Partial Agreement
in the Social and Public Health Field
Accord Partiel
dans le domaine social et de la santé publique

PUBLIC HEALTH COMMITTEE

COMMITTEE OF EXPERTS ON MATERIALS COMING INTO CONTACT WITH FOOD

POLICY STATEMENT CONCERNING

PAPER AND BOARD MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Version 2 – 13.04.2005

NOTE TO THE READER

The following documents are part of the Policy statement concerning paper and board materials and articles intended to come into contact with foodstuffs:

- Resolution ResAP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs
- Technical document No. 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs (Version No. 1)
- Technical document No. 2 - Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs (Version No. 2)
- Technical document No. 3 - Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs (Version No. 2)
- Technical document No. 4 - CEPI Guide for good manufacturing practice for paper and board for food contact, prepared by CEPI
- Technical document No. 5 - Practical Guide for users of Resolution ResAP (2002) 1 on paper and board materials intended to come into contact with foodstuffs (Version No. 1)
- Technical document No. 6 - Guidelines on the presentation of applications for safety evaluation of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs (Version No.1)

The documents are available 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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RESOLUTION RESAP (2002) 1 ON PAPER AND BOARD MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

RESOLUTION RESAP (2002)1 ON
PAPER AND BOARD MATERIALS AND ARTICLES
INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

(a*dopted by the Committee of Ministers on 18 September 2002*
at the 808th meeting of the Ministers' Deputies)

The Committee of Ministers, in its composition restricted to the Representatives of Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom, member states of the Partial Agreement in the Social and Public Health Field,

Recalling Resolution (59) 23 of 16 November 1959, concerning the extension of the activities of the Council of Europe in the social and cultural fields;

Having regard to Resolution (96) 35 of 2 October 1996, whereby it revised the structures of the Partial Agreement and resolved to continue, on the basis of revised rules replacing those set out in Resolution (59) 23, the activities hitherto carried out and developed by virtue of that resolution; these being aimed in particular at:

a. raising the level of health protection of consumers in its widest sense, including a constant contribution to harmonising – in the field of products having a direct or indirect impact on the human food chain as well as in the field of pesticides, pharmaceuticals and cosmetics – legislation, regulations and practices governing, on the one hand, quality, efficiency and safety controls for products and, on the other hand, the safe use of toxic or noxious products;

b. integrating people with disabilities into the community; defining – and contributing to its implementation at European level – of a model of coherent policy for people with disabilities, which takes account simultaneously of the principles of full citizenship and independent living; contributing to the elimination of barriers to integration, whatever their nature, whether psychological, educational, family-related, cultural, social, professional, financial or architectural;

Having regard to the action carried out for several years for the purposes of harmonising their legislation in the public health field and, in particular, with regard to paper and board materials and articles intended to come into contact with foodstuffs;

Considering that paper and board materials and articles intended to come into contact with foodstuffs may, by reason of migration of paper and board constituents to the foodstuffs, pose under certain conditions a risk to human health;

Emphasizing the fact that this resolution and the technical documents on paper and board materials and articles intended to come into contact with foodstuffs form a whole and should be read in conjunction with each other.

Taking the view that each member state, faced with the need to introduce regulations governing this matter, would find it beneficial to harmonise such regulations at European level,

Recommends to the governments of the member states of the Partial Agreement in the Social and Public Health field to take into account in their national laws and regulations on paper and board materials and articles intended to come into contact with foodstuffs the principles set out hereafter.

APPENDIX TO RESOLUTION RESAP (2002)1

1. Field of application

This resolution applies to materials and articles constituted of paper and board (excluding nonwovens [1]) 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. 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 this resolution [2] . 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 resolution, unless separated from the foodstuffs by a functional barrier [3] to migration.

Filtering layers of high grammage [4] 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 present resolution. [5]

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 the 'Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs', set out in Technical document No. 3. In addition paper and board may contain functional additives and synthetic fibres [6] . Paper and board may also contain other treatment agents and polymeric binders for organic and inorganic pigments.

3. Specifications

3.1. Paper and board used for all food contact applications under normal or foreseeable conditions of use should meet the following conditions:

3.2. 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 or a deterioration in the organoleptic characteristics thereof, in accordance with Article 2 of Directive 89/109/EEC.

[1] As defined by ISO 9092.

[2] Examples: Mineral coated papers and their components, including polymeric binders in the coating formula, are subject to this resolution. The plastic layer, or a layer of any other material, such as aluminium, waxes or paraffins in contact with foodstuffs, of a coated or laminated paper is excluded from this resolution. The paper behind the layer is not subject to this resolution if it can be shown that the layer is a functional barrier.

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

[4] Products with a weight to surface area ratio of 500 g/m^2 and above (BgVV Chapter XXXVI/1 – Papers and filter beds for use in boiling and hot-filtering).

[5] Tissue paper kitchen towels and napkins are covered by specific guidelines.

[6] Synthetic fibres should comply with EU Directive 90/128/EEC.

3.3. They should be manufactured in accordance with the 'CEPI guide for good manufacturing practice for paper and board for food contact' set out in Technical document No. 4 and using the 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 Technical document No. 1 and according to the conditions specified.

3.4. They 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.

3.5. They should not release substances which have an antimicrobial effect on foodstuffs. The method of analysis to be applied is laid down in the 'Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs' set out in Technical document No 2.

3.6. They should comply with the restrictions laid down in Table 1 and Table 2 hereafter and with either the QM [7] or SML restrictions [8] laid down 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 Technical document No. 1.

Table 1 - Restriction limits (QM) for cadmium, lead and mercury

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

[7] The restrictions in Table 1 of this resolution and 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 Technical document No. 1, expressed as QM (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), have been derived from guideline levels laid down in Council of Europe Resolution AP (96) 4 on maximum and guideline levels and on source-directed measures aimed at reducing the contamination of food by lead, cadmium and mercury and from the SML (specific migration limit) restrictions as laid down in EU Directives, respectively, based on toxicological assessment, applying the conventional ratio of 6 dm^2 of material coming into contact with 1 kg of foodstuffs and 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 the 'Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs' set out in Technical document No. 2.

[8] The SML restrictions are those set by the Commission of the European Communities in its directives relating to plastic materials intended to come into contact with foodstuffs.

3.7. 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 Technical document No. 2.

3.8. 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 dry foodstuffs or foodstuffs which are to be shelled, peeled or washed.

3.9. If it can be shown by calculation, taking into account the conditions of manufacture, that the restrictions laid down 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 Technical document No. 1, cannot be exceeded, no testing for compliance with these restrictions is necessary.

3.10. Paper and board produced with recycled fibres can be used as food contact material 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 resolution and with the

‘Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs’ set out in Technical document No 3.

3.11. Manufacturers of paper and board for 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.

References:

Council Directive of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (89/109/EEC*)*. Official Journal of the European Communities L40 11.2.89.

Council of Europe Resolution AP (96) 4 on maximum and guideline levels and on source-directed measures aimed at reducing the contamination of food by lead, cadmium and mercury. Adopted by the Committee of Ministers on 2 October 1996.

ISO 9092: 1988. Textiles - Nonwovens - Definition.

TECHNICAL DOCUMENT No. 1

LIST OF SUBSTANCES TO BE USED IN THE MANUFACTURE OF PAPER AND BOARD MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Version 1 – 10.06.2004

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1. CLASSIFICATION SYSTEM OF SUBSTANCES TO BE USED FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

General specifications

List 1 - Substances approved for the use of materials and articles intended to come into contact with food

1. Substances evaluated by SCF, classified in list 0-4, and used in compliance with specific migration limits or other restrictions, if any;

2. Substances evaluated and approved by the Committee of expert on materials coming into contact with food;

3. Substances approved in Partial Agreement member states or by FDA, based on an evaluation of a toxicological dossier, which meets the present SCF criteria;

4. Substances authorised as direct food additives in compliance with specific migration limits or other restrictions;

5. The substances which have been approved by Partial Agreement member states or by FDA applying scientific evaluation criteria of the time of their approval will be listed in a Temporary Appendix to List 1.

List 2 – Substances not approved for the use of materials and articles intended to come into contact with food

Substances which do not meet the criteria set for List 1 substances.

Complementary specifications

1. The substances of the Temporary Appendix should be integrated in List 1 or List 2 not later than five years after adoption of the List of substance.

2. List 1 and List 2 will be updated in principle once a year in order to take into account newly evaluated substances, new submissions by industry or substances to be deleted.

2. INTRODUCTION

2.1. The lists include:

A. LIST 1 OF ADDITIVES : list of additives assessed and approved by Partial Agreement member states
B. TEMPORARY APPENDIX TO LIST 1 OF ADDITIVES : list of additives approved by Partial Agreement member states or by FDA, applying evaluation criteria at the time of their approval
C. LIST 2 OF ADDITIVES : list of additives not yet assessed and not approved by Partial Agreement member states

2.1.1. The monomers used for the manufacture of polymeric additives are included in 3 Appendices:

- Appendix A : monomers assessed;
- Appendix B : monomers approved by Partial Agreement member states or by FDA, applying evaluation criteria at the time of their approval;
- Appendix C : monomers not yet assessed.

2.2. The lists do not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the listed acids, phenols or alcohols which can also be used. However, names containing "…acid(s), salts" appear in the lists, if the corresponding free acid(s) is (are) not mentioned. In such cases the meaning of the term "salts" is "salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc".

2.3. The lists do not include the following substances although they may be present:

▪ Substances which could be present in the finished product as:

  – impurities in the substances used;
  – reaction intermediates;
  – decomposition products.

▪ Oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesise them are included in the lists.

▪ Mixtures of the authorised substances.

2.4. Substances should be of good technical quality as regards the purity criteria.

3. INFORMATION AND ABBREVIATIONS

The lists contain the following information :

- PM/REF No : the EU packaging material reference number of the substance
- CAS No : the Chemical Abstracts Service Registry Number of the substance
- NAME : the chemical name of the substance or the substance group
- SCF-L : the number of the list in which the substance is classified by the Scientific Committee for food / EFSA
- RESTRICTIONS AND/OR SPECIFICATIONS : restrictions and/or specifications related to the substance
- ADI/TDI : acceptable daily intake or tolerable daily intake as defined in the reports of the Scientific Committee for food / EFSA.

A number of abbreviations are used under RESTRICTIONS AND/OR SPECIFICATIONS and ADI/TDI, the meanings of which are as follows :

- ACC : acceptable
- DL : detection limit of the method of analysis
- FCC : Food Chemicals Codex
- ND : not detectable
- NS : not specified
- SML : specific migration limit in food or in food simulants
- SML(T) : specific migration limit in food or in food simulants expressed as total of moiety/substance(s) indicated

4. NOTES RELATED TO THE COLUMN “RESTRICTIONS AND/OR SPECIFICATIONS”

(1)	Warning : there is a risk that the SML could be exceeded in fatty food simulants
(2)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 30015, 30120, 30200, 48030, 48050, 53765, 53860
(3)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 40320, 87040
(4)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 15760, 16990, 47680, 53650
(5)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 48640, 61360, 61600
(6)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 17260, 54880, 59280
(7)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 64300, 85840
(8)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 86960, 87120
(9)	Divinylbenzene may contain up to 40 % of ethylvinylbenzene
(10)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 10060, 23920
(11)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 10690, 10780, 10840, 11470, 11590, 11680, 11710, 11830
(12)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 19540, 19960, 64800
(13)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 20020, 20110, 20170, 20890, 21010, 21130, 21190
(14)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 12265, 26170, 26320
(15)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 13780, 20590
(16)	SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 15700, 16600, 16630, 18640, 19110, 25208, 25210, 25240

A. LIST 1 OF ADDITIVES

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
(10030)	000514-10-3	Abietic acid	2		1
(10060)	000075-07-0	Acetaldehyde	2	SML(T) = 6 mg/kg (10)	0,1
30000	000064-19-7	Acetic acid	1		NS
30015	000112-07-2	Acetic acid, 2-butoxyethyl ester	2	SML(T) = 3 mg/kg (2)	0,05
30120	000111-15-9	Acetic acid, 2-ethoxyethyl ester	2	SML(T) = 3 mg/kg (2)	0,05
30200	000110-49-6	Acetic acid, 2-methoxyethyl ester	2	SML(T) = 3 mg/kg (2)	0,05
30295	000067-64-1	Acetone	3		
(11470)	000140-88-5	Acrylic acid, ethyl ester	2	SML(T) = 6 mg/kg (11) (as acrylic acid)	0.1 (a.a)
31730	000124-04-9	Adipic acid	1		5
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester	2	SML = 18 mg/kg (1)	0,3
33120	-	Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C24)	3		
33350	009005-32-7	Alginic acid	1		NS
33801	-	n-Alkyl(C10-C13)benzenesulphonic acid	2	SML = 30 mg/kg	0,5
34230	-	Alkyl(C8-C22)sulphonic acid	2	SML = 6 mg/kg	0,1
34281	000151-41-7	Dodecylsulphuric acid	3		
34560	021645-51-2	Aluminium hydroxide	2		1 (as Al)
34660	001327-41-9	Aluminium hydroxychloride	2		1(as Al)
34720	001344-28-1	Aluminium oxide	2		1 (as Al)
35170	000141-43-5	2-Aminoethanol	3	SML = 0.05 mg/kg	
35320	007664-41-7	Ammonia	1		NS
35440	012124-97-9	Ammonium bromide	1		1(as Br)
35600	001336-21-6	Ammonium hydroxide	1		NS
35840	000506-30-9	Arachidic acid	0		
36000	000050-81-7	Ascorbic acid	1		ACC

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
36880	008012-89-3	Beeswax	0		
37040	000112-85-6	Behenic acid	0		
37280	001302-78-9	Bentonite	3		
37520	002634-33-5	1,2-Benzisothiazolin-3-one	2	SML = 1.2 mg/kg	0,02
37600	000065-85-0	Benzoic acid	1		5
38400	000100-51-6	Benzyl alcohol	1		5
40320	010043-35-3	Boric acid	2	SML(T) = 6 mg/kg (3) (as B)	0.1 (as B)
40594	000075-65-0	tert-Butanol	3		
40720	025013-16-5	tert-Butyl-4-hydroxyanisole (= BHA)	1	SML = 30 mg/kg	0,5
41280	001305-62-0	Calcium hydroxide	1		NS
41520	001305-78-8	Calcium oxide	1		NS
41600	012004-14-7 037293-22-4	Calcium sulphoaluminate	2		1 (as Al)
42080	001333-86-4	Carbon black	3	To be fixed	
42500	-	Carbonic acid, salts	1		NS (CO3)
42640	009000-11-7	Carboxymethylcellulose	2		NS
42720	008015-86-9	Carnauba wax	3		
42800	009000-71-9	Casein	0		
42880	008001-79-4	Castor oil	3		
43120	008001-78-3	Castor oil, hydrogenated	3		
43280	009004-34-6	Cellulose	0		
43600	004080--31-3	1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	2	SML = 0.3 mg/kg	0,005
43680	000075-45-6	Chlorodifluoromethane	2	SML = 6 mg/kg	0,1
43760	026172-55-4	5-Chloro-3-methyl-4-isothiazolin-3-one	4A	SML = ND (DL = 0.01 mg/kg)	
44160	000077-92-9	Citric acid	1		NS
44640	000077-93-0	Citric acid, triethyl ester	1		20

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
45450	068610-51-5	p-Cresol - dicyclopentadiene - isobutylene, copolymer	3	SML = 0.05 mg/kg (1)	
45560	014464-46-1	Cristobalite	3		
46070	010016-20-3	alpha-Dextrin	0		
46080	007585-39-9	beta-Dextrin	0		
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (= BHT)	1	SML = 3 mg/kg	0,05
-	000107-06-2	1,2-Dichloroethane (FCC)	-	In compliance with the FCC specifications	
47680	000111-46-6	Diethyleneglycol	2	SML(T) = 30 mg/kg (4)	0,5
48030	000112-34-5	Diethyleneglycol monobutyl ether	2	SML(T) = 3 mg/kg (2)	0,05
48050	000111-90-0	Diethyleneglycol monoethyl ether	2	SML(T) = 3 mg/kg (2)	0,05
(15790)	000111-40-0	Diethylenetriamine	3	SML = 5 mg/kg	
48460	000075-37-6	1,1-Difluoroethane	3		
48620	000123-31-9	1,4-Dihydroxybenzene	2	SML = 0.6 mg/kg	0,01
48640	000131-56-6	2,4-Dihydroxybenzophenone	2	SML(T) = 6 mg/kg (5)	0,1
49225	000124-40-3	Dimethylamine	3	SML = 0.06 mg/kg	
49540	000067-68-5	Dimethyl sulphoxide	3		
49840	002500-88-1	Dioctadecyl disulphide	2	SML = 3 mg/kg	0,05
51760	025265-71-8 000110-98-5	Dipropyleneglycol	2		1,5
-	055963-33-2	Distarch phosphate (= E1412)	-		ACC
-	068130-14-3	Distarch phosphate acetate (= E1414)	-		ACC
(16697)	000693-23-2	Dodecanedioic acid	3		
52000	027176-87-0	Dodecylbenzenesulphonic acid	2	SML = 30 mg/kg	0,5
52640	016389-88-1	Dolomite	3		
-	-	Enzyme preparations (FCC)	-	In compliance with the FCC specifications	
-	000089-65-6	Erythorbic acid (= E315)	-		6
52800	000064-17-5	Ethanol	1		ACC

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
53255	000100-41-4	Ethylbenzene	3	SML = 0.6 mg/kg	0.1 : 10
53280	009004-57-3	Ethylcellulose	2		NS
(16950)	000074-85-1	Ethylene	3		
53360	000110-31-6	N,N'-Ethylenebisoleamide	3		
53440	005518-18-3	N,N'-Ethylenebispalmitamide	3		
53520	000110-30-5	N,N'-Ethylenebisstearamide	3		
53540	000107-15-3	Ethylenediamine	2	SML = 12 mg/kg	0,2
53600	000060-00-4	Ethylenediaminetetraacetic acid	2		2,5
53650	000107-21-1	Ethyleneglycol	2	SML(T) = 30 mg/kg (4)	0,5
53670	032509-66-3	Ethyleneglycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	2	SML = 6 mg/kg	0,1
53765	000111-76-2	Ethyleneglycol monobutyl ether	2	SML(T) = 3 mg/kg (2)	0,05
53860	000109-86-4	Ethyleneglycol monomethyl ether	2	SML(T) = 3 mg/kg (2)	0,05
(17020)	000075-21-8	Ethylene oxide	4A	SML = ND (DL = 0.01 mg/kg)	
(17050)	000104-76-7	2-Ethyl-1-hexanol	1	SML = 30 mg/kg	0,5
54260	009004-58-4	Ethylhydroxyethylcellulose	2		NS
(17170)	061788-47-4	Fatty acids, coco	3		
54710/1	061790-12-3	Fatty acids, tall oil	3		
(17236)	061790-37-2	Fatty acids, tallow	3		
54760	061790-38-3	Fatty acids, tallow, hydrogenated	3		
(17245)	008016-13-5	Fish oil	3		
-	-	Food starch, modified (with the exception of specific substances mentioned elsewhere in the list) (FCC)	-	In compliance with the FCC specifications	
54880	000050-00-0	Formaldehyde	3	SML(T) = 15 mg/kg (6)	
55040	000064-18-6	Formic acid	1		3
55120	000110-17-8	Fumaric acid	1		6
-	000526-95-4	Gluconic acid (= E574)	-		NS
(17530)	000050-99-7	Glucose	0		

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
-	-	Glucose syrup (FCC)	-	In compliance with the FCC specifications	
-	000142-47-2	Glutamic acid, monosodium salt (= E621)	-		NS
56080	025637-84-7	Glycerol dioleate	1		NS
56240	027902-24-5	Glycerol diricinoleate	3		
56320	001323-83-7	Glycerol distearate	1		NS
56960	025496-72-4	Glycerol monooleate	1		NS
57440	001323-38-2	Glycerol monoricinoleate	3		
57520	031566-31-1	Glycerol monostearate	1		NS
-	000056-40-6	Glycine (= E640)	-		ACC
58400	009000-30-0	Guar gum	1		NS
58480	009000-01-5	Gum arabic	1		NS
59240	000124-09-4	Hexamethylenediamine	2	SML = 2.4 mg/kg	0,04
59280	000100-97-0	Hexamethylenetetramine	3	SML(T) = 15 mg/kg (6) (as formaldehyde)	
59990	007647-01-0	Hydrochloric acid	1		NS
-	007722-84-1	Hydrogen peroxide (FCC)	-	In compliance with the FCC specifications	
(18880)	000099-96-7	4-Hydroxybenzoic acid	2		10
60160	000120-47-8	4-Hydroxybenzoic acid, ethyl ester	1		10
60200	000099-76-3	4-Hydroxybenzoic acid, methyl ester	1		10
60240	000094-13-3	4-Hydroxybenzoic acid, propyl ester	1		10
60560	009004-62-0	Hydroxyethylcellulose	2		NS
61120	009005-27-0	Hydroxyethyl starch	2		NS
61360	000131-57-7	2-Hydroxy-4-methoxybenzophenone	2	SML(T) = 6 mg/kg (5)	0,1
61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	2	SML(T) = 6 mg/kg (5)	0,1
-	053124-00-8	Hydroxypropyl distarch phosphate (= E1442)	-		NS
61800	009049-76-7	Hydroxypropyl starch	1		NS

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
62160	007681-53-0	Hypophosphorous acid, sodium salt	3		
62190	008013-17-0	Invert sugar	0		
62720	001332-58-7	Kaolin	1		NS
62960	000050-21-5	Lactic acid	1		NS
63240	008006-54-0	Lanolin (Pharmacopeia grade)	0		
63280	000143-07-7	Lauric acid	0		
63940	008062-15-5	Lignosulphonic acid	3	SML = 0.24 mg/kg	
(19534/1)	068424-45-3	Linseed oil fatty acids	3		
64300	001310-65-2	Lithium hydroxide	2	SML(T) = 0.6 mg/kg (7) (as Li)	0.01 (as Li)
-	009000-40-2	Locust bean gum (= E410)	-		NS
64800	000110-16-7	Maleic acid	2	SML(T) = 30 mg/kg (12)	0,5
64640	001309-42-8	Magnesium hydroxide	1		NS
65020	006915-15-7	Malic acid	1		NS
65520	000087-78-5	Mannitol	1		ACC
(20020)	000079-41-4	Methacrylic acid	2	SML(T) = 6 mg/kg (13)	0,1
65960	000067-56-1	Methanol	3		
66240	009004-67-5	Methylcellulose	2		NS
66620	000075-09-2	Methylene chloride	3	SML = 0.05 mg/kg	
66700	009004-65-3	Methylhydroxypropylcellulose	2		NS
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	4A	SML = ND (DL = 0.01 mg/kg)	
(21940)	000924-42-5	N-Methylolacrylamide	4A	SML = ND (DL = 0.01 mg/kg)	
67840	-	Montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol	3		
67850	008002-53-7	Montan wax	3		
67891	000544-63-8	Myristic acid	1		NS
68140	007697-37-2	Nitric acid	2		3

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
69040	000112-80-1	Oleic acid	1		NS
69760	000143-28-2	Oleyl alcohol	3		
70400	000057-10-3	Palmitic acid	1		NS
(22795/1)	-	Palm oil fatty acids	3		
71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	2		3
72060	008009-03-8	Petrolatum (FCC)	9	In compliance with the FCC specifications	
72640	007664-38-2	Phosphoric acid	1		70 (as P)
74880	000084-74-2	Phthalic acid, dibutyl ester	2	SML = 3 mg/kg (1)	0,05
75120	000084-66-2	Phthalic acid, diethyl ester	2	SML = 12 mg/kg (1)	0,2
(23505)	000110-85-0	Piperazine	3		
77280	009005-02-1	Polyethyleneglycol dilaurate	2		10
77360	009005-07-6	Polyethyleneglycol dioleate	2		10
77550	-	Polyethyleneglycol ester of coconut oil fatty acids	2		10
77895	068439-49-6	Polyethyleneglycol (EO = 2-6) monoalkyl(C16-C18) ether	3	SML = 0.05 mg/kg	
78080	009004-81-3	Polyethyleneglycol monolaurate	2		10
78160	009004-96-0	Polyethyleneglycol monooleate	2		10
78240	009004-94-8	Polyethyleneglycol monopalmitate	2		10
78320	009004-97-1	Polyethyleneglycol monoricinoleate	2	SML = 42 mg/kg	0,7
79040	009005-64-5	Polyethyleneglycol sorbitan monolaurate	1		10
79120	009005-65-6	Polyethyleneglycol sorbitan monooleate	2		10
79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate	1		10
79280	009005-67-8	Polyethyleneglycol sorbitan monostearate	1		10
79440	009005-71-4	Polyethyleneglycol sorbitan tristearate	1		10
79520	-	Polyethyleneglycol stearate	2		10
-	-	Polymers of MW > 10,000 made of monomers of appendix A	-	See appendix A	
80720	008017-16-1	Polyphosphoric acids	1		70 (as P)

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
81600	001310-58-3	Potassium hydroxide	1		NS
81680	007681-11-0	Potassium iodide	1	SML = 1 mg/kg (as I)	0.017 (as I)
81840	000057-55-6	1,2-Propanediol	1		25
81880	000071-23-8	1-Propanol	3		
81882	000067-63-0	2-Propanol	1		1,5
82000	000079-09-4	Propionic acid	1		NS
82400	000105-62-4	1,2-Propyleneglycol dioleate	1		25
82960	001330-80-9	1,2-Propyleneglycol monooleate	1		25
83300	001323-39-3	1,2-Propyleneglycol monostearate	1		25
(24010)	000075-56-9	Propylene oxide	4A	SML = ND (DL = 0.01 mg/kg)	
83440	002466-09-3	Pyrophosphoric acid	1		70
83470	014808-60-7	Quartz	3		
83580/1	008002-13-9	Rapeseed oil	3		
(24065/1)	-	Rapeseed oil fatty acids	3		
83840	008050-09-7	Rosin	2		1
84000	008050-31-5	Rosin, ester with glycerol	1		12,5
84080	008050-26-8	Rosin, ester with pentaerythritol	2		1
84240	065997-13-9	Rosin, hydrogenated, ester with glycerol	3		
84400	064365-17-9	Rosin, hydrogenated, ester with pentaerythritol	2		1
(24160)	008052-10-6	Rosin tall oil	3		
84640	000069-72-7	Salicylic acid	3		
84880	000119-36-8	Salicylic acid, methyl ester	1	SML = 30 mg/kg	0,5
85360	000109-43-3	Sebacic acid, dibutyl ester	3		
85840	053320-86-8	Silicic acid, lithium magnesium sodium salt	2-3	SML(T) = 0.6 mg/kg (7) (as Li)	0.01 (as Li)
85980	-	Silicic acid, salts	2		NS
86240	007631-86-9	Silicon dioxide	1		NS
86285	-	Silicon dioxide, silanated	3		

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
86440		Sodium aluminate	2		1 (as Al)
86560	007647-15-6	Sodium bromide	1		1 (as Br)
86720	001310-73-2	Sodium hydroxide	1		NS
86880	-	Sodium mono- or dialkylphenoxybenzenedisulphonate	2	SML = 9 mg/kg	0.15
86920	007632-00-0	Sodium nitrite	3	SML = 0.6 mg/kg	
86960	007757-83-7	Sodium sulphite	1	SML(T) = 10 mg/kg (8) (as SO2)	0.7(as SO2)
87040	001330-43-4	Sodium tetraborate	2	SML(T) = 6 mg/kg (3) (as B)	0.1 (as B)
87120	007772-98-7	Sodium thiosulfate	1	SML(T) = 10 mg/kg (8) (as SO2)	0.7(as SO2)
87200	000110-44-1	Sorbic acid	1		25
87600	001338-39-2	Sorbitan monolaurate	1		5
87680	001338-43-8	Sorbitan monooleate	1		5
87760	026266-57-9	Sorbitan monopalmitate	1		25
87840	001338-41-6	Sorbitan monostearate	1		25
88080	026266-58-0	Sorbitan trioleate	2		5
88240	026658-19-5	Sorbitan tristearate	1		25
88320	000050-70-4	Sorbitol	1		ACC
88630/1	008001-22-7	Soybean oil	3		
-	009045-28-7	Starch acetate (= E1420)	-		ACC
-	063798-35-6	Starch acetate adipate (= E1422)	-		ACC
88800	009005-25-8	Starch, edible	0		
88880	068412-29-3	Starch, hydrolysed	0		
-	066829-29-6	Starch octenylsuccinate, sodium salt (= E1450)	-		NS
-	065996-62-5	Starch, oxidised (= E1404)	-		ACC
-	011120-02-8	Starch phosphate (= E1410)	-		ACC
89040	000057-11-4	Stearic acid	1		NS
-	025383-99-7	Stearoyl-2-lactylic acid, sodium salt (= E481)	-		20
91170	000108-30-5	Succinic anhydride	2		NS

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
91920	007664-93-9	Sulphuric acid	1		NS
92000	007727-43-7	Sulphuric acid, barium salt	3	SML = 1 mg/kg (as Ba)	
92030	010124-44-4	Sulphuric acid, copper salt	2	SML = 30 mg/kg (as Cu)	0.5 (as Cu)
92080	014807-96-6	Talc	1		NS
(24905)	008002-26-4	Tall oil	3		
92100	061789-97-7	Tallow	3		
92150	001401-55-4	Tannic acids	3		
92160	000087-69-4	Tartaric acid	1		30
92220	-	Terpene resins, natural or synthetic (FCC)	9	In compliance with the FCC specifications	
92350	000112-60-7	Tetraethyleneglycol	1		10
92800	000096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)	2	SML = 0.48 mg/kg	0,008
93440	013463-67-7	Titanium dioxide	1		ACC
93540	000108-88-3	Toluene	3	SML = 1.2 mg/kg	
(25385)	000102-70-5	Triallylamine	3	To be fixed	
94560	000122-20-3	Triisopropanolamine	3	SML = 5 mg/kg	
95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	2		1
(25910)	024800-44-0	Tripropyleneglycol	2		1,5
(25960)	000057-13-6	Urea	0		
95680	000121-33-5	Vanillin	1		10
(26320)	002768-02-7	Vinyltrimethoxysilane	3	SML(T) = 0.05 mg/kg (14)	
95870	-	Wheat protein	0		
95880	008042-47-5	White mineral oil (FCC)	9	In compliance with the FCC specifications	
95935	011138-66-2	Xanthan gum	1		NS
96240	001314-13-2	Zinc oxide	2		1(as Zn)

B. TEMPORARY APPENDIX TO LIST 1 OF ADDITIVES

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	000071-48-7	Acetic acid, cobalt(II) salt	-	To be fixed
-	068440-00-6	Acids, fatty (C8-C18), animal	-	To be fixed
-	068937-84-8	Acids, fatty (C12-C18), methyl esters	-	To be fixed
-	067701-06-8	Acids, fatty (C14-C18 and C16-C18 unsaturated)	-	To be fixed
-	085736-49-8	Acids, fatty (C14-C18 and C16-C18 unsaturated), esters with ethyleneglycol	-	To be fixed
-	097404-28-9	Acids, fatty (C14-C26), aluminium salts	-	To be fixed
-	067701-03-5	Acids, fatty (C16-C18)	-	To be fixed
-	067701-08-0	Acids, fatty (C16-C18 and C18 unsaturated)	-	To be fixed
-	068955-98-6	Acids, fatty (C16-C18 and C18 unsaturated), branched and linear	-	To be fixed
-	067762-38-3	Acids, fatty (C16-C18 and C18 unsaturated), methyl esters	-	To be fixed
31352	085116-93-4	Acids, fatty (C16-C18), esters with pentaerythritol	9	To be fixed
-	068937-90-6	Acids, fatty (C18 unsaturated), trimers	-	To be fixed
-	025586-24-7	Acrylamide-acrylic acid-butyl acrylate-styrene, copolymer	-	To be fixed
-	025037-40-5	Acrylamide-butadiene-styrene, copolymer	-	To be fixed
-	026590-05-6	Acrylamide-diallyldimethylammonium chloride, copolymer	-	To be fixed
-	025085-02-3	Acrylamide-sodium acrylate, copolymer	-	To be fixed
-	035429-19-7	Acrylamide-N,N,N-trimethylaminoethyl methacrylate chloride, copolymer	-	To be fixed
-	026007-18-1	Acrylic acid-butadiene-fumaric acid-styrene, copolymer	-	To be fixed
-	009010-77-9	Acrylic acid-ethylene, copolymer	-	To be fixed
-	025134-51-4	Acrylic acid-2-ethylhexyl acrylate, copolymer	-	To be fixed
-	085566-12-7	Alcohols, C8-C10	-	To be fixed
-	067762-41-8	Alcohols, C10-C16	-	To be fixed
-	068526-86-3	Alcohols, C11-C14-iso, C13-rich	-	To be fixed
-	067989-40-6	Alcohols, C11-C15, secondary	-	To be fixed
-	068855-56-1	Alcohols, C12-C16	-	To be fixed
-	067762-25-8	Alcohols, C12-C18	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	090604-31-2	Alcohols, C13-C15	-	To be fixed
-	067762-30-5	Alcohols, C14-C18	-	To be fixed
-	071750-71-5	Alcohols, > C14	-	To be fixed
-	067762-27-0	Alcohols, C16-C18	-	To be fixed
-	068002-94-8	Alcohols, C16-C18 and C18 unsaturated	-	To be fixed
-	084539-77-5	Alcohols, C16-C20	-	To be fixed
-	090604-32-3	Alcohols, C18-C26	-	To be fixed
-	068784-12-3	Alkenyl(C15-C20)succinic anhydride	-	To be fixed
-	084989-41-3	2-Alkyl(C12-C16)-3-alkylidene(C13-C17)propiolactone	-	To be fixed
-	098246-87-8	2-Alkyl(C14-C16)-3-alkylidene(C15-C17)propiolactone	-	To be fixed
(33800)	068411-30-3	Alkyl(C10-C13)benzenesulphonic acid, sodium salts	(9)	To be fixed
-	085536-14-7	Alkyl(C10-C13 secondary)benzenesulphonic acid	-	To be fixed
-	085117-49-3	Alkyl(C10-C14)benzenesulphonic acid	-	To be fixed
-	068584-22-5	Alkyl(C10-C18)benzenesulphonic acid	-	To be fixed
-	063449-41-2	Alkyl(C8-C18)benzyldimethylammonium chlorides	-	To be fixed
-	068424-85-1	Alkyl(C12-C16)benzyldimethylammonium chlorides	-	To be fixed
-	085711-69-9	Alkyl(C13-C17 secondary)sulphonic acid, sodium salt	-	To be fixed
34275	085586-07-8	Alkyl(C12-C14)sulphuric acid, salts	9	To be fixed
34300	068955-20-4	Alkyl(C16-C18)sulphuric acid, sodium salt	9	To be fixed
-	090640-44-1	N-Alkyl(C12-C22)trimethylenediamines	-	To be fixed
-	012042-91-0	Aluminium chloride hydroxide	-	To be fixed
(12772)	000140-31-8	N-Aminoethylpiperazine	8	To be fixed
(12775)	000124-68-5	2-Amino-2-methyl-1-propanol	8	To be fixed
-	009037-22-3	Amylopectin	-	To be fixed
-	060164-73-0	Amylopectin acetate	-	To be fixed
-	113894-91-0	Amylopectin acetate phosphate	-	To be fixed
-	068909-37-5	Amylopectin, acid-hydrolyzed	-	To be fixed
-	113894-85-2	Amylopectin, acid-hydrolyzed, octenylsuccinate	-	To be fixed
-	222021-68-3	Amylopectin, compound with [3-(2,3-dihydroxypropoxy)propyl]silanetriol	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	143734-27-4	Amylopectin 2-(diethylamino)ethyl ether, hydrochloride	-	To be fixed
-	222021-71-8	Amylopectin 2-[(2,2-dimethoxyethyl)methylamino]-2-oxoethyl 2-hydroxy-3-(tri-methylammonio)propyl ether, chloride	-	To be fixed
-	222021-66-1	Amylopectin 2-hydroxy-3-[3-(trihydroxysilyl)propoxy]propyl 2-hydroxy-3-(trimethyl-ammonio)propyl ether, chloride	-	To be fixed
-	068936-82-3	Amylopectin 2-hydroxy-3-(trimethylammonio)propyl ether, chloride	-	To be fixed
-	222021-75-2	Amylopectin 2-hydroxy-3-(trimethylammonio)propyl 2-[methyl(2-oxoethyl)amino]-2-oxoethyl ether, chloride	-	To be fixed
-	125109-81-1	Amylopectin octadecenylsuccinate	-	To be fixed
-	113894-86-3	Amylopectin, oxidized	-	To be fixed
-	063055-37-8	Amylopectin phosphate	-	To be fixed
-	143734-26-3	Amylopectin phosphate, 2-(diethylamino)ethyl ether, sodium salt, hydrochloride	-	To be fixed
-	113894-92-1	Amylopectin phosphate, 2-hydroxypropyl ether	-	To be fixed
-	009005-82-7	Amylose	-	To be fixed
-	000084-65-1	Anthraquinone	-	To be fixed
-	000122-18-9	Benzylhexadecyldimethylammonium chloride	-	To be fixed
-	004404-43-7	4,4'-Bis[[4-anilino-6-[bis(2-hydroxyethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid	-	To be fixed
-	093965-04-9	4,4'-Bis[[4-anilino-6-[bis(2-hydroxyethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid, ammonium salt, compound with N-(2-aminoethyl)ethanolamine	-	To be fixed
-	004193-55-9	4,4'-Bis[[4-anilino-6-[bis(2-hydroxyethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid, disodium salt	-	To be fixed
-	085153-98-6	4,4'-Bis[[4-anilino-6-[bis(2-hydroxyethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid, potassium salt, compound with 2-aminoethanol	-	To be fixed
-	070942-01-7	4,4'-Bis[[4-anilino-6-[bis(2-hydroxyethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid, potassium sodium salt	-	To be fixed
-	016090-02-1	4,4'-Bis[(4-anilino-6-morpholino-s-triazin-2-yl)amino]-2,2'-stilbenedisulphonic acid, disodium salt	-	To be fixed
-	068971-49-3	4,4'-Bis[[4-[bis(2-hydroxyethyl)amino]-6-(2,5-disulphoanilino)-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, hexasodium salt	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	085187-63-9	4,4'-Bis[[4-[bis(2-hydroxyethyl)amino-6-methoxy]-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid, sodium salt, compound with 2-aminoethanesulphonic acid, monosodium salt and diethanolamine	-	To be fixed
-	085187-64-0	4,4'-Bis[[4-[bis(2-hydroxyethyl)amino-6-methoxy]-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid, sodium salt, compound with diethanolamine	-	To be fixed
-	093965-02-7	4,4'-Bis[[4-[bis(2-hydroxyethyl)amino]-6-(p-sulphoanilino)-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, sodium salt, compound with diethanolamine	-	To be fixed
-	016470-24-9	4,4'-Bis[[4-[bis(2-hydroxyethyl)amino]-6-(p-sulphoanilino)-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, tetrasodium salt	-	To be fixed
-	067786-25-8	4,4'-Bis[[4-[bis(2-hydroxypropyl)amino]-6-(p-sulphoanilino)-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, tetrasodium salt	-	To be fixed
-	031075-24-8	Bis(2-chloroethyl) ether - N,N,N',N'-tetramethylethylenediamine, copolymer	-	To be fixed
-	061789-77-3	Bis(coco alkyl)dimethylammonium chloride	-	To be fixed
(38870)	041098-56-0	4,4'-Bis[[4-diethylamino-6-(2,5-disulphoanilino)-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid, hexasodium salt	(7)	To be fixed
-	030381-98-7	Bis[2-[N-ethyl(perfluorooctane)sulphonamido]ethyl] phosphate, ammonium salt	-	To be fixed
-	085154-06-9	4-[[4-[Bis(2-hydroxyethyl)amino]-6-methoxy-s-triazin-2-yl]amino]-4'-[[4-methoxy-6-[(2-sulphoethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, sodium salt, compound with diethanolamine	-	To be fixed
-	085305-32-4	4-[[4-[Bis(2-hydroxyethyl)amino]-6-methoxy-s-triazin-2-yl]amino]-4'-[[4-methoxy-6-[(2-sulphoethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, sodium salt, compounds with 2-aminoethanesulphonic acid, monosodium salt and diethanolamine	-	To be fixed
-	061791-31-9	N,N-Bis(2-hydroxyethyl)cocoalkylamine	-	To be fixed
39280	000120-40-1	N,N-Bis(2-hydroxyethyl)lauramide	7	To be fixed
39520	000093-82-3	N,N-Bis(2-hydroxyethyl)stearamide	7	To be fixed
-	001854-26-8	N,N'-Bis(hydroxymethyl)-4,5-dihydroxyethyleneurea	-	To be fixed
-	085169-39-7	4,4'-Bis[[4-methoxy-6-[(2-sulphoethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid, sodium salt, compound with 2-aminoethanesulphonic acid, monosodium salt and diethanolamine	-	To be fixed
-	085154-07-0	4,4'-Bis[[4-methoxy-6-[(2-sulphoethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid, sodium salt, compound with diethanolamine	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
(39945)	052301-70-9	4,4'-Bis[[4-morpholino-6-(2,5-disulphoanilino)-s-triazin--2-yl]amino]-2,2'-stilbene-disulphonic acid, hexasodium salt	(7)	To be fixed
(39945)	093940-63-7	4,4'-Bis[[4-morpholino-6-(2,5-disulphoanilino)-s-triazin--2-yl]amino]-2,2'-stilbene-disulphonic acid, sodium salt	(7)	To be fixed
-	016079-88-2	1-Bromo-3-chloro-5,5-dimethylhydantoin	-	To be fixed
-	002491-38-5	2-Bromo-4'-hydroxyacetophenone	-	To be fixed
-	001303-86-2	Boron oxide	-	To be fixed
40460	000052-51-7	2-Bromo-2-nitro-1,3-propanediol	8	To be fixed
40480	007166-19-0	2-Bromo-2-nitrostyrene	8	To be fixed
40592	000078-92-2	2-Butanol	8	To be fixed
-	013397-26-7	Calcite	-	To be fixed
-	023570-56-1	Carbonic acid, potassium zirconium salt	-	To be fixed
-	068459-67-6	Castor oil, ester with glycerol	-	To be fixed
43230	008002-33-3	Castor oil, sulphated	9	To be fixed
-	068187-76-8	Castor oil, sulphated, sodium salt	-	To be fixed
-	009012-54-8	Cellulase	-	To be fixed
-	010049-04-4	Chlorine dioxide	-	To be fixed
-	000079-07-2	Chloroacetamide	-	To be fixed
-	051229-78-8	cis-1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	-	To be fixed
43630	000059-50-7	p-Chloro-m-cresol	8	To be fixed
-	060736-58-5	2-Chloro-3-(phenylsulphonyl)acrylonitrile	-	To be fixed
-	007758-19-2	Chlorous acid, sodium salt	-	To be fixed
43840	015659-56-0	Chromic chloride myristate	8	To be fixed
-	061788-46-3	Cocoalkylamines	-	To be fixed
-	061789-18-2	Cocoalkyltrimethylammonium chloride	-	To be fixed
-	000138-93-2	Cyanothiocarbamic acid, disodium salt	-	To be fixed
45700	000110-82-7	Cyclohexane	8	To be fixed
45710	000108-93-0	Cyclohexanol	8	To be fixed
-	076386-11-3	1-Decenylsuccinic acid	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	068424-95-3	Dialkyl(C8-C10)dimethylammonium chlorides	-	To be fixed
-	068391-05-9	Dialkyl(C12-C18)dimethylammonium chlorides	-	To be fixed
-	010222-01-2	2,2-Dibromo-2-cyanoacetamide	-	To be fixed
-	035691-65-7	1,2-Dibromo-2,4-dicyanobutane	-	To be fixed
-	001192-52-5	4,5-Dichloro-1,2-dithiol-3-one	-	To be fixed
-	000107-06-2	1,2-Dichloroethane	-	To be fixed
-	061789-77-3	Dicocoalkyldimethylammonium chloride	-	To be fixed
-	007173-51-5	Didecyldimethylammonium chloride	-	To be fixed
47620	000111-42-2	Diethanolamine	W8	To be fixed
47720	000120-55-8	Diethyleneglycol dibenzoate	W	To be fixed
48340	000140-01-2	Diethylenetriaminepentaacetic acid, pentasodium salt	8	To be fixed
-	015827-60-8	Diethylenetriaminepenta(methylenephosphonic acid)	-	To be fixed
-	068155-78-2	Diethylenetriaminepenta(methylenephosphonic acid), heptasodium salt	-	To be fixed
-	022042-96-2	Diethylenetriaminepenta(methylenephosphonic acid), sodium salt	-	To be fixed
-	085409-22-9	Dimethylalkyl(C12-C14)benzylammonium chloride	-	To be fixed
49202	068391-01-5	Dimethylalkyl(C12-C18)benzylammonium chloride	9	To be fixed
-	068609-88-1	Dimethylamine-epichlorohydrin, copolymer	-	To be fixed
-	042751-79-1	Dimethylamine-ethylenediamine-epichlorohydrin, copolymer	-	To be fixed
(16180)	005205-93-6	N-(Dimethylaminopropyl)methacrylamide	6A	To be fixed
49340	061789-71-7	Dimethyl(coco alkyl)benzylammonium chloride	9	To be fixed
-	005538-94-3	Dimethyldioctylammonium chloride	-	To be fixed
-	000128-04-1	Dimethyldithiocarbamic acid, sodium salt	-	To be fixed
49560	000533-74-4	3,5-Dimethyl-1,3,5,2H-tetrahydrothiadiazine-2-thione	8	To be fixed
51840	027138-31-4	Dipropyleneglycol dibenzoate	7	To be fixed
-	064742-47-8	Distillates (petroleum), hydrotreated light	-	To be fixed
-	058598-42-8	Docosenylsuccinic anhydride	-	To be fixed
-	029658-97-7	Dodecenylsuccinic acid	-	To be fixed
-	013877-83-3	2-Dodecenylsuccinic acid	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	013590-97-1	Dodecylguanidine hydrochloride	-	To be fixed
-	000112-55-0	n-Dodecyl mercaptan	-	To be fixed
-	025103-58-6	tert-Dodecyl mercaptan	-	To be fixed
-	083708-14-9	2-Eicosyl-3-heneicosylidenepropiolactone	-	To be fixed
-	003586-55-8	Ethyleneglycol bis(hydroxymethyl ether)	-	To be fixed
(54120)	000136-53-8	2-Ethylhexanoic acid, zinc salt	-	To be fixed
-	000126-92-1	2-Ethylhexylsulphuric acid, sodium salt	-	To be fixed
-	067969-69-1	N-Ethyl-N-(2-hydroxyethyl)perfluorooctanesulphonamide phosphate, diammonium salt	-	To be fixed
-	067762-63-4	Fatty acids, tall oil, butyl esters	-	To be fixed
-	061788-61-2	Fatty acids, tallow, methyl esters	-	To be fixed
-	068938-25-0	Fish oil fatty acids, hydrogenated	-	To be fixed
(54900)	093924-63-1	Formaldehyde-naphthalenesulphonic acid, copolymer, ammonium salts	-	To be fixed
(54900)	091078-68-1	Formaldehyde-naphthalenesulphonic acid, copolymer, sodium salts	-	To be fixed
55030	009011-05-6	Formaldehyde-urea, copolymer	D	To be fixed
-	031138-65-5	Glucoheptonic acid, sodium salt	-	To be fixed
-	000087-74-1	Glucoheptonic acid	-	To be fixed
55660	000111-30-8	Glutaraldehyde	7	To be fixed
-	000122-32-7	Glycerol trioleate	-	To be fixed
58310	000107-22-2	Glyoxal	6A	To be fixed
-	039346-76-4	Guar gum, carboxymethyl ether, sodium salt	-	To be fixed
-	039421-75-5	Guar gum, 2-hydroxypropyl ether	-	To be fixed
-	056000-16-9	3-(8-Heptadecenylidene)-2-(7-hexadecenyl)propiolactone	-	To be fixed
-	010126-68-8	3-Heptadecylidene-2-hexadecylpropiolactone	-	To be fixed
-	032072-96-1	Hexadecenylsuccinic anhydride	-	To be fixed
-	000112-02-7	Hexadecyltrimethylammonium chloride	-	To be fixed
59600	000107-41-5	Hexyleneglycol	7	To be fixed
-	267233-95-4	Hydrocarbons, resins, aromatic	-	To be fixed
-	267233-74-9	Hydrocarbons, resins, hydrogenated	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	000139-89-9	N-(2-Hydroxyethyl)ethylenediaminetriacetic acid, trisodium salt	-	To be fixed
61340	000149-44-0	Hydroxymethanesulphinic acid, sodium salt	8	To be fixed
-	051026-28-9	N-Hydroxymethyl-N-methyldithiocarbamic acid, potassium salt	-	To be fixed
62110	007681-52-9	Hypochlorous acid, sodium salt	6A	To be fixed
62270	000078-83-1	Isobutanol	8	To be fixed
-	058239-72-8	Isooctadecenylsuccinic anhydride	-	To be fixed
-	001318-74-7	Kaolinite	-	To be fixed
62860	008008-20-6	Kerosene	9	To be fixed
-	068424-48-6	Marine-oil fatty acids, hydrogenated	-	To be fixed
65770	002492-26-4	2-Mercaptobenzothiazole, sodium salt	6A	To be fixed
-	013701-59-2	Metaboric acid, barium salt	-	To be fixed
-	000137-41-7	Methyldithiocarbamic acid, potassium salt	-	To be fixed
-	006317-18-6	Methylenebis(thiocyanate)	-	To be fixed
-	160808-63-9	3-(15-Methylhexadecylidene)-2-(14-methylpentadecyl)propiolactone	-	To be fixed
-	000137-20-2	N-Methyl-N-oleoyltaurine	-	To be fixed
-	012001-26-2	Mica-group minerals	-	To be fixed
-	085117-50-6	Monoalkyl(C10-C14)benzenesulphonic acid, sodium salts	-	To be fixed
-	001318-93-0	Montmorillonite	-	To be fixed
-	064741-65-7	Naphtha (petroleum), heavy alkylate	-	To be fixed
-	064742-48-9	Naphtha (petroleum), hydrotreated heavy	-	To be fixed
-	028777-98-2	Octadecenylsuccinic anhydride	-	To be fixed
-	014481-60-8	N-Octadecyl-2-sulphosuccinamic acid, disodium salt	-	To be fixed
69480	000112-62-9	Oleic acid, methyl ester	7	To be fixed
69560	003687-45-4	Oleic acid, oleyl ester	7	To be fixed
71280	008002-74-2 063231-60-7	Hydrocarbon waxes, paraffin and microcrystalline	9	To be fixed
-	000079-21-0	Peroxyacetic acid	-	To be fixed
72046	007727-54-0	Persulphuric acid, ammonium salt	8	To be fixed
72048	007727-21-1	Persulphuric acid, potassium salt	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
72240	000090-43-7	2-Phenylphenol	D	To be fixed
-	013707-65-8	2-Phenylphenol, potassium salt	-	To be fixed
-	000132-27-4	2-Phenylphenol, sodium salt	-	To be fixed
-	010154-75-3	3-(Phenylsulphonyl)propionitrile	-	To be fixed
73680	000126-73-8	Phosphoric acid, tributyl ester	6B	To be fixed
73840	000126-71-6	Phosphoric acid, triisobutyl ester	6B	To be fixed
76430	008002-09-3	Pine oil	8	To be fixed
-	009003-04-7	Polyacrylic acid, sodium salt	-	To be fixed
-	026062-79-3	Poly(diallyldimethylammonium chloride)	-	To be fixed
-	068989-57-1	Polyethyleneglycol diesters of fatty acids (C16-C18 and C18 unsaturated)	-	To be fixed
-	061791-01-3	Polyethyleneglycol diesters of tall oil fatty acids	-	To be fixed
77920	009002-92-0	Polyethyleneglycol dodecyl ether	9	To be fixed
-	009004-82-4	Polyethyleneglycol dodecyl ether sodium sulphate	-	To be fixed
-	009014-92-0	Polyethyleneglycol dodecylphenyl ether	-	To be fixed
-	157707-43-2	Polyethyleneglycol ethers of C8-C18 alcohols	-	To be fixed
-	068439-46-3	Polyethyleneglycol ethers of C9-C11 alcohols	-	To be fixed
-	078330-21-9	Polyethyleneglycol ethers of C11-C14 isoalcohols, C13-rich	-	To be fixed
-	068131-40-8	Polyethyleneglycol ethers of C11-C15-secondary alcohols	-	To be fixed
77711	068439-50-9	Polyethyleneglycol ethers of C12-C14 alcohols	D	To be fixed
-	084133-50-6	Polyethyleneglycol ethers of C12-C14 secondary alcohols	-	To be fixed
-	068131-39-5	Polyethyleneglycol ethers of C12-C15 alcohols	-	To be fixed
-	068551-12-2	Polyethyleneglycol ethers of C12-C16 alcohols	-	To be fixed
77712	068213-23-0	Polyethyleneglycol ethers of C12-C18 alcohols	-	To be fixed
-	068155-01-1	Polyethyleneglycol ethers of C16 and C18-unsaturated alcohols	-	To be fixed
77760	061791-28-4	Polyethyleneglycol ether of tallow fatty alcohol	D	To be fixed
-	031694-55-0	Polyethyleneglycol glyceryl triether	-	To be fixed
77790	009004-95-9	Polyethyleneglycol hexadecyl ether	9	To be fixed
77880	009043-30-5	Polyethyleneglycol isotridecyl ether	8	To be fixed
78400	009016-45-9	Polyethyleneglycol nonylphenyl ether	P	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	068412-54-4	Polyethyleneglycol nonylphenyl ether, branched	-	To be fixed
78440	026027-38-3	Polyethyleneglycol 4-nonylphenyl ether	W7	To be fixed
-	009051-57-4	Polyethyleneglycol nonylphenyl ether ammonium sulphate	-	To be fixed
78140	009005-00-9	Polyethyleneglycol octadecyl ether	8	To be fixed
-	009036-19-5	Polyethyleneglycol tert-octylphenyl ether	-	To be fixed
-	009002-93-1	Polyethyleneglycol 4-tert-octylphenyl ether	-	To be fixed
78190	009004-98-2	Polyethyleneglycol oleyl ether	9	To be fixed
-	026636-37-3	Polyethyleneglycol 2,4,6-tri-tert-butylphenyl ether	-	To be fixed
79590	024938-91-8	Polyethyleneglycol tridecyl ether	9	To be fixed
-	069011-36-5	Polyethyleneglycol tridecyl ether, branched	-	To be fixed
-	060828-78-6	Polyethyleneglycol 2,6,8-trimethyl-4-nonyl ether	-	To be fixed
-	034398-01-1	Polyethyleneglycol undecyl ether	-	To be fixed
-	-	Polymers of MW > 10,000 made of monomers of appendices A and B	-	To be fixed
81245	009003-20-7	Polyvinyl acetate	D	To be fixed
81280	009002-89-5	Polyvinyl alcohol	7	To be fixed
81500	009003-39-8	Polyvinylpyrrolidone	9	To be fixed
-	068153-38-8	Resin acids and rosin acids, esters with diethyleneglycol	-	To be fixed
-	008050-25-7	Resin acids and rosin acids, esters with triethyleneglycol	-	To be fixed
-	084776-83-0	Resin acids and rosin acids, esters with trimethylolpropane	-	To be fixed
-	008050-33-7	Resin acids and rosin acids, ethoxylated	-	To be fixed
-	094114-24-6	Resin acids and rosin acids, tall-oil, maleated, reaction products with formaldehyde	-	To be fixed
-	000141-24-2	Ricinoleic acid, methyl ester	-	To be fixed
-	065997-04-8	Rosin, fumarated	-	To be fixed
-	095009-65-7	Rosin, fumarated, reaction products with formaldehyde	-	To be fixed
-	008050-28-0	Rosin, maleated	-	To be fixed
-	091081-53-7	Rosin, reaction products with formaldehyde	-	To be fixed
86670	007775-14-6	Sodium dithionite	8	To be fixed
-	001313-60-6	Sodium peroxide	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	064742-95-6	Solvent naphtha (petroleum), light aromatic	-	To be fixed
-	104037-82-3	Starch acetate, acid-hydrolyzed	-	To be fixed
-	068187-08-6	Starch acetate, oxidized	-	To be fixed
-	009067-33-8	Starch acetate phosphate	-	To be fixed
-	065996-63-6	Starch, acid-hydrolyzed	-	To be fixed
-	068584-86-1	Starch, acid-hydrolyzed, 2-hydroxypropyl ether	-	To be fixed
-	068584-85-0	Starch, acid-hydrolyzed, octenylsuccinate	-	To be fixed
-	068412-33-9	Starch, base-hydrolyzed	-	To be fixed
-	009063-36-9	Starch benzyl ether	-	To be fixed
-	077908-15-7	Starch 2-[bis(phosphonomethyl)amino]ethyl 2-hydroxy-3-(trimethylammonio)propyl ether, chloride	-	To be fixed
-	068511-18-2	Starch borate	-	To be fixed
-	089592-31-4	Starch carbamate	-	To be fixed
-	063100-00-5	Starch carbamate dihydrogen phosphate	-	To be fixed
-	009057-06-1	Starch carboxymethyl ether	-	To be fixed
-	009063-38-1	Starch carboxymethyl ether, sodium salt	-	To be fixed
-	071833-26-6	Starch 2-carboxy-2-sulphoethyl ether	-	To be fixed
-	009063-39-2	Starch 2-cyanoethyl ether	-	To be fixed
-	009047-50-1	Starch 2,3-dialdehyde	-	To be fixed
-	102962-62-9	Starch 2-(diethylamino)ethyl 2-[(2,2-dimethoxyethyl)methylamino]-2-oxoethyl ether, hydrochloride	-	To be fixed
-	037265-07-9	Starch 2-(diethylamino)ethyl ether, hydrochloride	-	To be fixed
-	068650-82-8	Starch 2-(diethylamino)ethyl ether, hydrochloride, oxidized	-	To be fixed
-	102962-65-2	Starch 2-[(2,2-dimethoxyethyl)methylamino]-2-oxoethyl 2-hydroxy-3-(trimethyl-ammonio)propyl ether, chloride	-	To be fixed
-	169435-77-2	Starch dodecenylsuccinate	-	To be fixed
-	181487-47-8	Starch dodecenylsuccinate, aluminium salt	-	To be fixed
-	164321-80-6	Starch dodecenylsuccinate, sodium salt	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	065996-64-7	Starch, enzyme-hydrolyzed	-	To be fixed
-	118367-88-7	Starch hydrogen dodecenylsuccinate	-	To be fixed
-	068584-87-2	Starch 2-hydroxyethyl ether, oxidized	-	To be fixed
-	071751-63-8	Starch 2-hydroxy-3-phenoxypropyl ether	-	To be fixed
-	071751-65-0	Starch 2-hydroxy-2-phenylethyl ether	-	To be fixed
-	222021-80-9	Starch, 2-hydroxy-1,3-propanediyl 2-hydroxy-3-(trimethylammonio)propyl ether, chloride	-	To be fixed
-	068412-86-2	Starch 2-hydroxypropyl ether, oxidized	-	To be fixed
-	222021-85-4	Starch 2-hydroxypropyl 2-hydroxy-3-(trimethylammonio)propyl ether, chloride	-	To be fixed
-	051635-87-1	Starch 2-hydroxy-3-sulphopropyl ether, sodium salt	-	To be fixed
-	056780-58-6	Starch 2-hydroxy-3-(trimethylammonio)propyl ether, chloride	-	To be fixed
-	221897-48-9	Starch 2-hydroxy-3-(trimethylammonio)propyl ether, chloride, oxidized	-	To be fixed
-	070563-14-3	Starch 2-hydroxy-3-(trimethylammonio)propyl ether, chloride, phosphate	-	To be fixed
-	037189-22-3	Starch methyl ether	-	To be fixed
-	009041-98-9	Starch 2-(4-morpholinyl)ethyl ether	-	To be fixed
-	052906-93-1	Starch octenylsuccinate	-	To be fixed
-	009087-61-0	Starch octenylsuccinate, aluminium salt	-	To be fixed
-	009063-43-8	Starch phenylcarbamate	-	To be fixed
-	143734-28-5	Starch phosphate, 2-(diethylamino)ethyl ether, sodium salt, hydrochloride	-	To be fixed
-	039433-68-6	Starch propionate	-	To be fixed
-	068921-22-2	Starch, reaction products with dimethylolethyleneurea	-	To be fixed
-	068584-90-7	Starch, reaction products with formaldehyde	-	To be fixed
-	039316-70-6	Starch succinate	-	To be fixed
-	011097-99-7	Starch sulphate	-	To be fixed
-	064734-99-2	Starch sulphosuccinate	-	To be fixed
-	068909-00-2	Starch, thermal hydrolyzed	-	To be fixed
91630	003006-15-3	Sulphosuccinic acid, dihexyl ester, sodium salt	6B	To be fixed
91680	001639-66-3	Sulphosuccinic acid, dioctyl ester, sodium salt	6B	To be fixed
91760	002673-22-5	Sulphosuccinic acid, ditridecyl ester, sodium salt	6B	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	085631-69-2	Tall-oil rosin, fumarated	-	To be fixed
-	095009-66-8	Tall-oil rosin, fumarated, reaction products with formaldehyde	-	To be fixed
-	008030-12-4	Tallow, hydrogenated	-	To be fixed
-	055566-30-8	Tetrakis(hydroxymethyl)phosphonium sulphate	-	To be fixed
92720	000137-26-8	N,N'-Tetramethylthiuram disulphide	8	To be fixed
-	021564-17-0	2-(Thiocyanomethylthio)benzothiazole	-	To be fixed
93585	000104-15-4	p-Toluenesulphonic acid	8	To be fixed
94000	000102-71-6	Triethanolamine	8	To be fixed
(25520)	000112-24-3	Triethylenetetramine	8	To be fixed
(25970)	061788-66-7	Vegetable oil fatty acids	9	To be fixed
-	009025-57-4	Xylanase	-	To be fixed
-	001300-72-7	Xylenesulphonic acid, sodium salt	-	To be fixed
-	001318-02-1	Zeolites	-	To be fixed
96480	032535-84-5 068309-95-5	Zirconyl ammonium carbonate	7	To be fixed

C. LIST 2 OF ADDITIVES

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	000125-12-2	Acetic acid, isobornyl ester	-	To be fixed
-	007585-20-8	Acetic acid, zirconium salt	-	To be fixed
32240	000105-99-7	Adipic acid, dibutyl ester	6B	To be fixed
32760	000627-93-0	Adipic acid, dimethyl ester	6B	To be fixed
-	090622-25-6	Alcohols, C8-C22, distillation residues	-	To be fixed
-	068603-18-9	Alcohols, C10-C16, distillation residues	-	To be fixed
-	068603-17-8	Alcohols, C16-C18, distillation residues	-	To be fixed
-	068911-61-5	Alcohols, C18-C32	-	To be fixed
-	098072-31-2	Alkenes (C7-C9), hydroformylation products, distillation residues, heavy cracked	-	To be fixed
-	068955-53-3	tert-Alkyl(C12-C14)amines	-	To be fixed
-	073138-27-9	tert-Alkyl(C12-C14)amines, ethoxylated	-	To be fixed
-	070592-80-2	Alkyl(C10-C16)dimethylamines N-oxides	-	To be fixed
-	084501-33-7	Alkyl(C12-C16, branched and linear)dimethylbetaines	-	To be fixed
-	068391-11-7	Alkylpyridine	-	To be fixed
-	085665-45-8	Alkyl(C8-C14)sulphuric acid, compounds with triethanolamine	-	To be fixed
-	090640-46-3	N-Alkyl(C12-C18)trimethylenediamines diacetates	-	To be fixed
-	068439-73-6	N-Alkyl(C14-C18 and C16-C18 unsaturated)trimethylenediamines	-	To be fixed
(12610)	000107-18-6	Allyl alcohol	6A	To be fixed
-	039290-78-3	Aluminium chloride hydroxide sulphate	-	To be fixed
-	000300-92-5	Aluminium hydroxide distearate	-	To be fixed
-	131148-05-5	Aluminium hydroxide silicate sulphate	-	To be fixed
-	001332-73-6	Aluminium hydroxide sulphate	-	To be fixed
(12730)	000060-32-2	6-Aminocaproic acid	8	To be fixed
-	006281-42-1	N-(2-Aminoethyl)ethyleneurea	-	To be fixed
-	000093-81-2	N-(2-Aminoethyl)-N-(2-hydroxyethyl)oleamide	-	To be fixed
-	001758-73-2	Aminoiminomethanesulphinic acid	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	000078-96-6	1-Amino-2-propanol	-	To be fixed
-	007617-78-9	3-Aminopropyl decyl ether	-	To be fixed
-	000105-83-9	N-(3-Aminopropyl)-N-methyl-1,3-propanediamine	-	To be fixed
-	068511-40-0	3-Aminopropyl tridecyl ether, branched	-	To be fixed
35300	000919-30-2	3-Aminopropyltriethoxysilane	8	To be fixed
-	013822-56-5	3-Aminopropyltrimethoxysilane	-	To be fixed
-	002869-34-3	1-Aminotridecane	-	To be fixed
-	065545-83-7	Ammonium chloride-dicyandiamide-ethylenediamine-formaldehyde, copolymer	-	To be fixed
-	009005-84-9	Amylodextrin	-	To be fixed
-	068441-21-4	Amylodextrin, reaction products with formaldehyde-urea polymer and starch	-	To be fixed
-	027776-21-2	Azobis(2-imidazolinylpropane) dihydrochloride	-	To be fixed
-	013472-08-7	Azobis(2-methylbutyronitrile)	-	To be fixed
38280	000106-51-4	Benzoquinone	8	To be fixed
-	000095-14-7	1H-Benzotriazole	-	To be fixed
-	094891-33-5	Benzyldimethyloctadecylammonium chloride, reaction products with hectorite	-	To be fixed
-	000111-44-4	Bis(2-chloroethyl) ether	-	To be fixed
-	068140-76-1	Bis(2-hydroxy-3-chloropropyl)methylamine - N,N,N',N'-tetramethylethylenediamine, copolymer	-	To be fixed
-	000139-41-3	N,N-Bis(2-hydroxyethyl)aminoacetic acid, sodium salt	-	To be fixed
39480	000093-83-4	N,N-Bis(2-hydroxyethyl)oleamide	7	To be fixed
-	061791-44-4	N,N-Bis(2-hydroxyethyl)tallowalkylamine	-	To be fixed
39630	000140-95-4	N,N'-Bis(hydroxymethyl)urea	8	To be fixed
-	004767-03-7	2,2-Bis(hydroxymethyl)propionic acid	-	To be fixed
-	035674-65-8	1,3-Bis(3-octadecylureido)propane	-	To be fixed
-	027344-41-8	4,4'-Bis(2-sulphostyryl)biphenyl, disodium salt	-	To be fixed
-	090268-92-1	Bis(tallow alkyl)carbamoyl chloride	-	To be fixed
-	035950-52-8	2-(2-Bromo-2-nitrovinyl)furan	-	To be fixed
-	067953-19-9	2-Butenedioic acid, bis(1,3-dimethylbutyl) ester	-	To be fixed
40618	005131-66-8	1-Butoxy-2-propanol	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	031069-81-5	Butyl acrylate-ethyl acrylate-methacrylic acid, copolymer	-	To be fixed
-	028159-98-0	2-(tert-Butylamino)-4-(cyclopropylamino)-6-(methylthio)-1,3,5-triazine	-	To be fixed
-	001948-33-0	2-tert-Butylhydroquinone	-	To be fixed
-	081869-18-3	N-(3-Carboxy-2-sulphopropionyl)-N-octadecenyl-DL-aspartic acid, tetrasodium salt	-	To be fixed
-	038916-42-6	N-(3-Carboxy-2-sulphopropionyl)-N-octadecyl-DL-aspartic acid, tetrasodium salt	-	To be fixed
-	003401-73-8	N-(3-Carboxy-2-sulphopropionyl)-N-octadecyl-L-aspartic acid, tetrasodium salt	-	To be fixed
-	009000-40-2	Carob gum	-	To be fixed
-	007775-09-9	Chloric acid, sodium salt	-	To be fixed
43470	011129-18-3	Cerium oxide	8	To be fixed
-	009012-76-4	Chitosan	-	To be fixed
-	001318-59-8	Chlorite group minerals	-	To be fixed
-	097659-51-3	Chloroacetic acid, sodium salt, reaction products with N-alkyl(C8-C22)trimethylene-diamines	-	To be fixed
-	068608-65-1	Chloroacetic acid, sodium salt, reaction products with 1-(2-hydroxyethyl)-2-imida-zoline 2-norcoco alkyl derivatives and sodium hydroxide	-	To be fixed
-	005915-41-3	2-Chloro-4-ethylamino-6-tert-butylamino-1,3,5-triazine	-	To be fixed
-	015733-22-9	p-Chloro-m-cresol, sodium salt	-	To be fixed
-	034911-46-1	2-Chloro-4'-hydroxy-2-isonitrosoacetophenone	-	To be fixed
-	132186-00-6	3-Chloro-2-hydroxypropyl-N,N,N-tripropylammonium chloride	-	To be fixed
-	061790-57-6	Cocoalkylamines, acetates	-	To be fixed
-	068953-13-9	Cocoalkylamines, acetates, reaction products with bentonite	-	To be fixed
-	061788-90-7	Cocoalkyldimethylamines, N-oxides	-	To be fixed
-	084501-44-0	N-Cocoalkyl-3-sulphosuccinamic acid, monosodium salts, compounds with triethanolamine	-	To be fixed
-	061791-63-7	N-Cocoalkyltrimethylenediamines	-	To be fixed
-	061791-64-8	N-Cocoalkyltrimethylenediamines, acetates	-	To be fixed
45040	061790-63-4 068440-04-0 068603-42-9	Coconut oil fatty acids diethanolamide	7	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	000101-83-7	N-Cyclohexylcyclohexylamine	-	To be fixed
-	000541-02-6	Decamethylcyclopentasiloxane	-	To be fixed
-	036362-09-1	2-(Decylthio)ethylamine hydrochloride	-	To be fixed
-	039306-95-1	Dextrin 2-hydroxypropyl ether	-	To be fixed
-	065546-83-0	Dextrin 2-hydroxy-3-(trimethylammonio)propyl ether, chloride	-	To be fixed
-	039405-17-9	Dextrin, phosphate	-	To be fixed
-	000135-57-9	2,2'-Dibenzamidodiphenyl disulphide	-	To be fixed
-	003252-43-5	Dibromoacetonitrile	-	To be fixed
-	073003-80-2	2,2-Dibromopropanediamide	-	To be fixed
-	025417-20-3	Dibutylnaphthalenesulphonic acid, sodium salt	-	To be fixed
-	000109-46-6	N,N'-Dibutylthiourea	-	To be fixed
-	096633-68-0	Dibutyltin bis(coco acyloxy) derivatives	-	To be fixed
47220	000077-58-7	Dibutyltin dilaurate	8	To be fixed
-	009067-34-9	Dicarboxy starch	-	To be fixed
47265	000095-50-1	1,2-Dichlorobenzene	7	To be fixed
47360	000075-71-8	Dichlorodifluoromethane	7	To be fixed
-	064359-81-5	4,5-Dichloro-2-octyl-4-isothiazolin-3-one	-	To be fixed
-	000078-87-5	1,2-Dichloropropane	-	To be fixed
-	000096-23-1	1,3-Dichloro-2-propanol	-	To be fixed
-	000067-43-6	Diethylenetriaminepentaacetic acid	-	To be fixed
-	068399-63-3	Diethylenetriaminetetra(methylenephosphonic acid), sodium salt	-	To be fixed
48370	000100-37-8	Diethylethanolamine	8	To be fixed
-	000105-55-5	N,N'-Diethylthiourea	-	To be fixed
-	000075-10-5	Difluoromethane	-	To be fixed
-	001322-93-6	Diisopropylnaphthalenesulphonic acid, sodium salt	-	To be fixed
-	000109-87-5	Dimethoxymethane	-	To be fixed
-	003845-76-9	N-(Dimethylaminopropyl)acrylamide	-	To be fixed
-	174514-06-8	2,2'-[[6-(Dimethylamino)-1,3,5-triazin-2,4-diyl]bis(imino-4,1-phenyleneimino-4,1-phenyleneazo)]bis(1,3-dimethyl-1H-imidazolium) dichloride	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	007473-98-5	2,2-Dimethyl-2-hydroxyacetophenone	-	To be fixed
-	000128-03-0	Dimethyldithiocarbamic acid, potassium salt	-	To be fixed
-	001643-20-5	N,N-Dimethyldodecylamine oxide	-	To be fixed
49465	000068-12-2	Dimethylformamide	6B	To be fixed
-	000077-71-4	5,5-Dimethylhydantoin	-	To be fixed
-	055121-81-8	Dimethyloctadecylbenzenesulphonic acid	-	To be fixed
-	068308-74-7	N,N-Dimethyl tall oil fatty amides	-	To be fixed
-	041319-54-4	Dioctadecylcarbamoyl chloride	-	To be fixed
51160	000123-91-1	Dioxane	6A	To be fixed
51360	068442-68-2	Diphenylamine, styrenated	9	To be fixed
51870	034590-94-8	Dipropyleneglycol monomethyl ether	8	To be fixed
-	064742-30-9	Distillates (petroleum), chemically neutralized middle	-	To be fixed
-	064742-80-9	Distillates (petroleum), hydrodesulfurized middle	-	To be fixed
-	064742-52-5	Distillates (petroleum), hydrotreated heavy naphthenic	-	To be fixed
-	064742-54-7	Distillates (petroleum), hydrotreated heavy paraffinic	-	To be fixed
-	064742-53-6	Distillates (petroleum), hydrotreated light naphthenic	-	To be fixed
-	064742-55-8	Distillates (petroleum), hydrotreated light paraffinic	-	To be fixed
-	064742-46-7	Distillates (petroleum), hydrotreated middle	-	To be fixed
-	064742-65-0	Distillates (petroleum), solvent-dewaxed heavy paraffinic	-	To be fixed
-	064741-96-4	Distillates (petroleum), solvent-refined heavy naphthenic	-	To be fixed
-	064741-88-4	Distillates (petroleum), solvent-refined heavy paraffinic	-	To be fixed
-	064741-91-9	Distillates (petroleum), solvent-refined middle	-	To be fixed
-	064741-97-5	Distillates (petroleum), solvent-refined light naphthenic	-	To be fixed
-	064741-89-5	Distillates (petroleum), solvent-refined light paraffinic	-	To be fixed
-	064742-91-2	Distillates (petroleum), steam-cracked	-	To be fixed
-	064741-44-2	Distillates (petroleum), straight-run middle	-	To be fixed
-	064741-86-2	Distillates (petroleum), sweetened middle	-	To be fixed
-	000112-40-3	Dodecane	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	068526-91-0	Dodecene, hydroformylation products, high-boiling	-	To be fixed
-	000123-01-3	Dodecylbenzene	-	To be fixed
-	053520-67-5	Eicosenylsuccinic anhydride	-	To be fixed
-	068797-57-9	Epichlorohydrin-imidazole, copolymer	-	To be fixed
-	058944-89-1	Epichlorohydrin-starch, copolymer	-	To be fixed
-	068412-87-3	Epichlorohydrin-starch hydroxypropyl ether, copolymer	-	To be fixed
-	025988-98-1	Epichlorohydrin-N,N,N',N'-tetramethylethylenediamine, copolymer	-	To be fixed
-	000106-88-7	1,2-Epoxybutane	-	To be fixed
52685	002530-83-8	[3-(2,3-Epoxypropoxy)propyl]trimethoxysilane	6A	To be fixed
-	092265-81-1	2,3-Epoxypropyl methacrylate - 2-ethoxyethyl acrylate - N-methylperfluorooctane-sulphonamidoethyl acrylate - trimethylethanolammonium chloride methacrylate, copolymer	-	To be fixed
-	007747-35-5	5-Ethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane	-	To be fixed
-	000142-59-6	Ethylenebis(dithiocarbamic acid), disodium salt	-	To be fixed
-	001429-50-1	Ethylenediaminetetra(methylenephosphonic acid)	-	To be fixed
-	022036-77-7	Ethylenediaminetetra(methylenephosphonic acid), sodium salt	-	To be fixed
-	026795-67-5	Ethylene oxide-morpholine, copolymer	-	To be fixed
-	068609-68-7	2-Ethylhexanol, manuf. of, by-products from, distillation residues	-	To be fixed
-	000141-98-0	Ethylthiocarbamic acid, O-isopropyl ester	-	To be fixed
-	068953-19-5	Fatty acids, coco, esters with propyleneglycol	-	To be fixed
-	061791-00-2	Fatty acids, tall oil, ethoxylated	-	To be fixed
-	068309-16-0	Fatty acids, tall oil, monoesters with diethyleneglycol	-	To be fixed
-	061790-69-0	Fatty acids, tall oil, reaction products with diethylenetriamine	-	To be fixed
-	068334-18-9	Fatty acids, tall oil, tetraesters with pentaerythritol	-	To be fixed
-	094581-09-6	Fatty acids, tall oil, triesters with trimethylolpropane	-	To be fixed
-	099035-71-9	Fish oil, hydrogenated, sulphonated, sodium salts	-	To be fixed
-	184539-90-0	Formaldehyde-melamine-starch, copolymer	-	To be fixed
-	068037-07-0	Formaldehyde, polymers with sulphonated phenol, sodium salts	-	To be fixed
-	085338-22-3	Formaldehyde, reaction products with propyleneglycol	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	037281-53-1	Formaldehyde-starch-urea, copolymer	-	To be fixed
-	009000-28-6	Ghatti gum	-	To be fixed
-	000090-80-2	Gluconic acid lactone	-	To be fixed
-	071195-64-7	Glutaric acid, diisobutyl ester	-	To be fixed
55880	001119-40-0	Glutaric acid, dimethyl ester	7	To be fixed
-	067701-27-3	Glycerol esters of C14-C18 acids	-	To be fixed
58000	068476-38-0	Glycerol trimontanate	7	To be fixed
-	000079-14-1	Glycolic acid	-	To be fixed
-	002836-32-0	Glycolic acid, sodium salt	-	To be fixed
-	000593-85-1	Guanidine, carbonate	-	To be fixed
-	005423-22-3	Guanidine, phosphate	-	To be fixed
-	039454-79-0	Guar gum, carboxymethyl, 2-hydroxypropyl ether	-	To be fixed
-	078615-64-2	Guar gum, dihydrogen phosphate	-	To be fixed
-	065497-29-2	Guar gum, 2-hydroxy-3-(trimethylammonio)propyl ether, chloride	-	To be fixed
-	012173-47-6	Hectorite	-	To be fixed
-	009025-56-3	Hemicellulase	-	To be fixed
-	094944-77-1	2-(8-Heptadecenyl)-4,5-dihydro-1-methyl-3-[2-[(1-oxo-9-octadecenyl)amino]ethyl]-(z,z)-1H-imidazolium methyl sulphate	-	To be fixed
-	027136-73-8	2-(Heptadecenyl)-1-(2-hydroxyethyl)imidazoline	-	To be fixed
-	000506-52-5	1-Hexacosanol	-	To be fixed
-	138063-67-9	1-Hexadecene - methoxypolyethyleneglycol monobutenedioate - 1-tetradecene, polymer	-	To be fixed
-	054111-93-2	Hexadecenylsuccinic acid	-	To be fixed
-	061412-52-0	2-Hexadecenylsuccinic acid	-	To be fixed
-	083763-21-7	15-Hexadecenylsuccinic acid	-	To be fixed
-	053473-28-2	Hexamethylenediaminetetra(methylenephosphonic acid), hexapotassium salt	-	To be fixed
-	038820-59-6	Hexamethylenediaminetetra(methylenephosphonic acid), potassium salt	-	To be fixed
-	024360-05-2	Hexamethylenetetramine hydrochloride	-	To be fixed
-	068937-28-0	1,6-Hexanediol, distillation overheads	-	To be fixed
-	267233-58-9	Hydrocarbons, resins, aliphatic	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	267233-83-0	Hydrocarbons, resins, coumarin-indene	-	To be fixed
-	267233-62-5	Hydrocarbons, resins, cyclodiene	-	To be fixed
-	064742-60-5	Hydrocarbon waxes, hydrotreated microcrystalline	-	To be fixed
-	090640-95-2	Hydrocarbons (C20-C50), solvent dewaxed heavy paraffinic, hydrotreated	-	To be fixed
-	000111-41-1	N-(2-Hydroxyethyl)ethylenediamine	-	To be fixed
60640	000150-39-0	N-(2-Hydroxyethyl)ethylenediaminetriacetic acid	8	To be fixed
-	002809-21-4	1-Hydroxyethylidenediphosphonic acid	-	To be fixed
-	029329-71-3	1-Hydroxyethylidenediphosphonic acid, sodium salt	-	To be fixed
-	003794-83-0	1-Hydroxyethylidenediphosphonic acid, tetrasodium salt	-	To be fixed
61055	000122-99-6	2-Hydroxyethyl phenyl ether	8	To be fixed
-	000126-11-4	2-(Hydroxymethyl)-2-nitro-1,3-propanediol	-	To be fixed
-	056780-58-6	2-Hydroxy-3-(trimethylammonio)propyl starch chloride	-	To be fixed
-	013824-96-9	Hypobromous acid, sodium salt	-	To be fixed
-	070983-43-6	Imidazolium compounds, 2-C4-C8-alkyl-1-(2-carboxyethyl)-4,5-dihydro-3-(hydroxyethyl), hydroxides, sodium salts	-	To be fixed
-	068650-39-5	Imidazolium compounds, 1-[2-(carboxymethoxy)ethyl]-1-(carboxymethyl)-4,5-dihydro-2-norcoco alkyl, hydroxides, inner salts, disodium salts	-	To be fixed
-	068647-53-0	Imidazolium compounds, 1(or 3)-(carboxymethyl)-4,5-dihydro-1-(hydroxyethyl)-2-norcoco alkyl, hydroxides, monosodium salts	-	To be fixed
-	068122-86-1	Imidazolium compounds, 4,5-dihydro-1-methyl-2-nortallow alkyl-1-(2-tallow amidoethyl), methyl sulphates	-	To be fixed
-	086088-85-9	Imidazolium compounds, 4,5-dihydro-1-methyl-2-nortallow alkyl-3-(2-tallow amidoethyl), methyl sulphates	-	To be fixed
-	009025-67-6	Inulinase	-	To be fixed
-	000089-65-6	Isoascorbic acid	-	To be fixed
(19120)	025339-17-7	Isodecanol	8	To be fixed
-	027458-93-1	Isooctadecanol	-	To be fixed
-	000123-51-3	Isopentanol	-	To be fixed
-	002210-25-5	N-Isopropylacrylamide	-	To be fixed
-	000556-61-6	Isothiocyanic acid, methyl ester	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	122625-12-1	Itaconic acid-vinyl acetate, hydrolyzed, sodium salt, copolymer	-	To be fixed
-	008016-28-2	Lard oil	-	To be fixed
-	068440-40-4	Lard oil, methyl esters, sulphurized	-	To be fixed
63970	005989-27-5	D-Limonene	8	To be fixed
-	009001-62-1	Lipase	-	To be fixed
-	101316-70-5	Lubricating oils (petroleum), C17-C32, solvent-extd., dewaxed, hydrogenated	-	To be fixed
-	092045-42-6	Lubricating oils (petroleum), C17-C35, solvent-extd., dewaxed, hydrotreated	-	To be fixed
-	083987-85-2	Magnesite, calcined	-	To be fixed
-	000142-16-5	Maleic acid, bis(2-ethylhexyl) ester	-	To be fixed
-	068186-70-9	Maleic acid, isodecyl ester	-	To be fixed
-	009050-36-6	Maltodextrin	-	To be fixed
(19977)	000060-24-2	2-Mercaptoethanol	8	To be fixed
(20860)	005039-78-1	Methacrylic acid, ester with trimethylethanolammonium chloride	8	To be fixed
-	032435-46-4	Methacrylic acid, 2-hydroxyethyl ester, hydrogen phosphate	-	To be fixed
-	028430-58-2	Methacrylic acid-methyl methacrylate-vinyl acetate, copolymer	-	To be fixed
-	030388-01-3	Methanethiosulphonic acid, 2-hydroxypropyl ester	-	To be fixed
-	000625-45-6	Methoxyacetic acid	-	To be fixed
66030	000150-76-5	4-Methoxyphenol	8	To be fixed
(20785)	026915-72-0	Methoxypolyethyleneglycol monomethacrylate	8	To be fixed
-	000134-84-9	4-Methylbenzophenone	-	To be fixed
-	062258-49-5	2-Methyl-2-butene - alpha-methylstyrene - 1,3-pentadiene, copolymer	-	To be fixed
-	026813-14-9	2-Methyl-2-butene - 1,3-pentadiene, copolymer	-	To be fixed
-	000137-32-6	2-Methyl-1-butanol	-	To be fixed
-	000583-59-5	2-Methylcyclohexanol	-	To be fixed
-	000074-87-3	Methyl chloride	-	To be fixed
-	002565-36-8	2,2'-Methylenebis(oxyethanol)	-	To be fixed
-	026172-54-3	2-Methyl-4-isothiazolin-3-one hydrochloride	-	To be fixed
66800	000139-99-1	Methyl oleate, sulphated	D	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
66860	000108-11-2	4-Methyl-2-pentanol	8	To be fixed
66905	000872-50-4	N-Methylpyrrolidone	8	To be fixed
-	000611-15-4	2-Methylstyrene	-	To be fixed
(22242)	006144-04-3	alpha-Methylstyrene, dimer	D	To be fixed
-	002031-67-6	Methyltriethoxysilane	-	To be fixed
-	068308-60-1	Mixture of lard oil, palm oil, soybean oil and tallow oil, hydrogenated	-	To be fixed
-	097593-30-1	Mono- and diglycerides of fatty acids (C8-C21 and C8-C21 unsaturated)	-	To be fixed
-	067701-33-1	Mono- and diglycerides of fatty acids (C14-C18)	-	To be fixed
67345	085251-77-0	Mono- and diglycerides of fatty acids (C16-C18)	9	To be fixed
-	068424-61-3	Mono- and diglycerides of fatty acids (C16-C18 and C18 unsaturated)	-	To be fixed
(22340)	000074-89-5	Monomethylamine	W8	To be fixed
-	065229-24-5	Myristic acid, pentahydroxydichromium salt	-	To be fixed
-	000091-20-3	Naphthalene	-	To be fixed
67910	000085-47-2	1-Naphthalenesulphonic acid	8	To be fixed
-	068153-01-5	Naphthalenesulphonic acids	-	To be fixed
-	003251-23-8	Nitric acid, copper(II) salt	-	To be fixed
-	000139-13-9	Nitrilotriacetic acid	-	To be fixed
-	005064-31-3	Nitrilotriacetic acid, trisodium salt	-	To be fixed
-	006419-19-8	Nitrilotris(methylenephosphonic acid)	-	To be fixed
-	002235-43-0	Nitrilotris(methylenephosphonic acid), pentasodium salt	-	To be fixed
-	094021-23-5	Nitrilotris(methylenephosphonic acid), tetrasodium salt	-	To be fixed
-	000557-61-9	1-Octacosanol	-	To be fixed
-	000112-88-9	1-Octadecene	-	To be fixed
-	028299-29-8	Octadecenylsuccinic acid	-	To be fixed
-	028805-58-5	Octenylsuccinic acid	-	To be fixed
-	094386-55-7	7-Octenylsuccinic acid	-	To be fixed
-	026530-20-1	2-Octyl-4-isothiazolin-3-one	-	To be fixed
(22690)	001806-26-4	4-Octylphenol	8	To be fixed
-	068511-92-2	Oleic acid, reaction products with diethylenetriamine, cyclized, diethyl sulphate-	-	To be fixed

		quaternized		
PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	068988-76-1	Oleic acid, sulphonated	-	To be fixed
-	007173-62-8	N-Oleyl-1,3-diaminopropane	-	To be fixed
-	025307-17-9	N-Oleyldiethanolamine	-	To be fixed
-	068514-74-9	Palm oil, hydrogenated	-	To be fixed
71120	008012-95-1	Paraffin oil	9	To be fixed
-	068188-18-1	Paraffin oils, sulphochlorinated, saponified	-	To be fixed
-	064742-43-4	Paraffin waxes (petroleum), clay-treated	-	To be fixed
-	064742-51-4	Paraffin waxes (petroleum), hydrotreated	-	To be fixed
-	092045-76-6	Paraffin waxes and hydrocarbon waxes, microcrystalline, hydrotreated	-	To be fixed
-	064771-71-7	Paraffins (petroleum), normal C>10	-	To be fixed
-	013081-97-5	Pentaerythritol distearate	-	To be fixed
-	051728-26-8	Pentaerythritol ethoxylate tetraacrylate	-	To be fixed
-	000354-33-6	Pentafluoroethane	-	To be fixed
-	068310-75-8	(Perfluorooctylsulphonylaminopropyl)trimethylammonium iodide	-	To be fixed
-	000614-45-9	Peroxybenzoic acid, tert-butyl ester	-	To be fixed
-	010058-23-8	Peroxymonosulphuric acid, monopotassium slt	-	To be fixed
-	068610-06-0	Phenol, isobutylenated	-	To be fixed
-	004169-04-4	2-Phenoxy-1-propanol	-	To be fixed
-	013598-36-2	Phosphonic acid	-	To be fixed
-	021056-98-4	Phosphonic acid, calcium salt	-	To be fixed
-	037971-36-1	2-Phosphono-1,2,4-butanetricarboxylic acid	-	To be fixed
-	092332-25-7	Phosphoric acid, bis(gamma,omega-perfluoroalkyl(C8-C14) esters, compounds with diethanolamine	-	To be fixed
-	053126-06-0	Phosphoric acid, butyl ester, potassium salt	-	To be fixed
-	000107-66-4	Phosphoric acid, dibutyl ester	-	To be fixed
-	084962-20-9	Phosphoric acid, mixed esters with 1-butanol and ethyleneglycol	-	To be fixed
-	001623-15-0	Phosphoric acid, monobutyl ester	-	To be fixed
-	068427-32-7	Phosphoric acid, monodecyl ester, potassium salt	-	To be fixed
74800	068515-42-4	Phthalic acid, dialkyl(C7-C11) esters	6B	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
75280	000084-69-5	Phthalic acid, diisobutyl ester	6B	To be fixed
76005	000085-70-1	Phthalic acid, mixed esters with butyl glycolate and butanol	6B	To be fixed
-	000643-79-8	Phthalic aldehyde	-	To be fixed
76445	009003-05-8	Polyacrylamide	9	To be fixed
76461	009003-01-4	Polyacrylic acid	7	To be fixed
-	009003-03-6	Polyacrylic acid, ammonium salt	-	To be fixed
-	025608-12-2	Polyacrylic acid, potassium salt	-	To be fixed
-	067762-19-0	Polyethyleneglycol alkyl(C10-C16) ethers, ammonium sulphate	-	To be fixed
-	068585-34-2	Polyethyleneglycol alkyl(C10-C16) ethers, sodium sulphate	-	To be fixed
77030	068891-38-3	Polyethyleneglycol alkyl(C12-C14) ethers, sodium sulphate	9	To be fixed
-	068585-40-0	Polyethyleneglycol alkyl(C16-C18) ethers, sodium sulphate	-	To be fixed
-	060864-33-7	Polyethyleneglycol benzyl (1,1,3,3-tetramethylbutyl)phenyl ethers	-	To be fixed
(11170)	026570-48-9	Polyethyleneglycol diester of acrylic acid	8	To be fixed
(20470)	025852-47-5	Polyethyleneglycol dimethacrylate	8	To be fixed
78040	032612-48-9	Polyethyleneglycol dodecyl ether ammonium sulphate	9	To be fixed
-	059269-54-4	Polyethyleneglycol dodecylphenyl ether sodium sulphate	-	To be fixed
-	146340-15-0	Polyethyleneglycol ethers of C12-C14 secondary alcohols, beta(2-hydroxyethoxy)-	-	To be fixed
-	073038-25-2	Polyethyleneglycol isotridecyl ether phosphate	-	To be fixed
77890	150413-26-6	Polyethyleneglycol isotridecyl ether sodium sulphate	8	To be fixed
-	068130-47-2	Polyethyleneglycol monoalkyl(C8-C10) ether phosphate	-	To be fixed
(21205)	025736-86-1	Polyethyleneglycol monomethacrylate	7	To be fixed
-	174200-85-2	Polyethyleneglycol monomethacrylate 2,4,6-tris(styryl)phenyl ether	-	To be fixed
-	068891-39-4	Polyethyleneglycol nonylphenyl ether, branched, sodium sulphate	-	To be fixed
78480	051811-79-1	Polyethyleneglycol nonylphenyl ether phosphate	9	To be fixed
78460	009014-90-8	Polyethyleneglycol nonylphenyl ether sodium sulphate	P	To be fixed
-	052623-95-7	Polyethyleneglycol octylphenyl ether phosphate	-	To be fixed
-	055348-40-8	Polyethyleneglycol tert-octylphenyl ether sodium sulphate	-	To be fixed
-	058853-83-1	Polyethyleneglycol 4-octylphenyl ether sodium sulphate	-	To be fixed
79600	009046-01-9	Polyethyleneglycol tridecyl ether phosphate	9	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	054116-08-4	Polyethyleneglycol tridecyl ether sodium sulphate	-	To be fixed
-	109909-39-9	Polyethyleneglycol 2,4,6-triisobutylphenyl ether sodium sulphate	-	To be fixed
79920	009003-11-6	Poly(ethylene propylene)glycol	9	To be fixed
-	009041-33-2	Poly(ethylene propylene)glycol allyl ether	-	To be fixed
-	052232-27-6	Poly(ethylene propylene)glycol allyl methyl ether	-	To be fixed
-	037311-00-5	Poly(ethylene propylene)glycol dodecyl ether	-	To be fixed
-	068987-81-5	Poly(ethylene propylene)glycol ethers of C6-C10 alcohols	-	To be fixed
-	068603-25-8	Poly(ethylene propylene)glycol ethers of C8-C10 alcohols	-	To be fixed
-	068154-97-2	Poly(ethylene propylene)glycol ethers of C10-C12 alcohols	-	To be fixed
-	069227-21-0	Poly(ethylene propylene)glycol ethers of C12-C18 alcohols	-	To be fixed
-	011111-34-5	Poly(ethylene propylene)glycol ether of ethylenediaminetetrapropanol	-	To be fixed
-	009038-43-1	Poly(ethylene propylene)glycol octadecyl ether	-	To be fixed
-	061725-89-1	Poly(ethylene propylene)glycol tridecyl ether	-	To be fixed
-	-	Polymers of MW > 10,000 made of monomers of appendices A, B and C	-	To be fixed
-	009016-87-9	Poly(methylene phenylene isocyanate)	-	To be fixed
82050	000108-32-7	Propylene carbonate	8	To be fixed
-	068551-11-1	Propylene, hydroformylation products, high-boiling	-	To be fixed
80985	037281-78-0	Polypropyleneglycol oleate butyl ether	9	To be fixed
-	009015-54-7	Protein hydrolyzates	-	To be fixed
-	012211-28-8	Proteinase, Bacillus subtilis, sutilains	-	To be fixed
-	007681-57-4	Pyrosulfurous acid, sodium salt	-	To be fixed
-	000123-75-1	Pyrrolidine	-	To be fixed
-	085566-47-8	Quaternary ammonium compounds, alkyl(C12-C16 branched and linear)ethyl-dimethyl, ethyl sulphates	-	To be fixed
-	068153-30-0	Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, chlorides, compounds with bentonite	-	To be fixed
-	097952-68-6	Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, salts with montmorillonite	-	To be fixed
-	061789-72-8	Quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, chlorides	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
83530	071011-24-0	Quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, chlorides, compounds with bentonite	9	To be fixed
-	071011-25-1	Quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, chlorides, compounds with bentonite and bis(hydrogenated tallow alkyl)dimethyl-ammonium chlorides	-	To be fixed
83500	071011-26-2	Quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, chlorides, compounds with hectorite	9	To be fixed
-	061789-80-8	Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, chlorides	-	To be fixed
-	071011-27-3	Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, chlorides, compounds with hectorite	-	To be fixed
83560	068953-58-2	Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, chlorides,salts with bentonite	9	To be fixed
-	094891-31-3	Quaternary ammonium compounds, dialkyl(C16-C18)dimethyl, salts with hectorite	-	To be fixed
-	163479-06-9	Quaternary ammonium compounds, trimethyltallow alkyl, salts with montmorillonite	-	To be fixed
-	064741-67-9	Residues (petroleum), catalytic reformer fractionator	-	To be fixed
-	092202-14-7	Rosin, fumarated, reaction products with glycerol and pentaerythritol	-	To be fixed
-	068002-57-3	Rosin, reaction products with triethanolamine	-	To be fixed
-	068918-19-4	Rosin, sulphurized	-	To be fixed
84720	000118-58-1	Salicylic acid, benzyl ester	7	To be fixed
84960	000118-55-8	Salicylic acid, phenyl ester	7	To be fixed
86300	063148-62-9	Silicone oils	9	To be fixed
-	064742-61-6	Slack wax (petroleum)	-	To be fixed
-	090669-78-6	Slack wax (petroleum), clay-treated	-	To be fixed
-	012199-37-0	Smectite-group minerals	-	To be fixed
-	007631-94-9	Sodium dithionate	-	To be fixed
-	007681-49-4	Sodium fluoride	-	To be fixed
-	011084-85-8	Sodium hypochlorite phosphate	-	To be fixed
-	064742-94-5	Solvent naphtha (petroleum), heavy aromatic	-	To be fixed
-	064742-88-7	Solvent naphtha (petroleum), medium aliphatic	-	To be fixed
-	036521-89-8	Sorbitan distearate	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
87440	071902-01-7	Sorbitan isostearate	9	To be fixed
87880	008007-43-0	Sorbitan sesquioleate	7	To be fixed
-	051938-44-4	Sorbitan sesquistearate	-	To be fixed
-	008016-70-4	Soybean oil, hydrogenated	-	To be fixed
89150	010119-53-6	Stearic acid, cerium salt	8	To be fixed
90000	000646-13-9	Stearic acid, isobutyl ester	7	To be fixed
90320	002778-96-3	Stearic acid, octadecyl ester	7	To be fixed
90640	031556-45-3	Stearic acid, tridecyl ester	7	To be fixed
-	008052-41-3	Stoddard solvent	-	To be fixed
91135	000106-65-0	Succinic acid, dimethyl ester	7	To be fixed
(24885)	005329-14-6	Sulphamic acid	8	To be fixed
-	068957-15-3	Sulphonic acids, C10-C16-alkane hydroxy and C12-C20-alkapolyene and C10-C16-alkene and C12-C20-alkene hydroxy, sodium salts	-	To be fixed
-	068439-57-6	Sulphonic acids, C14-C16-alkane hydroxy and C14-C16-alkene, sodium salts	-	To be fixed
-	061789-86-4	Sulphonic acids, petroleum, calcium salts	-	To be fixed
91520	005138-18-1	Sulphosuccinic acid	8	To be fixed
-	013419-59-5	Sulphosuccinic acid, trisodium salt	-	To be fixed
91560	002373-38-8	Sulphosuccinic acid, bis(1,3-dimethylbutyl) ester, sodium salt	6B	To be fixed
91570	010041-19-7	Sulphosuccinic acid, bis(2-ethylhexyl) ester	6B	To be fixed
91572	000577-11-7	Sulphosuccinic acid, bis(2-ethylhexyl) ester, sodium salt	D	To be fixed
-	006001-97-4	Sulphosuccinic acid, bis(1-methylpentyl) ester, sodium salt	-	To be fixed
91580	023386-52-9	Sulphosuccinic acid, dicyclohexyl ester, sodium salt	8	To be fixed
91650	000127-39-9	Sulphosuccinic acid, diisobutyl ester, sodium salt	6B	To be fixed
91672	055184-72-0	Sulphosuccinic acid, diisotridecyl ester, sodium salt	6B	To be fixed
91720	000922-80-5	Sulphosuccinic acid, dipentyl ester, sodium salt	6B	To be fixed
91780	067893-42-9	Sulphosuccinic acid, 4-[2-[(12-hydroxy-1-oxooleyl)amino]ethyl] ester, disodium salt	W8	To be fixed
91800	037294-49-8	Sulphosuccinic acid, isodecyl ester, disodium salt	6B	To be fixed
-	010124-43-3	Sulphuric acid, cobalt(II) salt	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	000077-78-1	Sulphuric acid, dimethyl ester	-	To be fixed
-	007782-99-2	Sulphurous acid	-	To be fixed
-	068425-17-2	Syrups, hydrolyzed starch, hydrogenated	-	To be fixed
-	061790-33-8	Tallow alkyl amines	-	To be fixed
-	061790-60-1	Tallow alkyl amines, acetates	-	To be fixed
-	061791-26-2	Tallow alkyl amines, ethoxylated	-	To be fixed
-	008030-78-2	Tallow alkyltrimethylammonium chloride	-	To be fixed
-	061791-55-7	N-Tallow alkyltrimethylenediamines	-	To be fixed
-	061791-54-6	N-Tallow alkyltrimethylenediamines, acetates	-	To be fixed
-	061790-85-0	N-Tallow alkyltrimethylenediamines, ethoxylated	-	To be fixed
-	091079-23-1	Tallow oil	-	To be fixed
-	267233-96-5	Terpenes and terpenoids, turpentine-oil, polymerized	-	To be fixed
-	008000-41-7	Terpineol	-	To be fixed
-	000127-18-4	Tetrachloroethylene	-	To be fixed
-	076386-13-5	1-Tetradecenylsuccinic acid	-	To be fixed
-	058338-68-4	2-Tetradecenylsuccinic acid	-	To be fixed
-	032582-32-4	2-Tetradecyl-1-octadecanol	-	To be fixed
-	064253-30-1	Tetraethyleneglycol bis(dodecylthiopropionate)	-	To be fixed
-	000811-97-2	1,1,1,2-Tetrafluoroethane	-	To be fixed
-	002207-75-2	1,4,5,6-Tetrahydro-4,6-dioxo-1,3,5-triazine-2-carboxylic acid, monopotassium salt	-	To be fixed
92450	000097-99-4	Tetrahydrofurfurol	8	To be fixed
-	019798-93-7	Tetrahydro-6-phenyl-2H-1,3-oxazine	-	To be fixed
-	005395-50-6	Tetrakis(hydroxymethyl)glycoluril	-	To be fixed
-	017464-88-9	Tetrakis(methoxymethyl)glycoluril	-	To be fixed
-	003555-47-3	Tetrakis(trimethylsiloxy)silane	-	To be fixed
(25185)	000140-66-9	4-(1,1,3,3-Tetramethylbutyl)phenol	6B	To be fixed
92685	000126-86-3	2,4,7,9-Tetramethyl-5-decyne-4,7-diol	8	To be fixed
-	000110-18-9	N,N,N',N'-Tetramethylethylenediamine	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	011117-11-6	Tetrapropylenebenzenesulphonic acid, calcium salt	-	To be fixed
92740	011067-82-6	Tetrapropylenebenzenesulphonic acid, sodium salt	8	To be fixed
(25201)	000111-48-8	Thiodiethyleneglycol	8	To be fixed
-	010595-72-9	Thiodipropionic acid, ditridecyl ester	-	To be fixed
-	010101-88-9	Thiophosphoric acid, trisodium salt	-	To be fixed
-	004189-44-0	Thiourea S,S-dioxide	-	To be fixed
-	028804-47-9	Toluenesulphonic acid, methyl ester	-	To be fixed
-	000593-50-0	1-Triacontanol	-	To be fixed
-	081741-28-8	Tributyltetradecylphosphonium chloride	-	To be fixed
93840	000087-90-1	Trichlorocyanuric acid	D	To be fixed
93920	000075-69-4	Trichlorofluoromethane	7	To be fixed
-	003380-34-5	2,4,4'-Trichloro-2'-hydroxydiphenyl ether	-	To be fixed
-	068479-04-9	N-[3-(Tridecyloxy)propyl]-1,3-diaminopropane, branched	-	To be fixed
-	102047-27-8	N-[3-(Tridecyloxy)propyl]-1,3-diaminopropane, branched, monoacetate	-	To be fixed
-	014806-72-5	Triethanolamine acetate	-	To be fixed
-	027323-41-7	Triethanolamine dodecylbenzenesulphonate	-	To be fixed
-	068171-29-9	Triethanolamine tris(dihydrogen phosphate), sodium salt	-	To be fixed
-	090552-54-8	Triethoxyoctylsilane	-	To be fixed
94270	000121-44-8	Triethylamine	8	To be fixed
-	013150-00-0	Triethyleneglycol dodecyl ether sodium sulphate	-	To be fixed
-	025446-78-0	Triethyleneglycol tridecyl ether sodium sulphate	-	To be fixed
-	000420-46-2	1,1,1-Trifluoroethane	-	To be fixed
94480	026523-64-8	Trifluorotrichloroethane	7	To be fixed
-	001067-25-0	Trimethoxypropylsilane	-	To be fixed
-	000095-63-6	1,2,4-Trimethylbenzene	-	To be fixed
94880	000067-48-1	Trimethylethanolammonium chloride	8	To be fixed
-	000108-74-7	1,3,5-Trimethylhexahydro-1,3,5-triazine	-	To be fixed
-	041203-81-0	Trimethylolpropane cyclic methylphosphonate (1:1) methyl methylphosphonate	-	To be fixed
-	057675-44-2	1,1,1-Trimethylolpropane trioleate	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS
-	068909-20-6	1,1,1-Trimethyl-N-(trimethylsilyl)silanamine, hydrolysis products with silica	-	To be fixed
-	004719-04-4	1,3,5-Tris(2-hydroxyethyl)hexahydro-1,3,5-triazine	-	To be fixed
-	090367-27-4	N,N,N'-Tris(2-hydroxyethyl)-N'-tallow alkyl-propylenediamine	-	To be fixed
-	018254-13-2	2,4,6-Tris(1-phenylethyl)phenol	-	To be fixed
(25950)	001852-04-6	Undecanedioic acid	8	To be fixed
-	093966-59-7	Urea sulphamate	-	To be fixed
-	025213-24-5	Vinyl acetate-vinyl alcohol, copolymer	-	To be fixed
-	068683-26-1	Vinyl acetate-vinyl neodecanoate, copolymer	-	To be fixed
-	000593-67-9	Vinylamine	-	To be fixed

APPENDIX A

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
10090	000064-19-7	Acetic acid	1		NS
(30140)	000141-78-6	Acetic acid, ethyl ester	1		NS
10120	000108-05-4	Acetic acid, vinyl ester	2	SML = 12 mg/kg	0,2
10630	000079-06-1	Acrylamide	4A	SML = ND (DL = 0.01 mg/kg)	
10660	015214-89-8	2-Acrylamido-2-methylpropanesulphonic acid	3	SML = 0.05 mg/kg	
10690	000079-10-7	Acrylic acid	2	SML(T) = 6 mg/kg (11)	0,1
10780	000141-32-2	Acrylic acid, n-butyl ester	2	SML(T) = 6 mg/kg (11) (as acrylic acid)	0.1 (as acrylic acid)
10840	001663-39-4	Acrylic acid, tert-butyl ester	2	SML(T) = 6 mg/kg (11) (as acrylic acid)	0.1 (as acrylic acid)
11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	3	SML = 0.05 mg/kg	
11245	002156-97-0	Acrylic acid, dodecyl ester	3	SML = 0.05 mg/kg (1)	
11470	000140-88-5	Acrylic acid, ethyl ester	2	SML(T) = 6 mg/kg (11) (as acrylic acid)	0.1 (as acrylic acid)
11530	000999-61-1	Acrylic acid, 2-hydroxypropyl ester	3	SML = 0.05 mg/kg	
11590	000106-63-8	Acrylic acid, isobutyl ester	2	SML(T) = 6 mg/kg (11) (as acrylic acid)	0.1 (as acrylic acid)
11680	000689-12-3	Acrylic acid, isopropyl ester	2	SML(T) = 6 mg/kg (11) (as acrylic acid)	0.1 (as acrylic acid)
11710	000096-33-3	Acrylic acid, methyl ester	2	SML(T) = 6 mg/kg (11) (as acrylic acid)	0.1 (as acrylic acid)
11830	000818-61-1	Acrylic acid, monoester with ethyleneglycol	2	SML(T) = 6 mg/kg (as acrylic acid)	0.1 (as acrylic acid)

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
12100	000107-13-1	Acrylonitrile	4A	SML = ND (DL= 0.01 mg/kg)	
12130	000124-04-9	Adipic acid	1		5
12265	004074-90-2	Adipic acid, divinyl ester	3	SML(T) = 0.05 mg/kg (14)	
12375	-	Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)	3		
12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	2	SML = 6 mg/kg	0,1
12763	000141-43-5	2-Aminoethanol	3	SML = 0.05 mg/kg	
12789	007664-41-7	Ammonia	1		NS
13090	000065-85-0	Benzoic acid	1		5
13390	000105-08-8	1,4-Bis(hydroxymethyl)cyclohexane	3		
13395	004767-03-7	2,2-Bis(hydroxymethyl)propionic acid	3	SML = 0.05 mg/kg	
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	2	SML = 0.6 mg/kg	0.01
13510	001675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (= BADGE)	7	SML = 1 mg/kg	
13630	000106-99-0	Butadiene	4A	SML = ND (DL = 0.01 mg/kg)	
13720	000110-63-4	1,4-Butanediol	3	SML = 0.05 mg/kg	
13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	4A	SML(T) = ND (DL = 0.01 mg/kg, as epoxy group, Mw = 43) (15)	
13840	000071-36-3	1-Butanol	3		
13870	000106-98-9	1-Butene	3		
13900	000107-01-7	2-Butene	3		
14200	000105-60-2	Caprolactam	2	SML = 15 mg/kg	0,25
14411	008001-79-4	Castor oil	3		
14500	009004-34-6	Cellulose	0		
(45760)	000108-91-8	Cyclohexylamine	2		1
15250	000110-60-1	1,4-Diaminobutane	2		0,6
(46640)	000128-37-0	2,6-Di-tert-butyl-p-cresol (= BHT)	1		0,05

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
15695	000461-58-5	Dicyanodiamide	2		1
15700	005124-30-1	Dicyclohexylmethane 4,4'-diisocyanate	4A	SML(T) = ND (DL = 0.01 mg/kg, as NCO) (16)	
15760	000111-46-6	Diethyleneglycol	2	SML(T) = 30 mg/kg (4)	0,5
15790	000111-40-0	Diethylenetriamine	3	SML = 5 mg/kg	
(48800)	000097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	2	SML = 12 mg/kg	0,2
16090	000080-09-1	4,4'-Dihydroxydiphenylsulphone	3	SML = 0.05 mg/kg	
16145	000124-40-3	Dimethylamine	3	SML = 0.06 mg/kg	
16150	000108-01-0	Dimethylaminoethanol	2	SML = 18 mg/kg	0,3
16390	000126-30-7	2,2-Dimethyl-1,3-propanediol	3	SML = 0.05 mg/kg	
16480	000126-58-9	Dipentaerythritol	2		1
16600	005873-54-1	Diphenylmethane 2,4'-diisocyanate	4A	SML(T) = ND (DL = 0.01 mg/kg, as NCO) (16)	
16630	000101-68-8	Diphenylmethane 4,4'-diisocyanate	4A	SML(T) = ND (DL = 0.01 mg/kg, as NCO) (16)	
16660	000110-98-5 025265-71-8	Dipropyleneglycol	2		1,5
16690	001321-74-0	Divinylbenzene	4A	SML = ND (DL = 0.01 mg/kg) (9)	
16697	000693-23-2	Dodecanedioic acid	3		
16701	000112-53-8	1-Dodecanol	3		
16704	000112-41-4	1-Dodecene	3	SML = 0.05 mg/kg	
(52000)	025155-30-0	Dodecylbenzenesulphonic acid, sodium salt	2	SML = 30 mg/kg	0,5
16750	000106-89-8	Epichlorohydrin	4A	SML = ND (DL = 0.01 mg/kg)	
16780	000064-17-5	Ethanol	1		
16950	000074-85-1	Ethylene	3		
16960	000107-15-3	Ethylenediamine	2	SML = 12 mg/kg	0,2

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
16990	000107-21-1	Ethyleneglycol	2	SML(T) = 30 mg/kg (4)	0,5
17005	000151-56-4	Ethyleneimine	4A	SML = ND (DL = 0.01 mg/kg)	
17020	000075-21-8	Ethylene oxide	4A	SML = ND (DL = 0.01 mg/kg)	
17050	000104-76-7	2-Ethyl-1-hexanol	1	SML = 30 mg/kg	0,5
17236	064755-01-7	Fatty acids, tallow, calcium salts	3		
17236	008052-48-0	Fatty acids, tallow, sodium salts	3		
17260	000050-00-0	Formaldehyde	3	SML(T) = 15 mg/kg (6)	
17275	000064-18-6	Formic acid	1		3
17290	000110-17-8	Fumaric acid	1		6
18010	000110-94-1	Glutaric acid	0		
18100	000056-81-5	Glycerol	1		NS
(56960)	025496-72-4	Glycerol monooleate	1		NS
18115	031566-31-1	Glycerol monostearate	1		NS
18250	000115-28-6	Hexachloroendomethylenetetrahydrophthalic acid	4A	SML = ND (DL = 0.01 mg/kg)	
18280	000115-27-5	Hexachloroendomethylenetetrahydrophthalic anhydride	4A	SML = ND (DL = 0.01 mg/kg)	
18310	036653-82-4	1-Hexadecanol	3		
18460	000124-09-4	Hexamethylenediamine	2	SML = 2.4 mg/kg	0,04
18640	000822-06-0	Hexamethylene diisocyanate	4A	SML(T) = ND (DL = 0.01 mg/kg, as NCO) (16)	
18670	000100-97-0	Hexamethylenetetramine	3	SML(T) = 15 mg/kg (6) (as formaldehyde)	
(59990)	007647-01-0	Hydrochloric acid	1		NS
18880	000099-96-7	4-Hydroxybenzoic acid	2		10
(62160)	007681-53-0	Hypophosphorous acid, sodium salt	3		
19000	000115-11-7	Isobutene	3		

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
19110	004098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	4A	SML(T) = ND (DL = 0.01 mg/kg, as NCO) (16)	
19150	000121-91-5	Isophthalic acid	3	SML = 5 mg/kg	
19270	000097-65-4	Itaconic acid	0		
19460	000050-21-5	Lactic acid	1		NS
19480	002146-71-6	Lauric acid, vinyl ester	3		
19518	000060-33-3	Linoleic acid	0		
19540	000110-16-7	Maleic acid	2	SML(T) = 30 mg/kg (12)	0,5
19960	000108-31-6	Maleic anhydride	2	SML(T) = 30 mg/kg (12) (as maleic acid)	0,5
19990	000079-39-0	Methacrylamide	4A	SML = ND (DL = 0.01 mg/kg)	
20020	000079-41-4	Methacrylic acid	2	SML(T) = 6 mg/kg (13)	0,1
20050	000096-05-9	Methacrylic acid, allyl ester	3	SML = 0.05 mg/kg	
20110	000097-88-1	Methacrylic acid, butyl ester	2	SML(T) = 6 mg/kg (13) (as methacrylic acid)	0.1 (as m. acid)
20170	000585-07-9	Methacrylic acid, tert-butyl ester	2	SML(T) = 6 mg/kg (13) (as methacrylic acid)	0.1 (as m. acid)
20530	002867-47-2	Methacrylic acid, 2-(dimethylamino)ethyl ester	4A	SML = ND (DL = 0.01 mg/kg)	
20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	4B	SML(T) = ND (DL = 0.01 mg/kg, as epoxy group, Mw = 43) (15)	
20890	000097-63-2	Methacrylic acid, ethyl ester	2	SML(T) = 6 mg/kg (13) (as methacrylic acid)	0.1 (as m. acid)
21010	000097-86-9	Methacrylic acid, isobutyl ester	2	SML(T) = 6 mg/kg (13) (as methacrylic acid)	0.1 (as m. acid)
21130	000080-62-6	Methacrylic acid, methyl ester	2	SML(T) = 6 mg/kg (13) (as methacrylic acid)	0.1 (as m. acid)
21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol	2	SML(T) = 6 mg/kg (13) (as methacrylic acid)	0.1 (as m. acid)

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
21490	000126-98-7	Methacrylonitrile	4A	SML= ND (DL = 0.01 mg/kg)	
21520	001561-92-8	Methallylsulphonic acid, sodium salt	3	SML = 5 mg/kg	
21550	000067-56-1	Methanol	3		
(66120)	010605-21-7	Methyl benzimidazolecarbamate	2	SML = 0.6 mg/kg	0,01
21640	000078-79-5	2-Methyl-1,3-butadiene	4A	SML = ND (DL = 0.01 mg/kg)	
(66620)	000075-09-2	Methylene chloride	3	SML = 0.05 mg/kg	
(66725)	000108-10-1	Methyl isobutyl ketone	3	SML = 5 mg/kg	
21940	000924-42-5	N-Methylolacrylamide	4A	SML = ND (DL = 0.01 mg/kg)	
22555	000112-92-5	1-Octadecanol	3		
22763	000112-80-1	Oleic acid	1		NS
22766	000143-28-2	Oleyl alcohol	3		
22775	000144-62-7	Oxalic acid	2	SML = 6 mg/kg	0,1
22840	000115-77-5	Pentaerythritol	2		1
22870	000071-41-0	1-Pentanol	3		
22960	000108-95-2	Phenol	2		1,5
23170	007664-38-2	Phosphoric acid	1		70 (as P)
23173	001314-56-3	Phosphoric anhydride	1		70 (as P)
23230	000131-17-9	Phthalic acid, diallyl ester	4A	SML = ND (DL = 0.01 mg/kg)	
23380	000085-44-9	Phthalic anhydride	2		1
23740	000057-55-6	1,2-Propanediol	1		25
23770	000504-63-2	1,3-Propanediol	3	SML = 0.05 mg/kg	
23920	000105-38-4	Propionic acid, vinyl ester	2	SML(T) = 6 mg/kg (10) (as acetaldehyde)	0,1
23980	000115-07-1	Propylene	3		
24010	000075-56-9	Propylene oxide	4A	SML = ND (DL = 0.01 mg/kg)	

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
24055	000089-05-4	Pyromellitic acid	3	SML = 0.05 mg/kg	
24070	073138-82-6	Resin acids and rosin acids	2		1
24100	008050-09-7	Rosin	2		1
(86480)	007631-90-5	Sodium bisulphite	1	SML(T) = 10 mg/kg (8) (as SO2)	0,7
(87600)	001338-39-2	Sorbitan monolaurate	1		5
(87760)	026266-57-9	Sorbitan monopalmitate	1		25
(88240)	026658-19-5	Sorbitan tristearate	1		25
24490	000050-70-4	Sorbitol	1		
24550	000057-11-4	Stearic acid	1		NS
24610	000100-42-5	Styrene	4B	To be fixed	
24760	026914-43-2	Styrenesulphonic acid	3	SML = 0.05 mg/kg	
24820	000110-15-6	Succinic acid	1		NS
24850	000108-30-5	Succinic anhydride	2		NS
24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	3	SML = 5 mg/kg	
24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	3	SML = 0.05 mg/kg	
(91920)	007664-93-9	Sulphuric acid	1		NS
24905	008002-26-4	Tall oil	3		
24910	000100-21-0	Terephthalic acid	2	SML = 7.5 mg/kg	0,125
24970	000120-61-6	Terephthalic acid, dimethyl ester	2		1
25120	000116-14-3	Tetrafluoroethylene	3	SML = 0.05 mg/kg	
25150	000109-99-9	Tetrahydrofuran	2	SML = 0.6 mg/kg	0,01
25205	000108-88-3	Toluene	3	SML = 1.2 mg/kg	
25208	026471-62-5	Toluene diisocyanate	4A	SML(T) = ND (DL = 0.01 mg/kg, as NCO) (16)	
25210	000584-84-9	2,4-Toluene diisocyanate	4A	SML(T) = ND (DL = 0.01 mg/kg, as NCO) (16)	

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
25240	000091-08-7	2,6-Toluene diisocyanate	4A	SML(T) = ND (DL = 0.01 mg/kg, as NCO) (16)	
25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine	2	SML = 30 mg/kg	0,5
25510	000112-27-6	Triethyleneglycol	2		5
25600	000077-99-6	1,1,1-Trimethylolpropane	2	SML = 6 mg/kg	0,1
25960	000057-13-6	Urea	0		
26050	000075-01-4	Vinyl chloride	4A	SML = ND (DL = 0.01 mg/kg)	
26170	003195-78-6	N-Vinyl-N-methylacetamide	3	SML(T) = 0.05 mg/kg (14)	
26320	002768-02-7	Vinyltrimethoxysilane	3	SML(T) = 0.05 mg/kg (14)	
26370	001330-20-7	Xylene	3	SML = 1.2 mg/kg	

APPENDIX B

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
11440	044992-01-0	Acrylic acid, ester with trimethylethanolammonium chloride	8	To be fixed
-	013106-44-0	Acrylic acid, ester with trimethylethanolammonium methyl sulphate	-	To be fixed
-	000106-74-1	Acrylic acid, 2-ethoxyethyl ester	-	To be fixed
11500	000103-11-7	Acrylic acid, 2-ethylhexyl ester	7	To be fixed
-	025268-77-3	Acrylic acid, N-methylperfluorooctanesulphonamidoethyl ester	-	To be fixed
12235	000627-93-0	Adipic acid, dimethyl ester	6B	To be fixed
12769	013531-52-7	N-(2-Aminoethyl)-1,3-diaminopropane	8	To be fixed
12772	000140-31-8	N-Aminoethylpiperazine	8	To be fixed
13255	010563-26-5	N,N'-Bis(3-aminopropyl)ethylenediamine	8	To be fixed
-	000105-83-9	N,N-Bis(3-aminopropyl)methylamine	-	To be fixed
-	007398-69-8	Diallyldimethylammonium chloride	-	To be fixed
16115	025167-70-8	Diisobutene	8	To be fixed
-	046830-22-2	Dimethyl(acryloyloxyethyl)benzylammonium chloride	-	To be fixed
16180	005205-93-6	N-(Dimethylaminopropyl)methacrylamide	6A	To be fixed
-	003033-77-0	(2,3-Epoxypropyl)trimethylammonium chloride	-	To be fixed
18055	001119-40-0	Glutaric acid, dimethyl ester	7	To be fixed
18120	000107-22-2	Glyoxal	6A	To be fixed
20860	005039-78-1	Methacrylic acid, ester with trimethylethanolammonium chloride	8	To be fixed
-	006891-44-7	Methacrylic acid, ester with trimethylethanolammonium methyl sulphate	-	To be fixed
20920	000688-84-6	Methacrylic acid, 2-ethylhexyl ester	8	To be fixed
-	000105-59-9	N-Methyldiethanolamine	-	To be fixed
21970	000923-02-4	N-Methylolmethacrylamide	7	To be fixed
(67910)	000085-47-2	1-Naphthalenesulphonic acid	8	To be fixed
(67912)	000120-18-3	2-Naphthalenesulphonic acid	8	To be fixed
-	004067-16-7	Pentaethylenehexamine	-	To be fixed
-	061788-44-1	Phenol, styrenated	-	To be fixed
-	000120-07-0	N-Phenyldiethanolamine	-	To be fixed
25480	000102-71-6	Triethanolamine	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
25520	000112-24-3	Triethylenetetramine	8	To be fixed
25550	000552-30-7	Trimellitic anhydride	7	To be fixed
-	000593-67-9	Vinylamine	-	To be fixed
-	013162-05-5	N-Vinylformamide	-	To be fixed
26230	000088-12-0	Vinylpyrrolidone	6A	To be fixed
26260	001184-84-5	Vinylsulphonic acid	6A	To be fixed
-	003039-83-6	Vinylsulphonic acid, sodium salt	-	To be fixed

APPENDIX C

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	000108-22-5	Acetic acid, isopropenyl ester	-	To be fixed
10157	000098-86-2	Acetophenone	8	To be fixed
-	002754-27-0	Acetoxytrimethylsilane	-	To be fixed
-	000107-02-8	Acrolein	-	To be fixed
-	045021-77-0.	(3-Acrylamidopropyl)trimethylammonium chloride	-	To be fixed
10720	000999-55-3	Acrylic acid, allyl ester	6A	To be fixed
-	024615-84-7	Acrylic acid, 2-carboxyethyl ester	-	To be fixed
10990	002156-96-9	Acrylic acid, decyl ester	7	To be fixed
11005	012542-30-2	Acrylic acid, dicyclopentenyl ester	8	To be fixed
11020	019485-03-1	Acrylic acid, diester with 1,3-butanediol	8	To be fixed
11050	001070-70-8	Acrylic acid, diester with 1,4-butanediol	8	To be fixed
11080	004074-88-8	Acrylic acid, diester with diethyleneglycol	8	To be fixed
11090	002223-82-7	Acrylic acid, diester with 2,2-dimethyl-1,3-propanediol	8	To be fixed
11100	057472-68-1	Acrylic acid, diester with dipropyleneglycol	8	To be fixed
11110	002274-11-5	Acrylic acid, diester with ethyleneglycol	8	To be fixed
11140	013048-33-4	Acrylic acid, diester with 1,6-hexanediol	8	To be fixed
11170	026570-48-9	Acrylic acid, diester with polyethyleneglycol	8	To be fixed
11180	017831-71-9	Acrylic acid, diester with tetraethyleneglycol	8	To be fixed
11190	001680-21-3	Acrylic acid, diester with triethyleneglycol	8	To be fixed
11195	042978-66-5 068901-05-3	Acrylic acid, diester with tripropyleneglycol	8	To be fixed
11200	002426-54-2	Acrylic acid, 2-(diethylamino)ethyl ester	8	To be fixed
11230	002439-35-2	Acrylic acid, 2-(dimethylamino)ethyl ester	7	To be fixed
11260	000106-90-1	Acrylic acid, 2,3-epoxypropyl ester	6A	To be fixed
11520	002918-23-2	Acrylic acid, 2-hydroxyisopropyl ester	7	To be fixed
11560	005888-33-5	Acrylic acid, isobornyl ester	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
11650	029590-42-9	Acrylic acid, isooctyl ester	8	To be fixed
11770	002478-10-6	Acrylic acid, monoester with 1,4-butanediol	8	To be fixed
11950	000937-41-7	Acrylic acid, phenyl ester	7	To be fixed
12058	003524-68-3	Acrylic acid, triester with pentaerythritol	8	To be fixed
12062	075577-70-7	Acrylic acid, triester with 1,1,1-trimethylolpropane tris(2-hydroxyethyl) ether	8	To be fixed
-	000814-68-6	Acryloyl chloride	-	To be fixed
-	099561-04-3	Alcohols, tallow	-	To be fixed
-	000107-05-1	Allyl chloride	-	To be fixed
-	061790-33-8	Amines, tallow	-	To be fixed
-	061788-45-2	Amines, tallow, hydrogenated	-	To be fixed
12730	000060-32-2	6-Aminocaproic acid	8	To be fixed
-	001760-24-3	N-(2-Aminoethyl)--3-(aminopropyl)trimethoxysilane	-	To be fixed
12771	000111-41-1	N-(2-Aminoethyl)ethanolamine	W7	To be fixed
12775	000124-68-5	2-Amino-2-methyl-1-propanol	8	To be fixed
12784	000056-18-8	N-(3-Aminopropyl)-1,3-diaminopropane	8	To be fixed
-	003179-76-8	(3-Aminopropyl)diethoxymethylsilane	-	To be fixed
-	000056-84-8	Aspartic acid	-	To be fixed
-	000078-67-1	Azobisisobutyronitrile	-	To be fixed
-	003287-99-8	Benzylamine, hydrochloride	-	To be fixed
-	000100-44-7	Benzyl chloride	-	To be fixed
13240	003377-24-0	2,2-Bis(4-aminocyclohexyl)propane	8	To be fixed
13321	000080-04-6	2,2-Bis(4-hydroxycyclohexyl)propane	8	To be fixed
(39630)	000140-95-4	N,N'-Bis(hydroxymethyl)urea	8	To be fixed
13660	000584-03-2	1,2-Butanediol	8	To be fixed
-	000106-88-7	1-Butene oxide	-	To be fixed
13960	001852-16-0	N-(Butoxymethyl)acrylamide	6A	To be fixed
-	000110-65-6	2-Butynediol	-	To be fixed
14260	000502-44-3	Caprolactone	7	To be fixed
-	000079-07-2	Chloroacetamide	-	To be fixed
(43630)	000059-50-7	p-Chloro-m-cresol	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	000088-04-0	4-Chloro-3,5-dimethylphenol	-	To be fixed
-	000126-83-0	3-Chloro-2-hydroxypropanesulphonic acid, sodium salt	-	To be fixed
-	003327-22-8	(3-Chloro-2-hydroxypropyl)trimethylammonium chloride	-	To be fixed
-	007790-94-5	Chlorosulphonic acid	-	To be fixed
(43920)	015242-96-3	Chromic chloride stearate	9	To be fixed
-	000123-73-9	Crotonaldehyde	-	To be fixed
14800	003724-65-0	Crotonic acid	7	To be fixed
14836	014861-06-4	Crotonic acid, vinyl ester	7	To be fixed
14905	000108-93-0	Cyclohexanol	8	To be fixed
-	002873-97-4	Diacetone acrylamide	-	To be fixed
-	000078-90-0	1,2-Diaminopropane	-	To be fixed
15340	000109-76-2	1,3-Diaminopropane	8	To be fixed
15414	000096-76-4	2,4-Di-tert-butylphenol	8	To be fixed
15418	000128-39-2	2,6-Di-tert-butylphenol	8	To be fixed
-	010222-01-2	2,2-Dibromo-2-cyanoacetamide	-	To be fixed
-	000330-54-1	N'-(3,4-Dichlorophenyl)-N,N-dimethylurea	-	To be fixed
15735	000111-42-2	Diethanolamine	8	To be fixed
-	000109-89-7	Diethylamine	-	To be fixed
(48370)	000100-37-8	Diethylethanolamine	-	To be fixed
-	000868-63-3	N,N'-(1,2-Dihydroxyethylene)bisacrylamide	-	To be fixed
-	003845-76-9	N-(Dimethylaminopropyl)acrylamide	-	To be fixed
16225	000109-55-7	N,N-Dimethyl-1,3-diaminopropane	8	To be fixed
-	000115-10-6	Dimethyl ether	-	To be fixed
-	046917-07-1	Dimethyl(methacryloyloxyethyl)benzylammonium chloride	-	To be fixed
16400	003377-92-2	2,2-Dimethylpropionic acid, vinyl ester	7	To be fixed
16420	000123-91-1	Dioxane	6A	To be fixed
16510	000138-86-3	Dipentene	8	To be fixed
16685	023235-61-2	Ditrimethylolpropane	8	To be fixed
-	002627-95-4	1,3-Divinyltetramethyldisiloxane	-	To be fixed
-	058598-42-8	Docosenylsuccinic anhydride	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	000112-55-0	Dodecylmercaptan	-	To be fixed
16709	027193-86-8	Dodecylphenol	9	To be fixed
16717	025134-21-8	Endomethylenemethyltetrahydrophthalic anhydride	8	To be fixed
16719	003813-52-3	Endomethylenetetrahydrophthalic acid	8	To be fixed
16720	000826-62-0	Endomethylenetetrahydrophthalic anhydride	8	To be fixed
-	040618-18-6	Epoxysuccinic acid, disodium salt	-	To be fixed
-	000106-86-5	1,2-Epoxy-4-vinylcyclohexane	-	To be fixed
-	002956-58-3	N,N'-Ethylenebisacrylamide	-	To be fixed
-	000094-04-2	2-Ethylhexanoic acid, vinyl ester	-	To be fixed
-	028106-30-1	Ethylstyrene	-	To be fixed
17150	000078-27-3	1-Ethynylcyclohexanol	8	To be fixed
17305	000141-02-6	Fumaric acid, bis(2-ethylhexyl) ester	8	To be fixed
17350	000105-75-9	Fumaric acid, dibutyl ester	7	To be fixed
17392	007283-70-7	Fumaric acid, diisopropyl ester	7	To be fixed
17476	002459-05-4	Fumaric acid, monoethyl ester	7	To be fixed
(55660)	000111-30-8	Glutaraldehyde	7	To be fixed
-	001830-78-0	Glycerol 1,3-dimethacrylate	-	To be fixed
-	000123-34-2	Glycerol 1-monoallyl ether	-	To be fixed
-	000298-12-4	Glyoxylic acid	-	To be fixed
18320	000629-73-2	1-Hexadecene	8	To be fixed
18400	000592-42-7	1,5-Hexadiene	7	To be fixed
-	004719-04-4	Hexahydro-1,3,5-tris(2-hydroxyethyl)-1,3,5-triazine	-	To be fixed
-	000107-46-0	Hexamethyldisiloxane	-	To be fixed
-	015894-70-9	Hexamethylenebis(dicyanodiamide)	-	To be fixed
-	022527-59-9	Hexamethylenediamine hydrochloride	-	To be fixed
-	003779-63-3	Hexamethylenediisocyanate cyclic trimer	-	To be fixed
18700	000629-11-8	1,6-Hexanediol	7	To be fixed
-	007722-84-1	Hydrogen peroxide	-	To be fixed
-	003699-54-5	N-(2-Hydroxyethyl)ethyleneurea	-	To be fixed
-	003445-11-2	N-(2-Hydroxyethyl)pyrrolidone	-	To be fixed
18910	000288-32-4	Imidazole	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
18970	000078-83-1	Isobutanol	8	To be fixed
19030	016669-59-3	N-(Isobutoxymethyl)acrylamide	6A	To be fixed
-	025265-77-4	Isobutyric acid, monoester with 2,2,4-trimethyl-1,3-pentanediol	-	To be fixed
-	002210-25-5	N-Isopropylacrylamide	-	To be fixed
19265	030399-84-9	Isostearic acid	8	To be fixed
19315	000617-52-7	Itaconic acid, dimethyl ester	8	To be fixed
19570	000999-21-3	Maleic acid, diallyl ester	6A	To be fixed
19600	000105-76-0	Maleic acid, dibutyl ester	7	To be fixed
19720	001330-76-3	Maleic acid, diisooctyl ester	7	To be fixed
19750	000624-48-6	Maleic acid, dimethyl ester	7	To be fixed
19780	002915-53-9	Maleic acid, dioctyl ester	7	To be fixed
19915	000925-21-3	Maleic acid, monobutyl ester	7	To be fixed
19933	003990-03-2	Maleic acid, monoethyl ester	7	To be fixed
19936	007423-42-9	Maleic acid, mono(2-ethylhexyl) ester	8	To be fixed
19945	003052-50-4	Maleic acid, monomethyl ester	7	To be fixed
(65768)	000149-30-4	2-Mercaptobenzothiazole	6A	To be fixed
-	016215-21-7	3-Mercaptopropionic acid, butyl ester	-	To be fixed
20005	051410-72-1	Methacrylamidopropyltrimethylammonium chloride	6A	To be fixed
20320	003179-47-3	Methacrylic acid, decyl ester	7	To be fixed
20380	001189-08-8	Methacrylic acid, diester with 1,3-butanediol	8	To be fixed
20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	7	To be fixed
-	000109-16-0	Methacrylic acid, diester with triethyleneglycol	-	To be fixed
20560	000142-90-5	Methacrylic acid, dodecyl ester	7	To be fixed
20935	002495-27-4	Methacrylic acid, hexadecyl ester	7	To be fixed
20940	000142-09-6	Methacrylic acid, hexyl ester	7	To be fixed
-	024599-21-1	Methacrylic acid, 2-hydroxyethyl ester, monophosphate	-	To be fixed
-	052628-03-2	Methacrylic acid, 2-hydroxyethyl ester, phosphate	-	To be fixed
20945	004664-49-7	Methacrylic acid, 2-hydroxyisopropyl ester	7	To be fixed
20950	000923-26-2	Methacrylic acid, 2-hydroxypropyl ester	8	To be fixed
20980	007534-94-3	Methacrylic acid, isobornyl ester	8	To be fixed
21205	025736-86-1	Methacrylic acid, monoester with polyethyleneglycol	7	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
21220	032360-05-7	Methacrylic acid, octadecyl ester	8	To be fixed
-	086261-90-7	Methacrylic acid, 2-(2-oxo-1-imidazolidinyl)ethyl ester	-	To be fixed
21370	010595-80-9	Methacrylic acid, 2-sulphoethyl ester	7	To be fixed
-	031098-21-2	Methacrylic acid, 3-sulphopropyl ester, potassium salt	-	To be fixed
21415	002549-53-3	Methacrylic acid, tetradecyl ester	7	To be fixed
(65910)	002530-85-0	[3-(Methacryloxy)propyl]trimethoxysilane	8	To be fixed
-	000625-45-6	Methoxyacetic acid	-	To be fixed
21580	003644-11-9	N-(Methoxymethyl)acrylamide	6A	To be fixed
21610	003644-12-0	N-(Methoxymethyl)methacrylamide	6A	To be fixed
21620	000107-98-2	1-Methoxy-2-propanol	8	To be fixed
21630	001187-59-3	N-Methylacrylamide	6A	To be fixed
-	000920-46-7	Methacryloyl chloride	-	To be fixed
-	000109-83-1	N-Methyl-2-aminoethanol	-	To be fixed
-	029385-43-1	Methylbenzotriazole	-	To be fixed
21733	000115-19-5	2-Methyl-3-butyn-2-ol	8	To be fixed
-	034066-95-0	1-Methyldiethylenetriamine	-	To be fixed
21790	000110-26-9	Methylenebisacrylamide	6A	To be fixed
-	000096-29-7	Methyl ethyl ketone oxime	-	To be fixed
-	000077-49-6	2-Methyl-2-nitro-1,3-propanediol	-	To be fixed
22080	000108-11-2	4-Methyl-2-pentanol	8	To be fixed
22210	000098-83-9	alpha-Methylstyrene	7	To be fixed
22240	000622-97-9	p-Methylstyrene	6A	To be fixed
-	026591-72-0	1-Methyl-3-vinylimidazolium methyl sulphate	-	To be fixed
22340	000074-89-5	Monomethylamine	W8	To be fixed
22428	051000-52-3	Neodecanoic acid, vinyl ester	7	To be fixed
22435	054423-67-5	Neononanoic acid, vinyl ester	7	To be fixed
22535	025154-52-3	Nonylphenol	9	To be fixed
-	000556-67-2	Octamethylcyclotetrasiloxane	-	To be fixed
-	067554-50-1	Octylphenol	-	To be fixed
-	000112-90-3	Oleyl amine	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	003089-19-8	N-[2-(2-Oxo-1-imidazolidinyl)ethyl]methacrylamide	-	To be fixed
22861	000111-29-5	1,5-Pentanediol	8	To be fixed
-	000090-30-2	N-Phenyl-1-naphthylamine	-	To be fixed
-	002788-26-3	Phosphonosuccinic acid, tetramethyl ester	-	To be fixed
(76430)	008002-09-3	Pine oil	8	To be fixed
-	000074-98-6	Propane	-	To be fixed
-	068988-56-7	Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and isopropanol	-	To be fixed
-	000107-19-7	2-Propyn-1-ol	-	To be fixed
-	011099-06-2	Silicic acid, tetraethyl ester, polymer	-	To be fixed
-	007681-57-4	Sodium metabisulphite	-	To be fixed
(91520)	005138-18-1	Sulphosuccinic acid	8	To be fixed
-	000077-78-1	Sulphuric acid, dimethyl ester	-	To be fixed
-	007782-99-2	Sulphurous acid	-	To be fixed
-	007446-11-9	Sulphur trioxide	-	To be fixed
25030	016646-44-9	Tetra(allyloxy)ethane	6A	To be fixed
-	055566-30-8	Tetrakis(hydroxymethyl)phosphonium sulphate	-	To be fixed
-	064338-16-5	2,2,4,4-Tetramethyl-7-oxa-3,20-diazadispiro[5.1.11.2]heneicosan-21-one	-	To be fixed
25330	000070-55-3	p-Toluenesulphonamide	7	To be fixed
(93595)	000080-48-8	p-Toluenesulphonic acid, methyl ester	8	To be fixed
25350	004130-08-9	(Triacetoxy)vinylsilane	6A	To be fixed
25390	000101-37-1	Triallyl cyanurate	6A	To be fixed
25405	001025-15-6	Triallyl isocyanurate	6A	To be fixed
(93870)	000071-55-6	1,1,1-Trichloroethane	D	To be fixed
-	000088-06-2	2,4,6-Trichlorophenol	-	To be fixed
-	000108-77-0	2,4,6-Trichloro-1,3,5-triazine	-	To be fixed
-	000075-50-3	Trimethylamine	-	To be fixed
-	000108-67-8	1,3,5-Trimethylbenzene	-	To be fixed
-	025620-58-0	Trimethylhexamethylenediamine	-	To be fixed
25810	015625-89-5	1,1,1-Trimethylolpropane triacrylate	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
25930	001067-53-4	Tris(2-methoxyethoxy)vinylsilane	6A	To be fixed
25950	001852-04-6	Undecanedioic acid	8	To be fixed
-	000111-81-9	10-Undecenoic acid, methyl ester	-	To be fixed
-	002235-00-9	N-Vinylcaprolactam	-	To be fixed
-	001746-03-8	Vinylphosphonic acid	-	To be fixed
26215	000100-69-6	2-Vinylpyridine	6A	To be fixed
26217	000100-43-6	4-Vinylpyridine	6A	To be fixed
26305	000078-08-0	Vinyltriethoxysilane	6A	To be fixed

TECHNICAL DOCUMENT No. 2

GUIDELINES ON TEST CONDITIONS AND METHODS OF ANALYSIS FOR PAPER AND BOARD MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Version 2 -10.06.2004

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Page

1. Introduction

The *Technical document* gives guidance on the conditions and methods of analysis to be used for testing paper and board intended to come into contact with food. It should be read in conjunction with the specifications laid down in *Resolution ResAP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs*.

2. Sampling

Tests pieces from samples should be chosen so that all components are represented at the same percentage composition as in the original material or article. When an article is being tested, all auxiliaries used in production of the article should be taken into account, such as printing inks, lacquers, adhesives etc.

3. Testing for compliance with QMA[(1)] restrictions

3.1. General rule

Testing for compliance with QMA restrictions (mg/6dm^2) should measure the total concentration of the substance in the paper.

3.2 . QMA restrictions laid down in Table 1 and Table 2 of Resolution ResAP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs

In principle, testing for compliance with the QMA restrictions in Table 1 of *Resolution ResAP (2002) 1* should measure the total concentration of a substance in the paper. The substance can be measured in situ or by total release of the substance by extraction from the material or by degradation of the paper matrix.

The tests for compliance with the QMA restriction for cadmium, lead and mercury of Table 1 of *Resolution ResAP (2002) 1* which are listed in Section 7 of this document, are based on aqueous extraction[(2)] and do not necessarily determine the total concentration of the substances in the finished material or article. However, these tests are generally recognised as appropriate to establish compliance.

Testing for compliance with the purity restriction for pentachlorophenol of Table 2 of *Resolution ResAP (2002) 1* can be made using a method based on extraction of the total amount in the paper.

4. Testing for compliance with SML restrictions

4.1. General rule

In principle, testing for compliance with SML restrictions should be carried out by migration testing, using the conditions established in Directive 82/711/EEC and amendments, as well as in Directive 85/572/EEC. However, extraction tests could be used if, on the basis of scientific evidence, the results obtained using these tests are at least equal to those obtained by migration testing using the conventional EU test simulants or foodstuffs.

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(1) The numerical value of QMA expressed as mg/6dm^2 of material corresponds to the numerical value of SML expressed as mg/kg of food or food stimulant.

(2) Extraction using simulant B (3% aq. acetic acid w/v) should be used for paper intended to come into contact with acidic foodstuffs.

4.2. Migration tests

EU Directive 85/572/EEC as well as EU Directive 82/711/EEC and its amendments (Directive 93/8/EEC and Directive 97/48/EC) should be used for guidance on the selection of appropriate simulants and exposure conditions (time and temperature). However for those foodstuffs for which in Directive 85/572/EEC no simulant is provided ('dry foodstuffs'), migration testing should be carried out using modified polyphenylene oxide (MPPO) as a test medium.

Testing should take into account the worst foreseeable conditions of use for the material. This will include the type of foodstuff with which the paper comes into contact, and the time and temperature of contact.

5. Contact conditions differing from the conventional ratio of 1 kg to 6 dm^2

For contact conditions where the mass of food to contact area ratio differs from the conventional ratio of 1 kg food to 6 dm^2 of paper, the restriction to be applied (Q) is calculated as follows:

$$Q = \frac{QMA_{std}}{CA_{nor}} \times 6 \times m$$

Where: *Q* (quantity of substance in the finished material or article) is the restriction to be applied taking into account the conditions under normal or worst foreseeable conditions of use;

QMA_{std} is the QMA restriction under the conventional conditions of 1 kg to 6 dm^2;

m is the mass of food (in kg) under normal or worst foreseeable conditions of use;

CA_{nor} is the contact area (in dm^2) under normal or worst foreseeable conditions of use.

6. Speciality papers

6.1. Paper for use at high temperature such as baking paper

Migration testing should be carried out using only MPPO as a test medium regardless of the type of food and using the time and temperature of contact provided in Directive 82/711/EEC and its amendments.

Testing should take into account possible degradation products formed at elevated temperatures. When carrying out extraction testing to determine compliance with *Resolution ResAP (2002) 1* the sample should, in principle, be preheated in a closed container, according to the time and temperature conditions given in Directive 82/711/EEC and its amendments.

6.2. Paper used for filtering large volumes of liquid such as filters for industrial use and milk filters

6.2.1. Migration tests

Where the total volume to be filtered is from 1 to 10 l/dm^2 of paper, before testing, 0.5 l of the food or food simulant per dm^2 should be passed through the test material and discarded. A further portion, 0.5 l/dm^2, of the food or simulant should then be passed through the material and analysed to obtain the test result.

Where the total volume to be filtered is above 10 l/dm^2 of paper, before testing, one litre of the food or food simulant per dm^2 should be passed through the test material and discarded. A further portion, 1 l/dm^2, of the food or simulant should then be passed through the material and analysed to obtain the test result.

For filtration papers used to filter oils, migration tests should be carried out using olive oil simulant (or the recognised alternative fatty food simulants or substitute test media) or with the same type of oil as will be filtered in normal use of the paper.

6.2.2. Extraction tests and tests for QMA

For testing compliance with a QMA restriction, or when using extraction tests to determine compliance with an SML restriction, the material should be tested directly after the first 0.5 l/dm^2 has been passed through the material and discarded.

7. Methods of analysis

The Council of Europe and the EU Commission do not normally issue resolutions or directives in the field of methods of analysis. The progress in this area is so rapid that any method may be considered obsolete after a limited number of years. However, there is a need to provide guidance to analysts who carry out testing to ensure compliance with the requirements of *Resolution ResAP (2002) 1* (e.g. enforcement authorities, industry, food and food packaging retailers and certification laboratories).

It is recommended that internationally recognised and validated methods of analysis are applied. For the purpose of this document this includes methods recognised by the following bodies: CoE, EU, CEN, ISO.

If such a method does not exist currently, an analytical method with appropriate performance characteristics (accuracy and precision) at the specified limit may be used.

A list of current relevant CEN and ISO standards is given below:

- Determination of pentachlorophenol (EN 15320 in preparation)
- Determination of cadmium, lead and chromium in aqueous extract (ENV 12498)
  NB. This method is appropriate for contact with non acidic foodstuffs
- Determination of mercury in aqueous extract (ENV 12497)
  NB. This method is appropriate for contact with non acidic foodstuffs
- Preparation of a cold water extract (EN 645)
- Preparation of a hot water extract (EN 647)
- Sensory analysis. Part 2: Off flavour (taint) (EN 1230:2)
- Determination of microbiological properties. Part 1: Total bacteria count (ISO 8784-1)

- Determination of formaldehyde in an extract (EN 1541)
- Determination of antimicrobial constituents (EN 1104)
- Migration into modified polyphenylene oxide (MPPO) (CEN 14338 in preparation).

Analytical methods for testing of papers made from recycled fibres are summarised in Appendix A.

8. References

Council Directive 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 (82/711/EEC). Official Journal of the European Communities L297/26, 23.10.82.

Council Directive 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 (85/572/EEC). Official Journal of the European Communities L372/14, 31.12.85.

Commission Directive of 29 July 1997 amending for the second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (97/48/EC). Official Journal of the European Communities L222/10, 12.8.97.

Council of Europe Resolution AP (96) 4 on maximum and guideline levels and on source-directed measures aimed at reducing the contamination of food by lead, cadmium and mercury, adopted by the Committee of Ministers on 2 October 1996.

APPENDIX A

Analytical methods for testing of papers made from recycled fibres

The analytical methods listed below have been used for the analysis of papers made from recycled fibres. A number of these methods are not internationally recognised and/or validated. Those wishing to use these methods for testing purposes should ensure that they evaluate the performance of the methods.

Michler's ketone and 4,4'-bis(diethylamino)benzophenone

Determination by GC-MS as described in (1).

Diisopropylnaphthalenes

For the determination in paper the methods described in (2), (3), and (4) are used.

N.B.: CEN TC 172 is preparing a method for the determination of the total DIPN content in paper.

Partially Hydrogenated Terphenyls

A method is described in (5).

Phthalates

Analysis can be performed by GC/MS after solvent extraction, for details see (6) and (7).

Solvents

The content in residual solvents can be tested by Headspace-GC/MS according to (8).

Azo colourants

For analysis the method provided in (9) can be used. Following this method the azo colourants are cleaved reductively and the formed amines are determined by HPLC/DAD, TLC, GC/FID and/or MSD, or by CE/DAD. The aromatic amines freely available in paper before cleavage of the azo bond must be subtracted from the result after the cleavage.

Primary aromatic amines, suspected to be carcinogenic

For screening, the summation method as described in (10) can be used. If the sum of primary aromatic amines is above the detection limit it is necessary to determine the amines listed in the proposal for the EU Directive amending for the 19th time the Council Directive 76/769/EEC specifically.

N.B.: CEN TC 194 is preparing a screening method and a method for the specific determination of primary aromatic amines in food simulants.

Fluorescent whitening agents

A European standard method is available. (11)

Polycyclic aromatic hydrocarbons

N.B.: CEN TC 194 is preparing a GC/MS-method for the determination of polycyclic aromatic hydrocarbons in paper.

Benzophenone

A method is described in (12).

References

(1) Castle, L., Damant, A.P., Honeybone, C.A., Johns, S.M., Jickells, S.M., Sharman, M. and Gilbert, J. Migration studies from paper and board food packaging materials. Part 2. Survey for residues of dialkylamino benzophenone UV-cure ink photoinitiators. *Food Additives & Contaminants*, (1997), 14:45-52.

(2) Sturaro, A., Parvoli, G., Rella, R., Bardati, S. and Doretti, L. Food contamination by diisopropylnaphthalenes from cardboard packages. *International Journal of Food Science & Technology*, (1994), 29:593-603.

(3) Bebiolka, H. and Dunkel, K. Übergang von Di-isopropylnaphthalin aus Kartonverpackungen auf Lebensmittel. *Lebensmittelchemie*, (1997), 51:53-61.

(4) Boccacci Mariani, M., Chiacchierini, E. and Gesumundo, C. Potential migration of diisopropylnaphthalenes from recycled paperboard packaging into dry foods. *Food Additives & Contaminants*. (1999), 16:207-213.

(5) Sturaro, A., Parvoli, G., Rella, R. and Doretti, L. Hydrogenated terphenyls contaminants in recycled paper. *Chemosphere*, (1995), 30:687-694.

(6) MAFF: Food surveillance information sheet, Number 60 May 1995: Phthalates in paper and board packaging.
http://www.foodstandards.gov.uk/science/surveillance/maffinfo/

(7) Aurela, B., Kulmala, H. and Soderhjelm, L. Phthalates in paper and board packagings and their migration into Tenax and sugar. *Food Additives & Contaminants* (1999), 16:571-577.

(8) prEN 14479 Flexible packaging material - Determination of residual solvents by dynamic headspace gas chromatography.

(9) Amtliche Sammlung von Analysenverfahren nach § 35 LMBG, Methode B 82.02 - 2 "Nachweis der Verwendung verbotener Azofarbstoffe auf gefärbten textilen Bedarfsgegenständen".

(10) Amtliche Sammlung von Untersuchungsverfahren nach §35 Lebensmittel- und Bedarfsgegenständegesetz, Methode L 00-00-6: Bestimmung von primären aromatischen Aminen in wässrigen Lebensmittelsimulanzien. (Official Collection of Methods of Analysis under § 35 of the Foods and Other Commodities Act, Method No. L 00-00.6: Determination of primary aromatic amines in aqueous food simulants).

(11) EN 648 "Paper and board intended to come into contact with food - Determination of the fastness of fluorescent whitened paper and board".

(12) Johns, S.M., Gramshaw, J.W., Castle, L. and Jickells, S.M. Studies on functional barriers to migration. 1. Transfer of benzophenone from printed paperboard to microwaved food. *Deutsche Lebensmittel-Rundschau*, (1995) 91:69-73.

TECHNICAL DOCUMENT No. 3

GUIDELINES ON PAPER AND BOARD MATERIALS AND ARTICLES, MADE FROM RECYCLED FIBRES, INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Version 2 – 10.06.2004

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1. Introduction

The Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs are 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 2 of EU Framework Directive 89/109/EEC.

Paper and board made in part or in full from recycled fibres intended to come into contact with foodstuffs should comply with the requirements of *Resolution ResAP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs* and related technical documents. However such paper and board should be subject to some additional requirements to ensure their safety in use due to the presence in the feedstock of constituents of printing inks, adhesives and other substances, e.g. from paper not intended for food contact.

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 assurance.

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 Guidelines will be amended, as necessary, by the Committee of experts on materials coming into contact with food, to take account of technological developments in the processing of recovered paper, improvements in analytical techniques and increased knowledge of the toxicology of chemical substances.

2. Good manufacturing practice

Good manufacturing practice (GMP) is a fundamental part of quality control and product safety assurance.

Basic elements of GMP include:

- Availability of production manuals and instructions;
- Compliance with specified quality requirements for raw materials;
- Appropriate storage and handling conditions;
- The application of processes to avoid or remove contamination;
- Specifications for end-product testing;
- Information to ensure traceability and to maintain production records.

Some of these 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 3, 5 and 6 of the Guidelines.

Furthermore, see also *Technical document No. 4 - CEPI guide for good manufacturing practice for paper and board for food contact*.

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 *Technical document No. 4 - CEPI guide for good manufacturing practice for paper and board for food contact*).

The groups of recovered paper listed below are defined in generic terms for the purpose of the Guidelines. Where industry use 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.

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

Paper and board manufactured with substances of *Technical document No. 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 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 *Technical document No. 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 or lightly printed or lightly coloured[1].

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);

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);

White writing and printing paper originating from offices (EN 643:2001 - 3.05);

White continuous stationery paper (computer paper) (EN 643:2001 - 3.07);

Unprinted or lightly printed, unused kraft paper (EN 643:2001- 4.07, 4.08);

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[1] 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.)

Unprinted or lightly printed, unused packages (EN 643:2001 - 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 643:2001 - 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 643:2001 - *1.04, 1.05);*

Unused boxes and sheets of corrugated board (EN 643:2001 - 4.01);

Printed paper from households, such as newspaper, pamphlets, magazines, catalogues etc. (EN 643:2001 - 1.11);

Mixed papers and board from households (EN 643:2001 - 1.02, 5.01);

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

3.2. 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;

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

Old archives from libraries, offices etc., if they contain PCBs.

3.3. Speciality papers

For paper intended for contact with hot, aqueous liquids, such as tea bags, coffee filters and cooking pouches, or for use at high temperature, such as baking paper, recovered paper of Groups 2 and 3 should not be used.

4. Foodstuff types

4.1. Classification of 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 should be used to determine the food type for individual foodstuffs except where Chapter 4 of the Guidelines indicates otherwise.

4.1.1. 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 include 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.

4.1.2. 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.

4.1.3. Type III - Foodstuffs which are shelled or peeled or washed before consumption

Examples of Type III foodstuffs are fruits, vegetables, nuts and potatoes.

5. Current process technologies and their purpose

This chapter describes current process technologies applied to the raw materials taking into account the intended use of the end-product. It deals with the processes applied to the recovered paper at the fibre preparation stage. Paper-making processes are not covered. The information in this chapter is based on current technical knowledge and should be reviewed in the light of technological developments. It is recognised that the groups of recovered paper defined in Chapter 3 of the Guidelines differ in their potential for chemical and microbiological contamination of foodstuffs depending on the intended use of the end-product. Recycling process technologies should be adequate to counter this potential for contamination without imposing unnecessary restrictions. The most efficient processes should therefore be applied where necessary. The use of chemical reagents, the effects of washing together with process water treatments, and temperature controls provide some of the means for achieving chemical decontamination of raw materials.

These process technologies, which are summarised in Table 1 of Chapter 5 of the Guidelines and defined in Appendix 1 below should be seen in the context of the Consolidated matrix of Chapter 7 of the Guidelines. They link raw materials to the intended use of the end-product, and to the wider context of Good manufacturing practice (see *Technical document No. 4 - CEPI guide for good manufacturing practice for paper and board for food contact*).

5.1. Types of process

5.1.1. Mechanical cleaning

Repulping, deflaking cleaning and screening are examples of mechanical cleaning and they are intended to remove physical impurities. However, their impact on chemical contamination is significant, and is due to the dilution effect since these processes are carried out at low consistency. Low size components such as fillers and “fines” (fine fibre fraction) are released in the process water, and may be removed at subsequent stages. In addition the level of insoluble contaminants is reduced at this stage. It must be emphasised that part of the process water, including dissolved and suspended material, is not re-used in the recycling plant, but is rejected to the wastewater treatment plant.

5.1.2. Washing

Washing is carried out by successively lowering the consistency by dilution and increasing by thickening. Some processes are best carried out at high consistency for mechanical and energy efficiency reasons, such as dispersion. Some screening and cleaning has to take place prior to this stage at a low consistency, which means that a thickening stage is employed. Normally, this is carried out by squeezing out excess water, for example in a screw press, belt press or drum filter. Water-soluble contaminants are dissolved and may be removed if adequate process water treatments are used.

5.1.3. De-inking by washing or flotation

De-inking may be carried out either by washing or by flotation. The purpose of de-inking is to remove ink from printed material. Together with ink particles, some dissolved and colloidal contaminants are removed. Surface-active agents, such as soaps, are used to help separation.

5.1.4. Thermal treatment

This stage is carried out at high consistency. The fibres are subjected to high mechanical forces together with a steam treatment, generally at temperatures of 60° C, but temperatures of 140 °C may be applied. This process is called hot dispersion and it can be combined with a chemical treatment by adding chemicals. Thermal treatment reduces the level of chemical and microbiological contamination.

5.1.5. Chemical treatment

Chemical treatment may be carried out together with hot dispersion. Generally used chemicals are hydrogen peroxide, formamidine sulfinic acid (FAS) and sodium hydrosulfite.

The purpose of bleaching is to increase the brightness of white grade papers. Generally used chemicals are hydrogen peroxide, FAS, sodium hydrosulfite, ozone and oxygen.

Process water treatment aims at controlling microbiological activity. It includes the use of biocides, slimicides and enzymes.

The purpose of process water clarification is to remove suspended solids and colloidal materials from the water to be re-circulated in order to provide water of a suitable quality to be re-used back in the process. It avoids recontamination at dilution stages.

Chemical treatments reduce the level of chemical and microbiological contamination.

TABLE 1 - CURRENT PROCESS TECHNOLOGIES AND THEIR PURPOSE

Unit operation	Type of process	Consistency (%)	Equipment / Use of chemicals	Purpose / Efficiency
Repulping	Mechan. Cleaning	5 – 15	Pulper Use of alkali and/or peroxide (in de-inking lines)	Separation of fibres from each other, from fillers and other non-fibre components Ink detachment
Deflaking	Mechan. Cleaning	5 – 15	Deflaker	Disintegration of fibre flakes into fibres Ink detachment
Pre-cleaning	Mechan. Cleaning	5 – 15	High density cleaner Rotating drum	Removal of coarse, high density contaminants (density > 1): sand, glass, pebble, metal particles
Pre-screening	Mechan. Cleaning	4 – 5	Pressurised screens with holes or slots	Removal of coarse, usually lightweight, contaminants: plastic films, textiles, etc., according to their size and shape
De-inking by flotation	De-inking	1 – 1.5	Flotation cells Use of surfactants (soaps)	Removal of ink particles, specks, low size stickies, etc. (sub-millimetre size)
De-inking by washing	De-inking, Washing	1 – 1.5	Washer Use of surfactants (soaps)	Removal of ink particles, specks, low size stickies, etc. (sub-millimetre size)
Washing	Washing	1 – 1,5	Washer	Removal of specks, low size stickies, etc. (sub-millimetre size), of soluble and colloidal material
Fine cleaning	Mechan. Cleaning	0.7 – 1	Cleaner Hydrocyclone	Removal of ink particles, residual high density impurities
Fine screening	Mechan. Cleaning	0.7 – 4	Pressurised screens with slots or holes	Removal of residual low density impurities according to size and shape (varnishes, sticky agglomerates, ink particles, etc.)
Thickening	Washing	0.7 – 5 15 – 30	Filter drum Screw press	Raise consistency, in particular prior to hot dispersion or bleaching, removal of fillers, dissolved material, fines, etc.
Hot dispersion	Thermal treatment	20 – 30	Disperser (high speed) Kneader (low speed) Use of direct steam and possibly peroxide Temp. 60 – 130°C	Dispersion of visible impurities: ink particles, specks, hot melt adhesives, waxes, etc. Residual ink detachment Microbiological decontamination
Bleaching	Chemicals treatment	15 – 30	Reactors, bleaching towers Oxidising or reducing agents Temp. 60°C	Increase of brightness Removal of dyestuffs and in some cases optical brighteners Microbiological decontamination
Process water treatment	Chemical treatment		Use of biocides, antislimes	Microbiological control of process water
Clarification of recirculated water	Chemical treatment		Coagulation tanks Microflotation cells	Decrease of biological oxygen demand (BOD) and chemical oxygen demand (COD) Coagulation and removal of colloidal material and fillers

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 *Resolution ResAP (2002) 1* and related technical documents apply to the end-product. Additional restrictions for the end-product are specified in Table 2 of Chapter 6 of the Guidelines. 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. SCF or JECFA. Where restrictions have not yet been established by a recognised body, the requirements in Table 2 of Chapter 6 of the Guidelines have been made on grounds of prudence, to ensure that migration into foods is kept as low as reasonably achievable.

The end-product should be tested in accordance with the procedure specified in the Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs set out in *Technical document No. 2 – Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs*, in order to ensure compliance with Art. 2 of EU Directive 89/109/EEC.

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 Art. 2 of EU Directive 89/109/EEC 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 tests for possible unknown toxic substances are desirable. However, at present the implementation of chemical screening tests for unknown substances might not be feasible. Furthermore, the knowledge about the applicability of toxicological screening tests for paper and board is insufficient for the time being although it should be noted that studies are in progress to establish the validity of these tests for paper and board. The use of these chemical or toxicological screening tests on paper and board should be evaluated and should be recommended in the future where necessary, based on new developments and results in this field.

TABLE 2 - SPECIFIC REQUIREMENTS

Substance	Requirements (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 (diethylamino) 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)	Levels in paper and board should be kept as low as reasonably achievable, to minimise migration into food
Partially hydrogenated terphenyls (HTTP)	Levels in paper and board should be kept as low as reasonably achievable, to minimise migration into food
Phthalates	See EU Directive 90/128/EEC or Synoptic document (convert TDI to SML using convention TDI x 60=SML and convert SML to QM using the formula specified 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 Technical document No. 2)
Solvents	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
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) Testing required for Food Type I only
Fluorescent whitening agents (FWA)	The migration of these substances should not be detectable when measured in foodstuffs[1] Testing required for Food type I only
Primary aromatic amines, suspected to be carcino-genic [2]	These substances should not be detectable when measured in paper (limit of detection of 0.1 mg/kg paper) Testing required for Food Type I only
Polycyclic aromatic hydrocarbons (PAH)	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

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

[2] 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

7. Consolidated matrix

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 of the Guidelines.

The process technologies listed in Table 3 of Chapter 7 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 Chapter 6 of the Guidelines. Other processes or combination of processes may be used in order to fulfil these requirements. It is the responsibility of industry to demonstrate through Good manufacturing practice (see *Technical Document No. 4 – CEPI Guide for good manufacturing practice for paper and board for food contact*) that the end-product meets the requirements of Art. 2 of Council Directive 89/109/EEC.

TABLE 3 - CONSOLIDATED MATRIX
PART I

The matrix should be read in conjunction with the rest of the Guidelines

Food type (Chapter 4)	**Recovered paper group** (Chapter 3)	**Process technologies** (Chapter 5) (other processes or combinations of processes may be used provided that the end-product fulfils the requirements of Chapter 6)	**Additional end-product requirements** (Chapter 6) (tests should be carried out for other toxic substances whenever there are grounds to suspect their presence in the end-product)
Food type I Aqueous and/or fatty foodstuffs (including defrosted)	Group 1: Paper and board manufactured with substances listed in Technical document No. 1	Mechanical cleaning	The requirements of Table 2 of the Guidelines do not apply
	Group 2: Paper and board manufactured with substances not listed in Technical document No. 1, unprinted or lightly printed or lightly coloured	Mechanical cleaning Washing Chemical treatment, unless it is not necessary Thermal treatment, unless it is not necessary	Michler's ketone, DEAB, DIPNs, HTTP, Phthalates, Solvents, Azo colourants, FWAs, Aromatic amines, Polycyclic aromatic hydro-carbons, Benzophenone
Food type II Dry, non-fatty foodstuffs, including frozen	Group 1: 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' (Technical document No. 1)		The requirements of Table 2 of the Guidelines do not apply
	Group 2: Paper and Board which may be manufactured with substances not listed in Technical document No. 1, unprinted or lightly printed or lightly coloured	Mechanical cleaning Washing Thermal treatment, unless it is not necessary	DIPNs, HTTP, Phthalates, Solvents, Polycyclic aromatic hydrocarbons, Benzophenone
	Group 3: Printed paper and board, corrugated board from supermarkets and paper and board from households and industry	Mechanical cleaning Washing Chemical treatment, unless it is not necessary Thermal treatment, unless it is not necessary De-inking, unless it is not necessary	DIPNs, HTTP, Phthalates, Solvents, Polycyclic aromatic hydrocarbons, Benzophenone
Food type III Foodstuffs which are shelled, peeled or washed	Group 1: Paper and board manufactured with substances Listed in Technical document No. 1	Mechanical cleaning	The requirements of Table 2 of the Guidelines do not apply
	Group 2: Paper and Board which may be manufactured with substances not listed in Technical document No. 1, unprinted or lightly printed or lightly coloured	Mechanical cleaning	The requirements of Table 2 of the Guidelines do not apply
	Group 3: Printed paper and board, corrugated board from supermarkets and paper and board from households and industry	Mechanical cleaning Washing	The requirements of Table 2 of the Guidelines do not apply

APPENDIX 1

Recovered paper process technologies

1.1. Repulping

This is always the first step. During pulping, fibres are separated and some additives added to the paper during the printing and converting process are separated from the fibres.

Various kinds of devices can be used : low, medium or high consistency pulpers and drums are proposed by machinery suppliers.

The choice of the type of pulper has to be made by considering various parameters including the efficiency of defiberizing and energy consumption but mainly with respect to:

- efficient ink detachment when de-inking is to be carried out. Chemicals (e.g. caustic soda, sodium silicate and soap) are used in the pulping stage in order to improve ink release from the fibres. Bleaching chemicals (such as hydrogen peroxide) can also be used in this stage;

- minimising the breaking-up of contraries, which could reduce their removal efficiency.

1.2. Removal of contraries

The removal of contraries is based on their physico-chemical properties, which differ from those of cellulosic fibres :

- differences in size : particles smaller than fibres can be removed by washing and contaminants larger than fibres can be removed by screening (Fig. 1 and 3);

- differences in density : particles having a density other than 1 can be removed by centrifugal cleaning. Some cleaners are designed to remove high density (>1); contaminants and others to remove lightweight contaminants (density < 1) (Fig 2);

- differences in surface properties : flotation can remove hydrophobic particles, additives (collectors) are generally used to improve the flotation efficiency (Fig 4).

In order to ensure good cleaning efficiency, size, shape and density must be considered; flotation efficiency mainly depends on surface properties.

Figure 1: Principle of screening

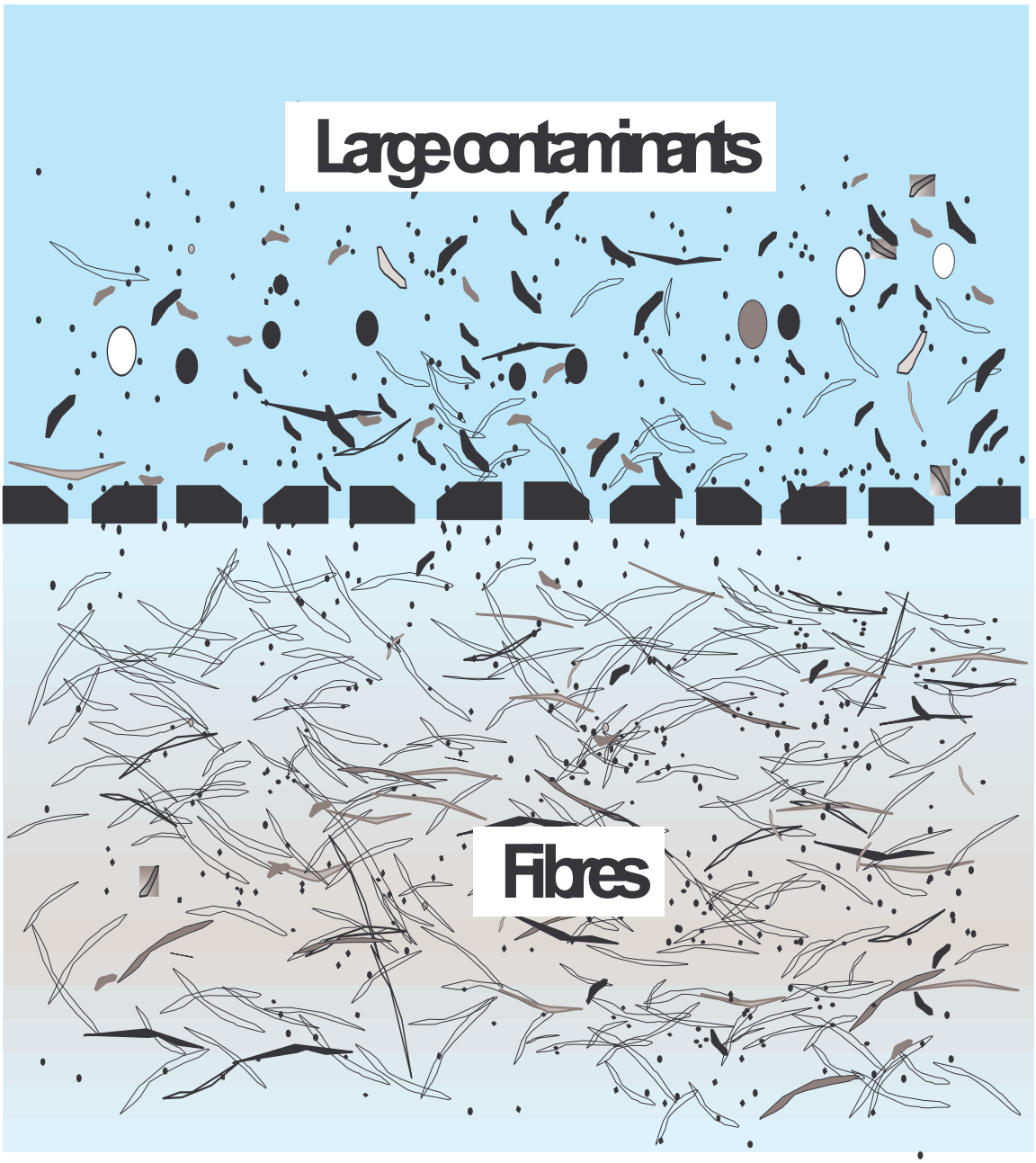
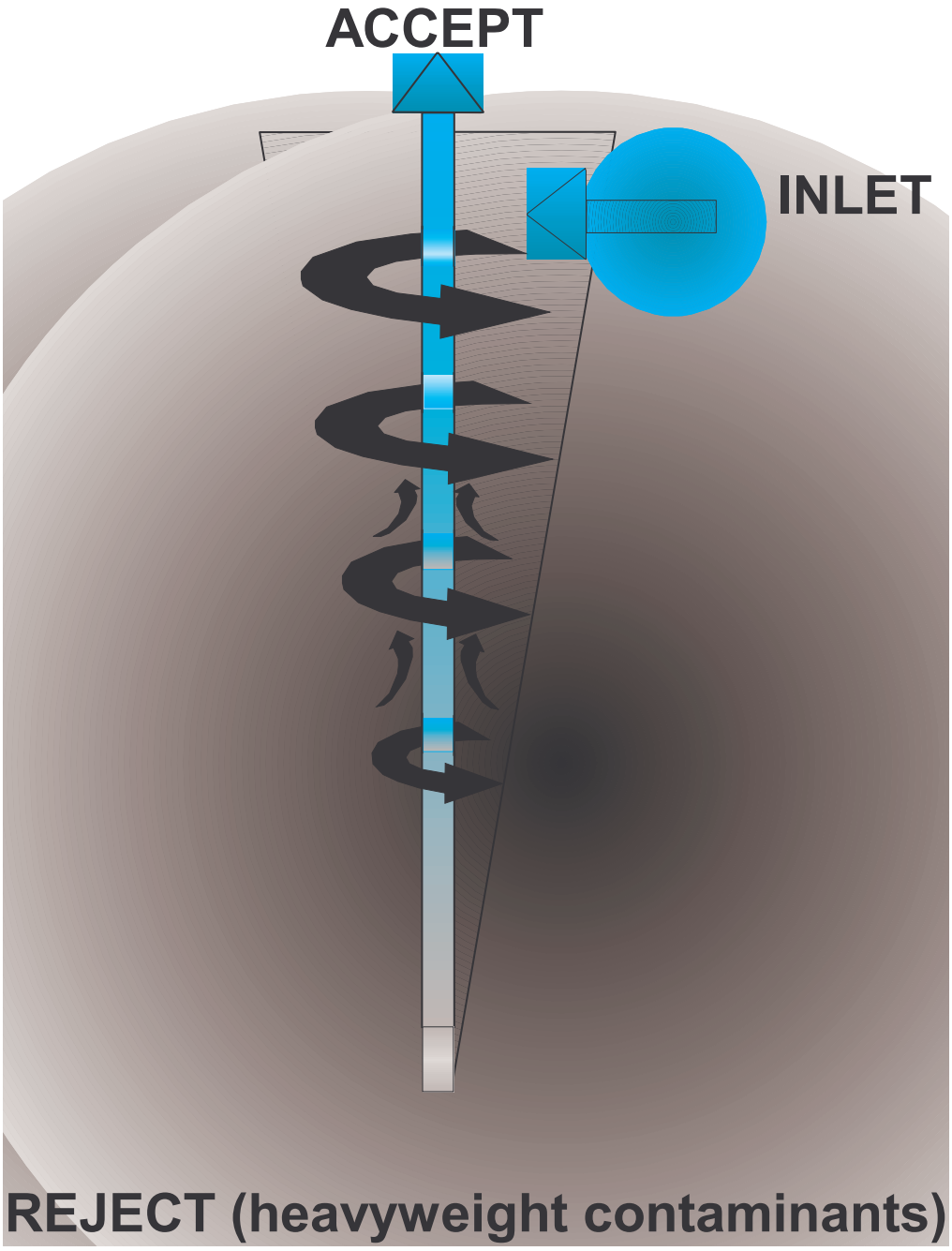
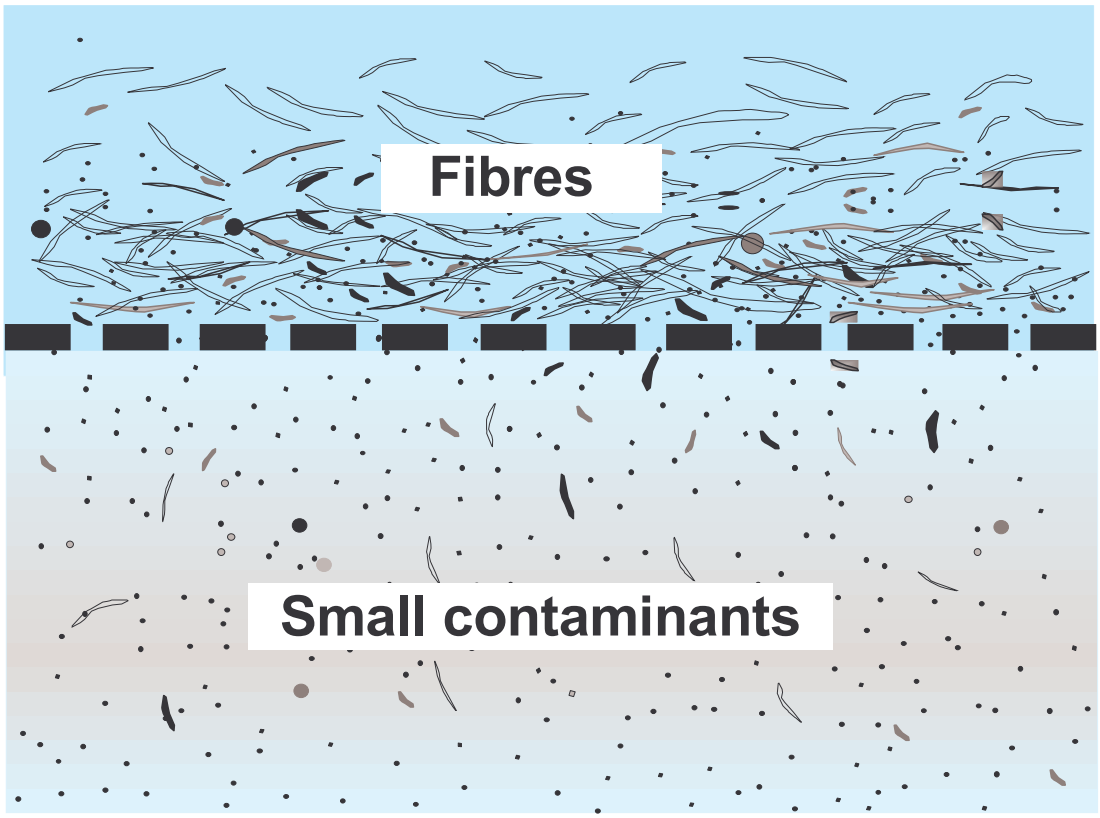


Figure 2: Principle of cleaning



Washing can remove fillers and finely divided ink particles, as well as colloidal materials dispersed in water. Very efficient cleaning is obtained. The drawback is the use of important volumes of water, which need a suitable treatment, and a significant loss of fibrous and non-fibrous material. The losses are removed as sludge by the water treatment.

Figure 3 : Principle of washing



Flotation can remove ink (oil-based ink with hydrophobic characteristics), varnishes and various adhesive particles. Flotation efficiency also depends on particle size, which has to be severely controlled at the pulping stage.

Cleaning (heavy contaminants) can remove metals, sand, glass, and some varnish particles. This technique is also used to remove toner ink after agglomeration with appropriate chemicals.

Cleaning (lightweight contaminants) can remove hot melt adhesives and various plastic particles.

Screening can remove large contaminants including plastic films, shives, wet strength papers. Hole screens are efficient with flat contraries, such as varnish particles ; they are followed by slot screens which remove granular particles. The slot width is usually 150 µm. Screens with 80 µm wide slots are currently being developed.

Process water treatments are implemented in order to remove fillers and inks from washing waters and, in some cases, colloids in thickening water. The most common technique involves microflotation. Additional treatments with biocides are used to control microbial growth in the circuits. This is also applicable to water on the paper machine.

1.3. De-inking by flotation

De-inking lines are made up of a combination of the various techniques. The number of stages in the process depends on the grade of the furnish and the quality requirement of the de-inked pulp to be produced.

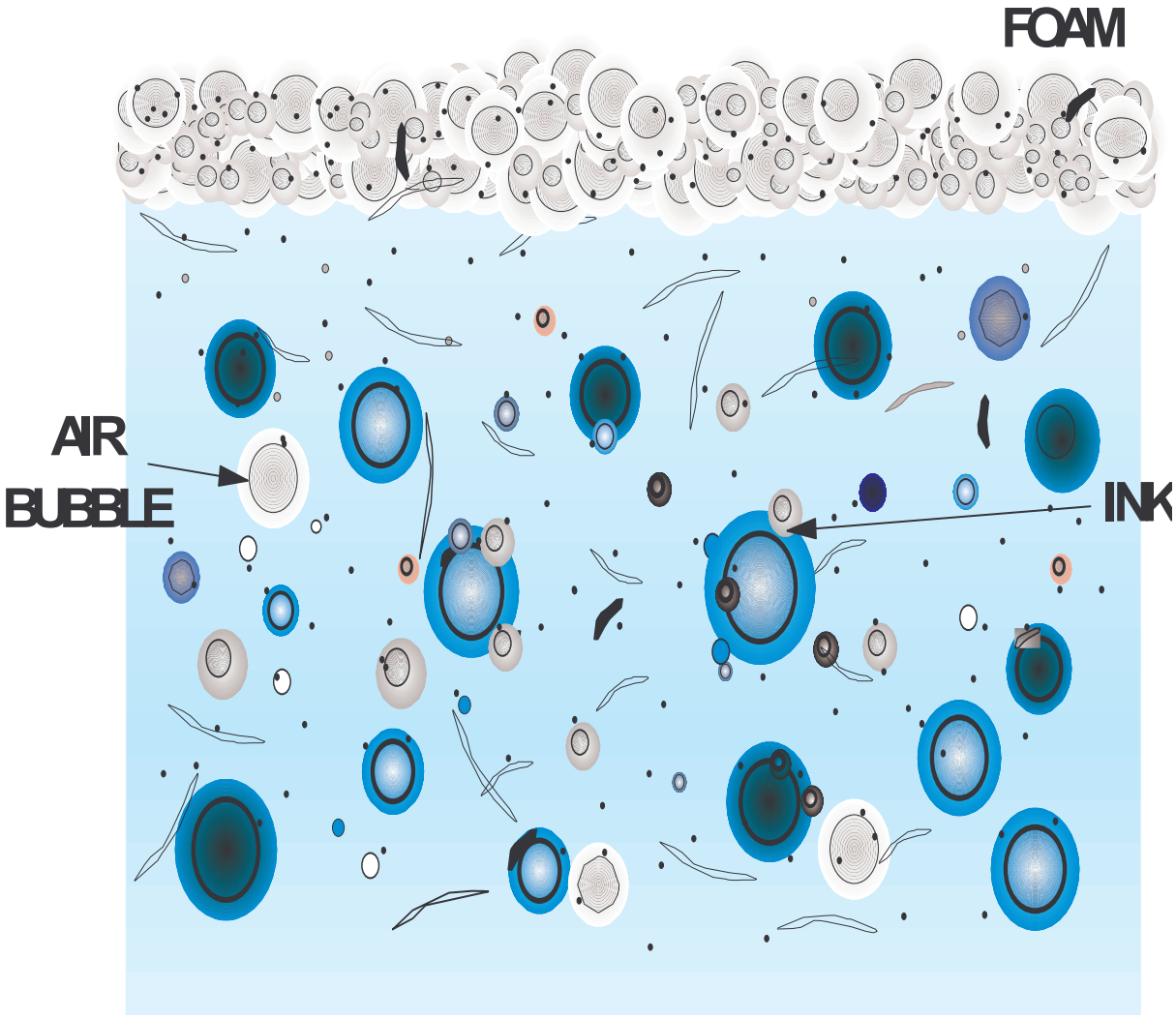
Recovered papers are defiberised in a medium consistency pulper or a drum pulper (15 to 18% consistency). After dilution, coarse screening removes large contraries such as plastic films and wet-strength papers. High density cleaning removes heavy contraries such as staples and sand.

Hole and slot screening are performed at medium consistency (up to 4 %). Then, the pulp is diluted down to between 1 and 1.4 % consistency and submitted to flotation. Cleaning stages (heavy and lightweight) take place after flotation, generally after a complementary dilution (down to 0.7 %). A fine slot screening stage is generally implemented after cleaning. Then the pulp is thickened on a disk filter. The white water is treated and re-used for dilution in the various stages of the process. After the filter, the pulp is stored or diluted with water from the paper machine.

After the thickening stage on the filter, a screw press is used to increase the consistency up to 30 %, and the pulp may be submitted for hot dispersing and peroxide bleaching.

Post-de-inking (a second de-inking stage, using the same techniques as in the first stage) performed after hot dispersing and bleaching is carried out in some mills, as an efficient way to improve brightness and cleanliness.

Figure 4: Principle of de-inking by flotation



1.4. Hot-dispersion

This technology, which is not concerned with contraries removal, can also be used in recovered fibres processing lines. Hot dispersing with low-speed kneaders or high-speed dispergers can be used to disperse residual contaminants such as hot-melt adhesives or specks from varnish particles and toner inks. Some contaminants such as adhesive particles from labels or tapes show little dispersion ability.

Hot dispersion is an efficient treatment for the detachment of residual ink particles in the case of processes involving two or more de-inking loops[1].

1.5. Bleaching

So-called upgrading treatments can be applied to the pulp, whether de-inked or not. Brightness is often an important concern and bleaching treatments can be applied to the reprocessed pulp. Hydrogen peroxide (oxidative) bleaching and sodium hydrosulfite (or FAS) (reducing) bleaching are the most common treatments used for recovered paper bleaching[2]. Bleaching restores the initial brightness of cellulosic fibres by destroying chromophores[3]. This chemical action may also remove undesired chemical substances and micro-organisms. Bleaching is in certain cases aimed at colour stripping or destruction of optical brightening agents[4]. Visual uniformity of the pulp (so-called cleanliness) is also an important quality. As described previously, this can be improved by hot dispersing.

1.6. Other upgrading treatments

1.6.1. Oxygen treatment

This treatment is carried out in a gaseous oxygen environment, at a high temperature and under pressure, with metal chelating agents.

1.6.2. Ozone treatment

Ozone is produced by circulating pure oxygen gas between electrodes at a high voltage. It is a highly reactive gas, which destroys chromophores and micro-organisms. Under certain conditions, colourants and fluorescent whitening agents may be removed[5].

1.7. Clarification of recirculated water

Process waters are always re-used to a certain extent. The trend is towards more and more closed systems. The drawback is an increased concentration of unwanted substances: dissolved organic and inorganic substances (carbohydrates such as starch and hemicelluloses, salts, colloids etc.), suspended solids (fines, fibres, filler and ink particles etc). Increased values of chemical and biological oxygen demand (resp. COD and BOD), suspended solids and microbiological counts are recorded.

Dissolved air flotation systems are used for the removal of suspended solids. Their efficiency is poor towards colloids (adhesives or polymeric additives arising from recovered papers). A chemical destabilisation using strongly cationic polyelectrolytes will cause coagulation of the colloids, which then may be partially removed in the microflotation cells[6].

1.8. Process water treatment

Microbial growth is controlled by selected biocides. The aim of so-called anti-slime treatments is to avoid the development of scale (aggregates of microbial colonies) or catalase, an enzyme which is produced by most aerobic micro-organisms for fighting peroxides and free radical metabolites.

The presence of catalase results in hydrogen peroxide decomposition and low brightness gain at the bleaching stage [7]. An "absolute" microbiological cleanliness of process waters is unnecessary. A “critical control point” approach shows that most germs which are present in process waters are destroyed at further stages of the process.

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TECHNICAL DOCUMENT No. 4

CEPI GUIDE FOR GOOD MANUFACTURING PRACTICE FOR PAPER AND BOARD FOR FOOD CONTACT (prepared by CEPI - 19.12.2002)

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SECTION I – SCOPE, GENERAL PRINCIPLES, ETC.

1. Scope and field of application

This Good Manufacturing Practice (GMP) is a technical document containing recommendations for the guidance of paper and board manufacturers. The recommendations apply to the entire production process of paper and board and cover all fibrous compositions, virgin and/or recycled fibres. It also applies to all other activities which normally take place at the paper or board mill including coating, calendering, slitting, sheeting and other mill-based finishing operations. It does not cover converting operations such as plastic coating, corrugating, lamination and so on. It applies to paper and board as defined by the resolution.

Existing product liability legislation should be considered in order to make sure that due responsibility is taken by paper and board manufacturers for all manufacturing factors as they apply to the product end use. It will be the care of paper and board manufacturers to provide users with appropriate product information.

It shall be the responsibility of the users of the paper and board to inform the manufacturers of intended end use.

The recommendations 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 paper manufacturer.

A paper or paperboard material, which the customer has ordered, is thus manufactured according to an agreed quality standard which includes all requirements existing in relevant Directives or regulations or legislation which is applicable for food contact paper and board.

2. General aspects and principles

GMP is based on a quality management system, such as the ISO 9000 series of standards or another, equivalent, recognised scheme and on the relevant principles of a recognised hazard analysis system, such as HACCP (Hazard Analysis Critical Control Point, see Section II, below). These systems are related one to each other since they have the same principles.

For each stage of production, including the receipt of an order, the procurement of raw materials, the different steps of processing, manufacturing and testing, finishing and shipping of the product, a total control has to cover, for example:

manuals;
production instruction documents;
specifications for testing;
handling, storage, packaging, preservation, product identification and delivery;
personal training and commitment, internal auditing;
production and quality records.

A high level of housekeeping, in terms of “appropriate level of cleanliness and order”, has to be maintained throughout the whole process.

3. Particular aspects

Among the principles of the GMP, the following have to be highlighted:

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

3.2. Personnel training

All personnel should be made aware of their duties and responsibilities concerning the requirements of the current legislation and of this code of GMP. Their training should be performed and assessed in a suitable manner. New employees will be made aware of food contact manufacturing requirements as part of their induction process. Records of assessments and training received will be maintained.

3.3. Quality system

A quality system has to be installed and maintained in order to assure product conformity to the specified requirements. Procedures have to be implemented to avoid misunderstanding when producing the order.

3.4. Raw materials (pulps and non-fibrous components)

A system has to be implemented to ensure that only raw materials in conformity with the needs of the end product are purchased. Non-fibrous constituents shall be selected according to Technical document No 1 'List of substances used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs'.

Pulps shall comply with the resolution and, where applicable, with the guidelines on recycled fibres.

Only "qualified suppliers" are traded with.

Qualification may be either:

a) by certification to ISO 9000 (or another recognised system).

b) by the confidence, consistency and reliability established with a supplier due to the existence of a long-term business relationship backed up by continuing quality assurance tests on the raw material.

All materials from a new supplier or of a new grade must 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.

All incoming raw materials should be clearly identified and stored only in specially designated areas. Appropriate cleanliness and hygiene are to be maintained in the raw materials storage areas.

Control upon reception of raw materials is implemented taking into account also the extent of control carried out by the suppliers, and the fact that a registered proof of raw material compliance may be provided upon delivery.

3.5. Process control

The process has to be clearly defined and planned; it has to be demonstrated that the process runs continuously under controlled conditions. Great importance must be given to the control of the process parameters due to the complexity of paper and board technology, particularly to avoid and remove possible contamination in order to fulfil the end product requirements.

Each mill/producer has to identify and keep under control in its own process the critical control points related to the hazard analysis system (see below) and food contact requirements. The microbiological load within the mill should be monitored but testing should be performed only where indicated by the hazard analysis (see below).

3.6. Handling, storage, packaging preservation and delivery

These aspects 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 an end use that is permitted within the Directives, regulations, and legislation for food contact.

Appropriate cleanliness and hygiene are maintained in the storage areas.

A clear procedure needs to be developed to ensure dispatch of products that meet the agreed quality standards.

3.7. Traceability

An accurate system to enable tracking through the production process from raw materials through to final customer order has to be implemented.

3.8. Labelling

All finished products must be labelled so that production history, including details of raw materials, manufacturing dates, etc. may be traced.

3.9. Testing

Testing and inspection procedures have to be defined, to verify the compliance of the final product with the agreed quality standards and with the Resolution and Guidelines.

3.10. Quality records

The results 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.

3.11. Testing methods

When available, standardised testing methods are preferred (e.g. CEN, ISO, etc.).

3.12. Calibration procedures

Inspection, measuring and test equipment must be regularly maintained and calibrated; records of these activities should be kept.

3.13. Auditing

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

SECTION II - HAZARD ANALYSIS APPROACH

1. Inventory of hazards, suggested means of prevention

The manufacturing stages of reeled and sheeted articles intended to come into contact with foodstuff are listed, from raw materials to shipping.

The method implemented for the present Guide consists of listing the hazards related to each manufacturing stage using the principles contained in the HACCP method.

For each manufacturing stage, Tables 1 to 5 indicate which hazards may be encountered and the means of prevention.

Possible additional hazards related to specific processes, plants or products have to be inserted directly by each mill.

In Tables 1 to 5, hazards are defined in conformity with the definition given in the note below.

Note:

The HACCP method, as used in food manufacturing and processing, is described in the revised draft Guidelines indicated in Annex II of the document referenced ALINORM 97/13A *Revised draft Guidelines for the application of hazards, Analysis and Critical Control Point (HACCP) and system*, document which was elaborated by a commission from the international authority Codex Alimentarius. This document gives the following definition of the word “hazard”: *A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect* . The analysis of hazards through the HACCP method is a procedure consisting of collecting and estimating the information relative to the hazards and to the conditions leading to their presence, in order to identify which hazards and conditions are significant regarding food safety, so that they may be submitted to the HACCP plan mentioned in the standard.

2. Manufacturing stages for paper products

Raw materials
- selection prior to purchase
- transport (delivery to factory)
- reception
- storage
- handling

Fibre preparation process technologies
- de-flaking, de-inking, hot dispersion, etc.

Preparation and introduction of additives

Refining, cleaning, diluting, sheet formation

Drying

Surface treatments

Winding and finishing (calendering, cutting)

Control of finished product

Labelling

Storage of finished products

Shipping

TABLE 1

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 Technical document No 1 'List of substances used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs'
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 carrier 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 2

STAGES	POSSIBLE HAZARDS	SUGGESTED MEANS OF PREVENTION
NON-FIBROUS RAW MATERIALS **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 Annex II of the resolution
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 carrier and supplier.
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 microbiological source, linked with absence of cleanliness.	Appropriate premises. Maintenance of cleanliness of premises (appropriate cleaning, rodent 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 3

STAGES	POSSIBLE HAZARDS	SUGGESTED MEANS OF PREVENTION
RE-PULPING AND OTHER PROCESS TECHNOLOGIES	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 (rodent control, etc.).
	Contamination from a chemical source, linked with production shift (from non-food to food products)	Manufacturing specifications, grade shift procedure.
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.	Procedures. Records.
	Contamination from micro-organisms as a consequence of microbiological growth of a preparation (e.g. amylaceous glues).	Compliance with procedures. Cleaning of preparation chests. Storage conditions (e.g. temperature). Preventive treatment with biocides.

TABLE 4

STAGES	POSSIBLE HAZARDS	SUGGESTED MEANS OF PREVENTION
REFINING, CLEANING, DILUTING, SHEET FORMATION	Contamination from a microbiological source, linked with absence of cleanliness (chests, circuits).	Cleaning procedures. Underwire water treatment
	Contamination from a chemical source, from cleaning agents of clothing.	Where cleaning agent is not on positive list, segregation of cleaning water from other parts of machine is needed
SURFACE TREATMENT	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 microbiological growth of a preparation.	Compliance with procedures. Cleaning of preparation chests. Storage conditions (e.g. temperature). Preventive treatment with biocides
WINDING AND FINISHING **(FOR REELS)** **PALETTISATI0N (FOR SHEETS)**	Soiling due to condensation or to premises dust fallout onto the reel.	Appropriate maintenance of premises.
	Contamination from a chemical and/or microbiological source due to the lack of cleanliness of pallets or inappropriate treatment of the wood	
WRAPPING AND PACKAGING	Contamination (toxicological and /or organoleptic) from a chemical and/or microbiological source due to the lack of cleanliness or lack of integrity or from packaging materials.	Appropriate maintenance and cleanliness of premises. Selection of an appropriate packaging material.
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.
	Contamination from a microbiological source linked with humidity, temperature, and absence of cleanliness of premises (undesirable animals and insects).	Cleaning and sanitation (UV insect control lamps and rodent control)

TABLE 5

STAGES	POSSIBLE HAZARDS	SUGGESTED MEANS OF PREVENTION
VERIFICATION 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 to the required utilisation.	Compliance with procedures.
STORAGE OF FINISHED PRODUCTS	Degradation of the physical 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, rodent control).
	Contamination from a biological source such as animals, insects or micro-organisms, linked with absence of cleanliness within storage areas.	Compliance with procedures. Maintenance of cleanliness of premises (appropriate cleaning, rodent 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. Compliance with procedures.
	Contamination from a microbiological source, linked with bad condition and absence of cleanliness of means of transport.	
	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.

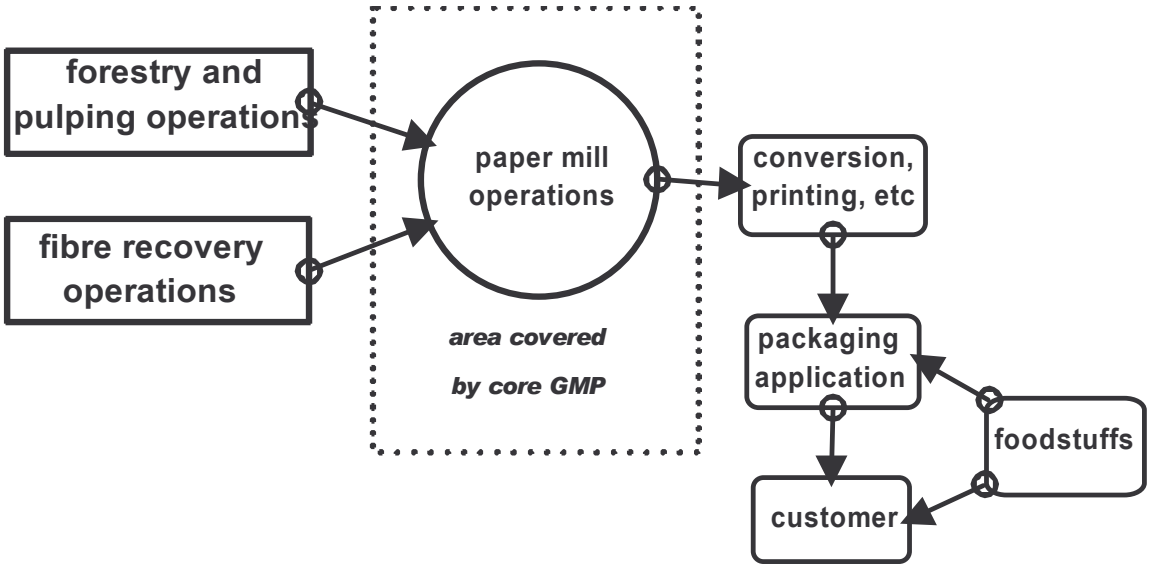
SECTION III - EXPLANATORY NOTE - THE PAPER-MAKING PROCESS AND GLOSSARY OF TERMS

1. Introduction

This note is designed to accompany the Good Manufacturing Practice written for paper and board for food contact. It contains a brief description and schematic diagram of the paper-making process (Figure 2) together with a glossary of terms (Table 6) used in the GMP.

2. The manufacturing chain

The following diagram shows a simplified form of the manufacturing chain from forest to foodstuff.



This shows clearly that the Good Manufacturing Practice covers only a restricted portion of the manufacturing chain. For the purposes of this document, this is referred to as “paper mill operations” and is now described in more detail and illustrated in the schematic diagram shown later. It is important to note that certain paper products are converted within the paper mill and then sold direct to retail outlets. These will be subject to special extensions to the GMP.

3. Paper manufacture (terms in *italics* are found in the glossary)

3.1 Raw Materials

Paper and board is manufactured mainly from pulp which is derived from wood using a variety of mechanical and chemical processes and recovered paper. The mixture used depends upon end use and ranges from 100% *virgin pulp* through to pulp made from 100% *recovered paper*. There are speciality areas which also use synthetic fibres, cotton, etc. *Pulp* is supplied direct from forestry and *pulping* operations. It is delivered to the paper mill in a dry state in stand-alone mills or in a wet state in mills which are integrated with *pulp* manufacture. *Recovered paper* comes from merchants who use collection systems. It may be subject to those treatments designed for recovered papers before being passed to the paper machine. These could include: *special pulping*, *de-inking, bleaching, hot dispersion, washing, oxygen treatment, ozone treatment* and *enzymatic treatment*.

Whatever the source, the *pulp* is passed to a *re-pulping* unit where it is mixed with up to 100 times its weight of water and subjected to violent agitation intended to produce a suspension of individual fibres in water. At this, and subsequent stages, *auxiliary chemicals, additives* and *fillers* may be added. The *auxiliary chemicals* and *additives* are usually combined with the fibrous raw materials at levels below 1% - 2%. Typical materials include sizing agents to bond the sheet together, pH control agents, de-watering aids, etc. *Fillers* usually consist of clay, calcium carbonate or titanium dioxide and are added to modify the optical properties of the paper and board or as a fibre substitute.

3.2 Paper machine

The fibrous suspension or *stock* is pumped, via *storage chests*, various types of cleaning equipment and *refiners*, to the paper machine. Here, yet further water is added to produce a fibre suspension of as little as 1 to 10 parts fibre to 1000 parts water and the resulting mixture is passed into a *head-box* which squirts it through a thin slit across the full machine width (typically 2 - 6 m) on to a moving woven *wire* mesh. The water is then removed by a mixture of gravity and suction in a process known as *sheet formation* where the cellulose fibres start to consolidate into a thin mat which is almost recognisable as paper.

This *web* is then lifted from the wire mesh and squeezed between a series of *presses* where its water content is lowered to nearly 50%. It then passes around a series of cast-iron cylinders, heated to temperatures in excess of 130ºC, where drying and microbiological decontamination takes place. It is then wound into a full machine width reel at a water content of 5% to 8%. Some papers may also undergo *surface treatments* e.g. sizing, grease-proofing, etc. before the reeling process. Throughout its passage from the *wire* mesh to the reeling operation, the paper *web* is supported on various types of *machine clothing* moving at the same speed.

Samples of paper removed from each machine reel are the subject of quality control testing and verification against the required specifications as part of the *quality system*.

3.3 Finishing, storage and despatch

Full machine width reels are passed into a separate area where they are subjected to further operations. These may be either simple operations where the reel is *slit* into a number of more narrow reels or cut into sheets. In some cases, intermediate processes may be performed such as wrapping, *coating* or *calendering*.

The products of the above operations are labelled and placed in a despatch area to await transport. Again, samples may be taken for quality control purposes and the results of earlier tests will be checked against the inventory to ensure that only approved material goes forward.

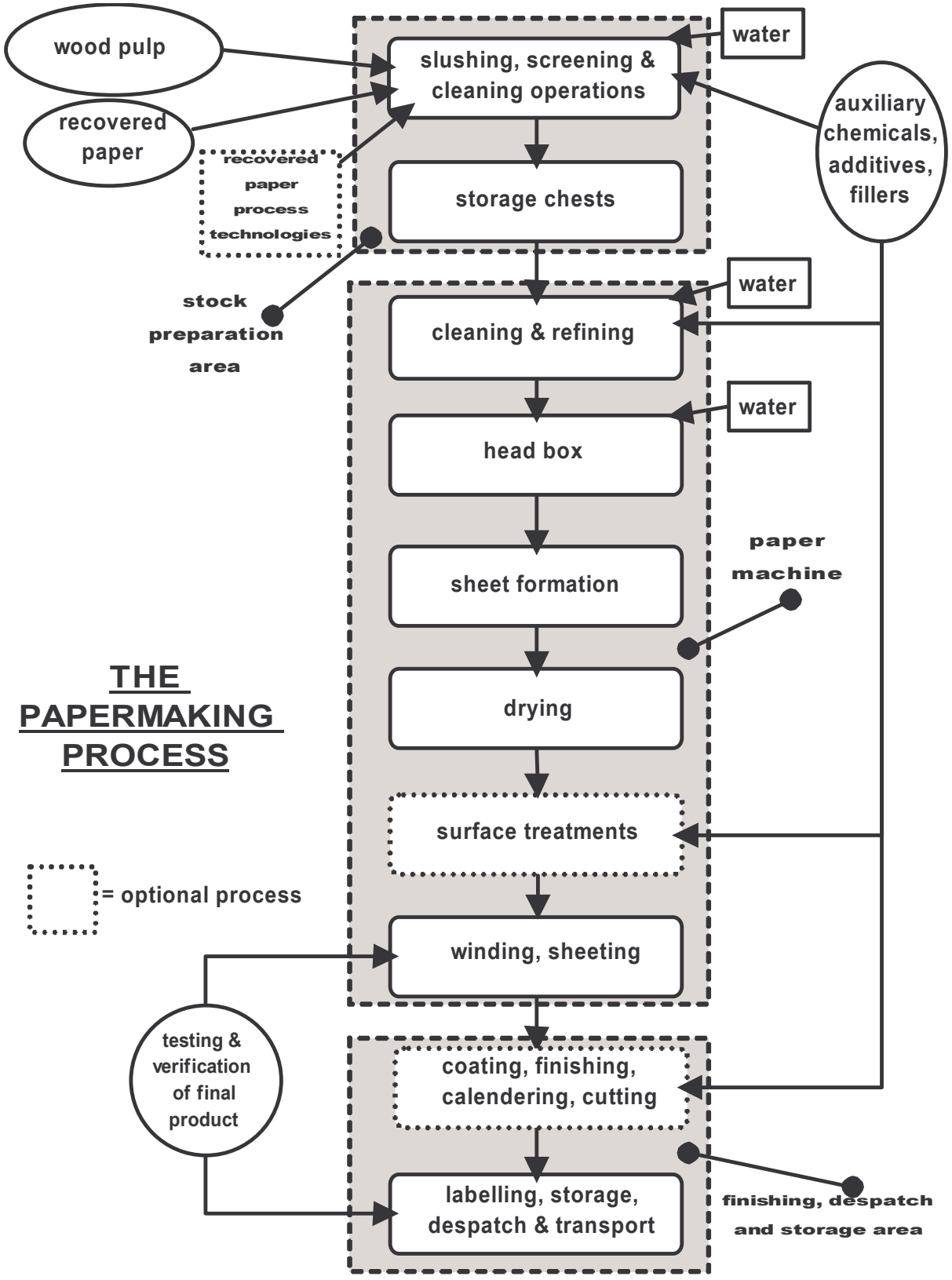

wood pulp
recovered paper
recovered paper process technologies
slushing, screening & cleaning operations
water
auxiliary chemicals, additives, fillers
storage chests
stock preparation area
water
cleaning & refining
water
head box
sheet formation
paper machine
THE PAPERMAKING PROCESS
drying
surface treatments
= optional process
winding, sheeting
testing & verification of final product
coating, finishing, calendering, cutting
labelling, storage, despatch & transport
finishing, despatch and storage area

Figure 2

4. Glossary of terms

Additive	Substance added to the paper-making process to provide specific properties of the final paper and board.
Auxiliary chemical	A chemical added to a stage of paper-making aimed at improving the efficiency of a part of the process.
Bleached pulp	Pulp which has been subjected to bleaching.
Bleaching	Removal or modification to a greater or lesser extent, of wood resins and coloured components of pulp to improve purity and brightness.
Calendering	Operation carried out on the partially dried paper or board with the aim of improving the surface finish and printability.
Chemical pulp	Cellulose fibres obtained by dissolving and removing the non cellulose components in wood.
Cleaning	A mechanical or hydrodynamic operation to remove unwanted material from the pulp. Equipment is typically rotating screens or centrifugal cyclones.
Coating	The process of applying to the surface of a paper or board one or more layers of a liquid suspension containing pigments and binders to form a superior printing surface on the finished product. The materials used may include: pigments (clay, talc, calcium carbonate, etc.), binders (starch, latex, casein, etc.) and auxiliary substances (dispersing agents, insolubilizing agents, water retention agents, etc.). Coating is performed either on the paper machine or as a separate operation which then involves further drying.
Cutting	Dividing one, or simultaneously more than one, *web* of paper or board in the cross direction to produce sheets.
De-inking	Any process enabling the removal of inks from the fibres. The two most common types are screening and flotation.
Disintegration	The process of converting dry *pulp* into *stock.*
Drying	The process of reducing the water content of paper and board after it has left the *press* section of the paper machine.
Enzymatic treatment*	Application of biotechnology to the treatment of recycled pulp (improvement of characteristics, *de-inking*, etc.).
Finishing	All the operations performed at the mill after the paper machine to prepare the product for shipment (e.g. separate *coating*, *cutting*, *winding,* wrapping, labelling etc.).
Head box	A vessel, the full width of the paper machine, which ejects stock through a thin slit on to the moving *wire* mesh.

Hot dispersion*	Pulp treatment operated under pressure using steam at a temperature close to or more than 100°C in order to remove contaminants from the fibres. Normally, an intense, mechanical disintegration stage is used.
Machine clothing	A set of plastic wires and textile felts conveying and carrying paper through the paper machine
Mechanical pulp	Paper-making fibres separated by mechanical means mainly from wood.
Oxygen treatment *	Treatment of the *stock* made by gaseous oxygen at high temperature and under pressure.
Ozone treatment *	Treatment of the *stock* made by ozone or oxygen/ozone mix.
Paper machine	The machine that produces paper or board. There are different types of paper-machine depending on the *web* forming technology (e.g. four drinier, cylinder, twin wire, single ply, multi-ply, etc.).
Press	Two rolls, pressed tightly together, through which the moving *web* passes and which removes water by suction and transfer to a moving textile blanket.
Pulp	Material, generally of natural vegetable origin, made ready for use in paper-making processes by conversion to a mass of individual fibres.
Pulping	Process to convert wood (and other fibrous raw materials) to paper-making fibres.
Quality System	The organisational structure, the procedures, the processes and the resources that are needed to handle the Quality Management System).
Recovered paper	Paper collected by paper printing and other converting plants and from other parts of the waste stream which is returned into the paper-making process by collection and sorting.
Refiner/refining	A machine through which paper-making *stock* is pumped before delivery to the *head-box*. The machine imparts heavy mechanical action to the fibres which modifies their properties in different ways according to the final properties required.
Re-pulping	A process to disintegrate, in water, dry *pulp* or paper for further processing.
Semi-chemical pulp	*Pulp* obtained by partial removal from the raw material of those non-cellulosic components that can be removed by chemical treatment, for example cooking
Sheet formation	See *web formation*.
Sheeting	See *cutting.*
Slitting	Dividing a *web* of paper or board in the longitudinal direction into two or more narrower webs.
Special pulping*	Pulping with a chemical product (soda, peroxide, etc.).

Stock	An aqueous suspension of paper-making *pulp*.
Stock preparation	Process steps for conversion of *pulp* to stock. Can consist of *disintegration,* adding water, *fillers* and *auxiliary chemicals*, diluting, mixing and mechanically treat the paper-making components.
Storage chest	A large vessel for storing *stock* awaiting processing into paper and board.
Surface treatment	Treatment consisting of the application of an appropriate material or additive to the surface of a paper or a board to change certain characteristics e.g. printability, porosity, grease-proofness, etc.
Thermo-mechanical pulp	Paper-making *pulp* made by mechanical means in combination with heating, from various raw materials, but usually wood.
Unbleached pulp	*Pulp* that has not been subjected to *bleaching*.
Virgin pulp	*Pulp* supplied to a paper mill which contains fibres not used before in the paper-making process.
Washing*	Treatment operated on a *pulp* which is alternately thickened and diluted and passed through a series of filters with counter-current flow; the operation is carried out to clean the *pulp.*
Web	The continuous length of paper or board during manufacture or conversion.
Web formation	In the paper machine, the initial process of forming the *web* by physical de-watering of the *stock.*
Winding	Operation of rolling-up a *web* of paper or board.
Wire	A closely woven wire mesh, normally made of synthetic fibre, on to which the paper *stock* is directed and which then allows the passage of water away from the moving paper *web.*

** denotes a process technology that can be applied during various parts of the pulping and paper-making process but, in this context, only applies to the treatment of recovered paper and board*

TECHNICAL DOCUMENT No. 5

PRACTICAL GUIDE FOR USERS OF RESOLUTION RESAP (2002) 1 ON PAPER AND BOARD MATERIALS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Version 1 - 10.06.2004

Table of contents

1. INTRODUCTION

The “Practical Guide” is intended for all bodies and persons concerned with the application of *Resolution ResAP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs* and the corresponding technical documents. These bodies and persons are manufacturers and converters of paper and board, food manufacturers and distributors, enforcement authorities, surveillance bodies and certification laboratories.

The document has no legally binding value. It is intended to provide:

- guidance for a correct application of *Resolution ResAP (2002) 1* and the related technical documents;
- guidelines for checking the compliance of a material or an article;
- explanations to specifications, and background information.

Materials coming into contact with foodstuffs are regulated in EU by the framework Directive 89/109/EEC, its Amendments and its approximation of the laws of the member states relating to materials and articles intended to come into contact with foodstuffs. It stipulates that all kinds of materials and articles intended to come into contact with foodstuffs “must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could endanger human health, bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof”.

Specifications of *Resolution ResAP (2002) 1* and the related technical documents are based on these principles.

2. FIELD OF APPLICATION

2.1. Materials and articles covered by Resolution ResAP (2001) 1

Resolution ResAP (2001) 1 covers paper, board and articles made from paper and/or board used for all food contact applications under normal or foreseeable conditions of use including contact with fatty, aqueous or dry foods and for filtering liquids and for high temperature use. Exceptions are expressed in Chapter 2.2.

Paper is sometimes and board is usually made of several layers. An example is corrugated board, where one or several layers of fluting are inserted between layers of linerboard. Another multi-layer product is folding boxboard, where the top and bottom layers may consist of bleached virgin fibres, while the body of the board may be made of recycled fibres. Every paper layer must fulfil the requirements of *Resolution ResAP (2002) 1*, unless separated from the food by a functional barrier to migration. Further information on functional barrier is given in Chapter 6.

Resolution ResAP (2002) 1 applies to materials and articles, although major attention is paid to materials. Articles intended for food contact are, for example, packages, coffee filters, adsorbent pads containing a layer of paper or cellulosic fibres, paper labels to be fastened to fruits that will be peeled, moulded fibre articles such as trays for eggs and fruits, filter papers having a grammage below 500 g/m² and disposable tableware.

The manufacturer of articles should consider all auxiliary materials and additives used in the production of the article, such as printing inks, lacquers, adhesives etc. It is the responsibility of the manufacturer or importer of the materials and articles intended for food contact, as well as the persons marketing these materials and articles, to ensure that all elements are in compliance with the Directive 89/109/EEC.

Many board grades consist of a fibrous layer covered by a so-called mineral coating (the terms mineral coating, pigment coatings and aqueous pigment coating are synonymous). These coatings are within the scope of Resolution AP (2001) 1, although they contain polymeric substances such as binders. Polymeric materials, commonly referred to as plastic pigments, are also used in some cases as pigments in coatings for paper and board. Dispersion coatings, which provide barriers against moisture or fats, are within the scope of *Resolution ResAP (2002) 1.*

2.2. Materials and articles not covered by the Resolution ResAP (2002) 1

Non-wovens are not classified as paper. They are distinguished from paper in accordance with ISO 9092.

Filtering layers (as specified by BfR XXXVI/1 of 1999-08-01) with a grammage of at least 500 g/m^2 whose main components are synthetic fibres, though they may also contain some cellulosic fibres.

For the time being there are no regulations dealing with non-wovens or with filtering layers at European level. However, where these materials are used in contact with food, they should comply with the Framework Directive.

Kitchen towels and napkins made from paper are not within the scope of *Resolution ResAP (2002) 1*. A Technical document on paper kitchen towels and napkins has been elaborated and is available.

A plastic layer applied to a material or article made of paper is excluded from the scope of the resolution on paper and board. It should be assessed according to the Directives on plastics materials and articles.

3. VERIFICATION OF COMPLIANCE

Resolution ResAP (2002) 1 states that papers "should be manufactured in accordance with *Technical document No. 4 - CEPI Guide for good manufacturing practice for paper and board for food contact…"*

Good manufacturing practice (GMP) is the basis of internal surveillance and a fundamental part of quality control and product safety assurance. A separate document describing GMP has been elaborated: *Technical document No. 4 – CEPI Guide for good manufacturing practice for paper and board for food contact*.

Basic elements of GMP include:

- Availability of production manuals and instructions
- Compliance with specified quality requirements for raw materials
- Appropriate storage and handling conditions
- The application of processes to avoid or remove contamination
- Specification for end-product testing
- Information to ensure traceability and to maintain production records

3.1. Multi-layer materials

Typical examples of multi-layer materials are corrugated board and laminates of papers with other materials such as plastic and/or metal foils.

Unless the presence of a functional barrier to the transfer of substances from the paper layer(s) to foodstuffs can be demonstrated, each paper layer should comply with the specifications of *Resolution ResAP (2002) 1* and related technical documents but tests need not be carried out for each layer separately. The material is tested as a whole. An example for assessing compliance is as follows:

For a corrugated board consisting of two layers of board and one of fluting, all layers containing recycled fibres:

- Each layer should comply with the specifications of *Resolution ResAP (2002) 1* and *Technical document No. 3 - Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs*, terms of raw materials, manufacture, use of substances of *Technical document No. 1 – List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs* and the type of foodstuff with which the material will come into contact.

- Where there is a restriction expressed as QM (QMA) or SML, this restriction refers to the whole material and must be assessed in terms of the whole material, not for each individual layer independently.

- Tests for anti-microbial effect and/or sensory tests are done using the whole material.

- Tests to determine compliance with the specific requirements for substances listed in Table 2 of *Technical document No. 3* should be carried out on the whole material.

- Adhesives and other possible auxiliary substances should be assessed as well.

Where a layer in a multi-layer material has been shown to act as a functional barrier to transfer, only the paper layers on the food contact side of the barrier layer need to comply with the specifications of *Resolution ResAP (2002) 1* and related technical documents. Migration testing can be carried out as described later because the presence of the functional barrier will prevent transfer from the layers behind the barrier.

3.2. Verification of compliance with specifications of Technical document No. 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs

3.2.1. Origin of SML and QM (QMA) restrictions

In *Technical document No. 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs* for some substances SML restrictions are laid down. The values of SML are identical to those established for the same substance in EU Directive 90/128/EEC relating to plastics materials and articles. These values were based on the restrictions laid down by SCF/EFSA on the basis of available toxicological documentation. It is recognised that the toxicological assessments carried out by the SCF/EFSA are based on data supplied for evaluation of the use of substances in the manufacture of plastics materials and articles and that they may not be directly applicable for paper and board. However, in the absence of data more relevant to the use of these substances in paper and board, it would appear prudent to adopt these restrictions.

The SML restrictions are also expressed on a QM (QMA) basis in the List. The restriction as QM (QMA) has been derived from the SML restriction by applying the SCF/EFSA convention of 6 dm^2 of material coming into contact with 1 kg of foodstuff and assuming 100% migration.

For example, for a substance with an SML restriction of 1 mg/kg food, the restriction expressed as QMA is 0.17 mg/dm^2 paper and board.

For situations where scientific data is established for the SML/QMA ratio which occurs under normal or foreseeable conditions of use, it is possible to apply the true transfer value which applies to the case in question to derive the QMA value from the SML restriction for compliance testing. For example, if the SML/QMA ratio is established as being 0.1, then, for an SML restriction of 1 mg/kg, the QMA value to be applied is 1.7 mg/dm^2, taking into account the conventional SCF/EFSA contact conditions.

3.2.2. Calculating QMA for contact not corresponding to the SCF conventional ratio

The conventional ratio of 6 dm^2 of paper in contact with 1 kg of food adopted for plastics is not always realistic for many uses of paper. The QM (QMA) restriction to be applied under normal or foreseeable conditions of use is calculated in accordance with the formula given in *Technical document No. 2 – Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs.*

3.2.3. Restrictions expressed as QM (QMA)

Testing for compliance of a substance with a restriction expressed as QM (QMA) may be done either by calculation or by analysing paper and board to determine the total amount of the substance in the paper.

Determining compliance by calculation

For determination of compliance with the QM (QMA) restriction by calculation it is necessary to know the mass of the substance used in manufacture and the area of paper manufactured using this substance. If a worst-case assumption is made that all the substance is incorporated into the paper, and calculations show that the QM (QMA) is not exceeded, then the material can be deemed to be in compliance for that substance.

If calculation using this worst-case assumption indicates that the QM (QMA) restriction is exceeded, but it is known that not all the substance will be incorporated into the paper, further calculations and/or analysis will need to be carried out. Such calculations shall be based on scientific evidence and/or experimental studies of the percentage incorporation of the substance into the finished paper.

Determining compliance by analysis

It is important to note that testing for compliance with a QM (QMA) restriction by analysis should determine the total concentration of the substance in the paper. The analytical method used to determine compliance will depend on the substance under consideration. For some substances, it may be possible to measure the substance *in situ*, for example by X-ray fluorescence. Where this is not possible, it will be necessary to separate the substance from the paper matrix. This may be done by extracting the substance from the paper, or by degrading the paper matrix, leaving the substance behind, for example by ashing. If extraction is carried out, extraction conditions must be selected such that as close as possible to 100% of the substance is extracted. If it is not possible to extract all of the substance, the percentage extraction should be determined in order that the total concentration of substance in the paper can be determined. If the paper matrix is degraded, degradation conditions should be selected such that the substance under examination is not degraded or volatilised or otherwise lost through the degradation process.

Expressing values calculated on mass per mass basis as mass per area

Paper manufacturers typically express content of substances in paper in mass per mass units, for example as milligrams per kilogram of paper (mg/kg). The following formula can be used to convert a calculated or analytically determined value in mg/kg to a mass per area basis (milligrams per square decimetre), so that it can be compared with the applicable QMA restriction (which is expressed as milligrams per square decimetre):

$$V_A \ (mg/dm^2) = \frac{V_M \bullet A}{100 \bullet 1000}$$

where:

V_A is the calculated or analytically determined value expressed as mass of substance per unit area of paper (mg/dm^2)

V_M is the calculated or analytically determined value expressed as mass of substance per unit mass of paper (mg/kg)

A is the grammage of the paper, expressed as grams per square metre (g/m^2).

Concept of QMA restrictions

The concept of QMA has been adopted for reasons of harmonisation between specifications laid down in *Resolution ResAP (2001) 1* and related technical documents and in EU Directives.

QMA is a restriction which is expressed in mg (of substance) in the material or article per 6 dm² (of surface in contact with food).This restriction is often used in the SCF/EFSA opinion instead of SML (mg per kg of food)where for the substances under examination a method of analysis is not available. In this specific case it is assumed that the substance migrates 100% and that 1 kg of food is contact with 6 dm² of the material or article.

3.2.4. Restrictions expressed as SML

Testing for compliance with the SML restrictions laid down in *Technical document No. 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs*, should be carried out by migration testing, using the conventional conditions. However, in order to determine compliance with the SML restrictions laid down in *Technical document No. 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs*, extraction tests could be used if, on the basis of scientific evidence, the results obtained using these tests are at least equal to those obtained by migration testing using the conventional EU test simulants or foodstuffs.

3.2.5. Verification of compliance with restrictions (QM, QMA, SML)

When testing a material for compliance with restrictions there are two possibilities: testing for compliance with the QM (QMA) restriction for a substance or testing for compliance with the SML restriction.

In general, it is envisaged that it is likely to be simpler to test for compliance with the QM (QMA) restriction for a substance, rather than to test for compliance with the SML restriction for that substance. It also may be possible to test for compliance with a QM (QMA) restriction by

calculation. Even if it is not possible to test for compliance by calculation, it is likely to be relatively simple to carry out an analysis to determine the total amount of substance in the paper (QM).

When the test for compliance with an SML restriction is based on the determination of QM (QMA), complete transfer of the substance must be assumed (worst case principle). It is not probable that a substance will transfer completely from a packaging material to a foodstuff in reality, but as the relation SML/QMA is unknown, complete transfer must be assumed.

There will also be materials for which testing for compliance with the QM (QMA) restriction by calculation or by analysis indicates that the QM (QMA) restriction will be exceeded. In such a situation, testing for compliance with the SML restriction should be carried out, if such a restriction exists.

There are two possibilities for testing for compliance with a restriction expressed as SML: migration testing or extraction testing.

Migration tests should be designed such that they mimic the contact conditions, which will occur under normal or foreseeable conditions of use as closely as possible. Tests can either be carried out using foodstuffs or using so-called ‘simulants’, which are intended to mimic foodstuffs.

It should be borne in mind that migration testing for paper and board using a liquid simulant often is difficult or impossible due to the penetration of the simulant. In this case a more appropriate test, which might be an extraction test, if adequately designed, could be used.

Extraction tests use solvents in place of foodstuffs. Extraction tests should be designed such that the results using these tests are equal or higher than those obtained by migration testing.

If for testing compliance using a simulant indicates that the SML restriction is exceeded, testing can be carried out with foodstuffs of the type which will used in contact with the material in actual or foreseeable use.

It should be borne in mind that there are no limits set for overall migration for paper, and there is, therefore, no requirement that such a test be carried out.

The reader should observe that QM (QMA) is expressed as milligrams per square decimetre or kilogram of paper, whereas SML is expressed as milligrams per kilogram of food or food simulant.

3.2.5.1. Migration testing

Migration tests should be designed such that they mimic the contact conditions which will occur under normal or foreseeable conditions of use as closely as possible. Tests can either be carried out using foodstuffs or using so-called 'simulants' which are intended to mimic foodstuffs.

Technical document No. 2 - Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs specifies time, temperature and simulants for testing. Further guidance on simulants, substitute test media and exposure conditions can be obtained in this Practical Guide.

Food has been divided into the following categories: aqueous, alcoholic, fatty and dry, non-fatty food (see *Technical document No. 2*). Wherever possible the tests should be done with the real foodstuffs, however very often it will be necessary to use simulants. The recommended procedure depends on the nature of the foodstuff as follows:

Contact with fats and oil

The recommended test simulant is olive oil (or recognised alternative fatty simulants). Alternatively, testing can be carried out with the actual foodstuff. If contact in actual use will only be with one side of the paper, then migration tests should be carried out using the food contact side.

Contact with solid fatty foods with a low-medium moisture content with fat on the surface

Under EU Directives for plastics, for these types of food with fat on the surface, the designated test simulant is olive oil (or a recognised alternative fatty food simulant or test medium).

Testing with olive oil may not be appropriate for testing these materials for technical reasons. Such reasons could include situations where there is complete penetration of the material when testing with olive oil but where this penetration does not occur in actual use of the material. In these circumstances, testing should be carried out using foodstuffs or with a more appropriate test medium. There is currently no generally recognised alternative simulant available for testing paper contacting these types of food, although studies are underway in Europe to develop suitable test protocols. In the absence of alternative recognised tests, it is suggested that materials are tested using extraction tests.

Contact with dry, non-fatty foods

Under EU Directives for plastics, testing is not required for materials and articles contacting dry foods. However, there is evidence to indicate that there can be transfer of substances from paper to foods and hence testing is required for paper contacting dry non-fatty foods. Testing should be carried out using foods or using modified polyphenylene oxide (MPPO) as food simulant as stated in *Technical document No. 2 - Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs*.

It may be worth stating, that the food types as given in *Technical document No. 3 - Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs* are only used for the description of the processing and additional requirements but not for the testing of compliance with the end-product requirements.

3.2.5.2. Testing by extraction

Extraction tests can be used in place of migration testing to determine compliance with SML restrictions provided it can be shown that the extraction tests used give values equal to or greater than those obtained by migration testing.

The extraction medium should be selected taking into account the type of foodstuff and the substance being tested for. See Directive 85/572/EEC.

For paper coming into contact with aqueous foods, a recommended extraction solvent is water, either cold or hot depending on the contact conditions in use.

3.3. Verification of compliance with specifications of Resolution ResAP (2002) 1 and Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs

3.3.1. Anti-microbial effect

Many paper manufacturers add biocides into the water circulation of the paper mill in order to avoid formation of microbial slime growth. Biocides are intended to act on microbial growth during the paper-making process and are not intended to be present in the finished paper. Substances which have an anti-microbial effect on foodstuffs should not be released.

Raw materials and auxiliaries for the production of paper and board sometimes contain biocides which can be transferred to the end product. An anti-microbial effect caused by these biocides also has to be avoided.

A CEN standard has been published for the study of possible release of anti-microbial substances.

3.3.2. Dioxins

Polychlorinated dibenzo-p-dioxins (PCDDs) and dibenzofurans (PCDFs) are halogenated aromatic compounds that have been identified as contaminants in almost every component of the global ecosystem. They are, for example, formed during the bleaching of pulp with chlorine. Consequently the European pulp manufacturers have discontinued bleaching with elemental chlorine. This has resulted in very low contents of dioxins in European paper.

Worst-case calculations indicate that even if there were to be 100% migration into food, dioxin levels contributed by paper intended for food contact would be considerably below the t-TDI (temporary tolerable daily intake) value for dioxins (1 pg/kg bw) recently proposed by the SCF/EFSA.

Therefore the Committee of experts decided not to include any specific limit for dioxins in the resolution. Instead there is a requirement for the manufacturer to choose raw materials and processes in such a way as to make sure that the content of dioxin is as low as possible.

3.3.3. Cadmium, lead and mercury

The restrictions on cadmium, lead and mercury in *Resolution ResAP (2002) 1* have been derived from guideline levels of *Resolution AP (96) 4 on maximum and guideline levels and source-directed measures aimed at reducing the contamination of food by lead, cadmium and mercury* and are based on toxicological assessment, applying the conventional ratio of 6 dm^2 of material coming into contact with 1 kg of food and assuming 100 % migration. For other ratios of paper area to mass of food (see para 6 in *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs*) to determine the QMA value applicable to the specific case should be determined. There is no restriction indicated for Cr^{+6}, as this would be reduced during paper manufacture, and can therefore never be identified in a paper or paper product.

Testing for cadmium, lead and mercury is not required for paper intended for contact with dry, non-fatty food. For fatty and/or aqueous foods, testing is performed from a water extract, unless the paper is intended for contact with acidic products, such as fruit juice. In this case 3% acetic acid is used as solvent.

CEN has published standards for hot and cold water extraction and prENs to determine cadmium, lead and mercury.

3.3.4. Pentachlorophenol and polychlorinated biphenyls

Pentachlorophenol (PCP) is a widely spread, possibly carcinogenic contaminant. PCP was used in the past as a timber preservative and traces can sometimes be found in paper. It is now forbidden in products within the EU, although it may still be present in raw materials imported from elsewhere.

Results of a survey in the UK showed that PCP in paper does not readily migrate into foods. The QM restriction of 0.15 mg/kg of paper should, therefore, provide an acceptable purity requirement. The determination is based on extraction with water in the EN standard.

Polychlorinated biphenyls (PCBs) were used in the past in the manufacture of carbonless copy paper. PCBs are no longer used for this purpose and, hence, modern day carbonless copy paper does not contain these substances. There is, however, the possibility that archived papers may contain copy paper containing PCBs. Hence, large batches of archived papers - if they contain PCB - should not be used as a source for recycled fibres. An EN for determining PCB is available.

Because there is evidence to indicate that PCBs in paper are no longer a major problem, no restriction is specified in the Resolution for these substances.

3.3.5. Sensory (organoleptic) characteristics

The main sensory properties of a foodstuff are odour and taste. It is not usual that a material in contact with food influences the odour of the foodstuff, though the material itself might have an odour. An odorous food packaging material has no market. Thus, the market is “self-regulating” as regards odour of a material intended for food contact.

The taste of a foodstuff is easily affected by surrounding materials. Unsuitable printing inks or varnishes on the outer surface of a board may transfer constituents to the content of the package causing an unpleasant change in the taste of the foodstuff. The storage conditions of a paper or board can cause transfer of taint. The terms ‘taint’ and ‘off-flavour’ are both used to indicate a deterioration in the taste of a foodstuff.

An EN method for testing sensory characteristics is available.

3.3.6. Microbiological quality

Resolution ResAP (2002) 1 states that materials and articles should be of suitable microbiological quality, taking into account the intended end-use of the material. The microbiological properties of the end product, i.e. the paper, are usually good, as sheet making and drying on the paper machine reduces the level of microbiological contamination significantly. When assessing the microbiological quality of a paper it is, therefore, important to consider the nature of the food to be packed, its microbiological load and the potential for the paper to influence this load.

4. USE OF RECYCLED FIBRES

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 3, 5 and 6 of *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs.*

Furthermore see also *Technical document No. 4 – CEPI Guide for good manufacturing practice for paper and board for food contact.*

4.1. General aspects

Recycled fibres are used to a great extent in many paper grades, such as newsprint, tissue and corrugated board. They are also used in some paper grades intended for food contact, mostly as inner layers in multi-layer materials intended for packing of dry, non-fatty food. A major volume of recycled fibres originates from recovered paper that has not been deinked, and sometimes can be identified by its typical greyish colour. Deinked recycled fibres are, however, very difficult to distinguish from virgin fibres, if at all.

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 of *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs* and tied to each other in a matrix (Table 3 in *Technical document No. 3*). Descriptions of process technologies given in *Technical document No. 3* provide flexibility to take account of mill-specific circumstances. They are given as examples but other processes or combination of processes may be used provided that the end product fulfils the requirements of Chapter 6 of *Technical document No. 3*. 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 Chapter 6 of *Technical document No. 3*. Manufacturers of paper containing recycled fibres shall be able to produce documentation on the origin of the recycled fibres (the kind of recovered paper that has been used), the main features of the cleaning process, and the results of analyses. It is in the responsibility of industry to demonstrate through Good manufacturing practice (see *Technical document No. 4 – CEPI Guide for good manufacturing practice for paper and board for food contact*) that the end product meets the requirements of Art. 2 of Council Directive 89/109/EEC. More details are given in Chapter 5 and Appendix 1 of *Technical document No. 3.*

4.2. Recovered paper collecting system

Details of collecting recovered paper and the main sources of recovered paper in Western Europe can be found in CEPI annual reports.

Further details on quality control at mill entry are given in *Technical document No. 4 – CEPI Guide for good manufacturing practice for paper and board for food contact.*

4.3. Verification of compliance with end product requirements

Analytical methods to be used for testing for compliance with end product requirements are set out in *Technical document No. 2 – Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs.*

4.3.1. Contact with food to be washed, shelled or peeled

The tests listed in Chapter 6, Table 2 “Specific requirements” and set out in *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs* are not required.

4.3.2. Contact with dry, non-fatty food

Diisopropylnaphthalenes (DIPNs). The main source is recovered carbonless copy paper, where DIPNs are used as solvents. Several researchers have shown that many paper grades based on recycled fibres contained significant amounts of DIPNs, and that DIPNs migrated readily, even into dry food and through an air space. The toxicology of DIPNs has not yet been fully evaluated, but the toxicological studies showed no reason to set a limit for the DIPN content. *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs*) state, by way of precaution, that levels in paper should be kept as low as reasonably achievable.

Partially hydrogenated terphenyls (HTP) also originate from carbonless copy paper and can be found in recovered paper. As a matter of prudence, *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs* state that levels in paper should be kept as low as reasonably achievable.

Phthalates are ubiquitous in the environment due to their widespread use in various products and their slow degradation. They can enter food packaging as additives in adhesives and in printing inks and varnish. Although printing inks are not in direct contact with food, it has been shown that the plasticisers they contain can migrate into food through the packaging material or during storage of reels and bales (set-off phenomenon). Phthalates classified as "Toxic" under the 28th Amendment of Dangerous Substances Directive 67/548/EEC are excluded from printing inks (CEPE exclusion list, September 2001, Selection Criteria A). The usage of phthalates has been significantly declining since a number of years.

The SCF has established a TDI for some phthalates and the limits are given in EU Directive 90/128/EEC or Synoptic Document. The indicated TDI-values should be converted to SMLs using the convention TDI x 60 [kg bodyweight/kg food] = SML (TDI is expressed as mass per mass of body weight, and SML as mass per mass of food).

Volatile solvents originate from gravure printing. *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs* recommend that solvents should be reduced to the lowest possible levels in the finished product.

Polycyclic aromatic hydrocarbons (PAHs). Some PAHs are suspected carcinogens. They occur sometimes as contaminants in, for example, printing inks oils. Under the selection criteria of the CEPE exclusion list, since years, printing inks do not contain mineral oils or any other hydrocarbon substances which are classified as "Toxic" under the Dangerous Substances Directive 67/546/EEC.

Benzophenone can be present in paper from the use of UV-cure inks and varnishes, where it is commonly used as a photo initiator. EU Directives for plastics list an SML of 0.6 mg/kg food for benzophenone.

4.3.3. Contact with fatty and/or aqueous food

In addition to the above analyses the following are recommended:

Michler´s ketone (4,4´-bis(dimethylamino)benzophenone). This substance, which is a suspect carcinogen, has seldom been found in paper. It was used in the past as a photo initiator in UV-cured inks but its use in printing inks for food contact materials is now prohibited in Europe. *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs*

recommend that the migration of this substance shall not be detectable when measured by a method with a limit of detection of 0.01 mg/kg of food.

4,4-Bis(diethylamino)benzophenone (DEAB) originates also from UV cured printing inks. For specifications and analysis, see Michler´s ketone.

Primary aromatic amines can originate from printing inks. The limit given in *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs* refers to the sum of the listed amines. A list of those aromatic amines that are of toxicological concern is given in the 19th amendment of EU Directive 76/769/EEC (2202/61/EC). Due to the ban in 2002/61/EC these substances will disappear.

Fluorescent whitening agents (FWAs) are added to many paper grades in order to improve the apparent brightness of the paper. In the USA and some European countries only a restricted number of FWAs are allowed in materials in contact with fatty or aqueous food. FWAs are listed in *Technical document No. 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs*, but migration should be not detectable. As the major part of recovered paper contains FWAs, it is highly probable that paper made of recycled fibres will contain these substances.

EN 648 specifies the test method for FWAs. The migration of optical brighteners is estimated visually and noted on a scale from 1 (strong migration) to 5 (no migration). This easurement should be regarded as a yes/no test: if the mark is 5, there is no migration and the material can be used in contact with fatty and/or aqueous food. If a value of 4 or lower is obtained, there is migration and the material is not in compliance.

Certain azo compounds form carcinogenic aromatic amines by cleavage of the azo group(s). Azo compounds originate from printing inks. The analytical procedure comprises cleaving of the azo group(s) and determination of the released amines. If the banned amines (see 2002/61/EC, the 19th amendment of EU Directive 76/769/EEC) are found at a content exceeding 0.1 mg/kg paper, the limit set for azo compounds is exceeded. The limit in *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs* refer to the sum of the listed amines. Due to the ban in 2002/61/EC these substances will disappear.

The analytical procedure is given in BfR´s *Untersuchung von Bedarfsgegenstände*, which also contains the list of the banned amines. The method is intended for the analysis of textiles, but it is also may be applicable to paper. It cannot be used for the estimation of migration into food.

4.3.4. Toxicological tests

The use of toxicological tests and test conditions will be evaluated and they may be recommended in the future, based on new developments and results in this field. A project to develop and to validate toxicological tests for paper and board is being funded under the Fifth Framework programme of the EU (Biosafepaper).

5. SPECIAL CASES

5.1. General considerations

Testing of materials and articles used in more specialised situations is covered in this chapter. These specialised uses include paper and board used in microwave and

conventional ovens; paper used in contact with frozen foods; filter papers; disposable tableware; adsorbent pads.

In general, diffusion (migration) of a substance increases linearly with the square root of time. Strictly, this applies only when the content of migrant and the mass of the foodstuff are infinite, but the rule can be applied in most practical cases when an article is in contact with a foodstuff. Diffusion also doubles with each 10°C increase of temperature. Consequently, short time tests at high temperatures are more severe than long time tests at low temperature (2 hours at 70°C would be more severe than 24 h at 40°C).

For the time being, migration from fibrous materials cannot be estimated by current diffusion models, though some work is being done in this direction. This is due to the heterogeneous and very complex structure of paper and board.

Where no specific test conditions are given for a specific situation, refer to *Technical document No. 2 - Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs* for selection of simulants and test conditions.

5.2. Use at high temperature

Ovenable boards are used for purposes such as packing ready-cooked meals that are heated at home in either microwave or conventional ovens. They are differentiated from baking papers by their generally lower temperature of use and by the fact that they do not contact fatty foods directly, although they may be used in the heating of fatty foods when they are separated from the food by a plastic layer.

Baking paper can be used in contact with fatty foods at high temperatures. Test conditions for baking papers intended for general household use are given in *Technical document No. 2 – Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs*. EU Directives for plastics should be consulted for test conditions applicable for more specific uses.

When testing ovenable paper and baking paper, degradation products formed at high temperatures should be taken into account in testing. For further details see *Technical document No. 2.*

If migration testing is carried out for paper intended for contact with hot, aqueous liquids, such as tea bags, coffee filters and cooking pouches the appropriate conditions (time, temperature and ratio of paper to liquid) should be chosen taking into account the intended use of the material.

If extraction testing is carried out to determine compliance, hot water extracts should be prepared.

5.3. Filters and filtering layers

The procedures to be followed when filters made of paper are examined, are described in *Technical document No. 2 – Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs.* The procedure is not based on scientific study but, in the absence of suitable data, is pragmatic and reflects what happens in real use.

Filtering layers are not within the scope of the resolution. The reader may find it useful to consult BfR XXXVI/1, where testing instructions can be found.

5.4. Disposable tableware

Contact with fatty and/or aqueous food is foreseeable, and contact temperatures must be considered from +4 °C up to 80 °C.

For paper beakers used for hot beverages, testing should be carried out for 1 h at 70°C. Where paper beakers are used for acidic juices, 3% (w/v) acetic acid should be used as a test simulant.

In principle, paper plates should be tested by filling with a foodstuff or simulant but, because of technical difficulties, extraction tests may be more appropriate. Isooctane [and 95% v/v ethanol] shall be used as extraction solvents for tableware contacting fatty foods; testing for 0,5 h at 60°C.

5.5. Contact only with food to be washed, shelled or peeled

For materials intended for contact only with foodstuffs to be washed, shelled or peeled, such as potatoes and apples, the tests listed in Chapter 6 of Table 2 of *Technical document No. 3 – Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs* are not required. The general requirements of *Resolution ResAP (2001)1* and of *Technical document No. 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs* are valid. Consequently, tests are to be made for pentachlorophenol, for release of anti-microbial agents and for substances restricted in *Technical document No. 1*, if these have been added during manufacture of the material. The same rules apply to moulded fibre products intended, for example, for eggs.

Typical foodstuffs which are washed, shelled or peeled before eating are for example citrus fruits, vegetables and peanuts.

5.6. Packages for frozen food

Frozen food that is fatty and/or aqueous is considered as dry, non-fatty food, provided that the food is not defrosted in contact with paper or board. Consequently, MPPO is a suitable food simulant for this application. Some examples of conditions for migration testing are given below.

If the package will not be heated together with the content, as for example when berries are frozen, and there is no hot fill, 10 days at 5°C are the appropriate conditions for migration testing.

A package may be filled with warm food at 60°C, for example a soup, then rapidly frozen and stored for a long period, and finally heated for 30 minutes to 70°C in the pack. This package should be tested for 1 hour at 70°C, only. Any transfer occurring during filling and frozen storage should be covered by the test conditions proposed. In this case, fatty food simulants (or alternative simulants or test media) are appropriate for migration testing.

5.7. Vegetable parchment and greaseproof paper

Vegetable parchment is a paper that has been modified by the action of sulphuric acid. This treatment gives it a high degree of resistance to penetration by organic liquids generally, and particularly fats, oils and greases (ISO DIS 4046-4).

Greaseproof paper is a paper that has a high resistance to penetration by grease or fats.

This resistance is obtained by intensive mechanical treatment during stock preparation.

There are also paper and board grades on the market which have been treated with fluorinated agents to provide grease and oil resistance. Substances used as grease-proofing agents are typically perfluoroalkyl phosphate esters or amine salts.

Vegetable parchment and greaseproof are intended for contact with fatty and/or aqueous food. No specific test conditions are given.

5.8. Absorbent pads

The perforated plastic in contact with the food is not a functional barrier. Consequently, for adsorbent pads containing cellulosic fibres, the fibrous layer should fulfil the specifications of

Resolution ResAP (2004) 1 and the related technical documents for materials in contact with fatty and/or aqueous food.

6. FUNCTIONAL BARRIER

The efficiency of a functional barrier is defined by a concentration of no concern (an accepted value) in a food or a food simulant as an end parameter. For all materials, there will be a time period where the material acts as a barrier to transfer of substances from other layers behind the barrier or from the environment. However, for some materials, there will come a time at which substances pass across the barrier and into the food. The time elapsed between the substances coming into contact with the barrier material and the time at which the concentration of no concern is exceeded in the food is the time for which that material acts as a functional barrier. For most materials, the time at which substances come into contact with the barrier is at manufacture or during converting processes (e.g. printing, application of adhesives etc.) Hence the start time for a barrier material can be considered as manufacture or converting, not just when the food is actually packaged in the material.

The full applicability of the functional barrier concept is limited currently by the lack of agreement concerning the level for a concentration of no concern and the lack of agreed methods to test whether or not materials act as functional barriers. To some extent, development of definitive methods is dependent upon the agreement of a level for a concentration of no concern.

Thus, for the time being, the usefulness of the functional barrier concept is generally restricted to substances included in *Technical document No. 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs* and to other substances for which information is available concerning their toxicology. For a substance on the list with an SML restriction, a material acts as a functional barrier for the time over which the material prevents transfer to food exceeding the SML restriction for that substance. The concept cannot currently be applied to substances for which no toxicological information is available.

The following discussions on barrier properties refer specifically to transfer of organic substances.

The barrier properties are influenced by the following factors:

Factors enhancing barrier properties	**Factors impairing barrier properties**
Contact conditions	
Low temperature	High temperature

Short time	Long time
Material properties	
Thick barrier material	Thin barrier material
High resistance to diffusion	Low resistance to diffusion
Inertness to food	Interaction (penetration) with food
Inertness to external factors	Interaction with external factors
Continuous layer	Discontinuous layer, (pinholes, cracks)
Restricted substances	
Low concentration in layers behind the barrier	High concentration in layers behind the barrier
Low mobility, high molecular weight of contaminants in layers behind the barrier	High mobility, low molecular weight of contaminants in layers behind the barrier

The best barrier materials will be impermeable so as to prevent diffusion. Metal foils are the most effective barriers provided they are not damaged or too thin. They should, however, not be placed in direct contact with acidic foods because of corrosion problems.

Various plastics can act as barriers but they are not totally impermeable. Thus they will generally not have as long a barrier effect as totally impermeable materials. Metallised plastics layers can act as barriers but are not as effective as continuous foil layers.

Some plastics, whilst not being totally impermeable, do delay transfer of organic substances significantly. Examples of such materials are polyvinylidene chloride, polyvinyl chloride, polyethylene terephthalate and polyethylene napthenate. Polyolefins generally do not delay transfer of organic substances as significantly.

Paper generally has a high permeability and will not generally form an effective barrier to migration where substances which can transfer across an air space are present.

An air gap could act as a barrier provided that the layer behind the barrier is low in volatile substances and contact between the food is minimal and the packaging is not subjected to high temperature.

The effectiveness of foil and other barrier layers is reduced if the layer is not continuous. A standard procedure for the detection of pinholes in a plastic layer on a paper material was developed by CEN.

A recognised procedure to demonstrate that an inner layer is a functional barrier would be welcome. As regards plastics, work is in progress to develop mathematical means based on kinetic studies in order to find out whether a functional barrier can be deemed to exist. Diffusion mechanisms are different in porous materials like paper, and other ways might be needed to study barrier properties.

7. GENERAL INFORMATION ON TEST METHODS AND STANDARDS

The Council of Europe and the EU Commission do not normally issue resolutions or directives in the field of methods of analysis. The progress in this area is so rapid that any method may be considered obsolete after a limited number of years. However, there is a need to provide guidance to analysts who carry out testing to ensure compliance, e.g. enforcement authorities, industry, retailers and certification laboratories.

It is recommended that internationally recognised and validated methods of analysis are applied. For the purpose of this document this includes methods recognised by the following bodies:

Council of Europe or European Commission;
CEN;
ISO.

References to the test methods can be found in *Technical document No. 2 – Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs*.

If such a method does not currently exist, an analytical method with appropriate performance characteristics (accuracy and precision) at the specified limit may be used.

8. ABBREVIATIONS

BfR	Bundesinstitut für Risikobewertung (Federal institute for risk evaluation)
CEN	Comité Européen de Normalisation (European Standardisation Organisation)
CEPE	European Council of Paint, Printing Inks and Artists´ Colours Industry
CEPI	Confederation of European Paper Industries
CoE	Council of Europe
DIS	Draft International Standard
EC	European Commission
EN	European Standard
FWA	Fluorescent Whitening Agent
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis of Critical Control Points
ISO	International Standardisation Organisation
MAFF	Ministry of Agriculture, Fisheries and Food (UK)
MPPO	Modified polyphenylene oxide (for example Tenax)
QM	Maximum quantity of substance in finished product
QMA	Maximum quantity of substance in finished product based on area
SCF/EFSA	EU Scientific Committee for Food / European Food Safety Authority
SML	Specific Migration Limit
TDI	Tolerable Daily Intake

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TECHNICAL DOCUMENT No. 6

GUIDELINES ON THE PRESENTATION OF APPLICATIONS FOR SAFETY EVALUATION OF SUBSTANCES TO BE USED IN THE MANUFACTURE OF PAPER AND BOARD MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Version 1 - 10.06.2004

Table of contents

Note to the reader

The Guidelines concerning the presentation of applications for safety evaluation of substances to be used in paper and board substances food contact materials, hereafter called 'Guidelines', is part of the Council of Europe's policy statements concerning paper and board materials and articles intended to come into contact with foodstuffs.

The document lays down:

- The guiding principles for the safety evaluation of food contact paper and board substances;
- The classification system for substances to be used in food contact materials and articles;
- The principles for petitioners to present an application for the safety evaluation of a paper and board substance to be used in food contact materials and articles prior to their authorisation.

The Guidelines should be read in conjunction with:

- Resolution ResAP (2002) 2 on paper and board materials and articles intended to come into contact with foodstuffs, adopted by the Committee of Ministers at its 808th meeting on 18 September 2002;
- Technical document No 1: List of substances used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs.
- EC Note for Guidance "Note for guidance of petitioner when presenting an application for safety assessment for a substance to be used in food contact materials prior to its authorisation" (http://europa.eu.int/comm/food/fs/sfp/food_contact/note_guidance_en.pdf)

The Guidelines are based on:

The Scientific Committee on Foods (SCF) guidelines 'For the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation' as set out in the European Communities document SCF/CS/PLEN/GEN/100 Final 19 December 2001, which is included in the EC Note for Guidance (Chapter II);
and
The Explanatory Guidance of the SCF Guidelines produced by the European Food Safety Authority (EFSA) Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) Food Contact Materials Working Group (AFC-FCM-WG). This AFC-FCM-WG Explanatory Guidance is included in the EC Note for Guidance (Chapter III).

For practical reasons, Chapters identical to the EC 'Note for Guidance' including the SCF Guidelines for food contact materials and the AFC-FCM-WG Explanatory Guidance of the SCF Guidelines are excluded from the present document.

CHAPTER 0

GENERAL INTRODUCTION

0.1. CONTEXT

1. Council of Europe resolutions on food contact materials are elaborated by the Committee of Experts on materials coming into contact with food, hereafter called Committee of Experts, and adopted by the Committee of Ministers.

2. They provide all stakeholders with a means of ensuring compliance with Article 2 of EU framework Directive 89/109/EEC on food contact materials, in particular for materials not yet covered by specific EU Directives.

3. The Guidelines concerning the presentation of an application for safety evaluation of paper and board substances to be used in food contact materials and articles, hereafter called the Guidelines are based on the same criteria and data requirements as applied by the European Commission's Scientific Committee on Food (SCF), as superseded by the European Food Safety Authority (EFSA) Scientific Panel on Food Additives, Flavouring, Processing Aids and Materials in Contact with Food (AFC), Food Contact Materials Working Group (AFC-FCM-WG).

4. The safety evaluations will be carried out by the *ad hoc* Group on safety evaluation of food contact substances, a subsidiary body of the Committee of Experts. It is composed of toxicologists and analysts nominated by the member states of the Partial Agreement in the Social and Public Health Field[2]. If necessary, other national experts, for example specialists for exposure, will be associated to the work of the *ad hoc* Group.

5. At present the *ad hoc* Group will be composed of experts from the following member states: Belgium, Finland, France, Germany Italy, The Netherlands, Slovenia, Sweden and Switzerland.

6. National Agencies for food safety or similar institutions, including universities, are considered as the adequate bodies for the evaluation of the files submitted by industry and the preparation of the Petitioner Summary Data Sheets (P-SDS) to be submitted to the *ad hoc* Group.

7. At present the French, Finnish, Netherlands, Slovenian and Swedish authorities have agreed to participate in the file evaluations of paper and board substances.

8. Confidentiality with regard to the information provided in the evaluation files by industry and the summary data sheets will be assured and based if needed on an agreement.

9. CEFIC was invited to submit a preliminary list of about 100 substances to be evaluated, of which about 20 substances should be selected for the priority evaluation list.

[2] Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, spain, Sweden, Switzerland, United Kingdom

10. The preliminary list will be discussed at a hearing between the *ad hoc* Group with industry representatives with a view to prepare the priority list of paper and board substances to be evaluated by the *ad hoc* Group.

11. The decision concerning the selection of the substances for the priority list will be taken by the Committee of experts.

0.2 GUIDELINES

The aim of the guidelines is to provide:

a) Guidelines for requesting the addition of new substances to Technical document No 1 - List of substances used in the manufacture of paper and board intended to come into contact with foodstuffs;

b) Guidelines for requesting the re-evaluation of substances already included in Technical document No 1 - List of substances used in the manufacture of paper and board intended to come into contact with foodstuffs;

c) Guidelines for the submission of technical dossiers accompanying such requests.

CHAPTER 1

COUNCIL OF EUROPE ADMINISTRATIVE GUIDANCE FOR PRESENTATION OF AN APPLICATION

1. INTRODUCTION

The aim of this chapter is to explain:

a. The administrative procedure to be followed by a petitioner requiring the evaluation or re-evaluation of a substance;

b. The follow-up of the request.

The term “petition” or “application” means the official request from a company to obtain an evaluation, or a re-evaluation of a substance for the purpose of introducing it into, or for a change to Technical document No 1 - List of substances used in the manufacture of paper and board intended to come into contact with foodstuffs. The Council of Europe classification system for substances is shown in Annex A of this chapter.

A typical petition consists of the following separate documents described below:

a. A letter requesting the evaluation or re-evaluation of the substance (see item 1.7.1 and 1.7.2, model letters No 1 and No 2);

b. A technical dossier compiled according to Section 1.8 of this chapter;

c. A Petitioner Summary Data Sheet (P-SDS) see EC ‘Note for guidance’, Chapter III, Annex 6).

Each document should be prepared as set out above in order to facilitate the examination of a petition by the Council of Europe and to avoid delays.

To avoid any loss in the mail the above-mentioned documents should be transmitted by registered post. In addition, the full information should be submitted In electronic format on standard physical media (CD-ROM or equivalent). The information should be certified as being identical to the one on paper. Common electronic formats should be used, such as MS Office or Adobe Acrobat Reader. The files should be searchable using the search facilities of standard software packages.

The applicant should keep additional paper and electronic copies readily available for the cases where the Council of Europe requires them.

1.1. ADDITION OF NEW SUBSTANCES

To obtain the insertion of a new substance into Technical document No 1 - List of substances used in the manufacture of paper and board intended to come into contact with foodstuffs, any person concerned is invited to submit a petition to the Council of Europe using model letter n° 1 (see Section 1.7.1) and containing always the technical dossiers as well as a separate Summary Data Sheet.

1.2. RE-EVALUATION OF SUBSTANCES

The re-evaluation of substances already included in Technical document No 1 - List of substances used in the manufacture of paper and board intended to come into contact with foodstuffs can result in two different situations:

a) The petitioner has obtained all the data requested for a substance currently classified in SCF lists 6-9 or in waiting list (W);

b) The petitioner has obtained further information on a substance currently classified in SCF lists 0-5 and believes that the additional data might then permit a different classification or restriction for that substance.

For the re-evaluation of a substance the petitioner is invited to submit a request to the Council of Europe, using model letter n° 2 (see Section 1.7.2), and accompanied always by the technical dossiers as well as a separate Summary Data Sheet.

It is underlined that the petitioner should always prepare a new, complete Summary Data Sheet, to replace the previous one.

1.3. TECHNICAL DOSSIERS

The technical dossier should contain the data mentioned in the Guidelines.

If the guidance given in the Guidelines is insufficient to establish the database to be submitted to the Council of Europe for a specific substance, the petitioner may consult the Council of Europe services for further advice. Because it is highly probable that the Council of Europe services will have to consult the *ad hoc* Group on toxicological evaluation of food contact substances (hereafter called *ad hoc* Group), it is recommended that the use of this option is restricted entirely to cases where the substance or the group of substances require special consideration. Some delay must be expected for this procedure (generally 2-6 months).

During the *ad hoc* Group's evaluation of the dossier it may be considered necessary to have additional tests carried out in order to confirm the significance of effects already found, or to provide further information. Such tests should be presented by using the model letter n° 2 related to a request of re-evaluation. In this special case a new Summary Data Sheet containing also the new data should be transmitted as a replacement of the previous one.

1.4. CONFIRMATION OF ADMINISTRATIVE ACCEPTABILITY OF THE PETITION (AAP)

After the receipt of a petition and its analysis, the Council of Europe will send a letter to the petitioner acknowledging receipt of the request (see item 1.7.4 and 1.7.5, model letters n° 3 and n° 4). In these letters the substance reference number (PM/REF.N.) and the CoE document reference number (CoE/XX) allocated by the Council of Europe services are mentioned. It is essential to quote both reference numbers in any future correspondence with the Council of Europe. The letter will confirm whether or not the request is in compliance with the instructions set out in this Note for Guidance (AAP). If the request does not comply with these instructions, the applicant will be asked to modify the request appropriately (transmission to the petitioner of an AAP negative). Note that the acceptance of the petition (AAP positive) does not imply that the documentation provided fully complies with the CoE Guidelines. The Council of Europe reserves the right to request additional information as

necessary for complete assessment of the substance. It has to be stressed that the justification for any departure from CoE guidelines or corresponding guidance must appear both in the technical dossier and in the Petitioner Summary Data Sheet.

1.5. MANAGEMENT OF THE TECHNICAL DOSSIERS

After each meeting the *ad hoc* Group prepares a report containing all the endorsed evaluations and the Council of Europe Secretariat will distribute this report on Internet website of Division of the Partial Agreement in the Social and Public Health Field:
www.coe.int/soc-sp

1.6. ESTIMATED TIME FOR EXAMINATION OF THE TECHNICAL DOSSIERS

It is difficult to estimate the time necessary for a evaluation of a substance. However, the estimated minimum time is, now, in the range of 6-12 months. It should be noted that the quantity and quality of the petitions play an important role in this context.

1.7. MODEL LETTERS

To facilitate this procedure petitioners should always use the model letters set out hereafter.

1.7.1. Model letter N° 1

REQUEST FOR THE EVALUATION OF A NEW SUBSTANCE (1)

Council of Europe
Partial Agreement Division in the
Social and Public Health Field
F-67075 Strasbourg

Our reference:..... Date:.....……..

Subject: Request for the evaluation of a monomer /additive (2)

The undersigned.....(3).....….....……

requests the addition of the following new substance:
.....(4).....

The person responsible for answering any detailed questions on the technical dossier is:
.....(5).....….....

Enclosed are the following:

a. the technical dossier (6)
b. a Petitioner Summary Data Sheet (7).

A copy of the request and a copy of the full technical dossier has also been sent to the…….. to be completed.

Moreover, one paper copy of the documentation under a. and b. above has also been sent to the …..to be completed.

Another paper copy of the documentation under a. and b. (but without the toxicological data) has been sent to the ……to be completed.

Additionally, three complete sets of the documentation under points a and b will be held available for the Council of Europe and sent to the persons indicated by the Council of Europe on request.

A sample of 250 g of the substance, the relevant product safety sheet, the spectroscopic data and a copy of the model letter belonging to it have been transmitted to Ms C. Simoneau, of the EC-Joint Research Centre, Institute for Health and Consumer Protection, Physical and Chemical Exposure Unit, T.P. 260, I-21020 ISPRA, Italy (Phone ..39-0332-785889 – Fax ..-39-0332-785707 E-mail: Catherine.Simoneau@jrc.it).

Yours sincerely,

Enclosures. a. Technical dossier.
b. Petitioner Summary Data Sheet.

1.7.2. Model letter N° 2

REQUEST FOR THE RE-EVALUATION OF A SUBSTANCE (1)

Council of Europe
Partial Agreement Division in the
Social and Public Health Field
F-67075 Strasbourg

Our reference:..... Date.....:.....

Subject: Request for the re-evaluation of a monomer/additive (2) PM/REF.N.....

The undersigned.....(3).....
requests re-evaluation of the following substance:
.....(4).....
The person responsible for answering detailed questions on the technical dossier is:
.....(5).....

Enclosed are the following:

a. Technical dossier (6)
b. Petitioner Summary Data Sheet (7).

A copy of the request and a copy of the full technical dossier has also been sent to the……to be completed.

Moreover, one paper copy of the documentation under a. and b. above has also been sent to the …..to be completed.

Another paper copy of the documentation under a. and b. (but without the toxicological data) has been sent to the ……to be completed.

Additionally, three complete sets of the documentation under points a. and b. will be held available for the Council of Europe and sent to the persons indicated by the Council of Europe on request. If not yet supplied in the past, a sample of 250 g of the substance, the relevant product safety sheet, the spectroscopic data and a copy of the model letter belonging to it have been transmitted to Ms C. Simoneau, of the EC-Joint Research Centre, Institute for Health and Consumer Protection, Physical and Chemical Exposure Unit, T.P. 260, I-21020 ISPRA, Italy (Phone ..39-0332-785889 – Fax ..-39-0332-785707 E-mail: Catherine.Simoneau@jrc.it).

Yours sincerely,

Enclosures. a. Technical dossier.
b. Petitioner Summary Data Sheet.

1.7.3 Explanation to model letters

The numbers between brackets in model letters nos. 1 and 2 have the following meaning:

(1) submit a separate request for each substance (except when a group of substances is being considered for a group evaluation and group restriction)

(2) delete monomer or additive as appropriate

(3) specify name, address, telephone, fax and E-mail of petitioner

(4) specify the chemical name, main chemical synonyms (e.g. IUPAC name) and trade names, CAS number

(5) specify name, address, telephone, fax and E-mail of the person responsible for the technical dossier

(6) see item 1.8.

(7) see EC 'Note for guidance', Chapter III, Annex 6

1.7.4. Model letter N° 3

RECEIPT OF A PETITION BY COUNCIL OF EUROPE

PETITION ACCEPTED AFTER THE AAP

Dear Mr/Ms .....

Ref. : Your petition dated ....., concerning the substance REF.N. .....

On behalf of the Council of Europe, I acknowledge receipt of the documentation referred to above which you have submitted for evaluation to the *ad hoc* Group.

Your documentation has been classified under document reference number **CoE No .....**

Your documentation has been classified already under SCF substance reference number **PM/REF.N. ……**

The substance reference number **CoE No .....** has been attributed to the substance // has been already attributed to the substance. The name of the substance is unchanged/changed to.....In all future correspondence referring to this documentation, please quote both these reference numbers as well the old and the new names.

The acceptance of your petition does not imply that the documentation provided is in full compliance with the CoE Guidelines. The Council of Europe reserves the right to request additional information.

Due to the large numbers of substances to be evaluated by the *ad hoc* Group it is not possible to indicate at the moment the date on which your substance will be examined. In principle, the Council of Europe will no longer send an individual letter to the petitioner to inform him on the evaluation unless there is a request from the petitioner.

I inform you that as a general rule, the scientific basis for the Committee of Experts opinions may be made available to the Member States' competent authorities, should they so request. Additionally, the method of analysis included in the petitions may be delivered to anyone who requests it**.** These general rules will be applicable in the case of your submission unless we hear to the contrary within 40 days from the date of this letter.

Moreover, I inform you that as a general rule the Council of Europe considers as the date of submission the date on which the petition was accepted (date of transmission of the AAP positive)

Yours sincerely,

1.7.5. Model letter N° 4

RECEIPT OF A PETITION BY COUNCIL OF EUROPE

PETITION REFUSED AFTER THE AAP

Dear Mr/Ms .....

Ref. : Your petition dated ....., concerning the substance CoE No. .....

On behalf of the Council of Europe, I acknowledge receipt of the documentation referred to above which you have submitted for evaluation by the *ad hoc* Group.

Your documentation has been classified under document reference number **CoE No.....**

The substance reference number **CoE No. .....** has been attributed to the substance // has been already attributed to the substance. The name of the substance is unchanged/changed to.....In all future correspondence referring to this documentation, please quote both these reference numbers as well the old and the new names.

Your documentation does not comply with the CoE Guidelines for the following reasons:
"..... ......"

Therefore, I regret to inform you that your petition cannot be examined until the technical dossier is completed or presented in the specified format set out in the above-mentioned document, a copy of which can be transmitted on your specific request. If you cannot conform to the Guidelines, the reasons should be given in the Petitioner Summary Data Sheet.

Moreover, I should inform you that as a general rule the Council of Europe considers as the date of submission the date on which the petition was accepted (date of transmission of the AAP positive).

Yours sincerely,

1.8. TECHNICAL DOSSIER

1. Technical dossiers, submitted to the Council of Europe or to the national authorities (for a provisional authorisation), should contain the data set out in Chapter III of the EC 'Note for guidance'.

2. New substances

For obtaining authorisation for the use of a new substance as a constituent of paper and board food contact materials, the petitioner is invited to submit to the Council of Europe the data requested in the CoE Guidelines.

3. Substances already evaluated by SCF or the CoE *ad hoc* Group

For re-evaluation of a substance for use as a constituent of food contact materials, that has already been examined but not fully evaluated by the *ad hoc* Group because of lack or insufficiency of technical data, the petitioner is invited to submit to the Council of Europe the data set out in Chapter III of the EC 'Note for guidance'.

4. Guidelines

The petitioner is invited to follow in both above-mentioned cases the CoE Guidelines and the EC Note for Guidance Chapter III (Explanatory Guidance of the SCF guidelines for Food Contact Materials.

Note that the CoE Guidelines emphasise that *"Any reference to published information on the substance applied for and, where applicable, to related compounds critical to support the application should be accompanied by a copy of the relevant documents."*

ANNEX A

CLASSIFICATION SYSTEM FOR SUBSTANCES TO BE USED FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

A.1. General specifications

List 1 - Substances approved for the use of materials and articles intended to come into contact with food

1. Substances evaluated by SCF, classified in list 0-4, and used in compliance with specific migration limits or other restrictions, if any;

2. Substances evaluated and approved by the Committee of expert on materials coming into contact with food;

3. Substances approved in Partial Agreement member states or by FDA, based on an evaluation of a toxicological dossier, which meets the present SCF criteria;

4. Substances authorised as direct food additives in compliance with specific migration limits or other restrictions;

5. The substances which have been approved by Partial Agreement member states or by FDA applying scientific evaluation criteria of the time of their approval will be listed in a Temporary Appendix to List 1.

List 2 – Substances not approved for the use of materials and articles intended to come into contact with food

Substances which do not meet the criteria set for List 1 substances.

A.2. Complementary specifications

1. The substances of the Temporary Appendix should be integrated in List 1 or List 2 not later than five years after adoption of the List of substance.

2. List 1 and List 2 will be updated in principle once a year in order to take into account newly evaluated substances, new submissions by industry or substances to be deleted.

CHAPTER II

PRESENTATION OF AN APPLICATION FOR ASSESSMENT OF A SUBSTANCE TO BE USED IN PAPER AND BOARD FOOD CONTACT MATERIALS AND ARTICLES

1. GUIDING PRINCIPLES

The general problem arising from the use of food contact materials derives from their content of substances capable of migrating into the contacted food. Therefore, to protect the consumer, an assessment of the potential hazards from oral exposure to those constituents that migrate into the food must be made.

To establish the safety from ingestion of migrating substances, both the toxicological data indicating the potential hazard and the likely human exposure data need to be combined.

However, the Committee of Experts is aware that for most substances used in food contact materials, human exposure data are not readily available.

The Committee of Experts will therefore continue to use data from studies on migration into food or food simulants and, for reasons of prudence, maintains the assumption that a person may consume daily up to 1 kg of food in contact with the relevant food contact material.

The Committee of Experts is aware that discussions on food consumption factors are ongoing and they may permit in future more accurate estimates of intake.

The Guidelines were developed to provide guidance to the applicant on the scope of the data requirement, the latter depending on the extent of the likely migration into food, and to enable the Committee of Experts to evaluate the paper and board substances used in the intended application as food contact material.

It should be noted however that the Guidelines should not be applied or interpreted too rigidly. For example, since the petitioner has knowledge of the identity, use of and potential exposure to the substance requested, and of the data base available for it, the petitioner may deviate from the Guidelines, provided valid, scientific reasons are given in the application. On the other hand, the petitioner should provide all available data, which are relevant for the evaluation by the Committee of Experts. In all cases the Committee of Experts may request additional data if the data submitted are equivocal or warrant further investigation.

As a general principle the greater the exposure through migration the more toxicological information will be required:

(a) In case of high migration (i.e. 5 – 60 mg/kg food) an extensive data set is needed to establish the safety;

(b) In case of migration between 0.05 – 5 mg/kg food a reduced data set may suffice;

(c) In case of low migration (i.e. <0.05 mg/kg food) only a limited data set is needed;

(d) In addition to the SCF, the Committee of Experts decided that compounds with a very low migration (i.e. <0.5 µg/kg food) will have low priority for toxicological evaluation and only a very limited data set is needed to establish the safety.

In determining the appropriate extent of the data set required the migration values should not be regarded as absolute limits but as indicative values.

The selection criteria for paper and board substances to be included to the priority list of substances to be evaluated are the following:

- structural alert indicative for carcinogenicity
- exposure
- new not evaluated substances
- end use (contact with fatty, dry foodstuffs, etc)
- if necessary other criteria might be considered.

The costs for the evaluation of the files and the preparation of the summary datasheets by national experts and/or institutes of the Partial Agreement member states should be covered by industry.

It should be noted that the Guidelines do not include any consideration of environmental aspects such as persistence in the environment, ecological impact of their constituents and their fate after the food contact material has been submitted to waste disposal treatment.

2. INFORMATION TO BE SUPPLIED WITH AN APPLICATION FOR SAFETY ASSESSMENT OF A SUBSTANCE

Applications submitted must contain sufficient details for evaluation. They should be structured in the order given below under 1-6. Justification for any deviation from the following guidelines must be given in the summary data sheet. Any reference to published information offered in support of an application should be accompanied by reprints or photocopies of such references. A summary data sheet must also be prepared.

2.1. Identity of the substance

Name and all relevant information concerning the substance, its impurities, its breakdown and reaction products.

2.2. Physical and chemical properties of the substance

All relevant physical and chemical information concerning the substance, its breakdown and reaction products.

2.3. Intended use of the substance

Statement of the intended use of the substance.

2.4. Authorisation of the substance

Information concerning authorisation for use of the substance in Partial Agreement member states, USA and other countries, e.g. Japan.

2.5. Migration/extraction data on the substance

To permit estimation of the likely maximum daily intake of the substance, its impurities, its breakdown and reaction products give, where practicable, information on their concentrations in the food itself. Alternatively; information on migration into food simulants or extraction of the paper and board material under standard conditions of migration/extraction testing, applying the worst case scenario. If known, include exposure estimates from other non-food contact material sources.

2.6. Data on the residual content of the substance

All relevant information concerning the residual content of the substance in the food contact material.

2.7. Toxicological data

2.7.1. General requirements

The general requirements for toxicological studies which have to be supplied for paper and board substances in food contact materials are set out below. It should be recognised that not all chemicals used in the manufacture of a food contact material will migrate into food. Many will form a stable part of a polymer, some will migrate only in minute quantities, if at all, others will disappear during production, while yet others will decompose completely to yield either no or vanishingly small residues. While many substances migrate in the same chemical form in which they were incorporated into food contact materials, others will migrate partially or totally in another chemical form. In such cases the toxicological requirements may also apply to the transformation or reaction products.

2.7.2. Core set

The core set of tests comprises:

- 3 mutagenicity studies in vitro:

  - a test for gene mutations in bacteria;

  - a test for chromosomal aberrations in cultured mammalian cells;

  - a test for gene mutations in cultured mammalian cells;

- 90-day oral toxicity studies;

- studies on absorption, distribution, metabolism and excretion;

- studies on reproduction in one species, and developmental toxicity, normally in two species;

- studies on long-term toxicity/carcinogenicity, normally in two species.

These studies should be carried out according to prevailing EU or OECD guidelines, including “Good Laboratory Practice”. The substances tested should be of the same specification as described in section 2.1.

Health information on people exposed occupationally would be regarded as useful ancillary information.

2.7.3. Reduced core set

Under certain circumstances the core set of tests not be required and only the tests indicated below may have to be provided.

In cases where migration is in the range from 0.05 – 5 mg/kg of food/food simulant, the following data are needed:

- the 3 mutagenicity tests mentioned in point 2.7.2;

- a 90-day oral toxicity study;

- data to demonstrate the absence of potential for accumulation in man.

In cases where migration is below 0.05 mg/kg of food/food simulant the following data are needed:

- the 3 mutagenicity tests mentioned in point 2.7.2.

In addition to the SCF guidelines, the Committee of Experts, decided that in cases where migration is below 0.5 µg/kg of food or food simulant a literature search for toxicological data on the substance and its impurities is needed, demonstrating the absence of a structural alert for carcinogenicity.

2.7.4. Special investigations/additional studies

If the above-mentioned studies or prior knowledge or structural considerations indicate that other biological effects such as peroxisomal proliferation, neurotoxicity, immunotoxicity or endocrinological events may occur, additional studies may be required.

At present no validated methods are available for studies in laboratory animals which would allow assessment of a substance's potential to cause intolerance and/or allergic reactions in susceptible individuals following oral exposure. However, studies on dermal or inhalation sensitisation may give information relevant for possible hazards from occupational exposure and could be helpful in assessing consumer safety.

Under certain circumstances, particularly those relating to the chemical nature of the substance to be used in food contact materials, the tests normally to be provided for the safety evaluations and risks assessments may be modified as outlined below.

2.7.4.1. Hydrolysable substances

If the chemical structure suggests ready hydrolysis of the substance in food and/or the gastrointestinal tract into components which already have been toxicologically evaluated, the rate of hydrolysis and its degree of completeness will determine the extent of toxicological testing necessary for an evaluation. In particular, it will depend on these parameters. Whether the unhydrolysed substance needs also to be included in the testing programme depends on the outcome of the hydrolysis studies.

2.7.4.2. Polymeric additives

Because only the fraction with molecular mass below 1000 D is regarded as toxicologically relevant, a distinction has been made between polymeric additives with a weight averaged

molecular mass (Mw) below 1000 D and those with Mw above 1000 D. For those polymeric additives with a Mw > 1000 D only a reduced set of data may be required. In deciding which data are needed, the data available on the monomers involved, the size of the fraction with molecular masses below 1000 D, and the proportion of the additive in the paper and board will be taken into account.

2.7.4.3. Foodstuffs/food ingredients

These can be used as monomers, as starting substances or as additives and will require only the data requested in sections 2.1 and 2.3.

2.7.4.4. Food additives

Those already evaluated by the SCF, will in the first instance, only require the data requested in sections 2.1, 2.3 and 2.6.

2.7.4.5. Biocides

Biocides intended to be present in food contact materials require additional considerations to those applied to microbiologically inert substances of food contact materials. The petitioner should provide evidence that any migration into food is not intentional but only incidental; that its use does not exert any preservative effect on the food; that it does not allow the selection on non-sensitive organisms on the surface of the food contact materials; and that it does not allow the development of biocide resistance in sensitive micro-organisms.
The petitioner should also provide evidence that the substance is not used to reduce the normal hygienic measures required in handling foodstuffs.

CHAPTER III

EXPLANATORY GUIDANCE FOR INFORMATION TO BE SUBMITTED FOR A SAFETY ASSESSMENT OF A SUBSTANCE

1. CoE EXPLANATORY GUIDANCE

This explanatory guidance is extracted from EC "Note for Guidance" related to plastics (see website http://europa.eu.int/comm/food/fs/sfp/food_contact/index_en.html) and is amended in order to take into account the technological properties of paper and board.

2. EC "NOTE FOR GUIDANCE"

For the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation migration, Chapters III and IV of the EC "Note for Guidance" should be consulted (but see also note 2.1 below). However, it should be noted that the chapters in the EC Note for Guidance were prepared for plastics materials and articles. Hence some parts may use terms and examples more applicable for plastics. To avoid repetition, the reader is advised to use the EC document, substituting 'polymer' with 'paper and board' where appropriate and providing the information as applicable for paper and board.

2.1. Section 5 of EC Note for Guidance 'Data on migration of substance'

Section 5 of the EC Note for Guidance "Data on migration of substance" has been amended by the *ad hoc* group to take into account the technical nature of paper and board in comparison with plastics. The amended section is shown in Annex A of this chapter.

ANNEX A

AMENDED SECTION 'DATA ON MIGRATION OF SUBSTANCE' (based on EC NOTE FOR GUIDANCE, CHAPTER III, SECTION 5)

5. DATA ON MIGRATION OF SUBSTANCE

For migration testing, the following CoE documents should be consulted: Technical Document No. 2 'Test conditions and methods of analysis for paper and board intended to come into contact with food', 'Practical Guide for users of Resolution AP(2002) 1' and EC Note for Guidance, Chapter III, Section 5.

5.1 specific migration (SM):

Answer 'SM determined' or 'SM not determined'. If SM is not determined give reasons. In general the determination of the specific migration will be requested to demonstrate worst case migration. Based on the level of migration the number of toxicity tests can be established. However there are a number of exceptions where specific migration can be replaced by the determination of the actual content of the substance followed by worst case calculation.
All experiments required for specific migration testing should be performed in triplicate.
In cases where it may be impossible to measure specific migration because of the properties of the substance, e.g. polymeric additives, a determination of overall migration could be used to demonstrate worst case migration of the substance.

5.1.1 substance:

Set out substances determined. Information on migration of decomposition products and/or impurities, if any, may be required as well.

5.1.2 test sample:

The test sample should always represent the worst case situation. In general, the material with the highest concentration of the substance and the greatest thickness should be used for testing. If the test sample is intended to represent a range of materials of different brands or grades, then the material should be selected that represents the worst case situation for migration or extraction testing. If the substance is used in different kinds of paper and board then, in principle, each type of paper and board should be tested. However, if it is properly argued, only migration or extraction tests with the material representing worst case may be acceptable. For example, if an additive is used in paper and board made from virgin fibres only and in board using recycled fibres, tests with the highest grammage of either the virgin or recycled material may suffice.

5.1.2.1 chemical composition: Set out the chemical composition of the test sample. Information should be provided particularly on the initial concentration of the substance, but information on the total composition is also required as the composition of the test specimen may influence the final migration of the substance.

5.1.2.2 physical composition: Set out the physical composition of the test sample, such as homogenous material, multi-ply, multi-layer with different layers etc. In the case of multi-ply and multi-layer materials, it should be indicated in which layer the substance is present. If this is not the direct food contact side, then also relevant information on the top-layers shall be given.

5.1.2.3 grammage of material: Set out the grammage of the paper and board material containing the substance. In multi-layer constructions, the grammage of individual layers of paper and board shall be given.

5.1.2.4 dimensions of test sample: Set out the dimensions of the test sample. The test sample is the sample manufactured for the purpose of the migration or extraction study. Provide information on shape e.g. sheet, tray, tube etc., thickness and grammage (in g/m^2). For multi-layer materials, the total thickness and the thickness of each relevant layer should be indicated. For articles with inhomogeneous thickness, the thickness at various places should be given. The dimensions of an article should be set out (height, length, width and/or diameter).

5.1.2.5 dimensions of test specimen: Describe briefly that part or section of the test sample from which the test specimen was taken, particularly in the case of inhomogeneous materials e.g. trays. Set out spatial dimensions of test specimen (length, height, width, diameter). Calculate the total area of the test specimen. In case of two-sided contact used for testing, calculate the total area of both sides. If the test specimen does not come into contact completely with the simulant (with use of one side migration cells) then calculate the actual contact area.

5.1.3 treatment of test sample prior to testing: Describe any treatments applied to food contact material prior to testing e.g. for filter papers, any prior passage of water, solvent or foodstuffs. Treatment of a test sample should be representative of use in practice.

5.1.4 test food(s)/food simulant(s)/ extraction solvent(s): Set out the foodstuff(s) or food simulant(s) or substitute test media or extraction solvent(s) used in migration testing. For the selection of the food

simulant refer to Technical Document No. 2 "Test conditions and methods of analysis for paper and board intended to come into contact with foodstuffs". The use of olive oil may be difficult for technical reasons. The use of alternative tests using volatile test media or extraction solvent(s) may be required. If testing is carried out with volatile test media or extraction solvents, evidence should be presented that use of these solvents produces migration equal to or higher than testing with food(s) or food simulant(s).

5.1.5 contact mode:

Set out whether the sample was tested on one or two sides. Set out in which way contact wit the simulants was achieved, e.g.: cell, total immersion, article filling etc. If tested on two sides, set out whether one or both sides of the test specimen are used in the calculation of the contact area.
For extraction testing, set out the conditions of extraction **-** identity of solvent(s), type of contact e.g. single sided, total immersion, use of agitation (if relevant) etc.

5.1.6 contact time and temperature

Set out the duration of the test and the test temperature. In the case of short contact times (≤2 h) at high temperature (≥100°C), describe or demonstrate maintenance of the temperature over the test period.

5.1.7 surface to volume ratio:

If using food simulant(s) or test media for migration testing, set out the dm^2 of test sample per kg of food or per L of simulant. Give the actual contact area of sample and the volume of simulant (or grammage in the case of modified polyphenylene oxide (MPPO). Calculate from these data the actual surface area to volume ratio applied in the migration test. Conventionally the ratio is 6 dm^2/kg simulant. For analytical reasons it is often necessary to deviate from that ratio which, in principle, is acceptable. However it should be carefully considered whether or not the migration, using a higher ratio of area to volume, could influence the final migration due to saturation of the simulant.
If using volatile test media or extraction solvents, give the contact area of the sample and the volume of simulant.

5.1.8 to 5.1.13 as per EC note for Guidance Chapter III but in 5.1.13 replace or add the following information:

- simulant or extraction solvent
- volume of food simulant or extraction solvent used in the test
- Actual concentration of the substance in the simulant or extraction solvent as obtained from the migration test or extraction, respectively

- migration in the food simulant or extraction solvent expressed in mg/dm^2.

5.2 overall migation (OM): Answer 'determined', 'not determined'.
In general, the determination of the OM as described in CEN methods EN 1186 is not required for the petitioning of an additive or a monomer and is not specified in the Resolution on Paper and Board ResAP (2002) 1 for determining compliance with the Resolution. However, overall migration could be used as a replacement for specific migration in those cases where the specific migration is impossible to measure because of the properties of the substance e.g. polymeric additives. The overall migration may be used to demonstrate worst case migration of the substance. It should be noted that determining overall migration for paper and board with fatty simulants is difficult due to the problem of conditioning paper to constant weight. This problem does not arise using aqueous simulants or volatile test media or extraction solvents. For quantification purposes, the conventional gravimetric tests as used for determining overall migration from plastics materials and articles described in CEN methods EN 1186 may be used, but they may not be suitable in many cases due to a lack of sensitivity or accuracy. Taking a larger area of the test might overcome this problem. If the surface area to volume ratio is increased in this way, consideration must be given to whether the substance will be limited with regard to solubility in the solvent.

Then as per **5.2.1 to 5.11** of the EC Note for Guidance.

CHAPTER IV

EXPLANATORY GUIDANCE FOR MIGRATION TESTING

The reader of these Guidelines is referred to Chapter IV of the EC Note for Guidance for explanatory guidance for migration testing. However, it should be recognised that the EC note for guidance was prepared to provide guidance on migration testing for plastics materials and articles. Hence some sections of Chapter IV of the EC note may not be applicable for paper and board. The reader's attention is referred to Annex A of this chapter where further explanation or clarification is given for paper and board. The sections in Annex A should be read in place of those in the EC note for guidance for the purposes of preparing an application to be submitted to the Council of Europe for safety evaluation of a substances to be used in the manufacture of paper and board. It should be noted that the clarifications are not exhaustive and that sections of Chapter IV of the EC Note for Guidance not addressed in Annex A may still contain information more specific for plastics than for paper and board. However, it should be possible for the reader to use the principles laid down in these sections of the EC Note and to apply them to migration testing of paper and board.

It should be noted that an applicant preparing a submission to the Council of Europe is not obliged to use the procedures laid down in Chapter IV of the EC Note for Guidance together with the amendments noted in Annex A. These documents are provided for guidance purposes only and it is recognised that they may not be applicable for testing all types of paper and board materials for migration in all situations. The applicant can use other procedures for migration testing which they consider more appropriate for the particular material and substance under question. However, if they use other procedures than those laid down in these documents, they should provide full details in the application for safety assessment of the substance.

ANNEX A

The NOTA BENE and Introduction of Chapter IV of the EC Note for Guidance are deleted and replaced by:

1. Introduction

1.1 This document provides an explanation and guidance on the conducting of prescribed "migration tests" as well as the "substitute" and "alternative" tests referred to in EC Directive 97/48/EC (2nd amendment to Directive 82/711/EEC) and which, in principle, can be used for determining migration from paper and board, as noted in Technical Document No. 2 'Test Conditions and Methods of Analysis for Paper and Board Intended to Come into Contact with Foodstuffs. It is particularly aimed at the analysts who carry out testing to ensure compliance, e.g. enforcement authorities, industry, retailers and certification laboratories. It should also be used by analysts preparing a technical dossier to be submitted to the Council of Europe.

2.2 Food simulants

After 'rectified olive oil (simulant D) insert:

Council of Europe Technical Document No. 2 'Test Conditions and Methods of Analysis for Paper and Board Intended to Come into Contact with Foodstuffs notes that:

"for those foodstuffs which in Directive 85/572 no simulant is provided ("dry foodstuffs"), migration testing should be carried out using modified polyphenylene oxide (MPPO) as a test medium"

Therefore MPPO should be added to the list of simulants for paper and board. It should be noted that it is to be used for testing for materials coming into contact with dry foods.

2.8.3 Test media

Insert the following phrase between 2.8.3 and 2.8.3.1:

It should be noted that the comments in 2.8.3.1 and 2.8.3.2 on the use of iso-octane and ethanol 95%, respectively, are based upon data obtained for the determination of overall migration for plastics materials and articles. Insufficient data is available for paper and board to unequivocally accept these test media as giving equivalent migration to olive oil (simulant D). However, in the absence of suitable data, the use of these test media is considered acceptable. If using these test media to determine migration, the reader is advised to consider the chemical nature of the substance under consideration and its solubility in the test media compared to its known or anticipated solubility in the actual foodstuffs with which the paper and board may come into contact. The test medium with the most similar solubility to the food should be selected for migration testing. The reader is advised to pay particular attention to the note that 'the use of iso-octane (or 95% ethanol) in specific migration testing should therefore be considered on a case by case basis'.

2.8.3.3 Modified polyphenylene oxide (MPPO)

Insert at end:

Note also that MPPO can be used as a test medium for paper and board coming into contact with dry foodstuffs (see Council of Europe Technical Document No. 2 'Test Conditions and Methods of Analysis for Paper and Board Intended to Come into Contact with Foodstuffs' and section 2.2 of this Chapter).

2.9.3 Extraction test

After "…..10 mg/dm^2 is not exceeded" add the following paragraph

The comments noted above apply specifically to plastics materials and articles. Insufficient data is available to provide information on the most appropriate extraction solvents for paper and board. Some experimentation may be required to establish which are the most appropriate solvents in order to provide evidence that the requirement of 'equal or higher migration' is fulfilled.

3. Calculation of maximum possible migration

The reader is referred to the Council of Europe' Practical Guide for users of Resolution ResAP (2002) 1 for guidance on calculation of maximum possible migration for paper on board.

BIBLIOGRAPHY

1) Council Directive 82/711/EEC of 18 October 1982
(O.J. N. L 297 of 23.10.1982, p. 26).

2) Council Directive 85/572/EEC of 19 December 1985
(O.J. N. L 372 of 31.12.1985, p. 14).

3) Commission Directive 90/128/EEC of 23 February 1990
(O.J. N. L. 349 of 13.12.1990, p. 20).

4) Commission Directive amending Council Directive 82/711/EEC
(under press).

5) Council Directive 86/609/EEC of 24 November 1986
(O.J. N. L. 358 of 18.12.1986, p. 1).

6) Commission Directive 84/449/EEC of 25 April 1984
(O.J. N. L 251 of 19.09.1984).

7) Commission Directive 87/302/EEC of 18 November 1987
(O.J. N. L 133 of 30.05.1988, p. 1).

8) Council Directive 87/18/EEC of 18 December 1986
(O.J. N. L 15 of 17.01.1987, p. 29).

9) Council Directive 88/320/EEC of 9 June 1988
(O.J. N. 145 of 11.06.1988, p. 35).

10) Council Decision 89/569/EEC of 28 July 1989
(O.J. N. L. 315 of 28.10.1989, p. 1).

11) Commission Directive 90/18/EEC of 18 December 1989
(O.J. N. L. 11 of 13.01.1990, p. 37).

12) Commission Directive 97/48/EC of 29 July 1997
(O.J. N. L 222 of 12.08.1997, p. 10.)