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Paper and Board Food Contact Materials

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Content

Preface

The Nordic report on paper and board food contact materials (after this referred to as this document) is elaborated for, manufacturers and other business operators in the production chain. The document should ensure that the end-product does not constitute a risk to health and by all other means are produced in accordance with Article 3 of 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 repealing Directives 80/590/EEC and 89/109/EEC[1] (after this referred to as Regulation (EC) No 1935/2004). As long as it is not transposed into national legislation in the Nordic Countries, the fulfilment of the requirements in this document is not mandatory. Consequently industry may also find other ways of fulfilling requirements in Regulation (EC) No 1935/2004 Article 3.

The basis for this document is the Council of Europe Resolution on Paper and Board Materials and Articles intended to come into contact with foodstuffs AP (2002) 1 (after this referred to as CoE Res AP (2002) 1) and five technical documents (after this referred to as CoE Res AP (2002) 1 – TD 1-5)[2].

Requirements in this document on Good Manufacturing Practice (GMP), compliance declarations, documentation, traceability, active and intelligent materials and articles and functional barriers are harmonized with Regulation (EC) No 1935/2004, Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (after this referred to as Regulation (EC) No 2023/2006) and Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with food, and later amendments (after this referred to as Directive 2002/72/EC)[3].

Regulation (EC) No 1935/2004 gives no detailed answers with respect to levels of safe migration of substances in paper and board to food. According to this document substances used in the production of paper and board used for all food contact applications should have been evaluated by European Food Safety Authority in the EU (EFSA)[4], Bundesinstitut für Risikobewertung, Germany (BfR)[5] or Food and Drugs Administration

[1] Regulation (EC) No 1935/2004: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/framework_en.htm

[2] Council of Europe: http://www.coe.int

[3] EU-legislation: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm

[4] Reference is also made to Synoptic Document, available at EU-commissions home page for FCM: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

[5] Recommendation no XXXVI (36) on paper and board for food contact: http://bfr.zadi.de/kse

of the United States of America (FDA). Specifications and conditions of use must be respected. Substances may be used as long as they are evaluated for use in food contact materials or as direct food additives. For substances listed more than once, the newest EFSA-opinion prevails. Special attention should be paid to Food Consumption Factors[6] for paper and board made for contact with food for infants and small children.

Questions may be asked concerning safe use of the natural fibres of the paper and board, itself. In the Nordic work this is identified and recognized. The fibres of paper and board produced of Nordic tree types as well as tree types from other parts of the world, are not necessarily toxicologically evaluated, but are in this context generally regarded as safe.

In the future industry may develop new technologies such as nanotechnology, antimicrobial compounds, active and/or intelligent paper, new techniques on recycling and biodegradable materials. Paper and board industry is expected to act responsible when applying new technologies, especially in view of increasing safe, consumer oriented and environmentally safe food contact materials. It is foreseen that when biological tests (e. g. Biosafepaper project) have been fully accepted and validated for paper they may replace the specific requirements requested in this document. The Nordic group is open to meet these challenges, and we will do our best to update this document when necessary.

The Nordic countries have long traditions of cooperation on food contact materials, as well as in many other areas. Furthermore, these countries have similar legislation for different types of materials. With Denmark, Finland and Sweden being members of the European Union, and Iceland and Norway being associated through the European Economic Agreement (the EEA agreement), the subject of paper and board in contact with food was dealt with in a project group under the Nordic Council of Ministers.

Food industry, represented by members of the CIAA, has provided their valuable contribution in elaborating this document.

[6] Food reduction/consumption factors – Report, Nordic Council of Ministers (NMR), views from a Nordic workshop November 2002

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Project director was Per Fjeldal.

Summary in English

Paper and Board Food Contact Materials

This document is elaborated for, manufacturers, other business operators and interested parties in the production chain. The document should ensure that the end-product does not constitute a risk to health and by all other means are produced in accordance with Article 3 of Regulation (EC) No 1935/2004. This document may also provide a help to national enforcement authorities and laboratories. As long as it is not transposed into national legislation in the Nordic Countries, the fulfilment of the requirements in this document is not mandatory.

The basis for this document is the Council of Europe Resolution on Paper and Board Materials and Articles intended to come into contact with foodstuffs AP (2002) 1. However, legislative, scientific and technological development has been considered after the publication of CoE resolution as well as other development followed in the EU/EEA-area and elsewhere.

Requirements in this document on Good Manufacturing Practice (GMP), compliance declarations, documentation, traceability, active and intelligent materials and articles and functional barriers are harmonized with Regulation (EC) No 1935/2004, and existing measures given under the power of this regulation.

According to this document substances used in the production of paper and board used for all food contact applications should have been evaluated by EFSA, BfR or FDA. Specifications and conditions of use must be respected. Substances may be used as long as they are evaluated for use in food contact materials or as direct food additives. However, special attention should be paid to Food Consumption Factors e.g. for infants and small children.

This document applies to materials and articles constituted of paper and board which may comprise one or more layer(s) of fibres and are intended to come into contact with or are placed in contact with foodstuffs. Any layer which is composed of paper and board must fulfil the requirements of this document, unless separated from the foodstuffs by a functional barrier.

The fibres of paper and board produced of Nordic tree types, as well as tree types from other parts of the world, are not necessarily toxicologically evaluated, but are in this context generally regarded as safe. Paper and board are manufactured from cellulose-based natural fibres from bleached and unbleached fibre material, including recycled fibres. In

addition paper and board may contain several monomer or polymeric additives.

Detailed requirements to compliance declarations and documentation are essential elements in this document, specifying in detail what information shall be kept for inspection by national authorities and what information shall be provided in compliance declarations to the downstream user as a minimum. Requirements on compliance declarations are based on Directive 84/500/EEC including later amendments and Directive 2002/72/EC and amendments. Both are Directives operationalising the obligation in Article 16 of Regulation (EC) No 1935/2004 of issuing compliance declarations.

Specific restrictions are given on finished materials. For virgin fibres tests has to be carried out on heavy metals and PCP. More tests have to be carried out on products made from recycled fibres, dependent on which types of food the materials are intended for contact with. Until new biological tests have been fully accepted and validated for paper the specific requirements for recycled fibres in this document has to be checked for to ensure safe products.

Foods have been classified into three types, taking into account the nature of the food and the potential for migration in contact with paper and board. The classification laid down in EU Directive 85/572/EEC should be used to determine the food type for individual foodstuffs except where Chapter 6.4 indicates otherwise.

No specific process technologies in connection to the production of recycled fibres is required, only that end product testing is carried out, and restrictions given in relevant tables is respected. However, a short description from the producer of paper and board on which type of process technologies is used shall be included in the documentation.

1. Field of application

This document applies to materials and articles, including active and intelligent materials and articles, constituted of paper and board (excluding nonwovens) which may comprise one or more layer(s) of fibres and are placed in contact with foodstuffs, are intended to come into contact with or can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use. A plastic layer, or a layer of any other material, such as aluminium, waxes or paraffins applied to the paper and board is excluded from the requirements in this document. When the materials and articles consist of two or more layers, exclusively or not exclusively made of paper and board, any layer which is composed of paper and board must fulfil the requirements of this document, unless separated from the foodstuffs by a functional barrier to migration. A definition of properties for a functional barrier is defined in Annex No. 1 to this document

Filtering layers of high grammage and consisting to a large extent of non-fibrous material as well as tissue paper kitchen towels and napkins are excluded from the field of application of the document.

2. Definition

Paper and board are manufactured from cellulose-based natural fibres from bleached and unbleached fibre material. Recycled fibre materials may also be used in accordance with Chapter 6 of this document. In addition paper and board may contain functional additives and synthetic fibres[7]. Paper and board may also contain other treatment agents and polymeric binders for organic and inorganic pigments.

[7] Synthetic fibers should comply with requirements given in EU Directive 2002/72/EC.

3. Compliance declarations and documentation

At the marketing stages other than the retail stage, materials and articles as well as the substances intended for the manufacturing of these materials and articles, shall be accompanied by a compliance declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

Appropriate documentation to demonstrate that the materials and articles as well as the substances intended for the manufacturing of these materials and articles comply with the requirements of this document shall be made available by the business operator to the national competent authorities on request. That documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.

Reference to requirements for compliance declarations is made in Annex No. 2[8], and to requirements for specific documentation on finished materials and articles is made in Annex No. 3. Guidance on compliance declarations and documentation is also to be found in the Nordic Report on In-house documentation and traceability[9].

[8] The annex is based on requirements to compliance declarations of Directive 2002/72/EC for plastic materials and articles and later amendments and is adjusted to correspond to requirements on paper and board in this guideline

[9] Recommendations given in the report on In-house documentation and traceability should also be considered. Since the In-house documentation and traceability-report focus on all stages in the production, valuable information on documentation through the production chain may be achieved.

4. Traceability

Materials and articles shall fulfil Regulation (EC) No 1935/2004, Article 17, with respect to traceability. Requirements on traceability in CoE Res AP (2002) 1 – TD 4 shall also be respected.

In case of conflict EU Regulation prevails.

Guidance on traceability is also given in the Nordic Report on In-house documentation and traceability[10].

[10] Recommendations given in the report on In-house documentation and traceability should also be considered. Since the In-house documentation and traceability-report focus on all stages in the production, valuable information on documentation through the production chain may be achieved.

5. Specifications

5.1. Fulfilment of specifications

Paper and board used for all food contact applications under normal or foreseeable conditions of use should meet the conditions in this chapter.

5.2. General requirements

Paper and board used for all food contact applications should meet the requirements in 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 repealing Directives 80/590/EEC and 89/109/EEC

5.3. Good manufacturing practice

Paper and board used for all food contact applications should 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 and the CoE Res AP (2002) 1- TD 4[11] and using the substances of the lists referred to in 5.6. Specific restrictions, according to the conditions specified. In case of conflict EU Regulation prevails.

5.4. Microbiological quality

Paper and board used for all food contact applications should be of suitable microbiological quality, taking into account the intended end use of the material. For materials and articles intended to come into contact with aqueous and/or fatty foodstuffs, particular attention should be paid to pathogens.

[11] 'CEPI' guide for good manufacturing practice for paper and board for food contact'

5.5. Antimicrobial substances

Paper and board used for all food contact applications should not release substances, used as processing aids, which have an antimicrobial effect on foodstuffs. The method of analysis to be applied is laid down in CoE Res AP (2002) 1 – TD 2.

Antimicrobial substances (surface biocides) shall not be added to paper and board to have an effect on the surface of the materials or articles in its finished state. Instead of adding antimicrobial substances, good manufacturing practice[12] (see chapter 5.3) and good hygienic practice[13] should be followed.

However, if paper and board is intended to release and/or absorb substances having a technological effect in or on food, it should be regarded to be an active and/or intelligent material and/or article. Accordingly the provisions in Regulation (EC) 1935/2004, Article 4[14] should be observed.

5.6. Specific restrictions

Paper and board used for all food contact applications should comply with the restrictions laid down in Table 1 and Table 2 hereafter.

Substances used in the production of paper and board used for all food contact applications should comply with at least one of following requirements:

1. Substances evaluated by EFSA

Substances evaluated by the European Food Safety Authority (EFSA)[15] may be used if a positive opinion is achieved. Substances may be used even if they are evaluated for use in other food contact materials, such as plastic, regenerated cellulose or used as direct food additives.

2. Substances evaluated by BfR

Approved and listed substances according to Guidelines from Bundesinstitut für Risikobewertung, Recommendation XXXVI Papiere, Kartons

[12] GMP in food industry is also important to avoid the need for antimicrobial substances.

[13] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

[14] A Commission Regulation on A&I-materials is under preparation and this measure also has to be fulfilled when it enters into force

[15] Link to EFSA: http://www.efsa.europa.eu/en/science/AFC/AFC_opinions.html. Both direct food additives, plastic additives and additives to regenerated cellulose may be used. Substances evaluated by the former Scientific Committee in the EU may also be used as long as the opinion was positive, and assumed respecting specifications and conditions of use. The Synoptic Document may be a source to information for both EFSA and SCF opinions, only substances on list 0-4 may be used: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/synoptic_doc_en.pdf

und Pappen für den Lebensmittelkontakt[16] (paper and board for food contact) may be used.

3. Substances evaluated by FDA

Substances evaluated by Food and Drugs Administration of the United States of America (FDA)[17] may be used if a positive opinion is achieved. Substances may be used even if they are evaluated for use in other food contact materials and as direct food additives.

4. Substances listed in two or more of the sub items above

For substances listed in two or more of the sub items 1, 2 or 3 above, the newest EFSA-opinion prevails. If no EFSA-opinion is available the newest BfR opinion prevails.

Specifications and conditions of use must be respected for all substances of the sub items 1, 2 and 3 above. Fulfilling this requirement includes that concentration of the substance in food under no circumstances must be higher than if the specifications and conditions of use for the original material was followed or if the substance was added as a direct food additive.

Special attention should be paid to Food Consumption Factors[18]. If paper and board products are made specifically for infants and small children the producer has to be aware that the ingestion is relatively higher per kilo body weight compared to adults. A factor of 10 may be added. The intake of soft drinks and water may exceed one litre. The producer also has to be aware of this when doing interpretation of restrictions in different legislation. In legislation on drinking water a daily intake of two litres is set as default.

Table 1 – restriction limits (QM) for cadmium, lead and mercury[19]

Substance	Restriction, QM limit mg/dm^2 paper and board
Cadmium	0.002
Lead	0.003
Mercury	0.002

Table 2 – restriction limit for pentachlorophenol

Substance	Purity requirement mg/kg paper and board
Pentachlorophenol	0.15

[16] Link to BfR Recommendation 36: http://bfr.zadi.de/kse

[17] Link to FDA: http://www.cfsan.fda.gov/~dms/opa-fcn.html. Both direct food additives and additives to food contact materials may be used.

[18] Food reduction/consumption factors - views from a Nordic workshop November 2002

[19] EU Regulations introduces maximum limits for heavy metals in food. These restrictions also must be respected.

5.7 Further guidance on specific restrictions

The 'List of substances used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs' set out in CoE Res AP (2002) 1 – TD 1[20] may be of help for industry when selecting substances for use in the production. The list provides an overview on substances evaluated by EFSA, SCF, BfR and FDA until 2002 (updated 2005):

- 2.1 A – list 1 of additives
- 2.1.1, Appendix A – monomers

Only those substances evaluated by scientific bodies according to the conditions specified in the mentioned sub lists should be used. Substances shall respect either the QM or SML restrictions given in the tables.

The SML are calculated in the same way as in Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. It is assumed that a consumer with a body weight of 60 kg is consuming 1 kg food daily contemned with migrants up to the restriction given. However, special attention should be paid to Food Consumption Factors, e.g. for infants and small children ingesting more food per kilo body weight compared to adults.

QM[21] have been derived from guideline levels laid down in Council of Europe Guideline AP (96) 4. QM is relevant for restrictions based on opinions from EFSA, BfR Recommendation 36 and FDA, as well as restrictions in Table 1 of this document. The 'List of substances used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs' set out in CoE Res AP (2002) 1 – TD 1, is also expressing restrictions as QM.

The conventional ratio of 6 dm^2 of material coming into contact with 1 kg of foodstuffs is applied, assuming 100 % migration. For contact conditions where the mass of food to contact area ratio differs from the conventional ratio of 1 kg to 6 dm^2, the QM restriction to be applied should be calculated as specified in CoE Res AP (2002) 1 – TD 2.

5.7.1 Verification of compliance

Verification of compliance with the quantitative restrictions should to be carried out according to the conditions laid down in the 'Test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs' set out in CoE Res AP (2002) 1 – TD 2.

[20] Link to Council of Europe's policy statement concerning materials and articles intended to come into contact with foodstuffs: http://www.coe.int

[21] Maximum permitted quantity of the substance in the finished material or product expressed as mg per dm^2 of the surface in contact with foodstuffs

According to CoE Res AP (2002) 1 TD 2 testing for compliance with restrictions for other substances than given in the list of chapter 6, the best available method should be chosen[22].

5.8. Materials excluded from testing for compliance

Testing for compliance with the restrictions in Table 1 is not required for paper and board materials and articles intended to come into contact with food type III[23].

5.9. Compliance shown by calculations

If it can be shown by calculation, taking into account the conditions of manufacture that the restrictions laid down in the lists referred to in 5.6 (1, 2 and 3) Specific restrictions, cannot be exceeded, no testing for compliance with these restrictions is necessary.

5.10. Dioxins

Paper and board used for food contact applications should comply with the restrictions laid down in Table 3 hereafter.

Table 3 – restriction limit for dioxins

Substance	SML, pg TEQ /kg food or food simulant
Dioxins (polychlorinated dibenzodioxins and dibenzofurans) and dioxin-like PCBs	120

Testing is only mandatory for paper and board bleached with elementary chlorine.

Manufacturers of paper and board for all food contact applications should make sure that they use raw materials produced by processes which reduce dioxins (polychlorinated dibenzodioxins and dibenzofurans) to levels as low as reasonably achievable[24].

[22] If references are made to Directives 82/711/EEC or 85/572/EEC and amendments to these it is important to carefully evaluate the differences between plastic materials and paper and board, and to use the methods only when appropriate.

[23] Dry foodstuffs or foodstuffs which are to be shelled, peeled or washed

[24] Regulation (EC) 1881/2006 introduces maximum limits for dioxins in food. Paper and board must not release dioxins in levels that may be in contradiction to this requirement.

6. Paper and board materials and articles made from recycled fibres

Paper and board produced with recycled fibres can be used as food contact materials if it originates from specified qualities of recovered paper and board which has been subjected to appropriate processing and cleaning, provided that the finished materials comply with the specifications in this chapter[25].

6.1. Introduction

This chapter is for the guidance of the enforcement authorities, manufacturers and users in order to ensure that the use of the end-product does not constitute a risk to health in accordance with Article 3 of Regulation (EC) No 1935/2004.

Paper and board made in part or in full from recycled fibres intended to come into contact with foodstuffs should comply with the general requirements of this document. However, recycled paper and board should be subject to additional requirements to ensure their safety in use due to the presence in the feedstock of constituents of printing inks, adhesives and/or other substances, e.g. from paper not intended for food contact. These additional requirements are given in this chapter.

In order to ensure the safety of the end product the following aspects should be considered together:

- The source of recovered paper and board;
- The processing technologies applied to remove contaminants;
- The intended end use of the product.

These aspects are basic elements of product safety assuance.

As further elements of product safety assurance, tests should be carried out where appropriate or advisable as a matter of prudence, to determine the presence of specific substances in the end-product.

The Nordic group will do their best to update this document when necessary, to take account of technological developments in the process-

[25] Chapter 6 in this Guideline more or less corresponds with 'Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs' set out in CoE Res AP (2002) 1 – TD 3.

ing of recovered paper, improvements in analytical techniques, toxicology testing and increased knowledge of the toxicology of chemical substances.

6.2. Good manufacturing practice

GMP shall be fulfilled also for recycled paper and board materials and articles intended for contact with foodstuffs, see chapter 5.3. Some basic elements, which are particularly important for the production of paper and board made from recycled fibres intended to come into contact with foodstuffs, are covered in Chapters 6.3, 6.5 and 6.6 of this document.

6.3. Recovered paper groups

The aim of this chapter is to define the groups of recovered paper and board that can be used as raw materials in the manufacture of paper and board intended to come into contact with foodstuffs, as well as those groups of recovered paper and board which cannot be used as raw materials. These groups are defined in relation to the potential contaminants which could be present, so as to assist the selection and processing of raw materials as part of Good manufacturing practice (see CoE Res AP (2002) 1 – TD 4).

The groups of recovered paper listed below are defined in generic terms for the purpose of this document. Where industry uses other definitions such as their own specifications or, for example, the nomenclature in EN 643:2001 some of which are listed below for illustrative purposes, they should ensure correspondence with the groups below.

6.3.1. Recovered paper for use as raw materials

The descriptions within each group are given as examples. Where applicable, some grades listed in EN 643:2001 are indicated.

Group 1

a) Paper and board manufactured with substances of the ‘List of substances used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs’ set out in CoE Res AP (2002) 1 – TD 1, approved substances according to Guidelines from BfR or individually accepted substances[26].
b) Unprinted cuttings, shavings, sheets and rolls from food contact paper and board based on virgin fibres.

[26] Reference is made to chapter 5.6 specific restrictions

Group 2

a) Paper and board which may be manufactured with substances not mentioned in the 'List of substances used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs' set out in CoE Res AP (2002) 1 – TD 1, approved substances according to Guidelines from BfR or individually accepted substances[27], unprinted or lightly printed or lightly coloured[28].
b) Unprinted cuttings, shavings, sheets and rolls of printing and writing papers (EN 643:2001 - 3.14, 3.15, 3.16, 3.17, 3.18, 3.19);
c) Lightly printed or coloured cuttings, shavings, sheets and rolls of printing and writing papers (EN 643:2001 - 2.03, 3.01, 3.02, 3.03, 3.04, 3.09);
d) White writing and printing paper originating from offices (EN 643:2001 - 3.05);
e) White continuous stationery paper (computer paper) (EN 643:2001 - 3.07);
f) Unprinted or lightly printed, unused kraft paper (EN 643:2001 - 4.07, 4.08);
g) Unprinted or lightly printed, unused packages (EN 643:2001 - 3.12, 3.13, 4.05);
h) Unused kraft sacks and wrappings.

Group 3

a) Printed paper and board, corrugated board from supermarkets, paper and board from households and industry.
b) Printed or coloured material from printing shops, over-issues etc. (EN 643:2001 - 1.06, 2.02, 2.04, 2.07, 3.08, 3.11);
c) Unsorted white and coloured writing and printing paper originating from offices;
d) Boxes and sheets of corrugated board collected from supermarkets (EN 643:2001 - *1.04, 1.05);*
e) Unused boxes and sheets of corrugated board (EN 643:2001 - 4.01);
f) Printed paper from households, such as newspaper, pamphlets, magazines, catalogues etc. (EN 643:2001 - 1.11);
g) Mixed papers and board from households (EN 643:2001 - 1.02, 5.01);
h) Sheets, boxes and cases of solid and corrugated board and folding boxboard from households.

[27] Reference is made to chapter 5.6 specific restrictions

[28] Lightly printed: Papers where the ratio of printed area to unprinted area is very small. Examples of lightly printed papers are shavings and cuttings, not mixed with misprinted sheets, originating from printing shops. Lightly coloured: Papers where only shading dyestuffs have been added during manufacture. (For example yellow pages in telephone directories are not considered as lightly coloured.)

6.3.2. Recovered paper and board not for use as raw materials

a) Contaminated waste paper and board from hospitals;
b) Recovered paper and board which has been mixed with garbage and subsequently sorted out;
c) Used stained sacks which have contained for example chemicals and foodstuffs;
d) Covering materials, such as paper used for covering furniture during repair and painting work;
e) Batches mainly consisting of carbonless copy paper; (EN 643:2001-2.09)
f) Waste paper from households containing used hygienic paper, such as used kitchen towels, handkerchiefs and facial tissue;
g) Old archives from libraries, offices etc., if they contain PCBs.

6.4. Foodstuff types

Foods have been classified into 3 types, taking into account the nature of the food and the potential for migration in contact with paper and board. The classification laid down in EU Directive 85/572/EEC and later amendments should be used to determine the food type for individual foodstuffs except where Chapter 6.4 of this document indicates otherwise.

6.4.1. Type I - Aqueous and/or fatty foodstuffs

Aqueous foods range from those which are liquid to those which are solid but have a high to medium water content. Examples of liquid foodstuffs include beverages and water. Examples of solid foods with a high to medium water content include fresh fish, shellfish, meat and some cheeses.

Fatty foods range from those which are fully fatty to those which are solid, with a low to medium moisture content but which have fat on the surface. Example of the former includes animal and vegetable fats. Examples of the latter include pastry products, pizzas, hamburgers, cheeses and chocolate.

Frozen foods of Type I can be considered to be dry, non-fatty of Type II provided that the food is not defrosted in contact with paper and board.

6.4.2. Type II - Dry, non-fatty foodstuffs

Foodstuffs which are dry or with low moisture content and which do not have fat on the surface. Examples of such foods include sugar, pulses, some bakery wares, salt, tea and spices.

Type II foodstuffs, e.g. bread, which come into contact with paper and board at temperatures above room temperature, e.g. in microwave or conventional ovens, should be considered as Type I foodstuffs.

Frozen foodstuffs of Type II are considered to be foodstuff Type I if they are defrosted in contact with paper and board.

6.4.3. Type III - Foodstuffs shelled, peeled or washed before consumption

Examples of Type III foodstuffs are vegetables, nuts to be shelled or peeled and potatoes.

6.5. Current process technologies and their purpose

Industry is free to choose technologies suitable for the intended use of the end-product. Below examples on current process technologies applied to the raw materials are listed:

- Mechanical cleaning
- Washing
- De-inking by washing or flotation
- Thermal treatment
- Chemical treatment

For details about process technologies, see CoE Res AP (2002) 1 – TD 3.

6.6. End-product requirements

The aim of this chapter is to specify the requirements for the end-product and tests to be carried out.

Restrictions laid down in this document apply to the end-product. Additional restrictions for the end-product are specified in Table 4. These additional restrictions are for substances which have the potential to be present in paper made of recycled fibres, and to migrate into foodstuffs at levels which may pose a risk to health. The list is based on current knowledge of chemicals which are found in or could migrate from recycled fibres.

Some of the restrictions for particular substances are based on evaluations by recognised international bodies, e.g. EFSA or JECFA[29]. Where restrictions have not yet been established by a recognised body, the requirements in Table 4 of this document have been made on grounds of prudence, to ensure that migration into foods is kept as low as reasonably achievable.

[29] Joint FAO/WHO Expert Committee on Food Additives

The volatility of most solvents ensures that they are not present in the finished product. However, industry should take the necessary steps to ensure that residual solvents are reduced to the lowest possible levels in the finished product, so that migration into food does not pose a risk to health.

The end-product should be tested in accordance with the procedure specified in this document and in test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs set out in CoE Res AP (2002) 1 – TD 2, in order to ensure compliance with Article 3 of Regulation (EC) No 1935/2004.

It is not necessary to carry out specific testing for compliance if there is conclusive evidence, assuming 100 % migration based on the content in the end-product or in the raw materials that the migration of the substances is so low that compliance with Article 3 of Regulation (EC) No 1935/2004 is ensured.

Tests should be carried out for substances with a demonstrated toxic potential whenever there are grounds to suspect their presence in the end-product.

Chemical or toxicological screening protocols for possible unknown toxic substances are desirable. Non intentionally added substances (NIAS) shall be assessed in accordance with Annex 4, in this document

6.7. Risk reduction plans

Producers of paper and board shall prepare a risk reduction plan for contaminants in materials and articles made from recycled fibres.

6.8. Consolidated matrix

A consolidated overview is given in Table 5 of groups of recovered paper and end-product requirements depending on food type I-III and group of paper (1-3) to come into contact with.

Tests on end-products are necessary where there are actual or potential risks to health. These risks depend on the nature of the recovered paper, the effectiveness and purpose of recycling treatments and the nature of the contact with foodstuffs for the end-product. All of these elements are combined with the requirements in Chapter 6.6 of this document.

The process technologies listed in CoE Res AP (2002) 1 – TD 3, Table 1 hereafter provide flexibility to take account of mill-specific circumstances. The purpose of these processes is to reduce or eliminate the presence of contaminants in the finished product and to fulfil the requirements set in Table 4 of this document. Other processes or combination of processes may be used in order to fulfil these requirements. It is the re-

sponsibility of industry to demonstrate through Good Manufacturing Practice (see CoE Res AP (2002) 1 – TD 4) that the end-product meets the requirements of Article 3 of Regulation (EC) No 1935/2004.

Table 4 - Specific requirements for recycled fibres

Substance	Requirements[30] (Food types I and II unless otherwise specified)
Michler's ketone	The migration of this substance should not be detectable in foodstuffs (limit of detection of 0.01 mg/kg foodstuff) Testing required for Food Type I only
4,4'-Bis (diethyl amino) benzophenone (DEAB)	The migration of this substance should not be detectable when measured in foodstuffs (limit of detection of 0.01 mg/kg foodstuff) Testing required for Food Type I only
Diisopropylnaphthalenes (DIPNs)	Specific migration limit of 8 mg/kg food. Testing required only if office grades as e.g. EN 643:2001 – 2.05, 2.06, and 3.06 are used[31].
Partially hydrogenated terphenyls (HTTP)	The migration of these substances should not be detectable when measured in foodstuffs (limit of detection of 0.01 mg/kg foodstuff) Testing required only if office grades as e.g. EN 643:2001 – 2.05, 2.06, and 3.06 are used[31]
Phthalates	Specific migration limit[32]: DEHP 1.5 mg/kg foods DBP 0.3 mg/kg foods BBP 30 mg/kg foods DINP+DIDP 9 mg/kg foods DIBP 0.3 mg/kg foods All other phthalates: 1,5 mg/kg foods (group restriction)
Azo colourants	Soluble azo colourants which may cleave to form aromatic amines listed in the proposal for the EU Directive, amending for the 19th time the Council Directive 76/769/EEC. The aromatic amines should not be detectable when measured in paper (limit of detection of 0.1 mg/kg paper).[33] Testing required for Food Type I only
Fluorescent whitening agents (FWA)	The migration of these substances should not be detectable when measured in foodstuffs[34] Testing required for Food type I only
Primary aromatic amines, suspected to be carcinogenic[35]	These substances should not be detectable when measured in paper[36] (limit of detection of 0.1 mg/kg paper). Testing required for Food Type I only
Polycyclic aromatic hydrocarbons (PAH)[37]	The migration of these substances should not be detectable when measured in foodstuffs (limit of detection of 0.01 mg/kg foodstuff)
Benzophenone	Specific migration limit of 0.1 mg/dm^2 of paper
Bisphenol A	Specific migration limit of 3 mg/kg food

[30] For general requirements to report of analysis, see Annex No 3

[31] Please observe that batches mainly consisting of carbonless copy paper; (EN 643:2001- 2.09), which may me a major source to these substances are not to be used

[32] SML should be converted to QM using the formula specified in CoE Res AP (2002) 1 TD 2

[33] The same report of analysis may be used to prove fulfilment of the requirements for both azo colourants and primary aromatic amines

[34] Tests should be carried out according to EN 648

[35] See: proposal for the EU Directive, amending for the 19th time the Council Directive 76/769/EEC, opinions expressed by SCF, IARC and other competent bodies

[36] This requirement is generally stricter than the restriction not detectable in food (DL: 0.01 mg/kg foodstuff), when assuming a layer of paper (with an average thickness) in contact with 6 dm^2 food

[37] EU Regulation 1881/2006 puts up maximum limits for benzo(a)pyrene as an indicator for PAH in food. Restrictions are between 0.001 – 0.010 mg/kg for various foodstuffs dependent of the source of contamination. Directive 2005/10/EC sets criteria for the method of analysis. The detection limit should be at least 0.0003 mg/kg and the limit of quantification 0.0009 mg/kg.

Table 5 – Consolidated matrix. The matrix should be read in conjunction with the text of this document

Food type (Chapter 6.4)	Recovered paper group (Chapter 6.3)	Process technologies[38] (Chapter 6.5)	Additional end-product requirements[39] (Chapter 6.6)
Food type I Aqueous and/or fatty foodstuffs (incl de-frosted)	Group 1: Paper and board manufactured in accordance with requirements laid down in chapter 5.6.	Industry is free to choose technologies suitable for the intended use of end-product according to GMP.	The requirements of Table 4 of this document do not apply
	Group 2: Paper and board which is not necessarily manufactured in accordance with requirements laid down in chapter 5.6. – Unprinted or lightly printed or lightly coloured.	Industry is free to choose technologies suitable for the intended use of end-product according to GMP.	Michler's ketone, DEAB, HTTP, DIPNs, Phthalates, Azo colourants, FWAs, Aromatic amines, Polycyclic aromatic hydrocarbons, Benzophenone, BPA
Food type II Dry, non-fatty foodstuffs, including frozen	Group 1: Paper and board manufactured in accordance with requirements laid down in chapter 5.6.	Industry is free to choose technologies suitable for the intended use of end-product according to GMP.	The requirements of Table 4 of this document do not apply
	Group 2: Paper and board which is not necessarily manufactured in accordance with requirements laid down in chapter 5.6. – Unprinted or lightly printed or lightly coloured.	Industry is free to choose technologies suitable for the intended use of end-product according to GMP.	HTTP, DIPNs, Phthalates, Polycyclic aromatic hydrocarbons, Benzophenone, BPA
	Group 3: Printed paper and board, corrugated board from supermarkets and paper and board from households and industry.	Industry is free to choose technologies suitable for the intended use of end-product according to GMP.	HTTP, DIPNs, Phthalates, Polycyclic aromatic hydrocarbons, Benzophenone, BPA
Food type III Foodstuffs which are shelled, peeled or washed	Group 1: Paper and board manufactured in accordance with requirements laid down in chapter 5.6.	Industry is free to choose technologies suitable for the intended use of end-product according to GMP.	The requirements of Table 4 of this document do not apply
	Group 2: Paper and board which is not necessarily manufactured in accordance with requirements laid down in chapter 5.6. – Unprinted or lightly printed or lightly coloured.	Industry is free to choose technologies suitable for the intended use of end-product according to GMP.	The requirements of Table 4 of this document do not apply
	Group 3: Printed paper and board, corrugated board from supermarkets and paper and board from households and industry.	Industry is free to choose technologies suitable for the intended use of end-product according to GMP.	The requirements of Table 4 of this document do not apply

[38] Processes or combinations of processes may be used provided that the end-product fulfils the requirements of Chapter 6.6

[39] Tests should be carried out for other toxic substances whenever there are grounds to suspect their presence in the end-product. Biological tests may be accepted in future amendments of this guideline when they have been fully accepted and validated. They may then replace the specific test requirements for recycled fibres requested in today's guideline.

References

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 repealing Directives 80/590/EEC and 89/109/EEC.

Council of Europe Resolution on Paper and Board Materials and Articles intended to come into contact with foodstuffs AP (2002) 1 and five technical documents.

Guidelines from Bundesinstitut für Risikobewertung, Recommendation no XXXVI on paper and board for food contact.

Regulation (EC) No 2023/2006 of the European Commission on good manufacturing practice for materials and articles intended to come into contact with food

Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with food, and later amendments.

Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (4th amendment of Directive 2002/72/EC)

Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs. Amendments to this directive should be observed e.g. Directive 2007/17/EC.

Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs. Amendments to this directive should be observed e.g. Directive 93/8/EEC and 97/48/EEC.

Summary – Scandinavian/ Sammendrag på skandinavisk

Matkontaktmaterialer av papp og papir

Dette dokumentet er utarbeidet for produsenter, andre næringsdrivende og interessenter i produksjonskjeden av papp og papir. Kravene i dette dokumentet skal sikre at sluttproduktene ikke utgjør en helserisiko og for øvrig er produsert på en slik måte at artikkel 3 i forordning (EC) No 1935/2004 er oppfylt. Dokumentet kan også være til hjelp for nasjonale tilsynsmyndigheter og analyselaboratorier. Så lenge bestemmelsene ikke er gjennomført i nasjonalt regelverk i de nordiske land, vil de kun være å anse som veiledende.

Basisen for den tilnærmingen som er gjort er Europarådsresolusjonen for papp og papir AP (2002) 1 og dens fem tekniske dokumenter. Imidlertid har det skjedd en utvikling siden resolusjonen ble vedtatt både på regelverksområdet, innen vitenskapen og sett i forhold til den teknologiske utviklingen generelt både i EU/EØS-området og andre steder.

Krav til god produksjonspraksis, skriftlige erklæringer, dokumentasjon, sporbarhet, aktive og intelligente materialer og gjenstander og funksjonelle barrierer er harmonisert med forordning (EC) No 1935/2004 og eksisterende regelverk gitt som krav i denne forordningen.

I henhold til dette dokumentet skal stoffer brukt i produksjonen av papp og papir være evaluert av enten EFSA, BfR eller FDA. Begrensinger eller spesifikasjoner skal være overholdt. Stoffer kan brukes både om de er vurdert som tilsetningsstoffer til matkontaktmaterialer og om de er vurdert som direkte tilsetningsstoffer. Industrien skal spesielt ta hensyn til konsumpsjonsfaktorer for mat når det gjelder spedbarn og små barn.

Dokumentet omfatter de materialer og gjenstander som består av papp og papir som kan bestå av ett eller flere lag av fiber som er ment for kontakt med næringsmidler eller som er brakt i kontakt med næringsmidler. Alle lag som består av papp og papir må oppfylle kravene om de ikke er separert fra maten med en funksjonell barriere.

Fibere av papp og papir produsert av nordiske treslag, samt treslag fra andre deler av verden, er ikke nødvendigvis toksikologisk evaluert. Den nordiske myndighetsgruppen imidlertid at materialene i sin ubearbeidede form kan ansees å være trygge. Papp og papir er produsert av cellulosebaserte naturlige fibrer fra bleket og ublekede fibermaterialer, som også omfatter resirkulert fiber. I tillegg kan papp og papir være tilsatt ulike monomere eller polymere tilsetningsstoffer.

Detaljerte krav til skriftlige erklæringer og dokumentasjon er sentrale elementer i dette dokumentet. Hvilken dokumentasjon som skal oppbevares for inspeksjon for myndighetene og hvilke opplysninger som minst skal gis videre til neste ledd i produksjonskjeden beskrives i detalj. Sistnevnte krav er harmonisert med direktiv 84/500/EØF med senere endringer og direktiv 2002/72/EF med senere endringer. Begge disse direktivene operasjonaliserer kravet i artikkel 16 i forordning (EF) 1935/2004 til utstedelse av skriftlige erklæringer.

Spesifikke restriksjoner er gitt for materialer i ferdig form. For nyfiber skal analyser være gjennomført for tungmetaller og pentaklorfenol. Flere tester skal være utført hvis produktet består av resirkulert fiber, avhengig av hvilken type mat materialene skal bringes i kontakt med. Inntil nye biologiske testmetoder er fullt ut akseptert og validert for papp og papir må produkter av resirkulert fiber være testet i henhold til kravene i dette dokumentet.

Mat er delt inn i tre klasser etter potensial for migrasjon fra papp og papir. Klassifiseringen, lagt ned i EU-direktiv 85/572/EEA, brukes til å dele inn i ulike matvaretyper unntatt når kapittel 6.4 tilsier noe annet.

Det stilles ingen spesielle krav til prosessteknologi i forbindelse med produksjonen av resirkulerte fiber, bare at analyser er utført i henhold til gitte krav og at restriksjoner i de respektive tabeller er oppfylt. Produsenten skal imidlertid kort oppsummere hvilke prosessteknologier som er benyttet i dokumentasjonen av prosessen.

Summary – Finnish/Yhteenveto suomeksi

Paperi ja kartonki elintarvikkeen kanssa kosketukseen joutuvissa materiaaleissa

Pohjoismainen asiakirja elintarvikkeen kanssa kosketukseen joutuvista paperi- ja kartonkimateriaaleista ja tarvikkeista on laadittu valmistajia, muita tuotantoketjun toimijoita ja asianosaisia varten. Asiakirjan tarkoituksena on varmistaa, että lopputuote ei ole terveydelle vaarallinen ja on muutenkin kaikin tavoin valmistettu asetuksen (EY) N:o 1935/2004 3 artiklan mukaisesti. Tästä asiakirjasta voi myös olla hyötyä kansallisille valvontaviranomaisille ja laboratorioille. Tämän asiakirjan sisältämien vaatimusten täyttäminen ei ole pakollista niin pitkään, kuin asiakirjaa ei ole saatettu voimaan kansallisella lainsäädännöllä Pohjoismaissa.

Tämä asiakirja perustuu Euroopan neuvoston elintarvikkeen kanssa kosketukseen joutuvia paperi- ja kartonkimateriaaleja ja tarvikkeita koskevaan päätöslauselmaan AP (2002) 1 ja sen viiteen tekniseen asiakirjaan. EN –päätöslauselman jälkeen tapahtunut lainsäädännön, tieteen ja teknologian kehitys on kuitenkin otettu huomioon. Myös muuta EU/ETA –alueeella ja sen ulkopuolella tapahtunutta kehitystä on seurattu.

Tässä asiakirjassa mainitut hyvää valmistustapaa, kirjallisia vakuutuksia, dokumentaatiota, jäljitettävyyttä, aktiivisia ja älykkäitä materiaaleja ja tarvikkeita sekä estokerroksia koskevat vaatimukset on yhdenmukaistettu asetuksen (EY) N:o 1935/2004 ja sen nojalla säädettyjen toimenpiteiden kanssa.

Elintarvikkeen kanssa kosketukseen joutuvan paperin ja kartongin valmistuksessa käytettävien ainesten pitää tämän asiakirjan mukaisesti olla EFSA:n, BfR:n tai FDA:n arvioimia. Teknisiä ominaisuuksia ja käyttöehtoja on noudatettava. Vain sellaisia aineksia voidaan käyttää, jotka ovat arvioituja joko pakkausmateriaaleissa käytettäviksi aineksiksi tai elintarvikelisäaineiksi. Erityistä huomiota on kuitenkin kiinnitettävä ruoankulutustekijöihin esim. pikkulasten kohdalla (Food Consumption Factor).

Tämä asiakirja koskee paperi- ja kartonkimateriaaleja ja –tarvikkeita, jotka koostuvat yhdestä tai useammasta kuitukerroksesta ja jotka joutuvat kosketukseen tai jotka ovat jo kosketuksessa elintarvikkeen kanssa. Paperista ja kartongista koostuvan kerroksen on täytettävä tämän asiakirjan vaatimukset, jollei estokerros erota sitä elintarvikkeesta.

Pohjoismaisista samoin kuin muualta maailmasta peräisin olevista puulajeista valmistettuja kuituja pidetään tässä yhteydessä yleisesti tur-

vallisina, vaikka niitä ei olisikaan toksikologisesti arvioitu. Paperi ja kartonki valmistetaan selluloosapohjaisista luonnonkuiduista käyttämällä valkaistua ja valkaisematonta kuitumateriaalia, mukaanlukien kierrätyskuidut. Paperi ja kartonki voivat myös sisältää useita erityyppisiä monomeerisiä ja polymeerisiä lisäaineita.

Kirjallisia vakuutuksia ja dokumentaatiota koskevat yksityiskohtaiset vaatimukset ovat oleellinen osa tätä asiakirjaa. Niissä selostetaan kattavasti, mitä tietoja tarvitaan kansallisten viranomaisten suorittamia tarkastuksia varten ja mitä tietoja on vähintään sisällytettävä jatkokäyttäjälle tarkoitettuihin kirjallisiin vakuutuksiin. Kirjallisia vakuutuksia koskevat vaatimukset perustuvat direktiiveihin 84/500/ETY ja 2002/72/EY sekä niihin myöhemmin tehtyihin muutoksiin. Kummassakin direktiivissä toteutuu asetuksen (EY) N:o 1935/2004 16 artiklan vaatimus kirjallisen vaatimustenmukaisuusilmoituksen antamisesta.

Valmiita materiaaleja varten on erityisrajoituksia. Ensikuitutuotteet on testattava raskasmetallien ja PCP:n varalta. Kierrätyskuiduista valmistetut tuotteet on testattava perusteellisemmin, riippuen siitä minkä tyyppisten elintarvikkeiden kanssa ne tarkoitetaan kosketukseen. Ennen kuin uudet paperille ja kartongille tarkoitetut biologiset tutkimusmenetelmät on täysin hyväksytty ja validoitu on kierrätyskuidusta valmistettujen tuotteiden turvallisuus varmistettava tämän asiakirjan mukaisilla tutkimuksilla.

Elintarvikkeet on luokiteltu kolmeen ryhmään, ja luokittelussa on otettu huomioon elintarvikkeen luonne ja se, kuinka helposti migraatio paperista ja kartongista tapahtuu. Yksittäiset elintarvikkeet tulee määritellä direktiivissä 85/572/ETY esitetyn luokittelun mukaisesti, jollei tämän asiakirjan luvussa 6.4 muuta todeta.

Tämä asiakirja ei edellytä joidenkin tiettyjen prosessiteknologioiden käyttöä kierrätyskuitujen valmistuksessa, vaan niissä todetaan ainoastaan, että lopputuote on testattava tämän asiakirjan mukaisesti ja että kussakin taulukossa lueteltuja rajoituksia on noudatettava. Paperin ja kartongin valmistajan on kuitenkin liitettävä dokumentaatioon lyhyt kuvaus käytetyistä prosessiteknologioista.

Summary – Icelandic/Samantekt á Íslensku

Efni úr pappír og pappa sem ætlað er að snerta matvæli

Norræn greinargerð um efni og hluti úr pappír og bylgjupappa, sem ætlað er að snerta matvæli, er einkum ætluð framleiðendum, matvælafyrirtækjum og öðrum sem koma að framleiðslu og dreifingu matvæla. Henni er ætlað að tryggja að lokaafurð sé ekki skaðleg heilsu og sé að öðru leyti framleidd í samræmi við þriðju grein reglugerðar (EB) nr. 1935/2004. Greinargerðin ætti einnig að geta nýst opinberum eftirlitsaðilum og rannsóknastofum. Þar sem greinargerðin hefur ekki verið lögleitt á Noðurlöndum og er ekki lögboðið að fara að efni hennar

Greinargerðnar eru byggðar á ályktun Evrópuráðsins um efni og hluti úr pappír og bylgjupappa sem ætlað er að snerta matvæli AP (2002) 1 ásamt fimm fylgiskjölum um tæknileg atriði (FT). Einnig er tekið tillit til breytinga á löggjöf ásamt vísindalegum og tæknilegum framförum sem orðið hafa eftir að ályktun Evrópuráðsins var gefin út, en einnig breytinga sem orðið hafa á EB/EES svæðinu og annarsstaðar.

Kröfur í leiðbeiningunum um góða framleiðsluhætt (GFH), skriflegar yfirlýsingar, varðveislu gagna, rekjanleika, virkar og greindar umbúðir og virkt varnarlag eru í samræmi við reglugerð (EB) nr. 1935/2004, og þær ráðstafanir sem reglugerðin veitir.

Samkvæmt þessum leiðbeiningum ættu hráefni sem notuð eru við framleiðslu á pappír og pappa og ætlað er að snerta matvæli að vera metin af EFSA, BfR eða FDA. Fylgja þarf forskriftum og reglum um notkun. Hráefni má nota ef þau hafa verið metin með tilliti til notkunar í snertingu við matvæli eða sem aukefni í matvæli. Engu að síður ber að hafa hliðsjón af neyslustuðlum (Food Consumption Factors) til dæmis fyrir ungbörn og smábörn.

Greinargerðnar gilda um efni og hluti sem gerðir eru úr pappír og pappa og geta verið úr einu eða fleiri lagi af trefjum og er ætlað að snerta matvæli. Sérhvert lag af pappír eða pappa verður að uppfylla skilyrði þessara leiðbeininga, nema þau séu aðskilin frá matvælum með virku varnarlagi. Skilgreining á hugtakinu virkt varnarlag er í samræmi við skilgreiningu í tilskipun 2002/72/EB um plast.

Trefjar úr pappa og pappír sem framleiddar eru úr trjám frá Norðurlöndum eða trjátegundum annars staðar frá þarf ekki að meta með tilliti til eiturefna, en í þessum leiðbeiningum er gengið út frá því að þær séu skaðlausar.

Pappír og pappi er framleiddur úr náttúrulegum trefjum úr beðmi (sellulósa) úr bleiktum eða óbleiktum trefjum, einnig endurunnum trefjum. Að auki geta pappír og pappi innihaldið aukefni úr einliðum eða fjölliðum.

Mikilvægur þáttur í þessum leiðbeiningum eru nákvæmar forskriftir um skriflegar yfirlýsingar og varðveislu gagna, þar sem tiltekið er nákvæmlega hvaða gögnum þarf að halda til haga vegna opinbers eftirlits og hvaða lágmarksupplýsingar þarf að veita með skriflegri yfirlýsingu til viðskiptavina. Forskriftir vegna skriflegra yfirlýsinga eru byggðar á tilskipun 2002/72/EB.

Sértæk skilyrði gilda um lokaafurð. Mælingar á þungmálmum og PCP þarf að gera á nýjum trefjum. Fyrir endurunnar trefjar þarf frekari mælingar, mismunandi eftir því hvaða matvæli efninu er ætlað að snerta. Þar til ný líffræðileg próf fyrir pappír hafa verið samþykkt og fullgilt þarf að fylgjast með að sértækum kröfum fyrir endurunnar trefjar í þessum leiðbeiningum sé fylgt til að tryggja örugga framleiðslu

Matvælum er skipt í þrjá flokka eftir eðli þeirra og hversu líklegt ar að þau orsaki flæði í snertingu við pappír og pappa. Notast skal við flokkun sem birt er í tilskipun 85/572/EBE til að ákvarða í hvaða flokk tiltekin matvæli falla, nema annað sé tekið fram í kafla 6.4 í þessum leiðbeiningum. Kröfur um skriflega yfirlýsingu eru byggðar á tilskipunum 84/500/EB með síðari breytingum og 2002/72/EB með síðari breytingum. Í báðum þessum tilskipunum er nánar kveðið á um framkvæmd ákvæðis 16. greinar reglugerðar (EB) nr. 1935/2004 um skriflega yfirlýsingu.

Í þessum leiðbeiningum er ekki gert ráð fyrir sérstakri framleiðslutækni vegna framleiðslu á endurunnum trefjum. Einungis er gert ráð fyrir að lokaafurð sé prófuð í samræmi við greinargerðnar og þau skilyrði sem koma fram í viðeigandi töflum. Þó er ætlast til að skriflegum gögnum fylgi stutt lýsing á þeirri framleiðslutækni sem beitt er af framleiðanda.

Appendices

Annex 1. Functional barrier

This annex is harmonized with the definition of functional barrier of plastic materials and articles in Directive 2007/19/EC (4th amendment of Directive 2002/72/EC). Future leglisative work may require changes in the definition of a functional barrier in this document.

(1) Migration from layers behind a functional barrier into food

A functional barrier is any integral layer which under its normal or foreseeable conditions of use reduces all possible material transfers (permeation, migration and set-off) from any layer beyond the barrier into food to a toxicologically and organoleptically insignificant and to a technologically unavoidable level.

In a multi-layer material or article, the composition of each layer shall comply with this document.

(2) Composition of layers behind a functional barrier

A layer which is not in direct contact with food and is separated from the food by a functional barrier may be:

- Not in compliance with the restrictions and specifications set in this document and/or
- Manufactured with substances other than those referred to in this document (5.6. Specific restrictions) or in the national lists concerning the plastic materials and articles intended to come into contact with food.

(3) Maximum migration of substances behind a functional barrier

The migration of the substances in a layer which is not in direct contact with food and is separated from the food by a functional barrier into food or simulant shall not exceed 0.01 mg/kg, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) 882/2004. This limit shall always be expressed as concentration in foods or simulants. It shall apply to a group of compounds, if they are structurally and toxicologically related, e.g. isomers or compounds with the same relevant functional group, and shall include possible set-off transfer.

(4) Substances excluded from use behind a functional barrier

The substances referred to in paragraph 2(b) shall not belong to the following categories:

- Substances classified as proved or suspect "carcinogenic", "mutagenic" or "toxic to reproduction" substances in Annex I of Directive 67/548/EEC[40] and later amendments or
- Substances classified under the self responsibility criteria as "carcinogenic", "mutagenic" or "toxic to reproduction" according to the rules of Annex VI of Directive 67/548/EEC[40] and later amendments.

Annex 2. Requirements of compliance declarations

The declaration[41] shall be issued by the business operator in all stages of the production and shall contain the following information as a minimum:

(1) Identity and address

The identity and address of the business operator which manufactures or imports the paper and board materials or articles or the substances intended for the manufacturing of those materials and articles

(2) Identity of the materials and articles

The identity of the materials, the articles or the substances intended for the manufacturing of those materials and articles

(3) Date of the declaration

The date of the declaration

[40] Also taking into consideration Regulation (EC) no 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) no 793/93 and Commission Regulation (EC) no 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC and 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) no 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) and establishing a European Chemicals Agency

[41] The declaration is based on requirements on compliance declarations of Regulation (EC) 1935/2004, Article 16 and Directive 2007/19/EC (4th amendment of Directive 2002/72/EC).

(4) Fulfilment of requirements in this document, The Framework Regulation, GMP and national legislation

The confirmation that the paper and board materials and articles meet relevant requirements laid down in this document, Regulation (EC) No 1935/2004.

The confirmation that paper and board materials and articles are produced in accordance with Regulation (EC) No 2023/2006.

Reference to fulfilment of national legislation in force shall be made if applicable

(5) Information in specific substances

Adequate information relative to the substances used for which restrictions and/or specifications are in place under this document to allow the downstream business operators to ensure compliance with those restrictions

(6) Information on substances with restriction in food

Adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 95/31/EC, 95/45/EC and 96/77/EC to enable the user of these materials and articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food

(7) Specifications on the use of the material or article

Specifications on the use of the material or article, such as

- Type or types of food intended to be put in contact with;
- Time and temperature of treatment and storage in contact with the food;
- Ratio of food contact surface area to volume used to establish the compliance of the material or article

(8) Information on bleaching

Information on bleaching of the product shall be provided. If bleaching is applied, information about the use of elementary chlorine shall be provided.

(9) Information on recycled materials

Percentage of recycled materials (by weight) in finished materials or article shall be declared. If the product consists of two or more layers the declaration shall specify the content of recycled materials layer by layer. (See also documentation (g))

(10) Information on functional barriers

When a functional barrier[42] is used in a paper and board multi-layer, the confirmation that the material or article complies with the requirements described in field of application and Annex No. 1 to this document

The compliance declaration shall permit an easy identification of the materials and articles as well as substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.

The compliance declaration should be issued in accordance with the recommendations of the Nordic Report on In-house documentation and traceability.

Annex 3. Documentation

This annex is based on the requirements to documentation of Regulation (EC) 1935/2004, Article 16, and requirements on materials and articles in its finished state (end product) in this document. Requirements are related to producers of the end product. Requirements may be applied to earlier stages in the production chain if suitable. The documentation should be issued in accordance with the recommendations of the Nordic Report on In-house documentation and traceability.

Appropriate documentation to demonstrate that the materials and articles or the substances intended for the manufacturing of those materials and articles comply with the requirements of this document shall be made available by the business operator to the national competent authorities on request.

Appropriate documentation shall be made available to food industry under adequate confidential agreements, if necessary.

The documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.

List of documentation that should be made available on request:

[42] See definition of functional barriers in Annex

(A) Collection of compliance declarations

A compliance declaration according to Annex No. 2 to this document shall be kept as a part of the documentation. All compliance declarations collected from the upstream suppliers of intermediates/substances in the production shall also be kept as a part of the documentation.

(B) Good manufacturing practice, chapter 5.3 and 6.2

A written confirmation of the producer of paper and board that EU regulation (EC) 2023/2006 on GMP and CoE Res AP (2002) 1 – TD 4 is fulfilled, including a separate confirmation that a quality management system[43] and a hazard analyses system[44] is implemented.

A written confirmation that only substances of the lists referred to in paragraph 5.6 Specific restrictions are used according to the conditions specified. (See also documentation in connection to requirement 5.6)

(C) Microbiological quality, chapter 5.4.

If considered necessary, a report of analysis that confirms that testing is carried out according to CoE Res AP (2002) 1 – TD 2 shall be submitted.

(D) Antimicrobial substances[45], chapter 5.5.

A report of analysis that confirms that testing is carried out according to CoE Res ES AP (2002) 1 – TD 2, Hemmhoftest.

It shall also be confirmed that paper and board do not release substances used as processing aids, which have an antimicrobial effect on foodstuffs and that antimicrobial substances (surface biocides) is not added to have an effect on the surface of the materials or articles in its finished state.

(E) Specific restrictions, chapter 5.6.

A report of analysis that confirms testing (QM) for cadmium, lead and mercury according to CoE RES AP (2002) 1 – TD 2 and that the content of the metals in paper and board are lower than the restriction. According to chapter 5.8 products that are only intended to come into contact with dry foodstuffs or foodstuffs which are to be shelled, peeled or washed, excluded from testing for compliance according to table 1. Restrictions for products to only be brought in contact with food type III shall be stated both here and in the compliance declaration see Annex No. 2, paragraph (7) (i).

[43] ISO 9000 or equivalent
[44] For instance HACCP
[45] Used as processing aids

A report of analysis that confirms that testing for pentachlorophenol is carried out according to CoE Res AP (2002) 1 – TD 2 and that the SM is lower than the restriction.

Substances used in the production shall be listed. Reference should be given, for each substance, either to EFSA opinions, BfR Recommendation XXXVI or legislation from Food and Drugs Administration in the USA, indicating relevant restrictions or TDIs. If specific restrictions are present a report of analysis that confirms testing according to CoE Res AP (2002) 1 – TD 2 (chapter 5.7) shall be submitted if applicable. It should be clearly stated for each substance that SM is lower than the restriction.

If compliance is shown by calculations, this shall be indicated and the calculations shall be presented (with reference to chapter 5.9).

(F) Dioxins, chapter 5.10

A report of analysis stating that SM for dioxins (polychlorinated dibenzo-dioxins and dibenzofurans) and dioxin-like PCBs is below 120 pg TEQ/kg foods

For paper and board products, for which a report of analysis is not mandatory: information on how levels in paper and board are kept as low as reasonably achievable and if considered necessary a report of analysis stating the levels of dioxins as QM in paper and board or SM to food shall be submitted.

(G) Paper and board produced with recycled fibres, chapter 6

Percentage of recycled materials (by weight) in finished materials or article shall be declared. If the product consists of two or more layers the declaration shall specify the content of recycled materials layer by layer.

(H) Recovered paper for use as raw materials, chapter 6.3.1.

A declaration from the collector of recycled materials or the producer of intermediates that states that the recycled fibres consists exclusively of grades of recovered paper and board listed in this document.

(I) Recovered paper and board not for use as raw materials, chapter 6.3.2

A declaration from the collector of recycled materials or the producer of intermediates that grades of recovered paper and board listed in this document not for use as raw materials are not used.

(J) Foodstuff types, chapter 6.4

A declaration from the producer of paper and board on which type of foodstuffs the products are made for contact with. (This is also to be stated in the compliance declaration 3.2 – (7) (i)).

(K) Current process technologies and their purpose, chapter 6.5.

A short description from the producer of paper and board which type of process technologies is used.

(L) End-product requirements, chapter 6.6

The following documentation shall be included for each substance or groups of substances in table 4:

1. Michler's ketone
A report of analysis stating SM below limit of detection (< 0.01 mg pr kg food)

2. DEAB
A report of analysis stating SM below limit of detection (< 0.01 mg pr kg food)

3. DIPNs
A report of analysis stating SM < 8 mg pr kg food

4. HTTP
A report of analysis stating SM is below limit of detection (< 0.01 mg pr kg food)

5. Phthalates
A report of analysis stating SM is below the given concentrations (SML) in food:

Substance	CAS. No.	TDI	SML
Di-ethylhexyl- phthalate (DEHP)	000117-81-7	0.05 mg/kg BW	1.5 mg/kg[46]
Di-buthyl-pthalate (DBP)	000084-74-2	0.01 mg/kg BW	0.3 mg/kg[46]
Benzyl-butyl-phthalate (BBP)	000085-68-7	0.5 mg/kg BW	30 mg/kg
Di-iso-nonyl-phthalate (DINP)	068515-48-0	0.15 mg/kg BW	9 mg/kg
+ Diiso-decyl-phthalate (DIDP)	028553-12-0 068515-49-1 026761-40-0		
Di-isobutyl-phthalate (DIBP)	000084-69-5	0,01 mg/kg BW	0.3 mg/kg[46]
Group restriction	Phthalates[47]	0,05 mg/kg BW	1,5 mg/kg[46]

[46] 50 % of TDI allocated to exposure to migration from recycled fibres FCM

[47] Phthalates covered by this requirement: CAS no. 27987-25-3, 68515-42-4, 036648-21-3, 00084-69-5, 27554-26-3, 00131-11-3, 00084-77-5, 00084-76-4, 14117-96-5, 00117-84-0, 00119-06-

6. Azo colourants

A report of analysis stating QM < 0.1 mg pr kg paper/board shall be included. Report must specify (by CAS no) which substances are analyzed. See paragraph 9 - report may be used to prove fulfilment of the requirements for both azo colourants and primary aromatic amines.

7. Fluorescent whitening agents (FWA)

A certificate that states fulfilment of EN 648 – visible inspection

8. Primary aromatic amines, suspected to be carcinogenic

A report of analysis stating QM < 0.1 mg pr kg paper/board shall be included. Report must specify (by CAS no) which PAA-substances are analyzed. See paragraph 7 - report may be used to prove fulfilment of the requirements for both azo colourants and primary aromatic amines.

9. Polycyclic aromatic hydrocarbons (PAH)

A report of analysis stating SM below limit of detection (< 0.01 mg pr kg food) shall be included. Report must specify (by CAS no) which PAH-substances are analyzed.

10. Benzophenone

A report of analysis stating QM < 0.1 mg/dm^2 of paper/board

11. Bisphenol A

A report of analysis stating SM < 3 mg pr kg food

12. Substances with a demonstrated toxic potential

If applicable, a report of analysis for substances with a demonstrated toxic potential shall be included. Report must specify (by CAS no) which substances are analyzed.

Restrictions for substances with a demonstrated toxic potential shall, if possible, be based on evaluations by recognised international bodies, e.g. EFSA, BfR, FDA or JECFA. Alternatively SMLs from Directive 2002/72/EC may be applied. Where restrictions have not yet been established the SM should be kept below 0.01 mg/kg food, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) 882/2004.

13. Chemical or toxicological screening tests for NIAS

2, 00084-72-0, 01240-18-2, 00085-70-1 and substances with the following chemical name: Phthalic acid, bis(alkoxyalkyl C3-C18) ester, Phthalic acid, mixed exters with butyl glycolate and alcohols, aliphatic monohydroxylic (C1-C4), Phthalic acid, mixed exters with ethyl glycolate and alcohols, aliphatic monohydroxylic (C1-C4). Compare with for clarity: EFSA Statement of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) on the re-classification of some phthalates for consistency with the new SCF guidelines for FCM (expressed on 26 May 2004).

A report of the assessment carried out according to Annex 4 shall be included in the documentation.

If relevant, a report of analysis for chemical and/or toxicological screening tests shall be included in the documentation. The evaluated substances shall be based on the latest evaluations[48] of the detected substance.

(M) Risk reduction plans, chapter 6.7

A Risk reduction plan concerning future reductions of contaminants in paper and board shall be included in the documentation.

(N) General requirements for analysis and the reports of analysis for end-products requirements

The report of analysis shall be issued by the laboratory and shall contain the following information:

a) Identity and address of the laboratory that performed the analysis;
b) Identity of the materials and articles, or products that are analyzed;
c) Date of the analyses;
d) Results of the analyses and unit;
e) The detection limit of the method and the accuracy of the measurement;
f) Report of analysis shall confirm testing according to CoE Res AP (2002) 1 – TD 2, if applicable;
g) The migration of substances shall be measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) 882/2004

The report of analysis shall permit an easy identification of the materials and articles as well as substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or, of if necessary, when new scientific data are available.

[48] Assessed by a recognised international body for risk assessments, e.g. EFSA, BfR or FDA

Annex 4. Non intentionally added substances (NIAS)

(1) Risk assessments

Risk assessment is to be carried out for impurities from the recovered paper (grades) or manufacturing by-products, also known as non-intentionally added substances (NIAS), when necessary in order to demonstrate compliance with article 3 of the Framework Regulation (EC) No 1935/2004.

(2) Migration is higher than TTC

If the migration of those substances exceed 0.5 ppb (microgram/kg food) known as the concept threshold of toxicological concern (TTC), equating to an exposure of < 1.5 μg/person/day assuming a daily diet of 3 kg (1.5 kg foods and 1.5 kg of fluids) toxicological testing is required according to EFSA Guidelines. However, if the substance is toxicologically evaluated and a restriction is available the substance can be assessed.

(3) Migration is below TTC

Further, if the migration is below the TTC and if these substances do not belong to either of the following categories:

a) Substances classified as proved or suspect “carcinogenic”, “mutagenic” or “toxic to reproduction” substances in Annex I to Council Directive 67/548/EEC;
b) Substances classified under the self-responsibility criteria as ‘carcinogenic’, ‘mutagenic’ or ‘toxic to reproduction’ according to the rules of Annex VI to Directive 67/548/EEC

then toxicological testing is not required. However, available toxicological data and structure activity considerations should be taken into account.