

**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**

**CORK STOPPERS AND OTHER CORK MATERIALS
AND ARTICLES INTENDED TO COME INTO
CONTACT WITH FOODSTUFFS**

Version 2 – 05.09.2007

NOTE TO THE READER

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

- Resolution ResAP (2004) 2 on cork stoppers and other cork materials and articles intended to come into contact with foodstuffs
- Technical document No. 1 – List of substances to be used in the manufacture of cork stoppers and other cork materials and articles intended to come into contact with foodstuffs (12.07.2007)
- Technical document No. 2 - Test conditions and methods of analysis for cork stoppers and other cork materials and articles intended to come into contact with foodstuffs

The documents are available on the Internet website of the Partial Agreement in the Social and Public Health Field:

www.coe.int/soc-sp

Table of contents

	Page
Resolution ResAP (2004) 2 on cork stoppers and other cork materials and articles intended to come into contact with foodstuffs	5
Technical document No. 1 - List of substances to be used in the manufacture of cork stoppers and other cork materials and articles intended to come into contact with food (12.07.2007)	11
Technical document No. 2 - Test conditions and methods of analysis for cork stoppers and other cork materials and articles intended to come into contact with foodstuffs	31

**RESOLUTION ResAP (2004) 2 ON
CORK STOPPERS AND OTHER CORK MATERIALS
AND ARTICLES INTENDED TO COME INTO CONTACT
WITH FOODSTUFFS**

Resolution ResAP(2004)2
on cork stoppers and other cork materials and articles intended to come into contact
with foodstuffs

*(Adopted by the Committee of Ministers on 1 December 2004
at the 907th meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the Representatives of the States members of the Partial Agreement in the Social and Public Health Field,¹

Recalling Resolution No. R (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 No. R (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 No. R (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 application: 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 – a model 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 legislation in the public health field and, in particular, with regard to materials and articles intended to come into contact with foodstuffs;

Considering that cork stoppers and other cork materials and articles intended to come into contact with foodstuffs may, by reason of the migration of their components to the foodstuffs, pose in certain conditions a risk to human health;

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 States members of the Partial Agreement in the Social and Public Health Field to take into account in their national laws and regulations on cork stoppers and other cork materials and articles intended to come into contact with foodstuffs the principles set out hereafter.

¹ Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and United Kingdom

**Appendix to Resolution ResAP(2004)2
on cork stoppers and other cork materials and articles intended
to come into contact with foodstuffs**

1. Field of application

1.1. Resolution ResAP(2004)2 applies only to the cork part of cork stoppers and any other cork materials or articles whose main component is manufactured cork which, in the finished product state, is intended to come into contact with or is placed in contact with foodstuffs.

1.2. Plastic capsules or any other materials such as glass or metal are excluded from the field of application.

2. Definition

2.1. The definitions of ISO 633 concerning cork apply to the Resolution.

2.2. Cork stoppers or the cork part of stoppers should contain at least 51% of manufactured cork w/w.

2.3. The cork part of cork stoppers can be made of a whole piece or two or more pieces of cork or granulated cork which are bound together by means of glues, adhesives or by any other means.

3. Specifications

Cork used for food contact applications under normal or foreseeable conditions of use should meet the following conditions:

3.1. it should not transfer its constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or deterioration in the organoleptic characteristics thereof;

3.2. cork stoppers should be manufactured in accordance with the International Code of Cork Stoppers Manufacturing Practice, drawn up by the European Cork Federation (C.E. Liège), using the substances of *“Technical document No. 1 – List of substances to be used in the manufacture of cork stoppers and other cork materials and articles intended to come into contact with foodstuffs”* and according to the conditions specified;

3.3. silicones used should comply with Resolution ResAP(2004)5 on silicones used for food contact applications;

3.4. any other constituent than cork and not included in *“Technical document No. 1 – List of substances to be used in the manufacture of cork stoppers and other cork materials and articles intended to come into contact with foodstuffs”* should comply with corresponding European Union Directives, if any, and Article 2 of Directive 89/109/EEC and its future amendments;

3.5. additives used on the surface of cork stoppers or other cork materials and articles, such as paraffin and wax, should comply with European Union Directives on food additives, if any;

3.6. brand printing by hot stamp or with authorised pigments is authorised;

3.7. colorants or pigments of inks used for printing surfaces of cork stoppers and those used in the cork stoppers' treatment should be edible colorants or pigments and be in compliance with European Union regulations for foodstuffs;

3.8. any other colorants and pigments should comply with the restrictions set in "*Technical document No. 1 –List of substances to be used in the manufacture of cork stoppers and other cork materials and articles intended to come into contact with foodstuffs*";

3.9. cork stoppers and other cork materials and articles intended to come into contact with foodstuffs should comply with the following restriction limits and with either the QMA² or SML³ restrictions laid down in "*Technical document No. 1 – List of substances to be used in the manufacture of cork stoppers and other cork materials and articles intended to come into contact with foodstuffs*";

3.9.1. restriction limits for Pentachlorophenol as contaminant:

- residues in cork as QMA limit: 0.15 mg/kg cork
- migration into simulant: 150 ng/kg or l

3.9.2. restriction limit for Trichlorophenols as contaminant:

- migration into simulant: 2,000 ng/kg or l

3.10. verification of compliance with the quantitative restrictions should be carried out according to the conditions laid down in "*Technical document No. 2 – Test conditions and methods of analysis for cork stoppers and other cork materials and articles intended to come into contact with foodstuffs*";

3.11. migration tests should be conducted according to ISO 10.106 standards on cork articles;

3.12. Directives 82/711/EEC, 85/572/EEC, 93/8/EEC, 97/48/EEC, 2002/72/EEC and their future amendments should be applied, as appropriate, unless technically impracticable due to the nature of the material and the migration tests;

3.13. if more severe methods of analysis prove that the limit of maximum migrations are fulfilled then no migration tests will be required;

3.14. cork stoppers or cork articles used as agricultural products should comply with Article 2.i of Directive 98/8/EC concerning the placing of biocidal products on the market, and future amendments. The migration of residues of pesticides into foodstuffs should comply with European Union Directives on foodstuffs;

3.15. cork should not contain any fungi or yeast that could produce any microbiological contamination, which poses a risk to human health or could cause unacceptable changes in the foodstuffs which are in contact with the cork articles;

3.16. the residues of mycotoxins in cork should comply with the limits of European Union Directives for agricultural products and the migrations of these toxins to the foodstuffs should comply with the specific limits established in these directives for them.

¹ QMA : maximum permitted quantity of the substance in the finished material or article expressed as mg per dm² of the surface in contact with foodstuffs.

For contact conditions where the mass of food to contact area ratio differs from the conventional ratio of 1 kg to 6 dm², the QM restriction to be applied should be calculated as specified in "*Technical document No. 2 - Test conditions and methods of analysis for cork stoppers and other cork materials and articles intended to come into contact with foodstuffs*".

² The SML restrictions are those set in the European Union Directives for plastic materials intended to come into contact with foodstuffs.

References

ISO 10106 Cork stoppers - Determination of global migration.

ISO 10718 Cork stoppers - Enumeration of colony-forming units of yeasts, moulds and bacteria capable of growth in an alcoholic medium.

ISO 633. ISO 2569 - Vocabulary of cork.

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 93/8/EEC of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (97/48/CE) (Official Journal L 090 , 14.04.1993 P. 0022 – 0025).

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, 12.08.97).

Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (Official Journal L 220, 15.08.2002 P. 0018 – 0058).

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal L 123, 24.04.1998 P. 0001 – 0063).

TECHNICAL DOCUMENT No. 1

**LIST OF SUBSTANCES TO BE USED IN THE MANUFACTURE OF
CORK STOPPERS AND OTHER CORK MATERIALS AND ARTICLES
INTENDED TO COME INTO CONTACT WITH FOODSTUFFS**

(12.07.2007)

Table of contents

	Page
1. Classification system of substances to be used for materials and articles intended to come into contact with foodstuffs.....	13
2. Introduction.....	14
3. Glossary.....	15
4. Information and abbreviations	16
5. Notes related to the column “restrictions and/or specifications”	18
6. Lists of substances	19

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

- **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/EFSA, 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 experts 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/EFSA criteria;
4. Substances authorised as direct food additives in compliance with specific migration limits or other restrictions;
5. Substances which have been approved by Partial Agreement member states or by FDA applying scientific evaluation criteria of the time of their approval, 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 of 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 the adoption of the List of substances.
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

The Technical document No. 1 contains the lists of substances which may be used in the manufacture of cork stoppers and other cork materials and articles intended to come into contact with foodstuffs.

2.1 The lists of present technical document are as follows:

- A. **List 1 of monomers and other starting agents:** List of substances assessed and approved by Partial Agreement member states.
- B. **Temporary Appendix to List 1 of monomers and other starting agents:** List of substances approved by Partial Agreement member states or by FDA, applying evaluation criteria at the time of their approval.
- C. **List 2 of monomers and other starting agents:** List of substances not yet assessed and not approved by Partial Agreement member states.
- D. **List 1 of additives:** List of substances assessed and approved by Partial Agreement member states.
- E. **Temporary Appendix to List 1 of additives:** List of substances approved by Partial Agreement member states or by FDA, applying evaluation criteria at the time of their approval.
- F. **List 2 of additives:** List of substances not yet assessed and not approved by Partial Agreement member states.
- G. **List 1 of aids to processing:** List of substances assessed and approved by Partial Agreement member states.
- H. **Temporary Appendix to List 1 of aids to processing:** List of substances approved by Partial Agreement member states or by FDA, applying evaluation criteria at the time of their approval.
- I. **List 2 of aids to processing:** List of substances not yet assessed and not approved by Partial Agreement member states.

2.2 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.

2.3 The substances should be of good technical quality as regards the purity criteria.

3. GLOSSARY

For the purposes of the present Technical document No. 1, the following definitions are given:

Additive: A substance intentionally added to the cork material or article, to achieve a specific technical effect and/or enhance certain characteristics on final product.

Aids to processing: A substance used to facilitate and promote a specific technical effect during processing and/or to provide a suitable medium in which operations take place. Under normal and foreseeable conditions these substances do not become part of the final product, being lixiviated, consumed or neutralised during processing.

They include for example:

- Catalysts
- Buffering agents
- Surfactants
- Stabilizers
- Emulsifiers
- Solvents
- Redox agents
- Gases for modified atmosphere packaging

Monomers and starting substances: Any starting substance, regardless of its chemical nature (compound, mixture, monomer, oligomer, prepolymer, natural or synthetic macromolecules, etc.) used in any type of polymerisation process (e.g. polycondensation, polyaddition, curing) including the modification of natural or synthetic substances.

4. INFORMATION AND ABBREVIATIONS

The lists contain the following information:

- PM/REF No	:	The EU packaging material reference number of the substance
- CAS N°	:	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

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
- QM	:	Maximum permitted quantity of the residual substance in the material or article
- QM(T)	:	Maximum permitted quantity of the residual substance in the material or article expressed as total of moiety/substance(s) indicated
- ADI	:	Acceptable daily intake as defined in the reports of the Scientific Committee for food / EFSA
- TDI	:	Tolerable daily intake as defined in the reports of the Scientific Committee for food / EFSA
t-ADI	:	Temporary ADI
MTDI	:	Maximum tolerable daily intake
PMTDI	:	Provisional MTDI
PTWI	:	Provisional tolerable weekly intake

Definition of the SCF/EFSA Lists (briefly) :

- List 0	:	Substances which may be used and for which an ADI need not be established.
- List 1	:	Substances for which an ADI, a t-ADI, a MDI, a PMTDI, a PTWI or classification "acceptable" has been established.
- List 2	:	Substances for which a TDI or a t-TDI has been established.
- List 3	:	Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.
- List 4A (for monomers)	:	Substances for which an ADI or a TDI could not be established, but which could be used if the substance migrating is not detectable.
- List 4B (for monomers)	:	Substances for which an ADI or a TDI could not be established, but which could be used if the levels of monomer residues are reduced as much as possible.
- List 4 (for additives)	:	Substances for which an ADI or a TDI could not be established, but which could be used if the substance migrating is not detectable.
- List 5	:	Substances which should not be used.
- List 6	:	Substances for which there exist suspicions about their toxicity and for which data are lacking or are insufficient.
- List 6A	:	Substances suspected to have carcinogenic properties. These substances should be not detectable.
- List 6B	:	Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.
- List 7	:	Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.
- List 8	:	Substances for which no or only scanty and inadequate data were available.
- List 9	:	Substances and groups of substances which could not be evaluated due to the lack of specifications (substances) or to the lack of adequate descriptions (group of substances).
- List W	:	Waiting list. Substances not yet included in the Community Lists. New substances, i.e. substances never approved at national level.
- List W7	:	Substances for which some toxicological data exists, but for which an ADI or a TDI could not be established. The required additional information should be furnished.
- List W8	:	Substances for which no or only scanty and inadequate data were available.
- List W9	:	Substances and group of substances which could not be evaluated due to lack of specifications (substances) or to lack of an adequate description (group of substances).

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

(1)	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°: 16630, 25210 and 25240.
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A. LIST 1 OF MONOMERS AND STARTING SUBSTANCES

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
10120	000108-05-4	Acetic acid, vinyl ester	2	SML=12 mg/kg	0,2
10690	000079-10-7	Acrylic acid	2	SML=6 mg/kg	0,1
12100	000107-13-1	Acrylonitrile	4A	SML=ND (DL=0,01mg/kg)	
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	2	SML=0,6 mg/kg	0,01
16630	000101-68-8	Diphenylmethane-4,4'-diisocyanate	4A	SML(T)=ND (1) (DL=0,01mg/kg, as NCO)	
14500	009004-34-6	Cellulose	0		
14505	009004-35-7	Cellulose acetate	3		
15760	000111-46-6	Diethyleneglycol	2	SML=30 mg/kg	0,5
16950	000074-85-1	Ethylene	3		
(62255)	000075-28-5	Isobutane	3		
(62450)	000078-78-4	Isopentane	3		
21130	000080-62-6	Methacrylic acid, methyl ester	2	SML=6 mg/kg	0,1
22450	009004-70-0	Nitrocellulose	3		

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
22840	000115-77-5	Pentaerythritol	2		1
23590	025322-68-3	Polyethyleneglycol	2		5
23651	025322-69-4	Polypropyleneglycol	3		
24070	073138-82-6	Resin acids and Rosin acids	2		1
24100	008050-09-7	Rosin	2		1
24250	009006-04-6	Rubber, natural	3		
25210	000584-84-9	2,4-Toluene diisocyanate	4A	SML(T)=ND (1) (DL=0,01mg/kg, as NCO)	
25240	000091-08-7	2,6-Toluene diisocyanate	4A	SML(T)=ND (1) (DL=0,01mg/kg, as NCO)	
26050	000075-01-4	Vinyl chloride	4A	SML=ND (DL=0,01mg/kg)	
26110	000075-35-4	Vinylidene chloride	4B	SML=ND (DL=0,05mg/kg)	

B. TEMPORARY APPENDIX TO LIST 1 OF MONOMERS AND STARTING SUBSTANCES

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
(40455)	009003-55-8	Butadiene-Styrene copolymer	D	To be fixed	
-	-	Rubber latex, natural	-	To be fixed	
-	061788-66-7	Vegetable oil fatty acids	-	To be fixed	

C. LIST 2 OF MONOMERS AND STARTING SUBSTANCES

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
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(empty)

D. LIST 1 OF ADDITIVES

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
41520	001305-78-8	Calcium oxide	1		NS
42500	-	Carbonic acids, salts	1		NS
42800	009000-71-9	Casein	0		
(14685)	008001-31-8	Coconut oil	3		
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	4A	SML=ND (DL=0,01mg/kg)	
68320	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2	SML=6 mg/kg	0,1
74400	-	Phosphorous acid, tris (nonyl -and/or dinonylphenyl) ester	2	SML=30 mg/kg	0,5
76721	009016-00-6 063148-62-9	Polydimethylsiloxane (Mw > 6800)	2		1,5
81245	009003-20-7	Polyvinyl acetate	D	In compliance with FCC specif.	
83840	008050-09-7	Rosin	2		1
84080	008050-26-8	Rosin, ester with pentaerythritol	2		1
93440	013463-67-7	Titanium dioxide	1		ACC
95859	-	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	2	Specifications mentioned in 2002/72	20

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
95883	-	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	2	Specifications mentioned in 2002/72	4

E. TEMPORARY APPENDIX TO LIST 1 OF ADDITIVES

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
43760	026172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	7	To be fixed	
54060	024937-78-8	Ethylene-vinyl acetate, copolymer	D	To be fixed	
-	008002-74-2	Paraffin wax		To be fixed	
81280	009002-89-5	Polyvinyl alcohol	7	To be fixed	
94000	000102-71-6	Triethanolamine	8	To be fixed	

F. LIST 2 OF ADDITIVES

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
71300	064742-51-4	Paraffin waxes (petroleum), hydrotreated	W	To be fixed	
81160	009002-84-0	Polytetrafluoroethylene	D	To be fixed	
95860	-	Waxes, natural	D	To be fixed	

G. LIST 1 OF AIDS TO PROCESSING

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
35320	007664-41-7	Ammonia	1		NS
35600	001336-21-6	Ammonium hydroxide	1		NS
42500	-	Carbonic acid, salts	1		NS
41280	001305-62-0	Calcium hydroxide	1		NS
44160	000077-92-9	Citric acid	1		NS
52800	000064-17-5	Ethanol	1		ACC
55920	000056-81-5	Glycerol	1		NS
59330	000110-54-3	n-Hexane	8	In compliance with FCC specif.	
-	007722-84-1	Hydrogen peroxide	-	In compliance with FCC specif.	
-	007727-37-9	Nitrogen		Food additive (E 941)	
-	010028-15-6	Ozone	-	In compliance with FCC specif.	
72640	007664-38-2	Phosphoric acid	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
-	016731-55-8	Potassium metabisulphite		Food additive (E 224)	
81882	000067-63-0	2-Propanol	1		1,5
85680	001343-98-2	Silicic acid	2		NS
86720	001310-73-2	Sodium hydroxide	1		NS
86840	007681-57-4	Sodium metabisulphite	W	Food additive (E 223)	
88320	000050-70-4	Sorbitol	1		ACC
91840	007704-34-9	Sulphur	3		
91920	007664-93-9	Sulphuric acid	1		NS
-	007446-09-5	Sulphur dioxide		Food additive (E 220)	

H. TEMPORARY APPENDIX TO LIST 1 OF AIDS TO PROCESSING

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
45700	000110-82-7	Cyclohexane	8	To be fixed	
-	000079-21-0	Peracetic acid	-	To be fixed	
-	005329-14-6	Sulfamic acid	-	To be fixed	

I. LIST 2 OF AIDS TO PROCESSING

PM/REF No	CAS No	NAME	SCF-L	Restrictions and/or Specifications	ADI/TDI mg/kg bw
-	001313-60-6	Sodium peroxide	-	To be fixed	

TECHNICAL DOCUMENT No. 2

**GUIDELINES ON TEST CONDITIONS AND METHODS OF ANALYSIS
FOR CORK STOPPERS AND OTHER CORK MATERIALS
AND ARTICLES INTENDED TO COME INTO CONTACT WITH
FOODSTUFFS**

Table of contents

	Page
1. Introduction.....	33
2. Sampling	33
3. Testing for compliance with QMA restrictions	33
3.1. General rule	33
3.2. QMA restriction laid down in Resolution ResAP (2004)2 on cork stoppers and other cork materials and articles intended to come into contact with foodstuffs.....	33
4. Testing for compliance with SML restrictions	
4.1. General rule	33
4.2. Migration tests	33
5. Methods of analysis.....	34
6. References	35

1. Introduction

This technical document gives guidance on the test conditions and methods of analysis to be used for testing cork stoppers and other cork materials and articles intended to come into contact with food.

The *Technical document No. 2* should be read in conjunction with the specifications laid down in *Resolution ResAP (2004)2 on cork stoppers and other cork materials and articles intended to come into contact with foodstuffs* and the corresponding *Technical document No. 1 - List of substances to be used in the manufacture of cork stoppers and other cork materials and articles intended to come into contact with foodstuffs*.

2. Sampling

The cork stoppers and other cork materials and articles should be tested as a final product (i.e.: in a ready to use condition).

3. Testing for compliance with QMA restrictions

3.1. General rule

Testing for compliance with QMA restrictions should measure the concentration of the substance in the cork article.

3.2. QMA restriction laid down in Resolution ResAP (2004)2 on cork stoppers and other cork materials and articles intended to come into contact with foodstuffs

The testing for compliance with the QMA restriction for pentachlorophenol of *Resolution ResAP (2004)2* should measure the total concentration of this substance in the cork article.

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. 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.

Migration testing can be replaced by mathematical simulation or by calculation of the maximum possible migration (the so called “worst case calculation”). For both cases, the amount of the actual substance must be either previously known or determined by an exhaustive extraction.

4.2. Migration tests

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

Whenever possible, testing should be done using the same kind of food that is intended to come into contact with the cork article. However, if this is not possible and/or practical, a food simulant may be used.

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).

The International Standard: ISO 10106 specifies a test method for the *determination of the overall migration of cork stoppers*, on the basis of the above-mentioned EU Directives, using the conventional hydroalcoholic test simulants and related test conditions.

5. Methods of analysis

The Council of Europe does not normally issue resolutions 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. It is therefore recommended that the reader and/or interested part (e.g. enforcement authorities, industry, food and food packaging retailers and certification laboratories) search in the literature in order to find an adequate method.

Notwithstanding, there is a need to provide guidance to analysts who carry out testing to ensure compliance with the requirements of *Resolution ResAP (2004)2*.

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, an analytical validated method with appropriate performance attributes may be used. Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III of Regulation (EC) N° 882/2004.

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

- Water quality - Gas chromatographic determination of some selected chlorophenols in water (EN 12673).
- Pulp, paper and board. Determination of pentachlorophenol in an aqueous extract (EN 15320).
- Determination of acrylonitrile in food and food simulants (EN 13130-3)
- Determination of vinylidene chloride in food simulants (EN 13130-5)
- Determination of monoethylene glycol and diethylene glycol in food simulants (EN 13130-7).
- Determination of acetic acid, vinyl ester in food simulants (CEN/TS 13130-9)
- Determination of 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A) in food simulants (CEN/TS 13130-13).
- Cork stoppers - Sensory analysis (ISO 22308).
- Cork stoppers - Enumeration of colony-forming units of yeasts, moulds and bacteria capable of growth in an alcoholic medium (ISO 10718).

6. 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.

Regulation (EC) of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (Regulation (EC) N° 882/2004). Official Journal of the European Union L165 of 30 April 2004.