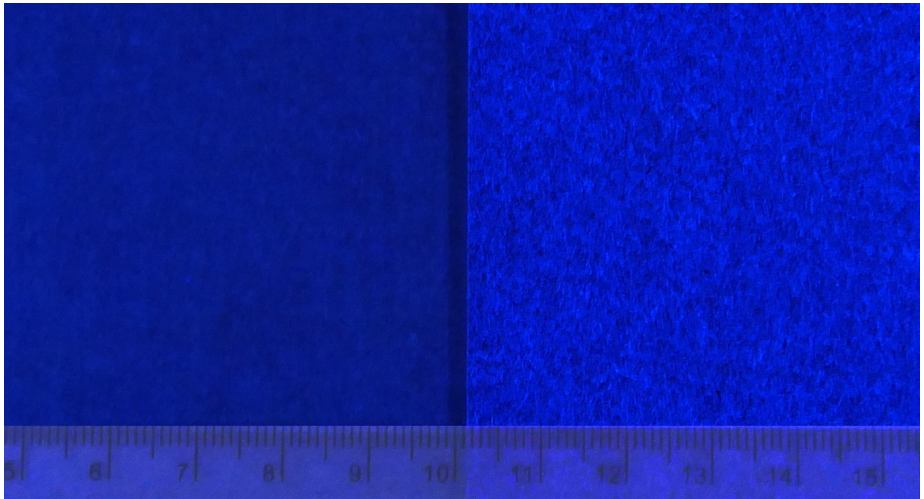
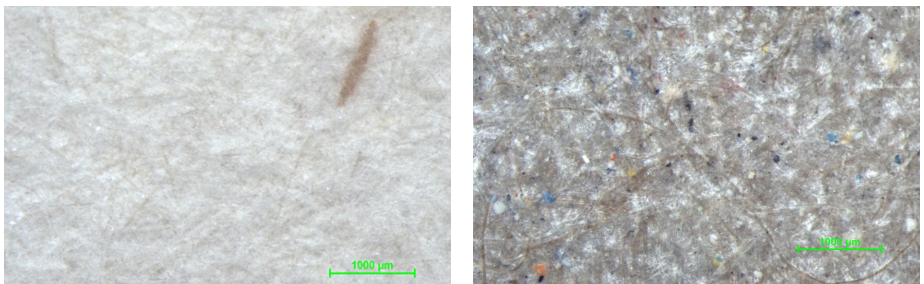


Figure 2. **Paperboard under transmission light microscopy: left, fresh fibre material; right, recycled material**



Figures 1 and 2: Austrian Agency for Health and Food Safety (AGES).

Identification by UV illumination

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

Identification by light microscopy

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

Marker substances for recycled material

Diisopropyl naphthalenes (DIPNs) are commonly used as solvents for dyes in carbonless copy paper. DIPNs may be detected in solvent extracts of paper and board according to EN 14719. Very low levels of DIPNs have been reported in fresh fibre paper and board as a result of cross-contamination from recycled paper.

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 % ethanol or methanol.

Other sources of marker substances may be printing ink components.

Supporting documentation and declaration of compliance

Resolution CM/Res (2020) 9 (Appendix, Section 8) sets out the general requirements for documentation supporting compliance and safety (supporting documentation) and the communication of this information along the chain of business operators (declaration of compliance). Further guidance will be made available in a separate document.

Supporting documentation

In addition to information requirements laid down for all food contact materials and articles as well as products intended for their manufacture, the supporting documentation needs to include the following information, as applicable:

- for fresh fibre paper and board: plant material used as the source of fibres and a description of the process(es) applied to obtain the fibres;
- process(es) applied for bleaching;

- grammage of the paper or board material or article and percentage of recovered fibre it contains;
- grade of the material being recycled, sorting procedure applied during recycling for recycled paper and board, criteria set and data supporting conformity with the criteria;
- cleaning procedure applied during recycling for recycled paper and board, criteria set and data supporting conformity with the criteria;
- if a functional barrier is used to reduce migration into food: description of the barrier, process used to apply the barrier, the criterion used to determine its effectiveness, the method of testing and the resulting data;
- if a barrier layer on the food contact surface of recycled paper or board is used to reduce migration into food: data, literature or reasoning that set-off and transfer from outer surfaces of the closures into the packaging make no relevant contributions to migration;
- if recycled material is used with a functional adsorbent to reduce migration into food: the criterion used to determine its effectiveness, the method of testing, data on the adsorption capacity and its interpretation for the range of applications for which it is suitable;
- if no measure is taken to reduce migration from recycled paper and board: the restrictions of use and data supporting absence of migration.

Declaration of compliance

In addition to the requirements laid down for all food contact materials and articles as well as products intended for their manufacture [Resolution CM/Res (2020) 9 (Appendix, Section 8.2)], the declaration of compliance needs to include the following, as applicable:

- information on the type of material, such as fresh and/or recycled material, in all layers;
- adequate information on recycled paper or board material (e.g. percentage in mixture with fresh fibres; quality of the recycled material; cleaning process);
- measures taken to render the material or article compliant with Resolution CM/Res (2020) 9 and this Technical Guide, such as specification of functional barrier or functional adsorbent;
- for recycled paper and board with a functional barrier applied to the food contact surface: storage conditions for the material or article, (e.g. related to

functional barrier effectiveness or set-off), duration of the useful shelf life, taking into account the period before being in food contact, and requirements on closure design;

- 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.

References

Please note that standard methods are listed in Annex III.

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Further reading

- Amtliche Sammlung von Analysenverfahren nach §35 LMBG, Methode B 82.02-2 „Nachweis der Verwendung verbotener Azofarbstoffe auf gefärbten textilen Bedarfsgegenständen“.
- Amtliche Sammlung von Untersuchungsverfahren nach §35 Lebensmittel- und Bedarfsgegenstandegesetz, Methode L 00-00-6: Bestimmung von primären aromatischen Aminen in wässrigen Lebensmittelsimulanzien. (Official Collection of Methods of Analysis under § 35 of the Foods and Other Commodities Act, Method No. L 00-00.6: Determination of primary aromatic amines in aqueous food simulants.)
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Annex I. References/links to national regulations or recommendations

France

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-vo2.pdf

Swiss Ordinance on Materials and Articles in Contact with Food (SR 817.023.21): <https://www.admin.ch/opc/de/classified-compilation/20143393/index.html#id-9>

Germany

BfR Recommendations for paper and board:

XXXVI. Paper and board for food contact: <https://bfr.ble.de/kse/faes/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>

Italy

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

Netherlands

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>

A subsequent amendment updated the positive lists with several new materials and was notified in 2016. The text of the amendment (i.e., not a consolidated version) is available in TRIS: <http://ec.europa.eu/growth/toolsdatabases/tris/en/search/?trisaction=search.detail&year=2016&num=208>

Annex II. Specific migration limits (SML) for some constituents or contaminants

Table 1

Substance	CAS No.	SML (mg/kg in food/ food simulant)	Notes	Reference and explanations
4,4'-Bis(dimethyl-amino) Benzophenone (Michler's ketone)	90-94-8	ND	1	Carcinogen class 1B according to Table 3.1 of Annex VI of Regulation (EC) No. 1272/2008
Bisphenol A	80-05-7	0.05	1	EFSA Journal (2015;13(1):3978): t-TDI 4 µg/kg bw per day, average bw 60 kg, allocation factor 20 %. Regulation (EU) No. 2018/213
		ND	1	Regulation (EU) No. 2018/213: applications for infants and young children as referred to in Regulation (EU) No. 609/2013

Substance	CAS No.	SML (mg/kg in food/ food simulant)	Notes	Reference and explanations
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	ND	1	The method of analysis should have a limit of detection: a) not higher than 0.001 mg/kg for migration in food simulant from paper and board not yet in contact with food; b) appropriate to ensure that compliance of the final food with Regulation (EC) No. 1881/2006 will not be compromised. Standard methods for analysis are listed in Annex III
Mineral oil hydrocarbons (MOH)	—	under discussion	1, 2	
Sum of benzophenone, 2-methyl benzophenone, 3-methyl benzophenone and 4-methyl benzophenone	119-61-9 131-58-8 643-65-2 134-84-9	0.6	1	Regulation (EU) 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
Sum of 2-methyl benzophenone, 3-methyl benzophenone, 4-methyl benzophenone	131-58-8 643-65-2 134-84-9	0.05	1	Swiss Ordinance (SR 817.023.21) Annex 10
Sum of dibutylphthalate (DBP) and diisobutylphthalate (DiBP)	84-74-2 84-69-5	0.3	1, 3	Regulation (EU) No. 10/2011 EFSA Journal (2005; 242: 1-17): TDI for DBP: 0.01 mg/kg bw per day. DiBP: comparable structure

Substance	CAS No.	SML (mg/kg in food/ food simulant)	Notes	Reference and explanations
Di(2-ethylhexyl) phthalate (DEHP)	117-81-7	1.5	1, 3	Regulation (EU) No. 10/2011, EFSA Journal (2005; 243: 1-20): TDI 0.05 mg/kg bw per day
1A/1B Classified PAAs		ND (0.002)	1, 4	Hazard class Carc./ Muta./Repr. 1A or 1B according to Table 3 of Annex VI of Regulation (EC) No. 1272/2008, especially those listed in Appendix 8 Entry 43 of Regulation (EC) No. 1907/2006
Sum of all primary aromatic amines (PAAs)		ND	1, 4	Table 3 of Annex VI of Regulation (EC) No. 1272/2008
Lead (Pb)	7439-92-1	ND	5	Regulation (EU) No. 10/2011
PFAS (per- and polyfluoroalkyl substances)		under discussion	6	The Opinion was adopted at the CONTAM Plenary meeting on 9 July 2020 and published in the EFSA Journal [26]

General comment: tests for contaminants that are known not to be present or not to migrate in the particular application can be omitted.

ND: Not detectable: unless otherwise specified the LOD should be not higher than 0.01 mg/kg food. These substances should not be intentionally added.

Note 1: Entry sources may be printing inks, adhesives, organic coatings and recovered fibres.

Note 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 reasonably feasible and to ensure that migration of genotoxic, carcinogenic MOAHs does not occur.

Note 3: Limits and groups will be adapted pending related amendments to Regulation (EU) No. 10/2011.

Note 4: Literature on PAAs: [24, 25].

Note 5: Entry sources for lead may be recovered fibres or contamination from intentionally added minerals.

Note 6: Restrictions under REACH will apply to one or more of these substances. National restrictions will also apply.

Annex III. 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.

CEN/TS 13130-13: Plastics substances subject to limitation – Determination of 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A) in food simulants;

EN 645: Paper and board intended to come into contact with foodstuffs.
Preparation of a cold water extract;

EN 646: Paper and board intended to come into contact with foodstuffs.
Determination of colour fastness of dyed paper and board;

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 1104: Paper and board intended to come into contact with foodstuffs.
Determination of the transfer of antimicrobial constituents;

EN 1230-1: Paper and board intended to come into contact with foodstuffs.
Sensory analysis. Odour;

EN 1230-2: Paper and board intended to come into contact with foodstuffs.
Sensory analysis. Off-flavour (taint);

EN 1541: Paper and board intended to come into contact with foodstuffs.
Determination of formaldehyde in an aqueous extract;

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;

- EN 14719:** Pulp, paper and board. Determination of the diisopropylnaphthalene (DIPN) content by solvent extraction;
- EN 15519:** Paper and board intended to come into contact with foodstuffs. Preparation of an organic solvent extract;
- EN 15845:** Paper and board. Determination of the cytotoxicity of aqueous extracts;
- EN 17163:** Pulp, paper and board. Determination of primary aromatic amines (PAA) in a water extract by a LC/MS method;
- ISO 8784-1:** Pulp, paper and board. Microbiological examination. Enumeration of bacteria and bacterial spores based on disintegration;
- 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;
- DIN 10955:** Sensory Analysis – Testing of packaging materials and packages for foodstuffs;
- EN 16619:** 2015 Food analysis – Determination of benzo[a]pyrene, benz[a]anthracene, chrysene and benzo[b]fluoranthene in foodstuffs by gas chromatography mass spectrometry (GC-MS);
- CEN/TS 16621:** 2014 Food analysis. Determination of benzo[a]pyrene, benz[a]anthracene, chrysene and benzo[b]fluoranthene in foodstuffs by high performance liquid chromatography with fluorescence detection (HPLC-FD).

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