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PUBLIC HEALTH COMMITTEE

COMMITTEE OF EXPERTS ON MATERIALS COMING INTO CONTACT WITH FOOD

POLICY STATEMENT CONCERNING

TISSUE PAPER KITCHEN TOWELS AND NAPKINS

Version 1 –22.09.2004

NOTE TO THE READER

The Guidelines for tissue paper kitchen towels and napkins are part of the Council of Europe's Policy statements on food contact materials.

Guidelines are technical documents and have no legal binding character.

They have to be considered as requirements to be taken into account as models for the implementation of national policies.

They lay down technical and scientific specifications for the manufacture of food contact materials and articles.

If necessary they are amended in the light of technical or scientific developments of manufacturing processes and techniques of food contact materials and articles.

The Guidelines were elaborated by a Group of national experts after consultation with the European Tissue Symposium (ETS) and adopted by the Committee of experts on materials coming into contact with food.

The document may be consulted on the Internet website of the Partial Agreement Department in the Social and Public Health Field:

www.coe.int/soc-sp

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1. EXPLANATORY NOTE

1.1. Introduction

There is a wide range of products that are made from tissue paper, including toilet paper, wipes, kitchen towels, handkerchiefs, facial tissues, household towels, napkins, products for industrial use, etc. Some tissue paper products, in particular kitchen towels and napkins, are sometimes put in contact with food by end users. These products exhibit the typical characteristics of tissue paper, such as softness, high absorption capacity and limited structural strength.

Tissue paper kitchen towels and napkins (hereafter, kitchen towels and napkins) are multifunctional products. Their main use is for hygiene and cleaning purposes, and they are not specifically intended for contact with foodstuffs. Food contact use remains limited and occasional.

The function of kitchen towels and napkins is primarily to clean and to absorb. Their use in contact with food is typically for a short period of time. In addition, it has been demonstrated that there is no significant migration from kitchen towels and napkins into food[1], and consumer exposure is very low.

In light of the products' multi-purpose use, the fact that they are not specifically intended for contact with foodstuffs, the absence of significant migration, and the low exposure of the consumers, they are excluded from the field of application of the Council of Europe Resolution AP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs, and they are covered by these specific Guidelines. Consequently the Technical documents implementing Resolution AP (2002) 1 do not apply either.

The Guidelines for tissue paper kitchen towels and napkins (hereafter called 'the Guidelines') recommend specifications that tissue paper kitchen towels and napkins should comply with in order to achieve safety of use for the consumer, in light of the general principles of the General Product Safety Directive 2001/95/EC. Kitchen towels and napkins covered by the Guidelines should be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not endanger human health, or bring about a deterioration of the organoleptic characteristics, or an unacceptable change in the composition of the food they may come into contact with.

In order to ensure the safety of tissue paper kitchen towels and napkins, the following aspects should be considered:

- Raw materials;
- Processing technologies;
- Intended use of the end product; and
- Level of exposure.

These aspects are basic elements of product safety, and appropriate tests should be carried out to verify the safety of kitchen towels and napkins.

The Guidelines do not contain an inventory list of chemicals used in paper manufacturing and converting of kitchen towels and napkins. They list instead chemical substances which are typically used, as well as substances not to be used. The specific characteristics of tissue paper and, in particular, the low migration profile and the low consumer exposure

[1] "Migration studies on tissues in contact with food", Committee of experts on materials coming into contact with food, RD 6.3D/1-39#1; and "Test report on presence of fluorescent whitening agents in two samples", Committee of experts on materials coming into contact with food, RD 6.3D/2-39#1.

which have been demonstrated, warrant that the proposed control of chemicals, in combination with the other recommendations contained in the Guidelines, are appropriate to protect consumers' health.

1.2. General principles

1.2.1. Introduction

The Guidelines are based on the specifications of Resolution AP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs. They have been adapted in light of the specific characteristics and usage of tissue paper kitchen towels and napkins.

1.2.2. Raw materials

Manufacturers of kitchen towels and napkins should use raw materials in accordance with the principles contained in the Guidelines. Restrictions on the use of printing inks are also covered by the Guidelines.

In restricting the materials that may be used to manufacture kitchen towels and napkins, account has been taken of the very low amounts of chemicals used in the manufacturing process. The Guidelines do not contain an inventory list of chemicals. Instead, they list chemical substances that are typically used, as well as substances that may not be used in the manufacturing of kitchen towels and napkins. In addition, specific tests are required for the chemicals that could potentially constitute a risk for consumers.

The specific restrictions for the main chemical families used in tissue paper manufacturing contained in the Guidelines are based on the solubility, cross-linking, binding to the fibres, and other technical considerations. They apply unless the amount of the relevant chemical present in the final product is such that, even assuming 100% migration, presence in the food is below 0.5 µg/ kg.

1.2.2.1. Dry strengths

Specific restrictions are imposed for some families of dry strengths, such as glyoxylated polyacrylamide, copolymer of acrylic acid and acrylamide, and polyacrylamide modified with DADMAC and other cationising agents or non modified. No specific restrictions are foreseen for other families. This is in accordance with current legislation, such as BfR Recommendation XXXVI, and Directive 2002/72/EC on plastic materials and articles intended to come into contact with foodstuffs.

1.2.2.2. Fixating agents

Specific restrictions are recommended for families of fixating agents that reflect the restrictions contained in BfR Recommendation XXXVI.

1.2.2.3. Laminating glues

A number of families of laminating glue agents may be used without restrictions, in line with current legislation, such as BfR Recommendation XXXVI. Use of copolymer of ethylene and acrylic acid, polyurethane, and copolymer of styrene and acrylic acid is subject to specific restrictions. These restrictions mirror the FDA 176-170. The restrictions of use on polyethylene glycol (PEG) are in line with BfR Recommendation XXXVI.

1.2.2.4. Dyes

Use of anionic direct dyes and cationic direct dyes is subject to the restrictions contained in Directive 2001/405/EC.

1.2.2.5. Pick-up and tail seal glues

In line with the provisions of BfR Recommendation XXXVI, use of polyethylene glycol (PEG) is only authorised if the amount of monoethylene glycol represents less than 0.2% of the PEG, and if the amount of PEG represents less than 7% of the paper. Other families of pick-up glue may be used without restrictions, as foreseen in current legislation such as BfR Recommendation XXXVI.

1.2.2.6. Wet strengths

The Guidelines contain restrictions in line with current legislation on food contact materials, such as BfR Recommendation XXXVI.

In the case of glyoxylated polyacrylamide, restrictions similar to those foreseen in Directive 2002/72/EC on plastic materials and articles intended to come into contact with foodstuffs are recommended.

1.2.2.7. Fluorescent whitening agents

Manufacturers of kitchen towels and napkins should only add amounts of fluorescent whitening agent up to a maximum of 0.3%. In addition, the products should be tested in accordance with EN 648, with a minimum score of 4. This restriction is in line with current legislation on food contact materials, such as BfR Recommendation XXXVI.

1.2.2.8. Softeners, debonders, absorbency aids

In accordance with current legislation on food contact materials, such as BfR Recommendation XXXVI, use of diester of quaternary ammonium salts is permitted if the amount of chemical represents less than 0.1% of the total product.

Manufacturers of kitchen towels and napkins should only use white mineral oil of food or medical grade.

Manufacturers of kitchen towels and napkins should carry out a general toxicity test (when available) when using quaternary amides, fatty acid amides, and non-ionic surfactants. A test is not required if migration is below 0.5 μg/kg food.

Use of butanedioic acid, sulfo, 1,4-bis(2-ethylhexyl)ester, sodium salt is only permitted in amounts that represent less than 0.8 mg/dm² of the total product. This restriction is in line with current food contact legislation, such as BfR Recommendation XXXVI.

1.2.3. Test conditions and methods of analysis

Manufacturers of kitchen towels and napkins should carry out appropriate tests to verify compliance with the restrictions contained in the Guidelines. The Guidelines generally recommend the use of standardised testing methods, such as EN ISO 15320, ENV 12498 - Aqueous extract, ENV 12497 - Aqueous extract, and EN 1541-Aqueous extract. The specific characteristics of tissue warrant, however, some modifications to standard testing conditions.

Thus, a specific migration test has been developed.[2] The specific migration test contained in Appendix 3 should be used, where appropriate, to measure migration from tissue paper.

Tissue paper kitchen towels and napkins may be made of recycled fibres. Manufacturers using recycled fibres should comply with additional restrictions.

The restrictions contained in the Guidelines generally follow the specifications of Resolution AP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs. However, a larger use of recycled papers is permitted because of the low migration profile of the products and the low consumer exposure of these products.

It should be noted that, contrary to food packaging materials, kitchen towels and napkins are not specifically intended to come into contact with specific types of foodstuff.

1.2.4. Good manufacturing practices

Good manufacturing practices (GMP) are a fundamental part of quality control and product safety assurance. The GMP contained in the Guidelines generally follow the GMP of the Council of Europe Policy statement concerning paper and board materials and articles intended to come into contact with foodstuffs (Technical document N° 4 - CEPI Guide for good manufacturing practice for paper and board for food contact).

The GMP of the Guidelines are however adapted to the production processes used in tissue mills and reflect the specific characteristics of kitchen towels and napkins. In addition, in contrast with the GMP contained in Technical document N° 4, the GMP of the Guidelines also cover converting activities.

The GMP of the Guidelines include specific rules on traceability, and a requirement for validation of the final product purity with every new (or substantial change in a current) tissue product. In the hazard analysis, process water treatment is included in the analysis for potential hazards.

The GMP of Technical document N° 4 contain a section with explanatory notes on the paper-making process and a glossary of terms that may also be used for reference with regard to the Guidelines.

2. FIELD OF APPLICATION

The Guidelines apply to all kitchen towels[3] and napkins made of tissue paper, which may comprise one or more layers of fibres, and which may also come into contact with food (hereafter called 'kitchen towels and napkins').

The Guidelines also apply to air-laid kitchen towels and napkins, unless they are non-wovens according to ISO 9092.[4]

[2] Committee of experts on materials coming into contact with food, Ad hoc Group on tissue papers, 1st meeting, Record 21.05.2001, p. 4.

[3] For the purposes of the Guidelines, professional towels/wipes used in a food environment are also considered kitchen towels.

[4] Supplementary Guidelines shall include specific requirements for air-laid kitchen towels and napkins. Until such requirements are approved by the Council of Europe, air-laid kitchen towels and napkins shall not be covered by the Guidelines.

3. DEFINITION OF TISSUE PAPER KITCHEN TOWELS AND NAPKINS

Tissue paper products are made from light weight, dry creped and some non-creped paper. Typical products are toilet paper, kitchen towels, handkerchiefs, facials, napkins, hand towels, and wipes. These products can be made of one or several plies, each ply of one or several layers, prepared as sheets or rolls, folded or unfolded, embossed or unembossed, with or without lamination, printed or unprinted and possibly finished by post treatment, e.g. lotion application.[5]

Kitchen towels and napkins are manufactured from cellulose-based natural fibres from bleached and unbleached fibre material, including recycled fibre materials. In addition, they may contain functional additives and synthetic fibres. Kitchen towels and napkins may be printed, and also printed surfaces may come into contact with foodstuffs.

There may be further technical developments in the manufacturing of tissue paper products. The Guidelines are based on the current state of technology and may have to be appropriately interpreted or amended in light of future developments.

4. SPECIFICATIONS

Kitchen towels and napkins covered by the Guidelines should meet the following conditions:

They should not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs with which they may come into contact, or a deterioration in the organoleptic characteristics thereof.

They should be manufactured in accordance with the good manufacturing practices set out in Section 8 - Good manufacturing practices.

Manufacturers of kitchen towels and napkins should use substances in conformity with the needs of the end product and in accordance with Section 5 - Raw materials. Specific requirements for recycled fibres are contained in Section 8 - Recycled fibres.

They should not release substances which have an anti-microbial effect on foodstuffs. Kitchen towels and napkins should be of suitable microbiological quality, taking into account their intended use, as described in the Guidelines. This is ensured by following the principles of good manufacturing practices.

Kitchen towels and napkins should comply with the restrictions laid down in Tables 1 and 2, and with either the QM or the SML restrictions laid down in Appendix 1.

Verification of compliance should be carried out in accordance with the principles set forth in Section 6 - Test conditions and methods of analysis.

[5] As defined in prEN 12625.

Table 1

Substance	Restriction QM limit (mg/dm^2 paper)
Cadmium Lead Mercury	0.002 0.003 0.002

Table 2

Substance	Purity requirement (ppm = mg/kg paper)
Pentachlorophenol	0.15

Manufacturers of kitchen towels and napkins 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.

5. RAW MATERIALS

5.1. Fibrous ingredients

Kitchen towels and napkins can be made from virgin fibres, from recycled fibres, or from a mixture of both. Selection of fibrous ingredients should be carried out in accordance with the principles set out in Section 7 - Recycled fibres, and Section 8 - Good manufacturing practices.

Kitchen towels and napkins may also contain synthetic fibres accepted for use as ingredients in food contact materials under European Community legislation, under national rules of states following the SCF evaluation guidelines, or under US legislation (FDA lists).

5.2. Non-fibrous ingredients
(other than printing inks, which are covered by paragraph 5.3)

Non-fibrous ingredients (other than printing inks) should be used in accordance with Appendix 1, which lays down specific requirements for functional additives and processing aids. The exclusion list specifies materials which should not be used.

5.3. Printing inks

Printing inks should be formulated using raw materials in accordance with the conditions set forth in Appendix 2.

A description of substances typically used in printing inks for kitchen towels and napkins is contained in Appendix 2.

6. TEST CONDITIONS AND METHODS OF ANALYSIS

6.1. Introduction

Manufacturers of kitchen towels and napkins should carry out appropriate tests to verify compliance with the provisions contained in the Guidelines. This Section is intended to lay down specific testing methods for kitchen towels and napkins, and provides practical assistance to manufacturers. The principles laid down in Section 8 - Good manufacturing practices also apply.

However, if it can be shown by calculation, taking into account the conditions of manufacture, that the restrictions laid down in Appendix 1 cannot be exceeded, no testing for compliance with these restrictions is necessary.

It has been demonstrated that standard test conditions for paper and board are not suitable for tissue paper.[6] The test methods described in the Guidelines take into account the unique properties of tissue paper, such as light weight, and strong absorption profile.

If kitchen towels and napkins are printed, tests should be carried out on the printed area. In migration tests the printed surface should be in contact with the food or food simulant.

6.2. Testing for purity restrictions

Testing for compliance with the QM restrictions laid down in the Guidelines should measure the total concentration of a substance in the paper. For the heavy metals water extraction should be used.

6.3. Migration test for tissue paper

Where migration tests are needed to verify compliance with the Guidelines, the method presented in Appendix 3 should be used. However, extraction tests can be used according to the relevant principles of Directive 97/48/EC if on the basis of scientific evidence, the results obtained using these tests are at least equal to those obtained by migration testing.

6.4. Antimicrobial effect test for tissue paper

Kitchen towels and napkins should not release substances which have an antimicrobial effect on foodstuffs. They should be tested according to test EN 1104.

6.5. Tests on PCP, heavy metals, and formaldehyde

Substance	**Testing method**
Pentachlorophenol (PCP)	EN ISO 15320
Lead	prENV 12498 - Aqueous extract
Cadmium	prENV 12498 - Aqueous extract
Mercury	prENV 12497 - Aqueous extract
Formaldehyde	EN 1541 - Aqueous extract

[6] "Migration studies on tissues in contact with food", Committee of experts on materials coming into contact with food, RD 6.3D/1-39#1.

6.6. Tests on colourants and fluorescent whitening agents

Migration tests of colourants and fluorescent whitening agents should be carried out according to standards EN 646[7] and EN 648[8] respectively, with a minimum score of 4.

7. RECYCLED FIBRES

In addition, kitchen towels and napkins produced with recycled fibres should be subject to the guidelines laid down in this section.

7.1. Introduction

This section gives guidance for manufacturers of kitchen towels and napkins made from recycled fibres. It offers practical advice on the factors relevant to the safety of the end product.

The section is intended to assist manufacturers of kitchen towels and napkins in reviewing their own quality systems, and it represents minimum standards which manufacturers of kitchen towels and napkins should observe and adapt to their own particular circumstances and requirements.

The scope is general and should be amended, as necessary, to take account of developments in collecting, selecting and processing of recovered paper, improvements in analytical techniques, and increased knowledge of the toxicology of chemical substances.

7.2. Classification of recovered paper

The section defines the characteristics of recovered papers and boards that can be used as raw materials in the manufacture of kitchen towels and napkins, as well as the characteristics of recovered papers and boards that cannot be used as raw materials. The characteristics are defined in relation to the potential impurities which could be present, so as to assist the selection and treatment of raw materials as part of GMP. The selection of raw materials is necessary to determine the appropriateness of recycling treatments, and it is therefore included in the matrix in Table 5.

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

7.2.1 Recovered paper permitted for use as raw materials

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

[7] EN 646, version December 2000.

[8] prEN 648:2002.

Group 1 Paper and board manufactured with substances of the Policy statement concerning paper and board materials and articles intended to come into contact with foodstuffs, Technical document N° 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs

- Unprinted cuttings, shavings, sheets and rolls from food contact paper and board based on virgin fibres.

Group 2 Paper and board which may be manufactured with substances not referred to in Technical document N° 1, unprinted or lightly printed or lightly coloured.

- Unprinted cuttings, shavings, sheets and rolls of printing and writing papers (EN 643: 3.14, 3.15, 3.16, 3.17, 3.18, 3.19).

- Lightly printed or coloured cuttings, shavings, sheets and rolls of printing and writing papers (EN 643: 2.03, 3.01, 3.02, 3.03, 3.04, 3.09).

- White writing and printing paper originating from offices (EN 643: 3.05).

- White continuous stationery paper (computer paper) (EN 643: 3.07).

- Unprinted or lightly printed, unused kraft paper (EN 643: 4.07, 4.08).

- Unprinted or lightly printed, unused packages (EN 643: 3.12, 3.13, 4.05).

- Unused kraft sacks and wrappings.

Group 3 Printed paper and board, corrugated board from supermarkets, paper and board from households and industry.

- Printed or coloured material from printing shops, over-issues, etc. (EN 643: 1.06, 2.02, 2.04, 2.07, 3.08, 3.11).

- Unsorted white and coloured writing and printing paper originating from offices.

- Boxes and sheets of corrugated board collected from supermarkets (EN 643: 1.04, 1.05).

- Unused boxes and sheets of corrugated board (EN 643:4.01).

- Printed paper from households, such as newspapers, pamphlets, magazines, catalogues, etc. (EN 643: 1.11).

- Mixed paper and board from households (EN 643: 1.02, 5.01).

- Sheets, boxes and cases of solid, and corrugated board, and folding boxboard from households.

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

- Contaminated waste paper and board from hospitals.

- Recovered paper and board which has been mixed with garbage and subsequently sorted out.

- Used stained sacks which have contained for example chemicals and foodstuffs.

- Covering materials such as paper used for covering furniture during repair and painting work.

- Batches mainly consisting of carbonless copy paper, except if migration of DIPN from the finished product is not detectable. If carbonless copy paper is used, a test on DIPN should be carried out on the finished product.

- Waste paper from households containing used hygienic paper, such as used kitchen towels, handkerchiefs and facial tissue.

- Old archives from libraries, offices, etc., containing PCB, unless content of PCB in the finished product is below 2 mg/kg. Where these raw materials are used, a test on PCB should be carried out on the finished product.

7.2.3. Precise specifications should be laid down between the tissue paper producer and the suppliers of papers and boards recovered for recycling, which should:

(a) Designate the grades of the papers and boards recovered for recycling which are used;
(b) Indicate precisely the conditions and means of transport used to ensure an appropriate level of hygiene and cleanliness; and
(c) Indicate precisely the conditions of compliance with the specifications to guarantee the delivery of the grade designated in the order form.

7.3. Recycling treatments

The section defines appropriate levels of recycling treatments for raw materials, taking into account that kitchen towels and napkins are not primarily intended to come into contact with foodstuffs. The information is based on current technical knowledge and should be reviewed in the light of technological developments.

Producers of kitchen towels and napkins should describe, for each stage or sequence (pulping, cleaning, deinking), the following parameters:

(a) Equipment used;
(b) Nature and concentration of additives when used;
(c) Nature of treatment, duration and, in relevant cases, applied temperature; and
(d) Consistency of recycled pulp.

It is recognised that the groups of recovered paper defined in Section 7.2 differ in their potential for chemical hazards. Recycling treatments should be adequate to counter these hazards without imposing unnecessary restrictions. The use of chemical reagents, the effects of dilution together with process water treatments, and temperature controls provide some of the means for achieving chemical decontamination of raw materials.

The treatments summarised in Table 3 should be seen as guidelines in the context of the matrix in Table 5.

Table 3 - Recovered paper treatments

Unit operation	Dilution (%)	Equipment / Use of chemicals	Purpose / Efficiency
Repulping	5 - 15	Pulper. Use of alkali and/or peroxide (in deinking lines)	Separation of fibres from each other, from fillers and other non-fibre compounds Ink detachment
Pre-cleaning	5 - 15	High density cleaner Rotating drum	Removal of coarse high density contaminants (density > 1): sand, glass, pebble, metal particles
Pre-screening	4 - 5	Pressurized screens with holes or slots	Removal of coarse, usually lightweight contaminants: plastic films, textiles, etc., according to their size and shape
Deinking	1 - 1.5	Washer Flotation cells Use of surfactants (soaps)	Removal of ink particles, specks, low size stickies, etc. (sub-millimetric size)
Hot dispersion	20 - 30	Disperser (high speed) Kneader (low speed) Use of direct steam and possibly peroxide Temperature 60-130°C	Dispersion of visible impurities: ink particles, specks, hot melt adhesives, waxes, etc. Residual ink detachment Microbiological decontamination
Process water treatment		Microflotation cells. Use of biocides, coagulants, flocculants	Microbiological control in process water, removal of dissolved and colloidal material, odour control
Bleaching	15-30	Reactors, bleaching towers Oxidising or reducing agents	Increase of brightness. Removal of dyestuffs and in some cases optical brighteners Microbiological decontamination

Producers of kitchen towels and napkins should ensure that (i) for recovered paper of Group 2, repulping, pre-cleaning, pre-screening, hot dispersion and chemicals, or any other process that allows the required purity standards to be reached, are applied, and that (ii) for recovered paper of Group 3, repulping, pre-cleaning, pre-screening, hot dispersion and deinking, or any other process that allows the required purity standards to be reached, are applied.

7.4. End product testing

The aim of this section is to list tests to be carried out on the end product under defined conditions. Manufacturers of kitchen towels and napkins made of recycled fibres should carry out these tests in addition to the tests contained in Section 6.

The migration potential from kitchen towels and napkins has been demonstrated to be very low[9], and the tests listed in Table 4 are appropriate to safeguard public health.

[9] "Migration studies on tissues in contact with food", Committee of experts on materials coming into contact with food, RD 6.3D/1-39#1.

Table 4 - Specific requirements

Substance	Restriction limit (QM)	Testing method
Formaldehyde	1 mg/dm²	EN 1541-Aqueous extract
DIPN	Levels of DIPN in the finished product should be kept as low as reasonably achievable.	pr EN 14719
PCB[10]	2 mg/kg	EN 15318

Toxicity analysis may be recommended in the future, based on new developments and results in this field. Where feasible, tests may be carried out for other toxic substances, whenever there are clear reasons to suspect their presence in the finished product.

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, which for kitchen towels and napkins is usually of a very short duration.

7.5. Consolidated matrix

The matrix in Table 5 consolidates all the guidelines addressed to producers of kitchen towels and napkins, who use the recovered paper substances of Group 2 and Group 3, following the classification of Section 7.2.

The guidelines contained in the matrix assure consumers' safety without imposing unnecessary restrictions on manufacturers of kitchen towels and napkins.

The guidelines regarding standard treatments in the matrix recognise the importance of providing for flexibility to take account of mill-specific circumstances. The purpose of these treatments is to reduce or eliminate the presence of contaminants in the finished product. Where treatments other than the standard treatments defined in this section are used, industry should ensure, through good manufacturing practices, that these other treatments have an effect which is comparable with regard to the presence of contaminants in the finished product.

[10] Testing the levels of PCB is only required when old archives have been used as raw material.

Table 5 - Consolidated matrix

Food type	Recovered paper group	Examples of treatments	Additional process validation
Any type of food including aqueous and/or fatty foodstuffs (including defrosted)	**Group 2**	Repulping, pre-cleaning, pre-screening, hot dispersion and chemicals, or processes that allow the required purity level to be reached.	• Chemical analysis for formaldehyde • Migration test of colourants and fluorescent whitening agents • Test on DIPN • Test on PCB, where old archives containing PCBs have been used as raw material
	Group 3	Repulping, pre-cleaning, pre-screening, hot dispersion and deinking, or processes that allow the required purity level to be reached.	• Chemical analysis for formaldehyde • Migration test of colourants and fluorescent whitening agents • Test on DIPN • Test on PCB, where old archives containing PCBs have been used as raw material

8. GOOD MANUFACTURING PRACTICES

GMP is a fundamental part of quality control and product safety assurance. The section gives guidance for manufacturers and converters of kitchen towels and napkins.

8.1. Introduction

The guidelines of the section aim to enhance the quality of kitchen towels and napkins, and to protect the health of end users. They take into account the specific characteristics of these products, such as light weight, a high degree of porosity, a strong absorption profile, intended softness, a limited structural resistance, manufacturing processes that enhance the quality of the product, and a low migration potential. Another factor that has been taken into consideration in making these guidelines is the low consumer exposure.

The guidelines in the section apply to the entire paper production process, including converting, and cover all fibrous compositions. They thus apply to all converting activities, which normally take place at the tissue mill — including calendering, slitting, embossing, printing and other tissue mill and converting based finishing operations — and to operations such as winding, doubling, and cutting.

Existing product liability legislation should be considered in order to make sure that due responsibility is taken by manufacturers of kitchen towels and napkins for all manufacturing factors as they apply to the product's end use.

The guidelines offer organisational and practical advice on the management of key factors affecting product quality and fitness for purpose, especially safety with respect to food contact. They cover all the production stages from the raw materials order (procurement) and supply, to the point where the product is dispatched from the manufacturer of kitchen towels and napkins.

Kitchen towels and napkins are thus manufactured according to a quality standard which includes all requirements existing in relevant directives, regulations or legislation that are applicable to such tissue products.

8.2. General aspects and principles

GMP is based on the principles of relevant quality management systems, such as the ISO 9000 series. It is also based on the relevant principles of a risk management system, such as HACCP.

The management systems will cover every stage of production, including the procurement of raw materials, the different steps of processing, manufacturing and testing, finishing, and shipping of the product, for example:

- Manuals;
- Production instruction document;
- Specifications for testing;
- Handling, storage, packaging, preservation, product identification and delivery;
- Personnel training, internal auditing; and
- Production and quality records.

An appropriate level of cleanliness, in terms of “good housekeeping”, has to be maintained throughout the whole process.

8.3. Aspects in particular

8.3.1. Management responsibility

The management has to make a strong commitment to the quality policy and assure that appropriate responsibility and authority is given, understood, and applied at each level of the organisation.

8.3.2. Personnel training

All personnel should be made aware of their duties and responsibilities under the current applicable legislation, and of the principles contained in this section. Their training should be performed and assessed in a suitable manner. New employees should be made aware of food contact manufacturing requirements as part of their introduction process. Records of assessments and training received should be maintained.

8.3.3. Quality system

A quality system should be implemented in order to assure product conformity to the specified requirements. Procedures have to be implemented to avoid misunderstanding when producing tissues of several grades at the same plant, i.e. kitchen towels and napkins and other tissue grades.

8.3.4. Raw materials (fibrous and non-fibrous ingredients)

A system has to be implemented in order to assure that only raw materials in conformity with the requirements of the end products are purchased. The provisions of Section 5 - Raw Materials and Section 7 - Recycled fibres are applicable.

Only “qualified suppliers” should be traded with. Qualification may be either (i) by certification to ISO 9000, or (ii) by the confidence, consistency and reliability established with a supplier due to the existence of a long-term relationship backed up by continuing quality assurance tests of the raw material.

All materials from a new supplier or of a new grade should be assessed for suitability for conversion to the final product. If the results are satisfactory, the material is accepted and can be ordered in the future against an agreed specification.

For recycled fibres, the order forms should specify the grades supplied. Upon receipt, supplies of recycled fibres should be subject to documentary, visual, and olfactory controls, and a control visa of receipt should be issued.

All incoming raw materials should be clearly identified and stored in such a way (if necessary, in separate areas) as to avoid any accidental use of raw materials that are not appropriate for kitchen towels and napkins. Appropriate cleanliness and hygiene are to be maintained in the raw materials storage areas to minimise the risk of raw material contamination.

8.3.5. Process control

The process has to be clearly defined and planned; it has to be demonstrated that the process is run continuously under controlled conditions. Great importance should be given to the control of the process parameters due to the complexity of tissue technology, in particular to avoid and remove possible contamination.

Each mill/producer has to identify and keep under control in its own process the critical control points as a result of a risk analysis.

8.3.6. Handling, storage, packaging, integrity, and delivery of the products

Handling, storage, packaging, integrity, and delivery of the products have to be maintained under control.

It is particularly important that items in stock are well identified and can only be dispatched for intended end use.

Appropriate cleanliness and hygiene should be maintained in the storage areas.

A procedure needs to be in place to ensure dispatch of only those products that meet the agreed quality standards.

8.3.7. Traceability

All finished products should be labelled so that relevant data of the production history can be traced.

Traceability of finished products and raw materials enables an efficient recall procedure within a tissue mill where kitchen towels and napkins are produced and along the supply chain, and it is therefore a fundamental tool to ensure consumer's safety. The information on traceability can also be made available to competent authorities if required.

In determining relevant traceability principles, account has to be taken of the consumer's exposure, which in the case of kitchen towels and napkins is very low.

In light of the principles of the EC directive on general product safety and the EC directive on materials and articles intended to come into contact with food, these Guidelines recommend that manufacturers of kitchen towels and napkins put in place the following procedures:

(a) For each delivery of raw materials, the date of delivery and the name of the supplier should be recorded. In addition, each delivery should be inspected on receipt to verify that it complies with relevant requirements. This information shall be kept for at least three years.

(b) Relevant documentation within the quality management system on the manufacturing site should be kept to enable identification of the finished products and raw materials that are considered to be involved in any recall of defective finished products.

(c) Manufacturers of kitchen towels and napkins should be able to identify the packaged kitchen towels and napkins, for instance by a code. Such identification should allow that a link between the product and the manufacturing site and date of production is made. The link between the identification of the product and the customer should be recorded and communicated to the customer where appropriate.

8.3.8. Testing

Testing and inspection procedures have to be defined to verify the compliance of the final product with the agreed quality and safety standards. The testing methods laid down in Section 6 - Test conditions and methods of analysis should apply, and for other tests, standardised testing methods, when available, are preferred (e.g. CEN, ISO, etc.).

When a new product (or any substantial change in the composition of the product and/or in the process used to make it) is to be launched, the product and/or process should be validated according to the testing methods laid down in Section 6 - Test conditions and methods of analysis.

The analyses for the purpose of process validation should be performed upon three identical but independently processed products. In addition, process deviation should be kept under control.

8.3.9. Quality record

The results of quality testing have to be recorded and filed. Procedures for quality recording have to be defined in order to guarantee the correct identification, collection, filing and distribution of the quality reports (to be kept for a minimum of one year).

8.3.10. Calibration procedures

Inspection, measuring, and test equipment should be regularly maintained and calibrated. Records of the calibration procedures should be kept for a minimum of one year.

8.3.11. Auditing

Procedures should be defined to verify the correct performance of the quality system.
These will vary according to the chosen quality scheme.

8.4. Inventory of hazards and suggested means of prevention

8.4.1. General aspects

The manufacturing stages of kitchen towels and napkins are listed from raw materials to shipping.

The hazards related to each manufacturing stage are described below. For the purpose of this section, “hazard” means a biological, chemical or physical agent in, or condition of, the product with the potential to cause an adverse health effect.

For each manufacturing stage Tables 6 to 10 indicate what hazards may be encountered, and the means of prevention. The tables illustrate the good practices to be implemented within the general context of these Guidelines. They indicate typical elements that need to be part of any risk management system. It is up to producers to include additional items based on their own risk analysis.

8.4.2. Manufacturing stages generally applied for kitchen towels and napkins

(The production of kitchen towels and napkins does not necessarily include each of the steps)

Raw materials
- Selection prior to purchase
- Transport (delivery to factory)
- Reception
- Storage
- Handling

Wet end processing
- Pulping
- Deinking
- Preparation and introduction of additives
- Refining, cleaning, diluting, sheet formation
- Process water treatment

Tissue sheet processing
- Drying
- Creping
- Calendering
- Winding, doubling, cutting
- Treatment with chemical additives

Mother reel handling
- Quality control of semi-finished products
- Storage of semi-finished products
- Transport to converting area

Converting
- Unwinding, doubling
- Printing
- Embossing
- Perforation
- Rewinding
- Log cutting / sheet cutting and folding
- Packaging
- Bundling

Finished product handling
- Quality control of finished products
- Conveying
- Palletising
- Storage of finished products
- Loading
- Transport to customer

Table 6

STAGES	POSSIBLE HAZARDS	SUGGESTED MEANS OF PREVENTION
FIBROUS RAW MATERIALS		
a) Selection prior to purchase	Contamination from a chemical and/or microbiological source, due to the use of raw materials whose safety has not been determined.	Reference to Section 5.1. of these Guidelines.
b) Transport (delivery to factory)	Contamination from a chemical and/or microbiological source, linked with absence of cleanliness (truck, etc.).	Reference to the specifications of both transporter and supplier.
c) Reception, storage, handling	Contamination from a chemical and/or microbiological source at the moment of storage, as a consequence of mixing up grades suitable for food-contact with unsuitable ones.	Separate areas (where relevant), compliance with procedures (quality assurance).

Table 7

STAGES	POSSIBLE HAZARDS	SUGGESTED MEANS OF PREVENTION
NON FIBROUS ADDITIVES		
a) Selection prior to purchase	Contamination from a chemical source, due to the use of raw materials whose safety has not been determined.	Reference to Section 5.2. of these Guidelines.
b) Transport (delivery to factory)	Contamination from a chemical and/or microbiological source, linked with absence of cleanliness (truck, tank, etc.).	Reference to the specifications of both transporter and supplier.

Table 7 (continued)

c) Reception, storage, handling	Labelling error leading to the introduction of incorrect material.	Indication upon order form about the product's technical reference. Definition of requirements upon ordering.
	Contamination from a chemical and/or microbiological source, linked with absence of cleanliness.	Appropriate premises. Maintenance of cleanliness of premises (appropriate cleaning, pest control, etc.).
	Usage error and contamination from a chemical and/or microbiological source, linked with cross contamination in case of bulk storage.	Separate areas (where relevant), compliance with procedures (quality assurance), storage duration and conditions (observance of expiry dates for use).

Table 8

STAGES	**POSSIBLE HAZARDS**	**SUGGESTED MEANS OF PREVENTION**
PULPING	Error about raw materials which may lead to the introduction of inadequate raw materials into the pulper.	Manufacturing specifications.
	Contamination of the pulp from micro-organisms brought by pests.	Maintenance of cleanliness of premises (pest control, etc.).
	Contamination from a chemical source, linked with production shift (from non-food to food products).	Manufacturing specifications, grade shift procedure.
DEINKING, PREPARATION AND INTRODUCTION OF ADDITIVES	Inadequacy of physical characteristics and/or possible contamination from a chemical source, linked with concentration error or overdose of hazardous products.	Compliance with procedures. Records.
	Contamination from micro-organisms as a consequence of microbiological growth of a preparation.	Compliance with procedures. Cleaning of preparation chests. Storage conditions (e.g. temperature). Preventive treatment with biocides.

Table 9

STAGES	POSSIBLE HAZARDS	SUGGESTED MEANS OF PREVENTION
REFINING, CLEANING, DILUTING, SHEET FORMATION	Contamination from a micro-biological source, linked with absence of cleanliness (chests, circuits).	Appropriate cleaning and/or anti-microbial treatment.
	Contamination from a chemical source, from cleaning agents of clothing.	If a chemical is not suitable for food contact, segregation of cleaning water from other parts of machine is needed.
PROCESS WATER TREATMENT	Proliferation of micro-organisms in process water.	Appropriate anti-slime treatment.
	Accumulation of dissolved and/or colloidal material.	Process water clarification, e.g. by flotation.
DRYING, CREPING, CALENDERING, WINDING, DOUBLING, CUTTING	Soiling due to condensation or to premises dust fallout onto the reel.	Appropriate maintenance and cleanliness of premises.
TREATMENT WITH CHEMICAL ADDITIVES	Inadequacy of physical characteristics and/or possible contamination from chemical components as a consequence of a quantity of deposit, possibly out of regulatory tolerance, or out of specification.	Compliance with procedures.
	Contamination from micro-organisms, linked with micro-biological growth of a preparation.	Compliance with procedures. Cleaning of preparation chests. Storage conditions (e.g. temperature). Preventive treatment with biocides.
MOTHER REEL HANDLING	Soiling due to condensation or to premises dust fallout onto the reel.	Appropriate maintenance and cleanliness of premises.
	Contamination from a chemical and/or microbiological source due to the lack of cleanliness of pallets or inappropriate treatment of the wood.	

Table 9 (continued)

PRODUCTION AREAS	Contamination from a chemical source, linked with leakage or residues from cleaning agents.	Restricted stored amount of hazardous cleaning products, or of their residues in production areas. Compliance with procedures.
	Possible contamination from a microbiological source linked with humidity, temperature, and absence of cleanliness of premises.	Cleaning and sanitation.
CONVERTING AREAS	Contamination from a chemical source, linked with leakage or residues from cleaning agents.	Restricted stored amount of hazardous cleaning products, or of their residues, in production areas. Compliance with procedures.
	Possible contamination from a microbiological source linked with humidity, temperature, and absence of cleanliness of premises (animals and undesirable insects).	Cleaning and sanitation (UV insect control lamps and rodent control).

Table 10

STAGES	POSSIBLE HAZARDS	SUGGESTED MEANS OF PREVENTION
IN-PROCESS CONTROL AND QUALITY CONTROL OF FINISHED PRODUCTS	Inadequacy of physical characteristics and/or chemical characteristics possibly out of the regulatory tolerance.	Compliance with procedures, process control, down-grading and identification of products which are out of specification, records. Clear and precise identification of samples for laboratory analysis.
LABELLING	Error of identification of paper or batch mix-up leading to the use of a paper unsuitable for the required utilisation.	Compliance with procedures.
STORAGE OF FINISHED PRODUCTS	Degradation of the physical or chemical characteristics of paper due to bad storage conditions (humidity, temperature) or to excessive storage duration.	Implementation of appropriate conditioning. Compliance with procedures. Preventive maintenance programme. Maintenance of cleanliness of premises (appropriate cleaning, pest control).
	Contamination from micro-biological source, linked with absence of cleanliness within storage areas.	Compliance with procedures. Maintenance of cleanliness of premises (appropriate cleaning, pest control).
SHIPPING	Paper identification error, batch mix-up, bad condition of loading and of means of transport, leading to using a paper unsuitable for the required utilisation.	Implementation of specifications regarding transport.
	Contamination from a micro-biological source, linked with bad conditions and absence of cleanliness of means of transport.	Compliance with procedures.
	Contamination from a chemical source through polluting products from previous transport.	Implementation of specifications regarding transport. Requirement for non-transportation of chemicals and odorous products in the vehicles used. Compliance with procedures.

APPENDIX 1

Non-fibrous constituents for use in the manufacture of kitchen towels and napkins

The Appendix does not cover printing inks, which are covered by Appendix 2.

Introduction

The Appendix lists families of chemicals and processing aids typically used in the paper making and converting of kitchen towels and napkins and the restrictions applicable thereto. It also contains a list of substances which may not be used in the paper making and converting of kitchen towels and napkins ("Exclusion list"). Only additives with a molecular weight of <1000 Dt need to be taken into consideration.

1. Functional additives

The main families of functional additives used in the manufacture of tissue paper kitchen towels and napkins are, based on their function, listed in the following table, with typical ranges, general migration potential, and relevant restrictions.

Table 11: Functional additives

Function / use	Chemical family	Typical range of dosage mg/dm²	Potential for migration		Restrictions
			In wet foodstuffs	In fatty foodstuffs	
Dry strength	Starch with primary, secondary or tertiary ammonium chloride functionality	0 to 7.5	High	Low	Epichlorohydrin < 1 ppm. Nitrogen content < 4%(w/w)
	Carboxymethylcellulose	0.03 to 5	High	Low	No restriction
	Oxidised starches	0 to 80	High	Low	No restriction
	Starch, phosphate esters	0.4 to 5	High	Low	No restriction
	Native Starch, enzymatically hydrolyzed	0 to 5	High	Low	No restriction
	Starch, acetyl esters	0 to 5	High	Low	No restriction
	Starch, carboxymethyl ether	0.075-1.5	High	Low	No restriction
	Glyoxylated polyacrylamide	0.075-1.8	Low	Low	Glyoxal in extract from product < 1.5 mg/dm² Acrylamide < 10 ppb in foodstuffs
	Copolymer of acrylic acid and acrylamide	0.075-0.90	Low	Low	Monomer acrylamide < 0.1 % in active material of commercial product Acrylamide < 10 ppb in foodstuffs
	Polyacrylamide, modified with DADMAC and other cationising agents, or non modified	0.075-0.90	Low	Low	Monomer acrylamide < 0.1 % in active material of commercial product Acrylamide < 10 ppb in foodstuffs

Table 11 (continued)

Fixating agents	Solution of an amine, amide and formaldehyde condensation product	0 to 500	Low	Low	Formaldehyde < 1 mg/dm² of finished paper
	Methylolamide, cationic	0 to 0.2	Low	Low	Formaldehyde < 1 mg/dm² of finished paper
	Aliphatic polyamine, cationic	0 to 300	Low	Low	< 0.4 g/dm²
Laminating glue	Carboxymethylcellulose	0 to 0.5	High	Low	No restriction
	Dextrin		High	Low	No restriction
	Copolymer of ethylene and acrylic acid		High	Moderate	The finished copolymer shall contain no more than 25 weight percent of polymer units derived from acrylic acid and no more than 0.35 weight percent of residual monomeric acrylic acid, and have a melt index not to exceed 350 as determined by ASTM method D1238–82, ‘‘Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer’’
	Copolymer of ethylene and vinyl acetate		High	Moderate	No restriction
	Polyamide resins		Low	Low	No restriction
	Polyvinyl alcohol		High	Low	No restriction
	Polyethylene glycol	0 to 1	High	Moderate	< 7% in the paper monoethylene glycol in PEG < 0.2 %
	Polyurethane	0 to 0.5	Low	Low	< 0.1 % by weight in finished product
	Copolymer of styrene and acrylic acid		Low	Moderate	Authorized if a minimum of 20% of acrylic acid is used in copolymer
Dye	Anionic Direct Dyes	0-100	Low	Low	Restriction given by Directive 2001/405/EC and in accordance with EN646 (score 4)
	Cationic Direct Dyes	0-100	Low	Low	Restriction given by Directive 2001/405/EC and in accordance with EN646 (score 4)

Table 11 (continued)

Pick-up glue	Carboxymethylcellulose	0 - 4*	High	Low	No restriction
	Methyl-cellulose		High	Low	No restriction
	Polyacrylic acid, sodium salt		Moderate	Low	No restriction
	Polyethylene glycol (PEG)		High	Moderate	PEG < 7% in the paper with monoethylene glycol in PEG < 0.2 %
	Polyvinyl alcohol		High	Low	No restriction
Tail seal glue	Carboxymethylcellulose	0 to 0.03*	High	Low	No restriction
	Methyl-cellulose		High	Low	No restriction
	Polyethylene glycol (PEG)		High	Moderate	< 7% in the paper with monoethylene glycol in PEG < 0.2 %
	Polyvinyl alcohol		High	Low	No restriction
Wet strength	Polyamide-epichlorohydrin resins	0 to 7.5	Low	Low	3-MCPD < 12 µg/l DCP < 2 µg/l in water extract[11]
	Oxidized starch	5	Low	Low	No restriction
	Glyoxylated polyacrylamide	0.075-3.0	Low	Low	Monomer acrylamide < 0.1 % in active material of commercial product Acrylamide < 10 ppb in foodstuffs
Fluorescent Whitening Agents	Diamino stilbene derivatives, disulphonated	0 to 1.5	Low	Low	<0.3% when added, and in accordance with EN648 (Score 4)
	Diamino stilbene derivatives, tetrasulphonated				
	Diamino stilbene derivatives, hexasulphonated				
	Distyryl diphenyl derivatives				

*Typical ranges of dosage were calculated for both “tail seal glue” and “pick-up glue”, from on-machine glue consumption versus kitchen roll production. Although “pick-up glue” is present only on the core and “tail seal glue” only at the end of the roll, it is calculated as an average for the total surface of the paper contained in the roll.

[11] Method is attached at Appendix 4.

Table 11 (continued)

Softeners, debonders, absorbency aids	Diester of quaternary ammonium salt	0.5 mg/dm²	High	Low	< 0.1 %
	White mineral oil	0 to 0.5	Low	High	Food or medical grade
	Quaternary amides	0 to 0.75	Moderate	Moderate	General toxicity test, or specific migration below 0.5 μg/kg food
	Fatty acid amides	0.075 - 3.0	Moderate	Moderate	General toxicity test, or specific migration below 0.5 μg/kg food
	Butanedioic acid, sulfo, 1,4-bis(2-ethylhexyl)ester, sodium salt.	0 to 0.8	High	Low	< 0.8 mg/dm²
	Non ionic surfactants	0 to 5	Moderate	Low	General toxicity test, or specific migration below 0.5 μg/kg food

This table may be updated as appropriate. Additives belonging to new chemical families should be reviewed by manufacturers on the basis of a general toxicity test (when available), or in accordance with the principles contained in the EU "Note for Guidance of petitioner when presenting an application for assessment of a substance to be used in food contact materials prior to the authorisation"[12], and can be used by manufacturers based on a favourable outcome of such a test.

The above restrictions do not apply if the amount of the relevant chemical present in the final product is such that, even assuming 100% migration, presence in the food is below 0.5 µg/ kg.

2. Processing aids

Some types of processing aids are used during the manufacturing of tissue paper. Their presence in the finished product is very limited, and does not serve a function therein.

The main families of processing aids used in tissue paper kitchen towels and napkins production are, based on their main function, listed in the following table.

Manufacturers of kitchen towels and napkins may use substances accepted for use in food contact materials under Council of Europe Policy statements on materials coming into contact with food, European Community legislation, national rules of Council of Europe member states, or under US legislation, provided the specific migration limit or other restriction is complied with. In addition, manufacturers of kitchen towels and napkins may use other processing aids if it can be shown by calculation that, taking into account processing conditions (such as dilution and retention factors), they do not exceed 10 µg/kg food. Processing aids above this limit may still be used, provided the restrictions contained in Table 11 are respected, or that it can be shown that migration into the food does not exceed 10 µg /kg food.

[12] "Note for Guidance of Petitioner when presenting an application for safety assessment of a substance to be used in food contact materials prior to its authorisation", SANCO DG /LR D (2002).

Table 12: Processing aids

List of processing aids in tissue papers	
Function / use	**Chemical family**
Antipitch	Magnesium silicate
	Talcum
Protection agent used during production process or storage of products	Cationic polymer
	Benzotriazole
	Formaldehyde
	Polyglycol and Dimethylene glycol
	Combination of dimethylamides of long chain unsaturated fatty acids and a copper corrosion inhibitor
	Cyanodithioimidocarbonate & dithiocarbamate in solution
	Dimethylamides of long chain unsaturated fatty acids and surfactants
	Dithiocarbamate + dithiocarbonate
	Enzymes stabilized in aqueous system
	k, n-methyldithiocarbamate (PNMDC)
	Lipase
	Bromine based chemicals
	Glutaraldehyde
	Isothiasolin
	Propane diols
	Hydrogen peroxide
	Sodium hypochlorite
	Ozone
Yankee coating component	Polyamide-epichlorhydrin resins
	Hydrocarbon oil based dispersion
	Non ionic and cationic surfactants
	Poly acrylates
	Poly glycols
	Poly saccharides
	Poly vinyl alcohols
	Polyamide resins
	Synthetic esters
	Vegetable oils
	Copolymer of adipic acid, diethylenetriamine and epichlorohydrin

Table 12 (continued)

List of processing aids in tissue papers	
Yankee coating component	Di-coco-dimethyl ammonium chloride
	Paraffin oil
	Phosphoric acid, monoammonium salt
	Formic Acid
	Polyethoxylated soya-amine
	Polymer of adipic acid, diethylenetriamine & epichlorohydrin
	Silicone oil
	Talcum
	Alcohols C12-18 ethoxylated
	Cetyl alcohol
	Paraffin
	Polyalkoxyl 10 oleyl ether
	Potassium sorbate
Defoamer	1-Tetracosanol
	Alkoxane copolymer based product
	C14-18 unsaturated esters with ethylene glycol
	C16-18 unsaturated esters with ethylene glycol
	Esters w/ pentaerythritol
	Fatty acids
	Medical white oil + oleate
	N-Docosanol
	N-Eicosanol
	Fatty acid esters
	Fatty acid ethoxylates
	Paraffin based hydrocarbons
	Vegetable and mineral oils
	Waxes
Dispersion agents and surfactants	Isopropyl alcohol
	Fatty acids
	Polyethylene imine

Table 12 (continued)

List of processing aids in tissue papers	
pH and charge control	2-Propenoic acid, ammonium salt, polymer with 2-propenamide
	Boric acid
	dimethyldioctadecylammonium
	Distillates (petroleum), hydrotreated light (aliphatic hydrocarbons)
	Sodium bicarbonate
	Carbon dioxide
	Sulphuric acid
	Sodium hydroxide
	Magnesium sulphate
Retention aids	Aluminium sulphate
	Bentonite
	Poly acrylamide
	Dimethyl epichlorhydrine
	Dimethyl amine
	Poly amido amines
	Polyethylene imine
Surfactant component	Ethanaminium
	Ethoxylated alcohols
	Hexanedioic acid
	Mono-octadecenoate
	N,N,N-Trimethyl-2-[(1-oxo-2-propenyl)xy]-chloride w/ 2-propenamide
	Refined heavy paraffinic petroleum distillates
	Urea
Broke treatment	Sodium- and potassium mono- & di-persulphate
	Ammonium persulphate
	Sodium hypochlorite
	Chlorine dioxide
	Peracetic acid
Drainage and retention aid	Colloidal silica

This table may be updated in light of new innovative substances, processes, or techniques.

3. Exclusion list

The following materials should not be used in the manufacture of kitchen towels and napkins:

(a) Substances and preparations that, as supplied to the manufacturers of kitchen towels and napkins, are carcinogenic, mutagenic, or toxic for reproduction, and are classified and labelled as toxic (T) with risk phrases R45, R46, R49, R60, R61, R62, R63, R64.[13]

(b) Substances and preparations that, as supplied to the manufacturers of kitchen towels and napkins, are classified and labelled as very toxic (T+) or toxic (T) with risk phrases R23, R24, R25, R26, R27, R28, R39, R48.[15]

(c) Colourants based on, and compounds of, antimony, arsenic, cadmium, chromium (VI), lead, mercury, and selenium.

(d) Soluble azo dyes which can decompose in the body to bioavailable carcinogenic aromatic amines of category 1 and 2 according to Directive 67/548.

[13] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

APPENDIX 2

Description of substances typically used in printing inks for kitchen towels and napkins

This Appendix contains information about the printing inks which are typically used by kitchen towels and napkins manufacturers. Typical printing inks for tissue paper are water-based systems.

1. Binders

Binders are the film-forming components of inks in which the colouring material may be finely dispersed or dissolved. Binders are important for the transfer of the ink from the press to the substrate. After the drying of the print, binders serve to adhere the ink film to the printed surface.

Typical binders used by the tissue paper industry are acrylic and methacrylic resins, including styrenation, and polyurethane resins. The typical monomers and starting substances of the polymeric acrylic or polyurethane binders have been evaluated by the Scientific Committee for Food and classified into SCF lists 0 to 4.

2. Colourants

Colouring materials (colourants) is a generic term including pigments, which are insoluble in the medium (the vehicle or the binder), or dyes, which are soluble in the medium. The colouring effect is due to the content of "chromophore groups" in these substances. Chromophore groups are unsaturated molecular groups which have the capability to absorb the visible light within certain wave length areas.

The colourants used in printing inks for tissue paper should meet the selection criteria of the Exclusion List contained in Appendix 1. Additionally, they should be chosen with regard to bleeding resistance against various chemicals, including food simulants according to agreed specifications. In particular, colourants should be tested following the EN 646 bleeding test with a minimum score of 4. Moreover, the colourants used in printing inks should also meet the following quality specifications.[14]

(a) Metals and metalloids

The content of metals and metalloids soluble in 0.1M HCl and expressed as a percentage in relation to the colourant should not exceed:

antimony	0.050 %
arsenic	0.010 %
cadmium	0.010 %
chromium (VI)	0.100 %
lead	0.010 %
mercury	0.005 %
selenium	0.010 %

With regard to barium, only pigments which allow the finished article to meet the specific migration limit (SML) of 1 mg barium/kg food should be used.

[14] These specifications reflect those of the Council of Europe Resolution AP (89)1 on the use of colourants in plastic materials coming into contact with food.

(b) Aromatic amines
The content of primary unsulphonated aromatic amines soluble in 1M HCl and expressed as aniline should not exceed 0.05 %. The total content of primary aromatic amines recognised to be human carcinogens (benzidine, 2-naphthylamine, 4-aminobiphenyl and 4-chloro-2-methylaniline) should not exceed 0.001 % of the colourant.

(c) Polychlorinated biphenyls (PCB's)
The content of PCB's should not exceed 25 mg/kg of the colourant, expressed as decachlorobiphenyl.

(d) Carbon black
The toluene-extractable fraction of carbon black should not exceed 0.15 % of the colourant.

3. Additives

An ink additive is a substance used normally in small quantities, which essentially determines the technical properties of the printing ink in their manufacture or in the printing process as well as in the printed product.

Typical additives used by manufacturers and converters of kitchen towels and napkins have been approved by the SCF. They include:

- Slip control agents, such as polyethylene wax and silicium dioxide. The polymers have a molecular weight >1000 Dt.

- Amine solubilisers, such as dimethylaminoethanol (DMEA) and ammonia. They are removed in the drying process.

- Defoamers, such as polydimethylsiloxane. Typical antifoam additives involve substances with a molecular weight >1000 Dt.

- Biocides, such as isothiazolinone derivatives are used in water borne systems. A worse case calculation for the typical biocide used will result in typical concentration in food below the detection limit set in the Synoptic document.

- Co-solvents, such as propylene glycol.

- Thickeners, such as polyurethane and polymer of acrylic acid, salt.

Overview table

Ink component	Example	SCF REF No.	Typical Range [%]
Binder (resin)	Styrene-acrylate copolymer Acrylate copolymer Urethane copolymer	31560	10 - 20
Pigment			5 - 30
Amine solubiliser	Ammonia Aminoalcohols	12789 / 35320 16150 / 49235 / 12775	1.5
Defoamer	Polydimethylsiloxane	23547 / 49525 / 76720/ 76721	0.1 - 0.5
Wax	Polyethylene wax	80000 / 76951	0 - 2
Thickener	Polyurethane Polymer of acrylic acid, salt	81230 80380	0 - 1
Biocide	Isothiazolinone derivatives (active agent: typically 1.5%)	37520 / 43760 / 66755	0.5
Co-solvent	Propylene glycol	23740 / 82065	0 - 2
Water		26360 / 95855	55 - 75

4. Substances not to be used for kitchen towels and napkins

Substances or preparations contained in the CEPE exclusion list[15] should not be used for the manufacture of printing inks for kitchen towels and napkins.

[15] Committee of experts on materials coming into contact with food, RD 8/8-35.1, as subsequently amended.

APPENDIX 3

Specific migration testing method for tissue paper

If required by the Guidelines, manufacturers of kitchen towels and napkins should use the following test to measure migration from tissue paper.

This test may be reviewed in light of new technical developments.

1. Principle

Three layers of paper are exposed to a semi-solid simulant in a sealed glass jar for 2 h at 40°C. Migrants are then extracted from the simulant using a solvent for analysis.

2. Reagents

Acetonitrile

Semi-solid simulant

- 40% diatomaceous earth (Celite 454)
- 5% olive oil
- 35% water (HPLC grade)

Internal standard, e.g. DBP-d4 for phtalates

The semi-solid simulant is prepared by weighing out the above substances in the correct proportions and mixing in a food mixer or similar device until a homogenous mixture is achieved. The homogeneity of the mixture is determined by measuring the moisture contents of triplicate portions taken randomly of the simulant. Once prepared, the semi-solid simulant must be kept in an airtight container at 5°C.

3. Apparatus

It is assumed that usual laboratory equipment is available.

- Ultrasonic bath.
- 250 ml wide-mouth glass screw-cap jars with caps.
- 40 ml screw-cap vials. Caps with PTFE-lined silicone septa.

4. Samples

Once received, the samples must be hermetically sealed and kept in a cool environment in order to prevent loss of volatiles.

5. Migration tests

Place four 250 ml jars with lids in an incubator at 40^{o}C to prewarm. An hour is sufficient.

Using the neck of the jar as a template, cut out 18 circular test pieces from the sample. Alternatively cut out circular test pieces with 7 cm diameters. The test pieces should be taken randomly, avoiding the outside sheets and sheets close to the cardboard tube if sample is in a roll. If the migration test is not to be carried out immediately the test pieces should be wrapped or placed in an airtight container.

Prewarm the semi-solid simulant and weigh out four portions of 10.0 g.

Remove warmed jars from the incubator and place 3 test pieces of cut paper in the bottom of 3 of the jars. Add the weighed portions of semi-solid simulant, ensuring even coverage. Place 3 further test pieces of paper on top of the semi-solid simulant and gently press down to ensure even contact. Seal the jars and place in the incubator at 40°C.

The fourth jar is the blank and should contain the last portion of semi-solid simulant and no paper.

Commence timing when the incubator door is shut and the indicated temperature returns to 40°C.

After 2 hours, remove the jars from the incubator. Open and discard the test pieces, ensuring that all adhering simulant is removed. Transfer the simulant to a 40 ml screw-cap vial via a funnel. Pipette 25 ml acetonitrile into the (now empty) test vessel, add a suitable internal standard (e.g.100μl of DBP-d4 for phthalates) using a microsyringe. Swirl to ensure thorough rinsing of the test vessel and transfer through the funnel into the 40 ml vial.

Extract the simulant by ultrasonic agitation for 1 hour. Allow to stand for at least half an hour. Remove an aliquot and filter through a 0.2μm syringe filter into an autosampler vial. Inject for analysis by GC-MS or HPLC. Select analytical conditions according to the chemical substances studied.

The following GC-MS conditions have been successfully used for DIPNs and phthalates.

Injection	splitless, 280°C
Column	5% phenylmethyl siloxane
	30m x 0.25mm id, 0.25μm film thickness
Oven programme	70°C hold for 2 min
	ramp to 310°C at 15°C/min
	hold for 4 min
Carrier gas	He, 1 ml/min, constant flow
Detector	MSD, SIM
	Ions m/z, 149 (phthalates), 153 (DBP-d4), 197 (DIPN)

6. Calculation of results

Determine the concentration of the migrants studied, in μg/g of semi-solid simulant by comparison against calibration standards using the internal standard procedure in the normal fashion. Multiply this by the mass of semi-solid simulant used (10g) and divide by the paper/food contact surface area (0.77 dm^2 if 7 cm diameter) to calculate the migration result in units of $\mu g/dm^2$.

APPENDIX 4

Method to determine 1,3-dichloro-2-propanol and 3-chloro-1,2-propanediol in an aqueous extract of paper

The following method serves to determine 1,3-dichloro-2-propanol and 3-monochloro-1,2-propanediol in an aqueous extract of paper. This method is based on the BfR method, and it should be used to measure compliance with the restrictions laid down for polyamide-epichlorohydrin resins in Appendix 1.

1. Principle

The analytes are separated from the aqueous extract via a solid phase extraction column. DCP and MCPD are derivatized using heptafluorobutyrylimidazole (HFBI) and measurements carried out using GC-ECD.

2. Chemicals

Unless otherwise stated, analytical grade chemicals are to be used. The water must be distilled or of a suitable purity.

2.1 1,3-dichloro-2-propanol (DCP), e.g. Fluka

2.1.1 DCP parent solution
50 mg of DCP is weighed into a 50 ml volumetric flask. The flask is filled up to the mark with acetonitrile.
The solution will keep in the refrigerator for one month.

2.2. 3-chloro-1,2-propanediol (MCPD), e.g. Merck

2.2.1 MCPD parent solution
50 mg of MCPD is weighed into a 50 ml volumetric flask. The flask is filled up to the mark with acetonitrile.
The solution will keep in the refrigerator for one month.

2.3 DCP-MCDP calibration solution
0.5 ml of each of the two solutions as given in 2.1.1 and 2.2.1 is pipetted into a 20 ml volumetric flask. The flask is filled up to the mark with diethyl ether. In a 100 ml volumetric flask 2.5 ml of this solution is filled up to the mark with diethyl ether.
The solution will keep in the refrigerator for one month.

2.4 3-methoxy-1,2-propanediol (internal standard, IS), e.g. Sigma

2.4.1 IS solution
50 mg of 3-methoxy-1,2-propanediol is weighed into a 100 ml volumetric flask. The flask is filled up to the mark with acetonitrile. 0.25 ml of this solution is pipetted into a 100 ml volumetric flask and filled up to the mark with diethyl ether.
The solution will keep in the refrigerator for one month.

2.5 Sodium chloride

2.6 Acetonitrile

2.7 Diethyl ether*, e.g. Merck

2.8 Isooctane for residue analysis

2.9 Elution solution: 95 ml diethyl ether / 5 ml isooctane

2.10 Heptafluorobutyrylimidazole (HFBI), e.g. Pierce

2.11 Solid phase extraction column, e.g. Extrelut 20, Merck

3. Apparatus

3.1 Rotary vacuum evaporator

3.2 GC apparatus with ECD

3.3 Capillary column, e.g. DB-5MS, 60m, I.D. 0.25 mm, film thickness 0.25µm.

4. Preparing samples

An aqueous extract is made with 1 g of tissue in 250 ml of water according to the principles of EN 645. This should be added to 29.25g of NaCl in a 250 ml volumetric flask.

5. Carrying out the experiment

20 ml of the extract 4 is placed on the extraction column. After a reaction time of 20 min. DCP and MCPD are slowly eluted into a 500 ml round-bottomed flask with 250 ml of elution solution (2.9). The ether is removed on the rotary vacuum evaporator (35–40°C, 800mbar). 1 ml of IS solution as given in 2.4.1 is added to the remaining isooctane.

Derivatisation is carried out in the 500 ml round-bottomed flask. After adding 200 µl of HFBI the flask is sealed and left to stand at room temperature for 15 minutes, with the flask being agitated occasionally. The contents are washed into a 25 ml volumetric flask and filled up with isooctane. 1.5 ml of water is added and the flask is vigorously agitated for one minute. When the phases have separated ca. 20ml of the organic phase is placed in a sealable glass jar containing 2 ml of water and again vigorously agitated for one minute. The organic phase is used in gas chromatographic analysis.

6. Calibration curves

0.1, 0.2, 0.5, 1.0 and 2.0 ml of the DCP-MCPD calibration solution as given in 2.3 (equivalent to 0.005, 0.010, 0.025, 0.050 and 0.100 ng/2µl of the solution used for measurement purposes) are made up to 6 ml with diethyl ether in a 25 ml volumetric flask containing 1 ml IS solution as given in 2.4.1. 15ml of isooctane is added. After addition of 200 µl of HFBI the flask is sealed and left to stand at room temperature for 15 minutes, with the flask being agitated occasionally. The volumetric flask is filled up with isooctane and the experiment continued further as described in 7.

A regression analysis is made of the ratios of the DCP and MCPD peak areas to that of the IS and of the content of DCP and MCPD in the volume of solution to be measured [ng/2µl].

* It is imperative that analytical quality diethyl ether is used here. The ether should neither be dried nor stabilized with ethanol.

7. Gas chromatographic conditions

Capillary column:	see 3.3
Carrier gas:	helium
Column pressure:	180kPa
Injection:	2 µl, splitless
Temperature programme:	2 min at 50°C
	1.5°C/min to 100°C
	5 min at 100°C
	25°C/min to 300°C
	10 min at 300°C (total: 58.33 min)
Injector temperature:	250°C
Detector temperature:	320°C

8. Evaluation

Using the regression equation resulting from 7, the content of analytes in the volume of solution to be measured x[ng] is calculated.

$$C_{DCP.MCPD}[\mu g / l] = \frac{x - a}{b} \cdot 50 \cdot 10^{-3}$$

$C_{DCP.MCPD}$	Content of DCP or MCPD in the aqueous extract [µg/l]
x	Content of DCP or MCPD in the volume of solution to be measured as given in the regression equation [ng]
a	Measurement solution volume [ml]
b	Volume of solution to be measured [ml]

For the ratios given in the test method the content of DCP or MCPD in cold aqueous extract ($C_{DCP.MCPD}$ [µg/l]) is as follows:

$$C_{DCP.MCPD}[\mu g / l] = \frac{x \cdot 25}{0.002} \cdot 50 \cdot 10^{-3} = x \cdot 625$$

9. Detection limit of the procedure

The detection limit of the procedure was determined in an inter-lab test with 8 participants as a 95 percentile of the lab-intern detection limits set according to DIN 32645 (calibration curve procedure):

DCP	2.3µg/l
MCPD	2.0µg/l