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

PACKAGING INKS APPLIED TO THE NON-FOOD CONTACT SURFACE OF FOOD PACKAGING

Version 2 – 10.10.2007

NOTE TO THE READER

The following documents are part of the Council of Europe's policy statement concerning packaging inks applied to the non-food contact surface of food packaging:

- Resolution ResAP (2005)2 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs

- Technical document No. 1: Requirements for the selection of packaging ink raw materials applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs (Version 1, 21.12.2006)

- Technical document No. 2, Part 1: Good Manufacturing Practices for the production of packaging inks formulated for use on the non-food contact surfaces of food packaging and articles intended to come into contact with food (prepared by CEPE)

- Technical document No. 2, Part 2: Code for Good Manufacturing Practices for flexible and fiber-based packaging for food (prepared by FPE in co-operation with CITPA)

- Technical document No. 3: Guidelines on test conditions for packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs

It is underlined that the Resolution and the technical documents form a whole and should be read in conjunction with each other.

Resolution ResAP (2005) 2 was adopted by the Committee of Ministers on 14 September 2005 at the 937th meeting of the Ministers' Deputies.

The present document includes a Mission Statement and the available Technical documents Nos. 1, 2 and 3 concerning the role of the Council of Europe's Committee of Experts on materials coming into contact with food.

Documents may be consulted on the Internet website of the Partial Agreement in the Social and Public Health Field.

www.coe.int/soc-sp

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MISSION STATEMENT

COUNCIL OF EUROPE AND FOOD CONTACT MATERIALS

1. Council of Europe

The Council of Europe is a political organisation which was founded on 5 May 1949 by ten European countries in order to promote greater unity between its members. It now numbers 47 member states[1].

The main aims of the Organisation are to reinforce democracy, human rights and the rule of law and to develop common responses to political, social, cultural and legal challenges in its member states. Since 1989 the Council of Europe has integrated most of the countries of central and eastern Europe into its structures and supported them in their efforts to implement and consolidate their political, legal and administrative reforms.

The work of the Council of Europe has led, to date, to the adoption of about 200 European conventions and agreements, which create the basis for a common legal space in Europe. They include the European Convention on Human Rights (1950), the European Cultural Convention (1954), the European Social Charter (1961), the European Convention on the Prevention of Torture (1987) and the Convention on Human Rights and Bioethics (1997). Numerous recommendations and resolutions of the Committee of Ministers propose policy guidelines for national governments.

The Council of Europe has its permanent headquarters in Strasbourg (France). By statute, it has two constituent organs: the Committee of Ministers composed of the Ministers of Foreign Affairs of the 47 member states, and the Parliamentary Assembly, comprising delegations from the 47 national parliaments. The Congress of Local and Regional Authorities of Europe represents the entities of local and regional self-government within the member states. A multinational European Secretariat serves these bodies and the intergovernmental committees.

2. The Partial Agreement in the social and public health field

Where a lesser number of member states of the Council of Europe wish to engage in some action in which not all their European partners desire to join, they can conclude a 'Partial Agreement' which is binding on themselves alone.

The Partial Agreement in the social and public health field was concluded on this basis in 1959.

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[1] Albania, Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Monaco, Montenegro, The Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland.

The areas of activity of the Partial Agreement in the social and public health field include two sectors:

- Protection of public health

- Rehabilitation and integration of people with disabilities.

At present, the Partial Agreement in the public health field has 18 member states[1].

The activities are entrusted to committees of experts, which are responsible to a steering committee for each area.

The work of the Partial Agreement committees occasionally results in the elaboration of conventions or agreements. The more usual outcome is the drawing-up of resolutions of member states, adopted by the Committee of Ministers. The resolutions should be considered as statements of policy for national policy makers. Governments have actively participated in their formulation. The delegates to the Partial Agreement committees are both experts in the field in question and responsible for the implementation of government policy in their national ministries.

The procedure provides for considerable flexibility in that any state may reserve its position on a given point without thereby preventing the others from going ahead with what they consider appropriate. Another advantage is that the resolutions are readily susceptible to amendment should the need arise. Governments are furthermore called upon periodically to report on the implementation of the recommended measures.

A less formal procedure is the elaboration of guidelines intended to serve as requirements or models for member states and industry.

Bodies of the Partial Agreement in the social and public health field enjoy close co-operation with equivalent bodies in other international institutions, in particular the Commission of the European Union. Contact is also maintained with international non-governmental organisations (NGOs) and industry, working in similar or related fields.

3. Council of Europe committees in the public health field

- Public Health Committee (Steering Committee)

- Committee of experts on materials coming into contact with food

  Ad hoc Groups of the Committee of experts:
  - Ad hoc Group on safety evaluation of food contact substances
  - Ad hoc Group on recycled fibres
  - Ad hoc Group on test conditions for paper and board

[1] Austria, Belgium, Bulgaria, Cyprus, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland.

- Ad hoc Group on tissue papers
- Ad hoc Group on packaging inks
- Ad hoc Group on coatings
- Ad hoc Group on cork
- Ad hoc Group on rubber
- Ad hoc Group on lead leaching from glass

- Committee of experts on nutrition, food and consumer health, and Ad hoc Groups

- Committee of experts on flavouring substances

- Committee of experts on cosmetic products, and Ad hoc Groups

- Committee of experts on pharmaceutical questions, and Ad hoc Groups

- Committee of experts on the legal classification of medicines as regards their supply, and Ad hoc Groups

4. Terms of reference of the Committee of experts on materials coming into contact with food

The overall aim of the Council of Europe Partial Agreement public health activities is to raise the level of health protection of consumers in its widest sense.

The terms of reference of the Committee of experts on materials coming into contact with food (hereafter called 'Committee of experts') are part of the overall aim of these activities and are related to precise problems concerning food contact materials and articles.

The representatives of the Partial Agreement member states and delegates of the Committee of experts are both experts in the field of food contact materials and responsible for the implementation of government policies in their national ministries.

The Commission of the European Union has a particular status of participation within the Committee of experts.

European industry branch associations may be represented at the level of the Ad hoc Groups, which are advisory bodies to the Committee of experts. Ad hoc Groups are not entitled to take formal decisions.

Hearings are regularly organised between the Committee of experts and the European industry branch associations on specific questions related to the work programme.

5. Main tasks of the Committee of experts on materials coming into contact with food

- **Elaboration of resolutions**

Resolutions elaborated by the Committee of experts are approved by the Public Health Committee and adopted by the Committee of Ministers[1];

They have to be considered as statements of policy or statements for national policy makers of the Partial Agreement member states to be taken into account in the national laws and regulations on food contact materials and articles, with the view of harmonising regulations at European level.

Resolutions lay down the field of application, the specifications and the restrictions concerning the manufacture of food contact materials and articles.

If necessary, they are amended in order to update their content.

- **Elaboration of guidelines**

Guidelines, set out in Technical documents, are approved by the Committee of experts and adopted by the Public Health Committee. They are not submitted to the Committee of Ministers.

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

They provide practical guidance for the application of resolutions and/or lay down technical and/or scientific specifications for the manufacture of food contact materials and articles.

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

Typical examples of guidelines are:

- List of substances to be used for the manufacture of food contact materials

- Test conditions and methods of analysis

- Good manufacturing practices (GMP)

[1] The Committee of Ministers is the Council of Europe's political decision-making body. It comprises the Ministers for Foreign Affairs of the forty-seven member states, or their permanent diplomatic representatives in Strasbourg. It monitors member states' compliance with their undertakings. Resolutions of the Partial Agreement in the social and public health field are adopted by the Committee of Ministers restricted to Representatives of the member states of the Partial Agreement.

- **Safety evaluations of substances to be used in food contact materials and articles**

Safety evaluations of substances to be used in food contact materials and articles are carried out by the ad hoc Group on safety evaluation of food contact substances and submitted for approval to the Committee of experts and adoption to the Public Health Committee.

- **Elaboration of opinions**

On request by the Committee of Ministers and/or the Public Health Committee, the Committee of experts elaborates opinions on specific questions related to food contact materials and articles.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RESOLUTION ResAP(2005)2 ON PACKAGING INKS APPLIED TO THE NON-FOOD CONTACT SURFACE OF FOOD PACKAGING MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

(*Adopted by the Committee of Ministers on 14 September 2005 at the 937th meeting of the Ministers' Deputies*)

The Committee of Ministers, in its composition restricted to the Representatives of the states of the Council of Europe which are members of the Partial Agreement in the Social and Public Health Field,[1]

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 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 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 legislation in the public health field and, in particular, with regard to materials and articles intended to come into contact with foodstuffs;

Considering that packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs may, through migration of constituents to the foodstuffs, under certain conditions, pose a risk to human health;

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

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 packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs the principles set out hereafter.

APPENDIX TO RESOLUTION RESAP(2005)2

1. SCOPE

1.1. This resolution applies to printing inks and varnishes (hereafter called “packaging inks”) and any layer of printing inks or varnishes, coloured or uncoloured, applied by an appropriate process to the non-food contact surface of any material or article intended to come into contact with foodstuffs.

1.2. Layers of packaging inks in direct contact with foodstuffs are excluded from the field of application of the present resolution.

1.3. When there is evidence that a substrate renders the migration of any substance in packaging inks substance impossible, and that the set-off or transfer via a gas phase can be excluded, the present resolution does not apply.

2. DEFINITIONS

In this resolution:

2.1. packaging inks are printing inks and varnishes intended to be printed on the non-food contact surface of materials and articles intended to come into contact with foodstuffs;

2.2. packaging inks means any mixture manufactured from colourants, binders, plasticisers, solvents, driers and other additives. They are solvent-based, water-borne, oleo-resinous or energy-curing (UV or electron beam) formulas. They are applied by a printing or varnishing process, such as flexography, gravure, letterpress, offset, screen printing (ink or varnish) and roller coating;

2.3. packaging inks, in their finished state, are thin films of dried or hardened printing ink or varnish on the non-food contact surface of substrates;

2.4. a substrate is any material or article intended to come into contact with food such as glass, metal, paper, board, plastic, textiles and laminates of these materials.

3. REQUIREMENTS

3.1. Printed materials and articles intended to come into contact with foodstuffs, should not, in their finished state and under normal and foreseeable conditions of use, 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 3 of Regulation (EC) No. 1935/2004.

3.2. In order to achieve this aim, the following requirements should be met:

3.2.1. the substances in packaging inks should be selected in conformity with the requirements for the selection of packaging ink substances as set out in Technical document No. 1:

3.2.1.1 only substances which are listed in the inventory list can be used in the manufacture of packaging inks covered by this resolution;

3.2.1.2 substances which are listed in the inventory list but not evaluated can be used subject to the condition that it can be demonstrated that they will not migrate into the food.[1] The demonstration can be carried out by "worse case calculation" or by a practical test as set out in Technical document No. 3;[2]

3.2.2. the packaging inks should be manufactured in accordance with the guides for good manufacturing practice set out in Technical document No. 2, Part 1;

3.2.3. the packaging inks should be applied in accordance with converters' good manufacturing practices as set out in Technical document No. 2, Part 2;

3.2.4. the finished printed material or article intended to come into contact with foodstuffs should meet the following requirements:

3.2.4.1 the printed or overprinted varnished layer of finished printed material or article should not come into direct contact with food;

3.2.4.2 global and specific migration from the finished printed material or article should not exceed the relevant limits;

3.2.4.3 there should be no, or only negligible, visible set-off or migration from the printed or varnished non-food contact layer to the food contact surface.

4. CONFORMITY ASSESSMENT

4.1. Verification of the compliance of the substances in packaging inks with the quantitative restrictions laid down by the resolution should be carried out in conformity with the rules set out in Technical document No. 3.[2]

4.2. The finished printed and/or varnished food contact material or article should be tested in accordance with the intended conditions of use (one side migration test on the side intended for food contact) and according to the rules set out in Technical document No. 3.[2]

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[1] For the purposes of control, this means that they shall not be detectable at the lowest concentration at which a substance can be measured with statistical certainty by a validated method of analysis. It is agreed that the detection limit would depend on the nature of the raw materials. However, this limit expressed as concentration shall not exceed 0.01 mg/kg of food or food simulant. It shall apply to the sum of migration of a group of compounds if they are structurally and toxicologically related (e.g. isomers).

[2] Technical document No. 3 – Guidelines on test conditions for packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs.

5. RESPONSIBILITY

The packaging ink suppliers are responsible for the composition of packaging inks in accordance with the requirements set out in this resolution. In line with Article 16 of Regulation (EC) No. 1935/2004, they should communicate without any unjustified delay to the concerned business operator, under appropriate confidentially agreements, the relevant information necessary to manufacturing the finished materials or articles in compliance with the rules applicable to them.

6. TRACEABILITY

The packaging ink suppliers are responsible for the traceability of packaging inks. They should have in place systems and procedures to allow the identification of the businesses from which and to which the packaging inks are supplied.

TECHNICAL DOCUMENT No. 1

REQUIREMENTS FOR THE SELECTION OF PACKAGING INK RAW MATERIALS APPLIED TO THE NON-FOOD CONTACT SURFACE OF FOOD PACKAGING MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Version 1 – 21.12.2006

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REQUIREMENTS FOR THE SELECTION OF PACKAGING INK RAW MATERIALS APPLIED TO THE NON-FOOD CONTACT SURFACE OF FOOD PACKAGING ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Introduction

The safety of food contact materials and articles is governed by the European Regulation EC 1935/2004. This stipulates that materials and articles in contact with food, whether printed or not, must not transfer to the foodstuffs any of their components which could endanger human health or bring about any unacceptable change in the composition of the foodstuffs or a deterioration in their organoleptic properties.

Council of Europe committees in the public health field are elaborating resolutions and guidelines for the manufacture of materials and articles intended to come into contact with foodstuffs, which are not yet covered by specific EC Directives.

This document gives guidance on the selection process of substances used in the manufacture of printing inks applied to the non-food contact surface of food packaging. For the preparations used in the manufacture of packaging inks, the selection process should be applied for each substance composing the preparation. This technical document should be read in conjunction with the specifications laid down in the Resolution AP (2005) 2 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs.

Definitions

Substances and preparations used in the manufacture of packaging inks are defined according to the Directives 67/548/EEC and 1999/45/EC:

"Substances" means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

"Preparations" means mixtures or solutions composed of two or more substances.

Explanations and working principles

Exclusion criteria

Substances and preparations which meet such a criterion or fall into one of these categories cannot be used in the manufacture of packaging inks. The exclusion criteria will be amended, if appropriate, in the light of new data on safety, health and environmental matters.

Inventory list

The Inventory List catalogues the individual substances currently used in the manufacture of packaging inks but not the preparations. The inventory list will be updated once a year by the Council of Europe Secretariat if necessary.

Evaluation of migration

The evaluation of a possible migration of any substances will be carried out by worst case calculation and/or practical extraction or migration tests. The conditions of testing and rules for worst case calculations are described in the Technical document No. 3.

The evaluation results should be made available to the Council of Europe and to the control authorities.

Limit of migration

The substances which are not evaluated should not be detectable in a migration test at the lowest concentration at which a substance can be measured with statistical certainty by a validated method of analysis. It is agreed that the detection limit would depend on the nature of the substance. However, this limit expressed in concentration shall not exceed 0.01 mg/kg of food or food simulant (analytical tolerance included). It shall apply to the sum of a group of compounds if they are structurally and toxicologically related, e.g. isomers.

Disclosure process

A substance can be disclosed by the industry to the Council of Europe for its insertion in the *inventory list*. The request should include the necessary information on the substance in regard to its safe use.

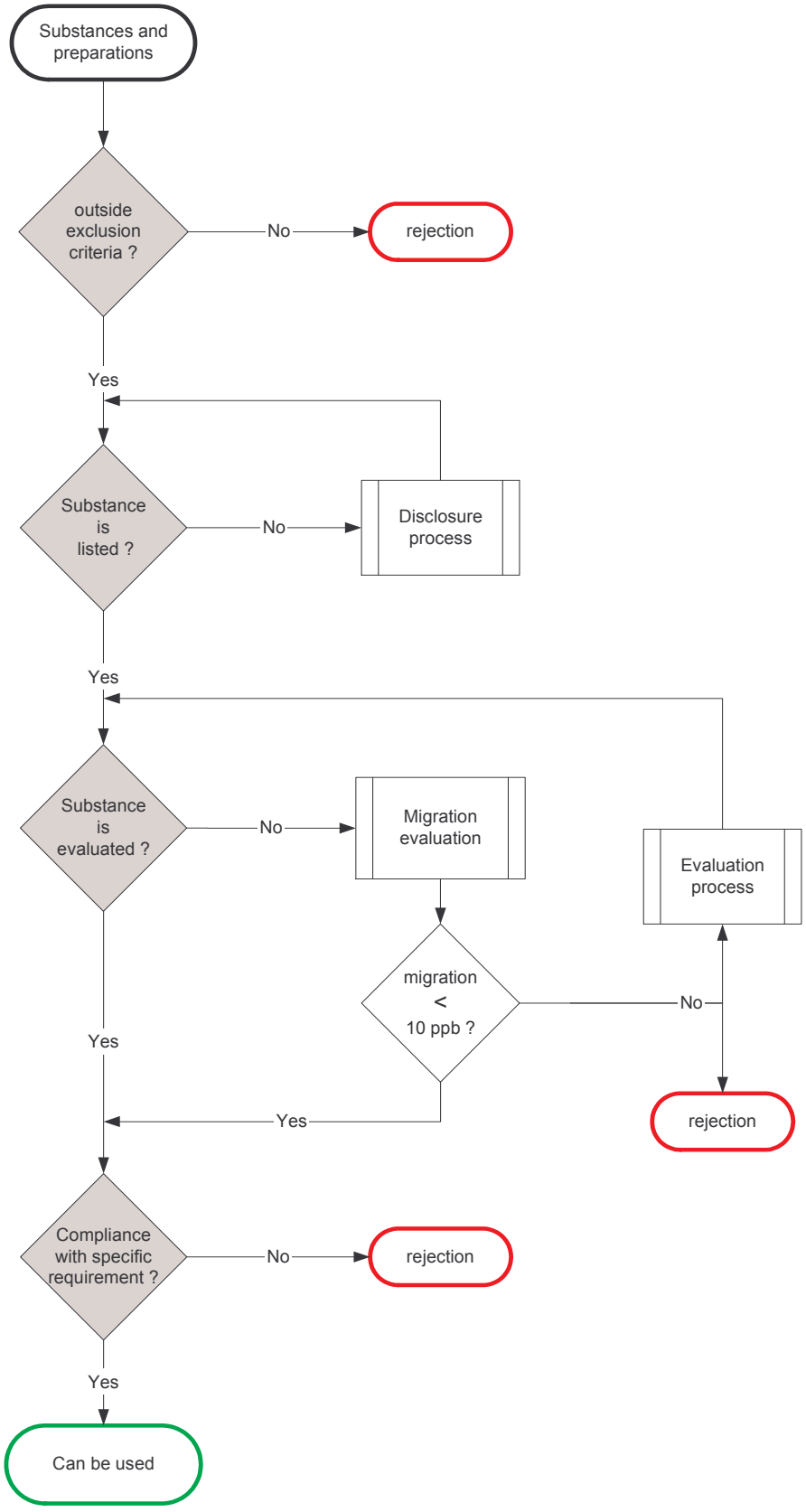
Evaluation process

To be registered in the list of evaluated substances (List 1), a substance should pass through an evaluation process based on the “Guidelines concerning the safety evaluation of substances to be used in food contact materials and articles” covered by Council of Europe resolutions. The Council of Europe accepts the safety evaluations of the European Food Safety Authority (EFSA) as well as the evaluations performed by other organisations recognised by EFSA.

Specific requirements

See part 4.

1. Selection Scheme for packaging ink substances



2. Exclusion criteria for Printing Inks and Related Products

Known substances and preparations which meet one of the following exclusion criteria are excluded as components for the manufacture of packaging inks:

2.1 Carcinogenic, mutagenic and toxic for reproduction substances classified as category 1 or category 2 or category 3 in Annex 1 of the Dangerous Substances Directive 67/548/EEC. Substances which, however, are classified as category 1, 2, or 3 but are evaluated by (a) Scientific Committees(s) and as a result can be used under the specified conditions, are admitted.

2.2 Substances classified under the self-responsibility criteria as carcinogenic, mutagenic or toxic for reproduction as category 1, 2 or 3 according to the rules of article 6 of Directive 67/548/EEC and its amendments.

2.3 Pigment colourants based on and compounds of antimony[1], arsenic, cadmium, chromium (VI), lead, mercury, selenium.

2.4 Azo dyes which can decompose in the body to bio-available carcinogenic aromatic amines of category 1 and 2 according to Directive 67/548/EEC.

2.5 Azo dyes which can decompose during the manufacture process to carcinogenic aromatic amines of category 1 and 2 according to Directive 67/548/EEC.

2.6 Substances and preparations which are not permitted according to Directive 76/769/EC (relating to the restrictions on the marketing and use of certain dangerous substances and preparations) and its amendments.

[1] With the exception of non-bio-available pigments in which antimony is a constituent of the crystal lattice and of organic derivatives not classified nor labelled as T or T+.

3. List of substances used for the manufacture of packaging inks

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;
- C.I. No — the Colour Index Number of the colourant;
- C.I. Name — the Colour Index Name of the colourant;
- NAME — the chemical name of the substance;
- SCF-L — the number of the list in which the substance is classified by the Scientific Committee for food/EFSA;
- RESTRICTION — restriction related to the substance;
- ADI/TDI — acceptable daily intake or tolerable daily intake as defined in the reports of the Scientific Committee of food/EFSA.

A number of abbreviations are used under RESTRICTION and ADI/TDI, the meanings of which are as follows:

- ACC — acceptable
- DL — detection limit of the method of analysis;
- 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.

NOTES

(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 Nos : 15760, 16990, 47680, 53650
(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 Nos : 48030, 48050, 53765
(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 Nos : 64115, 68690, 90290
(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 Nos : 68070, 68650
(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 Nos : 10690, 10780, 11470, 11710
(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 Nos : 16630, 19110, 25208

(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 Nos : 19540, 19960, 64800
(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 Nos : 20020, 20110, 20890, 21130
(9)	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 Nos : 75100, 75105
(10)	The product (PM/REF 95859) should have the following specifications: - Content of mineral hydrocarbons with carbon number less than 25, not more than 5% (w/w) - Viscosity not less than 8,5 x 10^{-6} m^2/s (= 8,5 centistokes) at 100°C - Average molecular weight not less than 480

3.1 Additives

Additives are substances used normally in small quantities, which essentially determine the technical properties of the printing ink, primer and/or overprint varnish in their manufacture or the printing process as well as in the printed product.

The different additive groups describing the principal technological functions are given in the table below for information.

(1)	**Acid catalyst**
(2)	**Adhesion promoter**
(3)	**Amine solubiliser**
(4)	**Antifoam agent**
(5)	**Antimist**
(6)	**Antistatic**
(7)	**Biocide**
(8)	**Chelating agent**
(9)	**Dispersing agent**
(10)	**Drier**
(11)	**Flow agent**

(12)	**Gellant**
(13)	**Ink stabiliser**
(14)	**Optical brightener**
(15)	**Photoinitiator**
(16)	**Plasticizer**
(17)	**Slip agent**
(18)	**Solvent**
(19)	**Suspension agent**
(20)	**Thickener**
(21)	**UV stabiliser**
(22)	**Wetting agent**

List 1 - Substances evaluated by SCF/EFSA

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
30045	000123-86-4	Acetic acid, butyl ester	1		6
30140	000141-78-6	Acetic acid, ethyl ester	1		NS
30295	000067-64-1	Acetone	3		
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester	2	SML = 18 mg/kg	0.3
34230	-	Alkyl(C8-C22)sulphonic acid	2	SML = 6 mg/kg	0.1
34560	021645-51-2	Aluminium hydroxide	2		1 (as Al)
35320	007664-41-7	Ammonia	1		NS
37600	000065-85-0	Benzoic acid	1		5
37680	000136-60-7	Benzoic acid, butyl ester	2		5
38400	000100-51-6	Benzyl alcohol	1		5
(13210)	001761-71-3	Bis(4-aminocyclohexyl)methane	3	SML = 0.05 mg/kg	
38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	2	SML = 0.6 mg/kg	0.01
40590	000071-36-3	1-Butanol	3		
41280	001305-62-0	Calcium hydroxide	1		NS
41960	000124-07-2	Caprylic acid	0		
42500	000471-34-1	Carbonic acid, calcium sait	1		NS
42640	009004-32-4	Carboxymethylcellulose, sodium salt	2		NS
42880	008001-79-4	Castor oil	3		
43300	009004-36-8	Cellulose acetate butyrate	3		
44160	000077-92-9	Citric acid	1		NS
44640	000077-93-0	Citric acid, triethyl ester	1		20
46070-46080	009004-53-9	Dextrin	0		
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (= BHT)	1	SML = 3 mg/kg	0.05
47680	000111-46-6	Diethyleneglycol	2	SML(T) = 30 mg/kg (1)	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

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
49235	000108-01-0	Dimethylaminoethanol	2	SML = 18 mg/kg	0.3
50320	015571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	2	SML = 0.04 mg/kg (as Sn)	0.0006(Sn)
51760	025265-71-8	Dipropyleneglycol	2		1.5
52000	027176-87-0	Dodecylbenzenesulphonic acid	2	SML = 30 mg/kg	0.5
52720	000112-84-5	Erucamide	3		
52800	000064-17-5	Ethanol	1		ACC
53280	009004-57-3	Ethylcellulose	2		NS
53600	000060-00-4	Ethylenediaminetetraacetic acid	2		2.5
53650	000107-21-1	Ethyleneglycol	2	SML(T) = 30 mg/kg (1)	0.5
53765	000111-76-2	Ethyleneglycol monobutyl ether	2	SML(T) = 3 mg/kg (2)	0.05
55920	000056-81-5	Glycerol	1		NS
56000	025395-31-7	Glycerol diacetate	1		NS
56080	025637-84-7	Glycerol dioleate	1		NS
56960	025496-72-4	Glycerol monooleate	1		NS
57440	001323-38-2	Glycerol monoricinoleate	3		
57760	000102-76-1	Glycerol triacetate	1		NS
57840	000060-01-5	Glycerol tributyrate	3		
56540	000122-32-7	Glycerol trioleate	3		
58160	000139-44-6	Glycerol tris(12-hydroxystearate)	3		
58790	036653-82-4	Hexadecanol	3		
60560	009004-62-0	Hydroxyethylcellulose	2		NS
60880	009032-42-2	Hydroxyethylmethylcellulose	2		NS
61440	002440-22-4	2-(2'-Hydroxy-5'-methylphenyl)benzotriazole	2	SML = 30 mg/kg	0.5
61840	000106-14-9	12-Hydroxystearic acid	3/0		
62720	001332-58-7	Kaolin	1		NS
63040	000138-22-7	Lactic acid, butyl ester	2		NS
63940	008062-15-5	Lignosulphonic acid	3	SML = 0.24 mg/kg	
64115	006904-78-5	Linoleic acid, manganese salt	2	SML(T) = 0.6 mg/kg (as Mn) (3)	0.01 (Mn)
64160	008001-26-1	Linseed oil	3		
64720	001309-48-4	Magnesium oxide	1		NS
64800	000110-16-7	Maleic acid	2	SML(T) = 30 mg/kg (7)	0.5

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
66240	009004-67-5	Methylcellulose	2		NS
66655	000078-93-3	Methyl ethyl ketone	3	SML = 5 mg/kg	
66700	009004-65-3	Methylhydroxypropylcellulose	2		NS
66725	000108-10-1	Methyl isobutyl ketone	3	SML = 5 mg/kg	
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	4A	SML = ND (DL = 0.01 mg/kg)	
67420	000141-43-5	Monoethanolamine	3	SML = 0.05 mg/kg	
67680	027107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	2	SML = 1.2 mg/kg (as Sn)	0.02 (Sn)
68070	052270-44-7	Neodecanoic acid, cobalt(II) salt	3	SML(T) = 0.05 mg/kg (as Co) (4) SML = 0.05 mg/kg (as neodecanoic acid)	
(22450)	009004-70-0	Nitrocellulose	3		
68225	000112-92-5	1-Octadecanol	3		
68650	006700-85-2	n-Octanoic acid, cobalt salt	3	SML(T) = 0.05 mg/kg (as Co) (4)	
68690	006535-19-9	n-Octanoic acid, manganese salt	2	SML(T) = 0.6 mg/kg (as Mn) (3)	0.01 (Mn)
68960	000301-02-0	Oleamide	3		
69040	000112-80-1	Oleic acid	1		NS
70400	000057-10-3	Palmitic acid	1		NS
71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	2		3
72800	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester	2	SML = 2.4 mg/kg	0.04
74880	000084-74-2	Phthalic acid, dibutyl ester	2	SML = 6 mg/kg	0.1
75100	-	Phthalic acid, diesters with primary, saturated C8-C10 branched alcohols containing more than 60% C9	2	SML(T) = 9 mg/kg (9)	0.15
75105	-	Phthalic acid, diesters with primary, saturated C9-C11 branched alcohols containing more than 90% C10	2	SML(T) = 9 mg/kg (9)	0.15
76720	009016-00-6 063148-62-9	Polydimethylsiloxane	2		1.5
76960	025322-68-3	Polyethyleneglycol	2		5
77360	009005-07-6	Polyethyleneglycol dioleate	2		10

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
77895	068439-49-6	Polyethyleneglycol monoalkyl(C16-C18) ether	3	SML = 0.05 mg/kg	
79360	009005-70-3	Polyethyleneglycol sorbitan trioleate	2		10
80000	009002-88-4	Polyethylene wax	3		
80800	025322-69-4	Polypropyleneglycol	3		
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
83610	073138-82-6	Resin acids and rosin acids	2		1
83840	008050-09-7	Rosin	2		1
84210	065997-06-0	Rosin, hydrogenated	2		1
84240	065997-13-9	Rosin, hydrogenated, ester with glycerol	3		
84320	008050-15-5	Rosin, hydrogenated, ester with methanol	2		1
(24160)	008052-10-6	Rosin tall oil	3		
85360	000109-43-3	Sebacic acid, dibutyl ester	3		
85980	001335-30-4	Silicic acid, aluminium salt	2		NS
85980	001344-00-9	Silicic acid, aluminium sodium salt	2		NS
86240	007631-86-9	Silicon dioxide	1		NS
86440	001302-42-7	Sodium aluminate	2		1 (as Al)
87680	001338-43-8	Sorbitan monooleate	1		5
87760	026266-57-9	Sorbitan monopalmitate	1		25
88630/1	008001-22-7	Soybean oil	3		
88640	008013-07-8	Soybean oil, epoxidized	2		1
89040	000057-11-4	Stearic acid	1		NS
90290	003353-05-7	Stearic acid, manganese salt	2	SML(T) = 0.6 mg/kg (as Mn) (3)	0.01 (Mn)
91200	000126-13-6	Sucrose acetate isobutyrate	1		10
91920	007664-93-9	Sulphuric acid	1		NS
92000	007727-43-7	Sulphuric acid, barium salt	3	SML = 1 mg/kg (as Ba)	
92080	014807-96-6	Talc	1		NS
92430	000109-99-9	Tetrahydrofuran	2	SML = 0.6 mg/kg	0.01
93120	000123-28-4	Thiodipropionic acid, didodecyl ester	3	SML = 5 mg/kg	
93440	013463-67-7	Titanium dioxide	1		

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
93980	000112-70-9	1-Tridecanol	3		
94320	000112-27-6	Triethyleneglycol	2		5
(25910)	024800-44-0	Tripropyleneglycol	2		1.5
95630	000057-13-6	Urea	0		
95859	-	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	2	See Note 10	20

Temporary appendix to list 1: substances evaluated by other agencies than EFSA

N O N E

List 2 - Substances not evaluated

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	071328-93-3	Abietic acid, 2-hydroxy-3-sulphopropyl ester, sodium salt	-	To be fixed
-	068214-33-5	Abietic acid, fumaric acid adduct, polymer with glycerol	-	To be fixed
-	068214-32-4	Abietic acid, fumaric acid adduct, polymer with pentaerythritol	-	To be fixed
-	068214-35-7	Abietic acid, maleic anhydride adduct, polymer with glycerol	-	To be fixed
-	068214-18-6	Abietic acid, maleic anhydride adduct, polymer with pentaerythritol	-	To be fixed
-	000127-25-3	Abietic acid, methyl ester	-	To be fixed
-	054839-24-6	Acetic acid, ethoxyisopropyl ester	-	To be fixed
-	000110-19-0	Acetic acid, isobutyl ester	-	To be fixed
30165	000108-21-4	Acetic acid, isopropyl ester	7	To be fixed
30210	000108-65-6	Acetic acid, 2-methoxyisopropyl ester	6B	To be fixed
30245	000109-60-4	Acetic acid, propyl ester	7	To be fixed
30480	000140-04-5	Acetylricinoleic acid, butyl ester	7	To be fixed
-	000140-03-4	Acetylricinoleic acid, methyl ester	-	To be fixed
-	068409-81-4	Acids, fatty, C6-C19, branched, cobalt(II) salts	-	To be fixed
-	067701-02-4	Acids, fatty, C14-C18	-	To be fixed
-	067701-06-8	Acids, fatty, C14-CI8 and C16-CI8 unsaturated	-	To be fixed
-	085736-49-8	Acids, fatty, C14-C18 and C16-CI8 unsaturated, esters with ethyleneglycol	-	To be fixed
-	085186-88-5	Acids, fatty, C16-C18 and C18 unsaturated, esters with sorbitol	-	To be fixed
-	068154-28-9	Acids, fatty, C18, butyl esters	-	To be fixed
-	063117-82-8	Acrylamide - acrylic acid - ammonium acrylate, copolymer	-	To be fixed
-	029300-12-7	Acrylamide - acrylonitrile - ethyl acrylate, copolymer	-	To be fixed
-	025135-39-1	Acrylic acid - ethyl acrylate - methyl methacrylate, copolymer	-	To be fixed
31560	025085-34-1	Acrylic acid - styrene, copolymer	D	To be fixed
-	029383-53-7	Acrylonitrile - butadiene - itaconic acid - styrene, copolymer	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	058394-64-2	Adipic acid, benzyl 2-ethylhexyl ester	-	To be fixed
-	003089-55-2	Adipic acid, benzyl octyl ester	-	To be fixed
-	068526-86-3	Alcohols, C11-C14-iso, C13-rich	-	To be fixed
-	067774-74-7	Alkyl(C10-C13)benzene	-	To be fixed
-	068989-00-4	Alkyl(Cl 0-Cl 6)benzyldimethylammonium chloride	-	To be fixed
-	066455-29-6	Alkyl(C12-C14)dimethylbetaines	-	To be fixed
-	068955-19-1	Alkyl(C12-C18)sulphuric acid, sodium salt	-	To be fixed
-	068649-05-8	3-Aminobutyric acid, N-coco alkyl derivatives	-	To be fixed
(12775)	000124-68-5	2-Amino-2-methyl-1-propanol	8	To be fixed
37520	002634-33-5	1,2-Benzisothiazolin-3-one	7	To be fixed
-	104133-71-3	Benzoic acid - ethylene oxide - formaldehyde - 4-nonylphenol - disodium sulphosuccinate, copolymer	-	To be fixed
-	007209-38-3	1,4-Bis(3-aminopropyl)piperazine	-	To be fixed
-	078952-69-9	4,4'-Bis[[1-[[(2,4-dimethylphenyl)amino]carbonyl]-2-oxopropyl]azo]-1,1'-biphenyl-2,2'-disulphonic acid	-	To be fixed
-	062174-79-2	1, 3-Bis[(2-ethylhexyl)oxy]propane-2-sodium sulphate	-	To be fixed
-	083721-45-3	2,3-Bis[(2-ethylhexyl)oxy]propane-1-sodium sulphate	-	To be fixed
-	061789-80-8	Bis(hydrogenated tallow alkyl)dimethylammonium chloride	-	To be fixed
-	061791-31-9	N,N-Bis(2-hydroxyethyl)(cocoalkyl)amine	-	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)(tallow alkyl)amine	-	To be fixed
-	016324-24-6	Bis(isopropoxy)aluminium mono(acetylacetonate)	-	To be fixed
-	017927-72-9	Bis(isopropoxy)titanium bis(acetylacetonate)	-	To be fixed
40080	013879-32-8	Bis(phenoxyethyl)formal	8	To be fixed
-	026635-93-8	N,N-Bis(polyoxyethylene)oleylamine	-	To be fixed
40592	000078-92-2	2-Butanol	8	To be fixed
40618	005131-66-8	1-Butoxy-2-propanol	8	To be fixed
-	003622-84-2	N-Butylbenzenesulphonamide	-	To be fixed
-	001907-65-9	N-Butyl-p-toluenesulphonamide	-	To be fixed
(14002)	000098-73-7	p-tert-Butylbenzoic acid	7	To be fixed
-	004197-69-7	2-Butylhydroquinone	-	To be fixed
-	068648-78-2	Butyraldehyde - vinyl acetate - vinyl alcohol, copolymer	-	To be fixed
41000	000096-48-0	gamma-Butyrolactone	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
(14330)	000592-35-8	Carbamic acid, butyl ester	8	To be fixed
43230	008002-33-3	Castor oil, sulphated	9	To be fixed
-	068187-77-9	Castor oil, sulphated, ammonium salt	-	To be fixed
-	068187-76-8	Castor oil, sulphated, sodium salt	-	To be fixed
-	068604-22-8	Castor oil, sulphurized	-	To be fixed
43760	026172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	7	To be fixed
-	004132-10-9	Citric acid, tricyclohexyl ester	-	To be fixed
-	001793-10-8	Citric acid, triisopentyl ester	-	To be fixed
-	061788-46-3	Coco alkyl amines	-	To be fixed
-	061788-93-0	(Coco alkyl)dimethyl amines	-	To be fixed
-	061788-90-7	(Coco alkyl)dimethyl amines, N-oxides	-	To be fixed
-	061789-18-2	(Coco alkyl)trimethylammonium chloride	-	To be fixed
-	061789-19-3	Coconut oil fatty acid amide	-	To be fixed
-	068140-01-2	Coconut oil fatty acid N-[3-(dimethylamino)propionamide]	-	To be fixed
-	068140-00-1	Coconut oil fatty acid monoethanolamide	-	To be fixed
-	068425-44-5	Coconut oil fatty acid monoethanolamide, ethoxylated	-	To be fixed
-	042739-64-0	Copper (phthalimidomethyl)phthalocyanine	-	To be fixed
-	068037-36-5	Copper phthalocyanine, sulphonated	-	To be fixed
-	073455-75-1	Copper phthalocyanine, sulphonated, compound with dodecylamine	-	To be fixed
45610	025609-89-6	Crotonic acid - vinyl acetate, copolymer	9	To be fixed
-	070693-20-8	Cyanamide, reaction products with carbon dioxide, ethylene oxide and octadecylamine	-	To be fixed
45700	000110-28-7	Cyclohexane	8	To be fixed
-	000080-30-8	N-Cyclohexyl-p-toluenesulphonamide	-	To be fixed
-	046911-70-0	2-Decyl-1-hydroxyethyl-2-imidazoline	-	To be fixed
-	001446-61-3	Dehydroabietylamine	-	To be fixed
-	025417-20-3	Dibutylnaphthalenesulphonic acid, sodium sait	-	To be fixed
-	000085-98-3	Diethyldiphenylurea	-	To be fixed
47720	000120-55-8	Diethyleneglycol dibenzoate	W	To be fixed
-	000106-01-4	Diethyleneglycol dipelargonate	-	To be fixed
-	000112-59-4	Diethyleneglycol monohexyl ether	-	To be fixed
-	000111-77-3	Diethyleneglycol monomethyl ether	-	To be fixed
-	067893-02-1	Dihydroabietic acid, methyl ester	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
59810	026266-77-3	Dihydroabietyl alcohol	8	To be fixed
-	024650-42-8	2,2-Dimethoxy-2-phenylacetophenone	-	To be fixed
-	010287-53-3	4-Dimethylaminobenzoic acid, ethyl ester	-	To be fixed
49340	061789-71-7	Dimethyl(cocoalkyl)benzylammonium chloride	9	To be fixed
-	000107-64-2	Dimethyldioctadecylammonium chloride	-	To be fixed
-	000107-54-0	3,5-Dimethylhexyn-3-ol	-	To be fixed
-	082199-01-7	1,6-Dimethylnaphthalenesulphonic acid, sodium salt - formaldehyde, copolymer	-	To be fixed
-	004196-89-8	2,2-Dimethyl-1,3-propanediol dibenzoate	-	To be fixed
-	003332-27-2	N,N-Dimethyltetradecylamine N-oxide	-	To be fixed
51870	034590-94-8	Dipropyleneglycol monomethyl ether	8	To be fixed
-	064742-13-8	Distillates (petroleum), acid-treated middle	-	To be fixed
-	064742-52-5	Distillates (petroleurn), hydrotreated heavy naphthenic	-	To be fixed
-	064742-54-7	Distillates (petroleurn), hydrotreated heavy paraffinic	-	To be fixed
-	064742-47-8	Distillates (petroleurn), hydrotreated light	-	To be fixed
-	064742-55-8	Distillates (petroleurn), hydrotreated light paraffinic	-	To be fixed
-	064742-56-9	Distillates (petroleurn), solvent-dewaxed light paraffinic	-	To be fixed
-	064741-96-4	Distillates (petroleurn), solvent-refined heavy naphthenic	-	To be fixed
-	064741-88-4	Distillates (petroleurn), solvent-refined heavy paraffinic	-	To be fixed
	064741-91-9	Distillates (petroleurn), solvent-refined middle	-	To be fixed
-	109037-68-5	N,N'-Ditallow alkyl[1,2-ethanediylbis(imino-3,1-propanediyl)]diamines, ethoxylated propoxylated	-	To be fixed
	000124-22-1	n-Dodecylamine	-	To be fixed
53215	001569-02-4	1-Ethoxy-2-propanol	8	To be fixed
-	000763-69-9	3-Ethoxypropionic acid, ethyl ester	-	To be fixed
-	052503-47-6	Ethylenediamine - ethylene oxide - propylene oxide, copolymer	-	To be fixed
-	055845-06-2	Ethylene oxide - formaldehyde - nonylphenol, copolymer	-	To be fixed
54120	000149-57-5	2-Ethylhexanoic acid	6B	To be fixed
54205	000136-51-6	2-Ethylhexanoic acid, calcium salt	6B	To be fixed
54130	024593-34-8	2-Ethylhexanoic acid, cerium salt	6B	To be fixed
54150	000136-52-7	2-Ethylhexanoic acid, cobalt(II) salt	6B	To be fixed
54190	015956-58-8	2-Ethylhexanoic acid, manganese salt	6B	To be fixed
-	061788-37-2	2-Ethylhexanoic acid, rare earth salts	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
54220	022464-99-9	2-Ethylhexanoic acid, zirconium salt	6B	To be fixed
-	029759-19-1	2-Ethylhexyl epoxystearate	-	To be fixed
-	001077-56-1	N-Ethyl-o-toluenesulphonamide	-	To be fixed
-	000080-39-7	N-Ethyl-p-toluenesulphonamide	-	To be fixed
54380	008047-99-2	N-Ethyltoluenesulphonamide	8	To be fixed
54900	009084-06-4	Formaldehyde - naphthalenesulphonic acid, copolymer, sodium salt	9	To be fixed
-	036290-04-7	Formaldehyde - 2-naphthalenesulphonic acid, copolymer, sodium salt	-	To be fixed
-	104376-68-3	Formaldehyde, reaction products with branched nonylphenol and cyclo-hexylamine, ethoxylated	-	To be fixed
54960	001338-51-8	Formaldehyde - toluenesulphonamide, copolymer	9	To be fixed
(17350)	000105-75-9	Fumaric acid, dibutyl ester	7	To be fixed
55160	000098-00-0	Furfurol	8	To be fixed
55880	001119-40-0	Glutaric acid, dimethyl ester	7	To be fixed
-	061215-87-0	Glycerol - pentaerythritol - phthalic anhydride, copolymer	-	To be fixed
-	000614-33-5	Glycerol tribenzoate	-	To be fixed
-	002540-54-7	Glycerol triricinoleate	-	To be fixed
-	000095-38-5	2-(8-Heptadecenyl)-2-imidazoline-1-ethanol	-	To be fixed
-	000112-02-7	Hexadecyltrimethylammonium chloride	-	To be fixed
-	092045-32-4	Heptane, branched and linear	-	To be fixed
(18449)	003089-11-0	N,N,N',N',N",N"-Hexakis(methoxymethyl)-2,4,6-triamino-1,3,5-triazine	8	To be fixed
59600	000107-41-5	Hexyleneglycol	7	To be fixed
-	005153-25-3	4-Hydroxybenzoic acid, 2-ethylhexyl ester	-	To be fixed
-	002809-21-4	1 -Hydroxyethane-1, 1 -diphosphonic acid	-	To be fixed
-	034375-28-5	N-Hydroxy-N-methylethanolamine	-	To be fixed
61415	000123-42-2	4-Hydroxy-4-methyl-2-pentanone	8	To be fixed
62270	000078-83-1	Isobutanol	8	To be fixed
-	025154-85-2	Isobuyl vinyl ether - vinyl chloride, copolymer	-	To be fixed
-	006846-50-0	Isobutyric acid, diester with 2,2,4-trimethyl-1,3-pentanediol	-	To be fixed
-	025265-77-4	Isobutyric acid, monoester with 2,2,4-trimethyl-1,3-pentanediol	-	To be fixed
-	053988-05-9	Isononanoic acid, calcium salt	-	To be fixed
-	084777-61-7	Isooctanoic acid, calcium salt	-	To be fixed
-	000078-59-1	Isophorone	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	003944-37-4	2-Isopropoxy-1-propanol	-	To be fixed
-	005495-84-1	2-Isopropylthioxanthone	-	To be fixed
-	027458-92-0	Isotridecanol	-	To be fixed
-	064742-81-0	Kerosine (petroleurn), hydrodesulphurized	-	To be fixed
-	000097-64-3	Lactic acid, ethyl ester	-	To be fixed
-	063697-00-7	Lactic acid, isopropyl ester	-	To be fixed
-	068512-34-5	Lignosulphonic acid, sodium salt, sulphomethylated	-	To be fixed
64240	008016-11-3	Linseed oil, epoxidized	7	To be fixed
-	091722-72-4	Linseed oil, maleated, monoethyl ester, ammonium salt	-	To be fixed
-	067746-08-1	Linseed oil, polymerized	-	To be fixed
-	068458-91 3	Linseed oil, polymer with adipic acid, isophthalic acid and trimethylolpropane	-	To be fixed
(19600)	000105-76-0	Maleic acid, dibutyl ester	7	To be fixed
(19690)	014234-82-3	Maleic acid, diisobutyl ester	7	To be fixed
(19720)	001330-76-3	Maleic acid, diisooctyl ester	7	To be fixed
(19780)	002915-53-9	Maleic acid, dioctyl ester	7	To be fixed
-	038638-76-5	Maleic anhydride - pentaerythritol - phthalic anhydride, copolymer	-	To be fixed
-	068440-42-6	Menhaden oil, polymerized, oxidized	-	To be fixed
-	002517-43-3	3-Methoxy-1-butanol	-	To be fixed
-	000107-70-0	4-Methoxy-4-methyl-2-pentanone	-	To be fixed
66050	000107-98-2	1-Methoxy-2-propanol	8	To be fixed
(21749)	000583-60-8	2-Methylcyclohexanone	8	To be fixed
-	000137-20-2	N-Methyl-N-oleoyltaurine, sodium salt	-	To be fixed
66905	000872-50-4	N-Methylpyrrolidone	8	To be fixed
-	061791-42-2	N-Methyl-N-(2-sulphoethyl)cocoacylamines, sodium salt	-	To be fixed
-	064741-65-7	Naphtha (petroleum), heavy alkylate	-	To be fixed
-	064742-82-1	Naphtha (petroleum), hydrodesulphurized heavy	-	To be fixed
-	064742-48-9	Naphtha (petroleum), hydrotreated heavy	-	To be fixed
-	064742-49-0	Naphtha (petroleum), hydrotreated light	-	To be fixed
67950	061789-36-4	Naphthenic acids, calcium salts	9	To be fixed
67930	061789-51-3	Naphthenic acids, cobalt salts	9	To be fixed
67946	001336-93-2	Naphthenic acid, manganese salts	9	To be fixed
68115	039049-04-2	Neodecanoic acid, zirconium salt	8	To be fixed
-	005064-31-3	Nitrilotriacetic acid, trisodium salt	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	002687-94-7	N-Octyl-2-pyrrolidinone	-	To be fixed
-	000112-90-3	Oleamine	-	To be fixed
69120	000142-77-8	Oleic acid, butyl ester	7	To be fixed
-	010402-16-1	Oleic acid, copper salt	-	To be fixed
69360	042254-63-7	Oleic acid, heptyl ester	7	To be fixed
-	000142-15-4	Oleic acid, 2-sulphoethyl ester, sodium salt	-	To be fixed
-	005420-17-7	Oleic acid, tetrahydrofurfuryl ester	-	To be fixed
-	010460-00-1	Oleylarmmoniurn acetate	-	To be fixed
-	007173-62-8	N-Oleyl-1,3-diaminopropane	-	To be fixed
70720	000540-10-3	Palmitic acid, hexadecyl ester	7	To be fixed
71120	008012-95-1	Paraffin oil	9	To be fixed
-	064771-72-8	Paraffins (petroleum), n-C5-C20	-	To be fixed
-	000078-22-8	Pentaerythritol monoricinoleate	-	To be fixed
-	004196-86-5	Pentaerythritol tetrabenzoate	-	To be fixed
72080	064742-16-1	Petroleum hydrocarbon resins	9	To be fixed
72135	000092-84-2	Phenothiazine	8	To be fixed
-	029761-21-5	Phosphoric acid, diphenyl isodecyl ester	-	To be fixed
-	000078-40-0	Phosphoric acid, triethyl ester	-	To be fixed
73840	000126-71-6	Phosphoric acid, triisobutyl ester	6B	To be fixed
74000	000078-42-2	Phosphoric acid, tris(2-ethylhexyl) ester	6B	To be fixed
(23178)	000101-02-0	Phosphorous acid, triphenyl ester	8	To be fixed
-	000085-71-2	Phthalic acid, mixed esters with ethyl glycolate and methanol	-	To be fixed
76460	009003-01-4	Polyacrylic acid	7	To be fixed
76460	009003-03-6	Polyacrylic acid, ammonium salt	7	To be fixed
76460	009003-04-7	Polyacrylic acid, sodium salt	7	To be fixed
-	063148-69-6	Polyesters of polyhydric alcohols	-	To be fixed
77030	068891-38-3	Polyethyleneglycol alkyl(C12-C14) ether, sodium sulphate	9	To be fixed
-	009086-52-6	Polyethyleneglycol bis(1-phenylethyl)phenyl ether	-	To be fixed
77200	061791-14-8	Polyethyleneglycol cocoamine	9	To be fixed
-	009014-93-1	Polyethyleneglycol dinonylphenyl ether	-	To be fixed
77711	068439-50-9	Polyethyleneglycol ethers of C12-C14 alcohols	D	To be fixed
-	068920-66-1	Polyethyleneglycol ethers of alcohols, C16-C18 and C18 unsaturated	-	To be fixed
-	068511-37-5	Polyethyleneglycol ethers of C12-C14 alcohols, phosphates	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	068585-34-2	Polyethyleneglycol ethers of C10-Cl6 alcohols, sodium sulphates	-	To be fixed
-	?	Polyethyleneglycol ether of 2,2-bis(4-hydroxyphenyl)propane	-	To be fixed
-	061790-85-0	Polyethyleneglycol ethers of N-(tallow alkyl)trimethylenediamines	-	To be fixed
77760	061791-28-4	Polyethyleneglycol ether of tallow fatty alcohol	D	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
78440	026027-38-3	Polyethyleneglycol 4-nonylphenyl ether	W7	To be fixed
-	009051-57-4	Polyethyleneglycol nonylphenyl ether, ammonium salt	-	To be fixed
-	068412-54-4	Polyethyleneglycol nonylphenyl ether, branched	-	To be fixed
78480	051811-79-1	Polyethyleneglycol nonylphenyl phosphate	9	To be fixed
78560	009002-93-1 009036-19-5	Polyethyleneglycol octylphenyl ether	9	To be fixed
-	026636-37-3	Polyethyleneglycol 2,4,6-tri-tert-butylphenyl ether	-	To be fixed
-	109909-39-9	Polyethyleneglycol 2,4,6-tris(isobutyl)phenyl ether sodium sulphate	-	To be fixed
-	073297-33-3	Polyethyleneglycol tris[1-(methylphenyl)ethyl]phenyl ether	-	To be fixed
-	070559-25-0	Polyethyleneglycol 2,4,6-tris(1-phenylethyl)phenyl ether	-	To be fixed
79680	009002-98-6	Polyethyleneimine	W9-D	To be fixed
-	068130-97-2	Polyethyleneimine, reaction products with 1,2-dichloroethane	-	To be fixed
79920	009003-11-6	Poly(ethylene propylene)glycol	7/9	To be fixed
-	068551-13-3	Poly(ethylene propylene)glycol ethers of C12-C15 alcohols	-	To be fixed
-	011111-34-5	Poly(ethylene propylene)glycol ether of ethylenediaminetetrapropanol	-	To be fixed
-	009038-95-3	Poly(ethylene propylene)glycol monobutyl ether	-	To be fixed
80077	068441-17-8	Polyethylene, oxidized	7	To be fixed
80340	027924-99-8	Poly(12-hydroxystearic acid)	7	To be fixed
80340	?	Poly(12-hydroxystearic acid), calcium salt	7	To be fixed
-	068071-29-4	Poly(2-methyl-1,3-butadiene), phenol-modified	-	To be fixed
-	009057-91-4	Polypropyleneglycol - toluene diisocyanate, copolymer	-	To be fixed
81230	-	Polyurethanes	9	To be fixed
81245	009003-20-7	Polyvinyl acetate	D	To be fixed
(23710)	063148-65-2	Polyvinylbutyrals	9	To be fixed
81390	025104-37-4	Poly(vinyl ethyl ether)	9	To be fixed
82050	000108-32-7	Propylene carbonate	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	029387-86-8	Propyleneglycol monobutyl ether	-	To be fixed
83280	026402-31-3	1,2-Propyleneglycol monoricinoleate	7	To be fixed
-	068188-14-7	Resin acids and rosin acids, barium salts	-	To be fixed
-	068554-12-1	Resin acids and rosin acids, hydrogenated, calcium salts	-	To be fixed
-	068475-37-6	Resin acids and rosin acids, polymerised, glycerol esters	-	To be fixed
-	068152-78-3	Resin acids and rosin acids, strontium salts	-	To be fixed
-	000151-13-3	Ricinoleic acid, butyl ester	-	To be fixed
-	000106-17-2	Ricinoleic acid, 2-hydroxyethyl ester	-	To be fixed
-	000141-24-2	Ricinoleic acid, methyl ester	-	To be fixed
-	061790-47-4	Rosin amines	-	To be fixed
-	068648-50-0	Rosin, dimerized, calcium salt	-	To be fixed
-	008050-09-7	Rosin, disproportionated	-	To be fixed
-	?	Rosin, ethoxylated, ammonium salt	-	To be fixed
-	065997-04-8	Rosin, fumarated	-	To be fixed
-	068201-58-1	Rosin, fumarated, polymer with formaldehyde	-	To be fixed
-	065997-11-7	Rosin, fumarated, polymer with pentaerythritol	-	To be fixed
-	068333-69-7	Rosin, maleated, polymer with pentaerythritol	-	To be fixed
-	008050-28-0	Rosin, maleic acid-modified	-	To be fixed
(24150)	065997-05-9	Rosin, polymerized	9	To be fixed
-	068152-68-1	Rosin, polymer with 2,2-bis(4-hydroxyphenyl)propane and formaldehyde	-	To be fixed
-	065997-07-1	Rosin, polymer with formaldehyde	-	To be fixed
-	083137-13-7	Rosin, reaction products with acrylic acid	-	To be fixed
85120	000122-62-3	Sebacic acid, bis(2-ethylhexyl) ester	6B	To be fixed
-	064742-96-7	Solvent naphtha (petroleurn), heavy aliphatic	-	To be fixed
-	064742-89-8	Solvent naphtha (petroleurn), light aliphatic	-	To be fixed
-	064742-88-7	Solvent naphtha (petroleurn), medium aliphatic	-	To be fixed
-	052551-46-9	Sorbitol tetraoleate	-	To be fixed
-	001333-71-7	Sorbitol trioleate	-	To be fixed
-	066071-86-1	Soybean oil, polymer with isophthalic acid and pentaerythritol	-	To be fixed
-	067700-65-6	Soybean oil, polymer with isophthalic acid and trimethylolpropane	-	To be fixed
-	066070-60-8	Soybean oil, polymer with pentaerythritol and phthalic anhydride	-	To be fixed
89120	000123-95-5	Stearic acid, butyl ester	7	To be fixed
89150	010119-53-6	Stearic acid, cerium salt	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
90000	000646-13-9	Stearic acid, isobutyl ester	7	To be fixed
-	090459-62-4	Stearic acid, reaction products with diethylenetriamine, dimethyl sulphate-quaternized	-	To be fixed
91135	000160-65-0	Succinic acid, dimethyl ester	7	To be fixed
-	012738-64-6	Sucrose benzoate	-	To be fixed
-	068608-26-4	Sulphonic acids, petroleum, sodium salts	-	To be fixed
91572	000577-11-7	Sulphosuccinic acid, bis(2-ethylhexyl) ester, sodium salt	6B	To be fixed
-	091845-13-5	Tall oil fatty acids, compounds with N-oleyl-1,3-diaminopropane	-	To be fixed
-	061789-01-3	Tall oil fatty acids, epoxidized, 2-ethylhxyl esters	-	To be fixed
-	061788-72-5	Tall oil fatty acids, epoxidized, octyl esters	-	To be fixed
-	068334-13-4	Tall oil fatty acids, 2-ethylhexyl esters	-	To be fixed
-	068333-78-8	Tall oil fatty acids, isooctyl esters	-	To be fixed
-	068410-37-7	Tall oil fatty acids, polymers with isophthalic acid, pentaerythritol and tall oil	-	To be fixed
-	061790-31-6	Tallow alkyl amides, hydrogenated	-	To be fixed
-	061790-33-8	Tallow alkyl amines	-	To be fixed
-	061788-45-2	Tallow alkyl amines, hydrogenated	-	To be fixed
-	061791-55-7	N-(Tallow alkyl)trimethylenediamine	-	To be fixed
-	067875-36-9	Terephthalic acid, polymer with 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,6-hexanediol and trimethylolpropane	-	To be fixed
-	069029-24-9	1-Tetradecanol phosphate	-	To be fixed
-	018268-70-7	Tetraethyleneglycol bis(2-ethylhexanoate)	-	To be fixed
-	070729-68-9	Tetraethyleneglycol diheptanoate	-	To be fixed
92685	000126-86-3	2,4,7,9-Tetramethyl-5-decyne-4,7-diol	8	To be fixed
-	068227-33-8	2,5,8,11-Tetramethyl-6-dodecyne-5,8-diol	-	To be fixed
(25300)	000088-19-7	o-Toluenesulphonamide	8	To be fixed
(25330)	000070-55-3	p-Toluenesulphonamide	7	To be fixed
-	001333-07-9	Toluenesulphonamide	-	To be fixed
93585	000104-15-4	p-Toluenesulphonic acid	8	To be fixed
-	000080-40-0	p-Toluenesulphonic acid, ethyl ester	-	To be fixed
93760	000077-90-7	Tributyl acetylcitrate	?	To be fixed
94000	000102-71-6	Triethanolamine	8	To be fixed
-	010277-04-0	Triethanolamine monooleate	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
94240	000077-89-4	Triethyl acetylcitrate	8	To be fixed
-	000094-28-0	Triethyleneglycol bis(2-ethylhexanoate)	-	To be fixed
-	000111-21-7	Triethyleneglycol diacetate	-	To be fixed
-	000120-56-9	Triethyleneglycol dibenzoate	-	To be fixed
-	025176-75-4	Triethyleneglycol dihexanoate	-	To be fixed
-	000106-10-5	Triethyleneglycol dioctanoate	-	To be fixed
-	000106-06-9	Triethyleneglycol dipelargonate	-	To be fixed
-	068583-52-8	Triethyleneglycol, mixed diesters with decanoic acid and octanoic acid	-	To be fixed
-	001528-48-9	Trimellitic acid, triheptyl ester	-	To be fixed
-	036631-30-8	Trimellitic acid, triisodecyl ester	-	To be fixed
-	053894-23-8	Trimellitic acid, triisononyl ester	-	To be fixed
-	000089-04-3	Trimellitic acid, trioctyl ester	-	To be fixed
-	025498-49-1	Tripropyleneglycol monomethyl ether	-	To be fixed
95730	009003-22-9	Vinyl acetate - vinyl chloride, copolymer	D	To be fixed
-	-	Waxes (paraffinic), refined, derived from petroleum based or synthetic hydrocarbon feedstocks	-	To be fixed
95880	008042-47-5	White mineral oil	9	To be fixed
96400	001314-23-4	Zirconium oxide	7	To be fixed

3.2 Binders (monomers)

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

List 1 - Substances evaluated by SCF/EFSA

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	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(T) = 6 mg/kg (5)	0.1
10780	000141-32-2	Acrylic acid, n-butyl ester	2	SML(T) = 6 mg/kg (as acrylic acid) (5)	0.1 (as acrylic acid)
11470	000140-88-5	Acrylic acid, ethyl ester	2	SML(T) = 6 mg/kg (as acrylic acid) (5)	0.1 (as acrylic acid)
11710	000096-33-3	Acrylic acid, methyl ester	2	SML(T) = 6 mg/kg (as acrylic acid) (5)	0.1 (as acrylic acid)
12130	000124-04-9	Adipic acid	1		5
12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	2	SML = 6 mg/kg	0.1
12820	000123-99-9	Azelaic acid	2		3
13090	000065-85-0	Benzoic acid	1		5
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	2	SML = 0.6 mg/kg	0.01
13720	000110-63-4	1,4-Butanediol	3	SML = 5 mg/kg	
13840	000071-36-3	1-Butanol	3		
14020	000098-54-4	4-tert-Butylphenol	3	SML = 0.05 mg/kg	
14110	000123-72-8	Butyraldehyde	3		
14200	000105-60-2	Caprolactam	2	SML = 15 mg/kg	0.25
14508	009004-36-8	Cellulose acetate butyrate	3		
14512	009004-39-1	Cellulose acetate propionate	3		

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
14710	000108-39-4	m-Cresol	3		
14740	000095-48-7	o-Cresol	3		
14770	000106-44-5	p-Cresol	3		
15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	3	SML = 5 mg/kg	
15760	000111-46-6	Diethyleneglycol	2	SML(T) = 30 mg/kg (1)	0.5
16390	000126-30-7	2,2-Dimethyl-1,3-propanediol	3	SML = 0.05 mg/kg	
16630	000101-68-8	Diphenylmethane 4,4'-diisocyanate	4A	SML(T) = ND (DL = 0,01 mg/kg (as NCO) (6)	
16750	000106-89-8	Epichlorohydrin	4A	SML = ND (DL = 0.01 mg/kg)	
16925	009004-57-3	Ethylcellulose	2		NS
16960	000107-15-3	Ethylenediamine	2	SML = 12 mg/kg	0.2
16990	000107-21-1	Ethyleneglycol	2	SML(T) = 30 mg/kg (1)	0.5
17260	000050-00-0	Formaldehyde	3	SML = 15 mg/kg	
17290	000110-17-8	Fumaric acid	1		6
18100	000056-81-5	Glycerol	1		NS
18460	000124-09-4	Hexamethylenediamine	2	SML = 2.4 mg/kg	0.04
18700	000629-11-8	1,6-Hexanediol	3	SML = 0.05 mg/kg	
19060	000109-53-5	Isobutyl vinyl ether	3	SML = 0.05 mg/kg	
19110	004098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	4A	SML(T) = ND (DL = 0,01 mg/kg (as NCO) (6)	
19150	000121-91-5	Isophthalic acid	3	SML = 5 mg/kg	
19532	008001-26-1	Linseed oil	3		
19540	000110-16-7	Maleic acid	2	SML(T) = 30 mg/kg (7)	0.5
19960	000108-31-6	Maleic anhydride	2	SML(T) = 30 mg/kg (as maleic acid) (7)	0.5
20020	000079-41-4	Methacrylic acid	2	SML(T) = 6 mg/kg (8)	0.1
20110	000097-88-1	Methacrylic acid, butyl ester	2	SML(T) = 6 mg/kg (as methacrylic acid) (8)	0.1 (as m. acid)
20890	000097-63-2	Methacrylic acid, ethyl ester	2	SML(T) = 6 mg/kg (as methacrylic acid) (8)	0.1 (as m. acid)

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
21130	000080-62-6	Methacrylic acid, methyl ester	2	SML(T) = 6 mg/kg (as methacrylic acid) (8)	0.1 (as m. acid)
21550	000067-56-1	Methanol	3		
22210	000098-83-9	alpha-Methylstyrene	3	SML = 0.05 mg/kg	
22450	009004-70-0	Nitrocellulose	3		
22780	000057-10-3	Palmitic acid	1		NS
22840	000115-77-5	Pentaerythritol	2		1
22960	000108-95-2	Phenol	2		1.5
23380	000085-44-9	Phthalic anhydride	2		1
23590	025322-68-3	Polyethyleneglycol	2		5
23651	025322-69-4	Polypropyleneglycol	3		
23740	000057-55-6	1,2-Propanediol	1		25
24100	008050-09-7	Rosin	2		1
24115	008050-31-5	Rosin, ester with glycerol	1		12.5
(84080)	008050-26-8	Rosin, ester with pentaerythritol	2		1
24520	008001-22-7	Soybean oil	3		
24610	000100-42-5	Styrene	4B		
24895	008001-21-6	Sunflower oil	3		
24910	000100-21-0	Terephthalic acid	2	SML = 7.5 mg/kg	0.125
25208	026471-62-5	Toluene diisocyanate	4A	SML(T) = ND (DL = 0,01 mg/kg (as NCO) (6)	
25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine	2	SML = 30 mg/kg	0.5
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)	

Temporary appendix to list 1: substances evaluated by other agencies than EFSA

N O N E

List 2 - Substances not evaluated

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
10157	000098-86-2	Acetophenone	8	To be fixed
11100	057472-68-1	Acrylic acid, diester with dipropyleneglycol	8	To be fixed
11170	026570-48-9	Acrylic acid, diester with polyethyleneglycol	8	To be fixed
11195	068901-05-3 042978-66-5	Acrylic acid, diester with tripropyleneglycol	8	To be fixed
13510	001675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (= BADGE)	7	To be fixed
-	053814-24-7	2,2-Bis(4-hydroxyphenyl)propane-epichlorohydrin copolymer diacrylate	-	To be fixed
(45520)	-	p-Cresol, styrenated	9	To be fixed
14910	000108-94-1	Cyclohexanone	6A	To be fixed
15040	000542-92-7	1,3-Cyclopentadiene	8	To be fixed
15730	000077-73-6	Dicyclopentadiene	8	To be fixed
16713	-	Drying oils	9	To be fixed
-	-	Drying oil acids	-	To be fixed
-	-	Epoxides, cycloaliphatic	-	To be fixed
17140	000109-92-2	Ethyl vinyl ether	7	To be fixed
18436	001687-30-5	Hexahydrophthalic acid	8	To be fixed
18441	000085-42-7	Hexahydrophthalic anhydride	8	To be fixed
20920	000688-84-6	Methacrylic acid, 2-ethylhexyl ester	8	To be fixed
22270	000107-25-5	Methyl vinyl ether	7	To be fixed
-	051728-26-8	Pentaerythritol ethoxylate tetraacrylate	-	To be fixed
25810	015625-89-5	1,1,1-Trimethylolpropane triacrylate	8	To be fixed
25975	-	Vegetable oil acids, dimers	8	To be fixed

3.3 Dyes

List 1 - Substances evaluated by SCF/EFSA

NONE

Temporary appendix to list 1: substances evaluated by other agencies than EFSA

CAS No	C.I. No	C.I. Name	Restriction
007576-65-0	47020	C.I. Disperse Yellow 54	To be fixed
000128-80-3	61565	C.I. Solvent Green 3	To be fixed
000082-38-2	60505	C.I. Solvent Red 111	To be fixed
020749-68-2	564120	C.I. Solvent Red 135	To be fixed
000081-48-1	60725	C.I. Solvent Violet 13	To be fixed
004702-90-3	48160	C.I. Solvent Yellow 93	To be fixed

List 2 - Substances not evaluated

CAS No	C.I. No	C.I. Name	Restriction
000129-17-9	42045	C.I. Acid Blue 1	To be fixed
003536-49-0	42051	C.I. Acid Blue 3	To be fixed
004368-56-3	62045	C.I. Acid Blue 62	To be fixed
071872-19-0	-	C.I. Acid Blue 317	To be fixed
004129-84-4	42650	C.I. Acid Violet 17	To be fixed
001934-21-0	19140	C.I. Acid Yellow 23	To be fixed
000587-98-4	13065	C.I. Acid Yellow 36	To be fixed
005601-29-6	-	C.I. Acid Yellow 129	To be fixed
003521-06-0	42025	C.I. Basic Blue 1	To be fixed
002787-91-9	51004	C.I. Basic Blue 3	To be fixed
003943-82-6	42140	C.I. Basic Blue 5	To be fixed
003251-84-1	44044	C.I. Basic Blue 55	To be fixed
000989-38-8	45160	C.I. Basic Red 1	To be fixed
000081-88-9	45170	C.I. Basic Violet 10	To be fixed
002390-63-8	45175	C.I. Basic Violet 11	To be fixed
006359-45-1	48013	C.I. Basic Violet 16	To be fixed
006358-36-7	41001	C.I. Basic Yellow 37	To be fixed
006428-31-5	35255	C.I. Direct Black 19	To be fixed
006473-13-8	35435	C.I. Direct Black 22	To be fixed
001330-38-7	74180	C.I. Direct Blue 86	To be fixed
012222-04-7	74190	C.I. Direct Blue 199	To be fixed
028407-37-6	24401	C.I. Direct Blue 218	To be fixed
203210-48-4	-	C.I. Direct Blue 301	To be fixed
001325-35-5	40002/40003	C.I. Direct Orange 15	To be fixed
006598-63-6	29156	C.I. Direct Orange 102	To be fixed
006227-02-7	27680	C.I. Direct Red 16	To be fixed
003441-14-3	29160	C.I. Direct Red 23	To be fixed
002610-11-9	28160	C.I. Direct Red 81	To be fixed

CAS No	C.I. No	C.I. Name	Restriction
?	-	C.I. Direct Red 262	To be fixed
006227-14-1	27885	C.I. Direct Violet 9	To be fixed
005489-77-0	27905	C.I. Direct Violet 51	To be fixed
003051-11-4	24890	C.I. Direct Yellow 4	To be fixed
001325-37-7	40000	C.I. Direct Yellow 11	To be fixed
008005-52-5	29000	C.I. Direct Yellow 44	To be fixed
003214-47-9	29025	C.I. Direct Yellow 50	To be fixed
067969-87-3	29042	C.I. Direct Yellow 118	To be fixed
072705-26-1	13965	C.I. Direct Yellow 157	To be fixed
?	-	C.I. Disperse Blue 355	To be fixed
213328-78-0	-	C.I. Disperse Blue 359	To be fixed
031482-56-1	11227	C.I. Disperse Orange 25	To be fixed
017418-58-5	60756	C.I. Disperse Red 60	To be fixed
000522-75-8	73300	C.I. Disperse Red 364	To be fixed
000128-95-0	61100	C.I. Disperse Violet 1	To be fixed
002832-40-8	11855	C.I. Disperse Yellow 3	To be fixed
027425-55-4	-	C.I. Disperse Yellow 82	To be fixed
003844-45-9	42090	C.I. Food Blue 2	To be fixed
003536-49-0	42051	C.I. Food Blue 5	To be fixed
004553-89-3	20285	C.I. Food Brown 3	To be fixed
003567-69-9	14720	C.I. Food Red 3	To be fixed
002611-82-7	16255	C.I. Food Red 7	To be fixed
000915-67-3	16185	C.I. Food Red 9	To be fixed
002783-94-0	15985	C.I. Food Yellow 3	To be fixed
001934-21-0	19140	C.I. Food Yellow 4	To be fixed
016823-51-1	61205:1	C.I. Reactive Blue 5	To be fixed
012238-09-4	74460	C.I. Reactive Blue 7	To be fixed
149315-83-3	-	C.I. Reactive Blue 238	To be fixed
070210-21-8	18279	C.I. Reactive Orange 5	To be fixed
070161-14-7	-	C.I. Reactive Orange 12	To be fixed
070616-89-6	18270	C.I. Reactive Orange 13	To be fixed
070210-20-7	18208	C.I. Reactive Red 24	To be fixed
064181-81-3	-	C.I. Reactive Red 43	To be fixed
070210-46-7	18209	C.I. Reactive Red 45	To be fixed
061951-82-4	25810	C.I. Reactive Red 120	To be fixed
171172-56-8	-	C.I. Reactive Red 220	To be fixed
140876-11-5	-	C.I. Reactive Red 228	To be fixed
132579-39-6	-	C.I. Reactive Red 235	To be fixed
050662-99-2	18972	C.I. Reactive Yellow 2	To be fixed
006539-67-9	13245	C.I. Reactive Yellow 3	To be fixed
004197-25-5	26150	C.I. Solvent Black 3	To be fixed
012237-22-8	-	C.I. Solvent Black 27	To be fixed
012237-23-9	-	C.I. Solvent Black 28	To be fixed
061901-87-9	-	C.I. Solvent Black 29	To be fixed
032517-36-5	-	C.I. Solvent Black 34	To be fixed
061931-53-1	12195 + 12197	C.I. Solvent Black 35	To be fixed
094765-62-5	-	C.I. Solvent Black 45	To be fixed
006786-83-0	44045:1	C.I. Solvent Blue 4	To be fixed
001328-54-7	74350	C.I. Solvent Blue 25	To be fixed
017354-14-2	61554	C.I. Solvent Blue 35	To be fixed
003861-73-2	13390	C.I. Solvent Blue 37	To be fixed
061725-69-7	-	C.I. Solvent Blue 44	To be fixed
037229-23-5	-	C.I. Solvent Blue 45	To be fixed

CAS No	C.I. No	C.I. Name	Restriction
012226-78-7	-	C.I. Solvent Blue 67	To be fixed
012237-24-0	-	C.I. Solvent Blue 70	To be fixed
061725-72-2	-	C.I. Solvent Brown 28	To be fixed
061901-89-1	-	C.I. Solvent Brown 35	To be fixed
061725-74-4	-	C.I. Solvent Brown 37	To be fixed
061725-75-5	-	C.I. Solvent Brown 42	To be fixed
061116-28-7	-	C.I. Solvent Brown 43	To be fixed
061969-45-7	-	C.I. Solvent Brown 44	To be fixed
071872-85-0	-	C.I. Solvent Brown 58	To be fixed
013463-42-8	18745:1	C.I. Solvent Orange 5	To be fixed
010127-28-3	18736:1	C.I. Solvent Orange 6	To be fixed
061725-76-6	-	C.I. Solvent Orange 11	To be fixed
061813-62-5	-	C.I. Solvent Orange 25	To be fixed
061901-91-5	-	C.I. Solvent Orange 41	To be fixed
013011-62-6	-	C.I. Solvent Orange 45	To be fixed
012237-30-8	-	C.I. Solvent Orange 54	To be fixed
013463-42-8	18745:1	C.I. Solvent Orange 56	To be fixed
061969-46-8	-	C.I. Solvent Orange 59	To be fixed
052256-37-8	12714	C.I. Solvent Orange 62	To be fixed
016294-75-0	68550	C.I. Solvent Orange 63	To be fixed
006925-69-5	564100	C.I. Solvent Orange 78	To be fixed
110342-29-5	-	C.I. Solvent Orange 99	To be fixed
050926-68-6	-	C.I. Solvent Red 7	To be fixed
033270-70-1	12715	C.I. Solvent Red 8	To be fixed
000085-83-6	26105	C.I. Solvent Red 24	To be fixed
003176-79-2	26110	C.I. Solvent Red 25	To be fixed
061725-78-8	16260 + 45170:1	C.I. Solvent Red 35	To be fixed
000509-34-2	-	C.I. Solvent Red 49	To be fixed
061725-81-3	-	C.I. Solvent Red 89	To be fixed
061901-92-6	-	C.I. Solvent Red 91	To be fixed
061901-93-7	-	C.I. Solvent Red 92	To be fixed
053802-03-2	-	C.I. Solvent Red 109	To be fixed
012237-26-2	-	C.I. Solvent Red 118	To be fixed
012237-27-3	-	C.I. Solvent Red 119	To be fixed
012227-55-3	-	C.I. Solvent Red 122	To be fixed
012239-74-6	-	C.I. Solvent Red 124	To be fixed
012271-00-0	-	C.I. Solvent Red 125	To be fixed
061969-48-0	-	C.I. Solvent Red 127	To be fixed
061725-84-6	-	C.I. Solvent Red 130	To be fixed
061725-85-7	-	C.I. Solvent Red 132	To be fixed
069899-68-9	-	C.I. Solvent Red 160	To be fixed
164251-88-1	-	C.I. Solvent Red 195	To be fixed
?	77301	C.I. Solvent Red 233	To be fixed
061725-86-8	16055 + 45170	C.I. Solvent Violet 2	To be fixed
052080-58-7	42535:1	C.I. Solvent Violet 8	To be fixed
061725-87-9	-	C.I. Solvent Violet 24	To be fixed
004314-14-1	12700	C.I. Solvent Yellow 16	To be fixed
006407-78-9	12740	C.I. Solvent Yellow 18	To be fixed
010343-55-2	13900:1	C.I. Solvent Yellow 19	To be fixed
005601-29-6	-	C.I. Solvent Yellow 21	To be fixed
037219-73-1	-	C.I. Solvent Yellow 25	To be fixed
006706-82-7	21230	C.I. Solvent Yellow 29	To be fixed

CAS No	C.I. No	C.I. Name	Restriction
061931-84-8	48045	C.I. Solvent Yellow 32	To be fixed
019125-99-6	561930	C.I. Solvent Yellow 43	To be fixed
002478-20-8	56200	C.I. Solvent Yellow 44	To be fixed
061725-88-0	-	C.I. Solvent Yellow 48	To be fixed
002481-94-9	11021	C.I. Solvent Yellow 56	To be fixed
061901-95-9	-	C.I. Solvent Yellow 62	To be fixed
012237-31-9	-	C.I. Solvent Yellow 79	To be fixed
012227-56-4	-	C.I. Solvent Yellow 81	To be fixed
012227-67-7	-	C.I. Solvent Yellow 82	To be fixed
012239-75-7	-	C.I. Solvent Yellow 83	To be fixed
061116-27-6	-	C.I. Solvent Yellow 83:1	To be fixed
061931-55-3	-	C.I. Solvent Yellow 88	To be fixed
061969-51-5	-	C.I. Solvent Yellow 89	To be fixed
144246-02-6	-	C.I. Solvent Yellow 135	To be fixed
109945-04-2	-	C.I. Solvent Yellow 146	To be fixed
104244-10-2	-	C.I. Solvent Yellow 162	To be fixed

3.4 Pigments

List 1 - Substances evaluated by SCF/EFSA

NONE

Temporary appendix to list 1: substances evaluated by other agencies than EFSA

CAS No	C.I. No	C.I. Name	Restriction
001333-86-4	77266	C.I. Pigment Black 7	To be fixed
012227-89-3	77499	C.I. Pigment Black 11	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15:1	To be fixed
000147-14-8	74160	C.I. PIgment Blue 15:2	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15:3	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15:4	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15:6	To be fixed
000574-93-6	74100	C.I. Pigment Blue 16	To be fixed
014038-43-8	77510	C.I. Pigment Blue 27	To be fixed
057455-37-5	77007	C.I. Pigment Blue 29	To be fixed
000081-77-6	69800	C.I. Pigment Blue 60	To be fixed
035869-64-8	20060	C.I. Pigment Brown 23	To be fixed
001328-53-6	74260	C.I. Pigment Green 7	To be fixed
001330-37-6	74255	C.I. Pigment Green 37	To be fixed
007429-90-5	77000	C.I. Pigment Metal 1	To be fixed
007440-50-8	77400	C.I. Pigment Metal 2	To be fixed
003468-63-1	12075	C.I. Pigment Orange 5	To be fixed
012236-62-3	11780	C.I. Pigment Orange 36	To be fixed
004424-06-0	71105	C.I. Pigment Orange 43	To be fixed
072102-84-2	12760	C.I. Pigment Orange 64	To be fixed
084632-50-8	561200	C.I. Pigment Orange 71	To be fixed
006041-94-7	12310	C.I. Pigment Red 2	To be fixed
002425-85-6	12120	C.I. Pigment Red 3	To be fixed
002814-77-9	12085	C.I. Pigment Red 4	To be fixed
006410-41-9	12490	C.I. Pigment Red 5	To be fixed
006410-32-8	12385	C.I. Pigment Red 12	To be fixed
007023-61-2	15865:2	C.I. Pigment Red 48:2	To be fixed
015782-05-5	15865:3	C.I. Pigment Red 48:3	To be fixed
001103-39-5	15630:2	C.I. Pigment Red 49:2	To be fixed
017852-99-2	15860:1	C.I. Pigment Red 52:1	To be fixed
005281-04-9	15850:1	C.I. Pigment Red 57:1	To be fixed
001309-37-1	77491	C.I. Pigment Red 101	To be fixed
006535-46-2	12370	C.I. Pigment Red 112	To be fixed
016043-40-6	73915	C.I. Pigment Red 122	To be fixed
005280-78-4	20735	C.I. Pigment Red 144	To be fixed
005280-68-2	12485	C.I. Pigment Red 146	To be fixed
004948-15-6	71137	C.I. Pigment Red 149	To be fixed
003905-19-9	20730	C.I. Pigment Red 166	To be fixed
002786-76-7	12475	C.I. Pigment Red 170	To be fixed
002379-74-0	73360	C.I. Pigment Red 181	To be fixed

CAS No	C.I. No	C.I. Name	Restriction
003089-17-6	73907	C.I. Pigment Red 202	To be fixed
031778-10-6	12514	C.I. Pigment Red 208	To be fixed
082643-43-4	-	C.I. Pigment Red 214	To be fixed
052238-92-3	20067	C.I. Pigment Red 242	To be fixed
088949-33-1	561300	C.I. Pigment Red 264	To be fixed
001047-16-1	73900	C.I. Pigment Violet 19	To be fixed
006358-30-1	51319	C.I. Pigment Violet 23	To be fixed
012225-08-0	12517	C.I. Pigment Violet 32	To be fixed
057971-98-9	51345	C.I. Pigment Violet 37	To be fixed
002379-75-1	73395	C.I. Pigment Violet 38	To be fixed
001345-05-7	77115	C.I. Pigment White 5	To be fixed
013463-67-7	77891	C.I. Pigment White 6	To be fixed
007727-43-7	77120	C.I. Pigment White 21	To be fixed
001332-73-6	77002	C.I. Pigment White 24	To be fixed
010101-41-4	77231	C.I. Pigment White 25	To be fixed
002512-29-0	11680	C.I. Pigment Yellow 1	To be fixed
006486-23-3	11710	C.I. Pigment Yellow 3	To be fixed
005979-28-2	20040	C.I. Pigment Yellow 16	To be fixed
051274-00-1	77492	C.I. Pigment Yellow 42	To be fixed
008007-18-9	77788	C.I. Pigment Yellow 53	To be fixed
012286-66-7	13940	C.I. Pigment Yellow 62	To be fixed
005580-57-4	20710	C.I. Pigment Yellow 93	To be fixed
005280-80-8	20034	C.I. Pigment Yellow 95	To be fixed
005590-18-1	56280	C.I. Pigment Yellow 110	To be fixed
079953-85-8	20037	C.I. Pigment Yellow 128	To be fixed
030125-47-4	56300	C.I. Pigment Yellow 138	To be fixed
036888-99-0	56298	C.I. Pigment Yellow 139	To be fixed
077465-46-4	-	C.I. Pigment Yellow 155	To be fixed
077804-81-0	21290	C.I. Pigment Yellow 180	To be fixed

List 2 - Substances not evaluated

CAS No	C.I. No	C.I. Name	Restriction
001325-87-7	42595:2	C.I. Pigment Blue 1	To be fixed
058569-23-6	42750:1	C.I. Pigment Blue 19	To be fixed
006417-46-5	42800	C.I. Pigment Blue 56	To be fixed
001324-76-1	42765:1	C.I. Pigment Blue 61	To be fixed
082338-76-9	42595:4	C.I. Pigment Blue 62	To be fixed
014154-42-8	741300	C.I. Pigment Blue 79	To be fixed
006992-11-6	12510	C.I. Pigment Brown 25	To be fixed
211502-16-8	-	C.I. Pigment Brown 41	To be fixed
001325-75-3	42040:1	C.I. Pigment Green 1	To be fixed
014302-13-7	74265	C.I. Pigment Green 36	To be fixed
003520-72-7	21110	C.I. Pigment Orange 13	To be fixed
006505-28-8	21160	C.I. Pigment Orange 16	To be fixed
015793-73-4	21115	C.I. Pigment Orange 34	To be fixed
012236-64-5	12367	C.I. Pigment Orange 38	To be fixed
063467-26-5	15602	C.I. Pigment Orange 46	To be fixed
052846-56-7	11775	C.I. Pigment Orange 62	To be fixed
006448-95-9	12315	C.I. Pigment Red 22	To be fixed
006471-49-4	12355	C.I. Pigment Red 23	To be fixed
007585-41-3	15865:1	C.I. Pigment Red 48:1	To be fixed
005280-66-0	15865:4	C.I. Pigment Red 48:4	To be fixed
001103-38-4	15630:1	C.I. Pigment Red 49:1	To be fixed
002092-56-0	15585	C.I. Pigment Red 53	To be fixed
005160-02-1	15585:1	C.I. Pigment Red 53:1	To be fixed
012224-98-5	45160	C.I. Pigment Red 81	To be fixed
080083-40-5	45160:3	C.I. Pigment Red 81:1	To be fixed
075627-12-2	45161:1	C.I. Pigment Red 81:2	To be fixed
068310-07-6	45161:2	C.I. Pigment Red 81:3	To be fixed
085959-61-1	45161:5	C.I. Pigment Red 81:4	To be fixed
063022-06-0	45160:4	C.I. Pigment Red 81:5	To be fixed
001332-25-8	77015 77491 77538	C.I. Pigment Red 102	To be fixed
068227-78-1	12433	C.I. Pigment Red 147	To be fixed
012237-63-7	45160:2	C.I. Pigment Red 169	To be fixed
012225-06-8	12515	C.I. Pigment Red 176	To be fixed
099402-80-9	12487	C.I. Pigment Red 184	To be fixed
061951-98-2	12516	C.I. Pigment Red 185	To be fixed
061847-48-1	12467	C.I. Pigment Red 188	To be fixed
061932-63-6	12477	C.I. Pigment Red 210	To be fixed
107397-16-0	-	C.I. Pigment Red 211	To be fixed
084632-65-5	56110	C.I. Pigment Red 254	To be fixed
036968-27-1	12474	C.I. Pigment Red 266	To be fixed
067990-05-0	12466	C.I. Pigment Red 269	To be fixed
001326-03-0	45170:2	C.I. Pigment Violet 1	To be fixed
001326-04-1	45175:1	C.I. Pigment Violet 2	To be fixed
001325-82-2	42535:2	C.I. Pigment Violet 3	To be fixed
010101-66-3	77742	C.I. Pigment Violet 16	To be fixed
012237-62-6	42535:3	C.I. Pigment Violet 27	To be fixed
064070-98-0	42555:2	C.I. Pigment Violet 39	To be fixed
001314-13-2	77947	C.I. Pigment White 4	To be fixed
001314-98-3	77975	C.I. Pigment White 7	To be fixed

CAS No	C.I. No	C.I. Name	Restriction
000471-34-1	77220	C.I. Pigment White 18	To be fixed
001318-74-7	77005	C.I. Pigment White 19	To be fixed
012001-26-2	77019	C.I. Pigment White 20	To be fixed
014807-96-6	77718	C.I. Pigment White 26	To be fixed
007631-86-9	77811	C.I. Pigment White 27	To be fixed
001657-16-5	11665	C.I. Pigment Yellow 4	To be fixed
004106-67-6	11600	C.I. Pigment Yellow 5	To be fixed
006358-85-6	21090	C.I. Pigment Yellow 12	To be fixed
005102-83-0	21100	C.I. Pigment Yellow 13	To be fixed
005468-75-7	21095	C.I. Pigment Yellow 14	To be fixed
004531-49-1	21105	C.I. Pigment Yellow 17	To be fixed
006358-37-8	21096	C.I. Pigment Yellow 55	To be fixed
006358-31-2	11741	C.I. Pigment Yellow 74	To be fixed
022094-93-5	21127	C.I. Pigment Yellow 81	To be fixed
005567-15-7	21108	C.I. Pigment Yellow 83	To be fixed
012225-18-2	11767	C.I. Pigment Yellow 97	To be fixed
069771-45-5	11745	C.I. Pigment Yellow 111	To be fixed
090268-23-8	21101	C.I. Pigment Yellow 126	To be fixed
068610-86-6	21102	C.I. Pigment Yellow 127	To be fixed
025157-64-6	12764	C.I. Pigment Yellow 150	To be fixed
031837-42-0	13980	C.I. Pigment Yellow 151	To be fixed
078952-72-4	21098	C.I. Pigment Yellow 174	To be fixed
090268-24-9	21103	C.I. Pigment Yellow 176	To be fixed
076199-85-4	56290	C.I. Pigment Yellow 185	To be fixed
023792-68-9	21094	C.I. Pigment Yellow 188	To be fixed
082199-12-0	11785	C.I. Pigment Yellow 194	To be fixed

4. Specific requirements for substances used in the manufacture of packaging inks

4.1 Purity requirements for colourants

All colourants used in the manufacture of packaging inks have to comply to the specifications given in Council of Europe Resolution AP (89) 1 on the use of colourants in plastic materials intended to come into contact with food.

4.2 Migration limits

All restrictions e.g. specific migration limit (SML) of substances listed in the *Inventory list* or in existing European regulations, such as the Plastics Directive 2002/72/EC, the Regenerated Cellulose Film Directive 2004/14/EC as well as in other Council of Europe resolutions are to be observed.

TECHNICAL DOCUMENT No. 2

Part 1

GOOD MANUFACTURING PRACTICES FOR THE PRODUCTION OF PACKAGING INKS FORMULATED FOR USE ON THE NON FOOD CONTACT SURFACES OF FOOD PACKAGING AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

(prepared by CEPE)

PREFACE

Over recent years, the National Association members of the European Printing Ink Association (EuPIA), a sector of the European Council of Paint, Printing Ink and Artists' Colours Industry (CEPE), have employed a common Exclusion List of raw materials that are avoided for formulating, manufacture and supply of printing inks. This has been recognised as a fundamental part of Good Manufacturing Practices (G.M.P.).

This Exclusion List has now been further enhanced by the production of a Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles. This Guideline sets out a Selection Scheme for Packaging Ink Raw Materials which further specifies requirements which such Raw Materials must meet in terms of purity, migration and toxicological properties.

The EuPIA Technical Committee has decided that, as a contribution to customer awareness, there was a need for a more specific G.M.P., especially aimed at packaging inks applied to the non food surface of packaging and articles. This would assist the harmonisation of the multinational practices of many printers, their packaging requirements and standards.

The National Associations have now fully endorsed this revised version of the G.M.P. for inks for food packaging and recommend its adoption from January 2006.

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1. Scope and Objective

These Good Manufacturing Practices (G.M.P.) apply to the manufacture of printing inks, primers, coloured lacquers and varnishes (hereafter referred to as “food packaging inks”) intended for use only on the non food contact surfaces of food packaging and articles.
Procedures for formulation, production and control are defined in order to warrant that food packaging inks:

- comply with existing regulations and/or generally accepted requirements for packaging and articles intended to come into contact with food.
- are fit for the purpose intended.
- meet agreed customers’ end use specifications.

2. Controls

2.1 *Manuals*

Detailed operational manuals cover receipt of orders, formulation, manufacture and product delivery to agreed standards. Recording systems ensure that each stage can be verified for correct action.

2.2 *Production Instruction Documents*

An instruction document (batch card) is issued for each batch of printing ink manufactured. This details the materials, quantities and equipment to be used and highlights any specific precautions to be followed. Each stage is recorded.

2.3 *Product Test Specifications*

Product test specifications exist for each food packaging ink manufactured. They list the tests which are required during manufacture and on completion, to ensure the batch meets the required specification and is fit for intended use according to agreed tests. The specification contains, where appropriate, the tolerances for each test.

3. Quality Review Procedure

In the event of non-compliance at any stage of the process or a confirmed complaint, a procedure exists to take corrective and preventative action to find the cause, rectify the problem, and if necessary make the appropriate improvement(s) to the manuals or other controls to prevent a repetition. A person is appointed to accept responsibility for ensuring that any non-compliance issue is dealt with, and corrective action completed

4. Personnel and Training

4.1 *Commitment*

The entire workforce, involving all levels of management is committed to the objectives of G.M.P..

4.2 *Training*

Training programmes and facilities are established to ensure that all personnel are fully aware of their functions and responsibilities and are competent to carry them out.

5. Raw Material Controls

5.1 *Objective*

G.M.P. requires complete co-operation with the suppliers of raw materials and knowledge of the needs of the customer. Raw materials are carefully selected to ensure that the components of the food packaging inks comply with the requirements of appropriate national legislation, are suitable for quality and are within agreed tolerances.

5.2 *Suitability*

Raw materials are selected in line with the above-mentioned EuPIA Guideline on Printing Inks for the non-food contact surface of food packaging materials and articles, so that, when food packaging inks are correctly applied, the printed surface should not:

- endanger human health.
- cause deterioration in the organoleptic nature of the packed foodstuff.
- bring about an unacceptable change in the composition or quality of the packed foodstuff.

Substances that are excluded according to the raw materials selection criteria of the “EuPIA Exclusion List for Printing Inks and Related Products” are not used.

5.3 *Identification*

A name, reference number and batch or delivery number identify each raw material, so it can be traced, as required by Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004.

5.4 Specifications

Each raw material has a specification agreed between the supplier and the food packaging ink manufacturer. The specification includes physical and chemical properties to maintain agreed ink manufacturing quality and print end-use technical requirements.

5.5 *Conformity*

Where appropriate, raw materials are tested in house or alternatively are supported by a certificate of conformity from the raw material supplier, relating to the agreed specification. In some instances pre-delivery samples representing the batch may be submitted to the ink manufacturer for special tests prior to the delivery being accepted.

5.6 *Traceability*

Where possible, traceability of a batch of raw materials is achieved by the delivery / batch reference numbers throughout the system.
If batch referencing is not possible an alternative system has to be put in place.

5.7 *Storage*

Raw materials are stored under conditions to prevent contamination or deterioration. Rejected materials should be clearly marked as such.

5.8 *Usage*

Raw material stocks are rotated and used on a first-in first-out basis.

6. Formulation

The following parameters are considered when formulating food packaging inks:

- Type of substrate and material combinations
- Type of foodstuffs to be packed
- Type of printing processes and printing equipment
- Package-forming and filling processes
- End-user specifications
- Compliance to health, safety and consumer protection regulations
- Compliance with environmental policies for printing, manufacturing processes and end-use.

Food packaging inks are formulated such that, when appropriately applied:

- they have the necessary adhesion of the dry layer to the substrate and resistance to physical and chemical stress,
- they are suitable for the method of application and for subsequent converting processes,
- they have the binder/colourant combination which will meet product resistance specifications such as ISO standards or other agreed end use specifications,
- they will have no visible transfer on the reverse side of printed matter.
- they will cause no deterioration of the organoleptic nature of the packed foodstuff,
- they will both minimise potential migration through the substrate or the set-off from the printed outer side to the food contact surface in the stack or the reel,
- they will allow compliance of the final product with the existing legal provisions.

7. Production

7.1 *Objective*

To convert raw materials into products specified to meet the customers' requirement.

7.2 *Manufacturing Instruction Document*

Manufacturing instructions are issued and followed for each batch, giving details of the raw materials, the quantities and the equipment to be used. Critical parts of the process are recorded and checked by the operator.

7.3 *Manufacturing Formulation*

Only raw materials that have passed the quality control procedures according to 5.5 are used in quantities and proportions necessary to obtain the quality of the product.

7.4 *Equipment*

The equipment used should be suitable to manufacture the products required and be maintained in good repair; clean and - where necessary - calibrated. Maintenance documentation is established.

8. Quality Control

8.1 *Objective*

To carry out laboratory and manufacturing tests on food packaging inks produced to ensure that the products supplied to the customer are fit for application and end use, and conform to customer specifications.

8.2 *Production Quality Control*

Testing of food packaging ink samples at selected stages of the process is carried out in order to establish whether the product is meeting the required quality standard. A procedure is set up for the production personnel to adjust the process or product within the specified limits when necessary.

8.3 *Testing*

Products are tested to meet specifications established at the formulation stage. Some additional test methods may be agreed with customers.

8.4 *Test Equipment*

All measuring equipment is tested and / or calibrated where appropriate to a schedule to ensure that the test results are accurate.

9. Product Information

9.1 *Identification and traceability*

A descriptive title or a trade name, reference number and specific batch number, identifies each product.

9.2 *Conformity*

Where appropriate, each delivery of food packaging inks can be supported by a statement of conformity, confirming that it meets the agreed specification.

9.3 *Data Sheets*

Each product has supporting product data sheets detailing relevant chemical, physical and safety data, and suitable end uses and methods of application.

10. Packaging

10.1 *Specification*

Packaging is selected to protect the food packaging ink during shipment and storage and conforms to the appropriate national, European and UN requirements for the nature of the product packed and the means of transport.

10.2 *Cleanliness*

New containers are inspected for cleanliness. Returned containers are inspected and cleaned, if necessary, to avoid any contamination with other products or foreign materials.

10.3 *Accurate Filling*

Filling controls are accurate within legal measuring limits. All weighing equipment is examined for accuracy, re-calibrated if necessary and frequently inspected.

10.4 *Labelling*

Each container has the minimum following information on labels:

- Identification of the producer
- Reference number and description of product
- Batch number
- Net weight
- Health, safety and transport information as required.

11. Storage

All products (including raw materials) are stored in conditions to prevent, as far as possible, any deterioration of the material. Where appropriate a procedure exists to test stock that may have been held for some time to ensure it has not drifted from specification. Rejected stock is clearly marked as such and isolated to avoid accidental use.

12. Delivery

All products are delivered in clean and clearly labelled suitable containers.

13. In-plant operations

Many inks are now blended at converter plants from basic constituents (concentrated coloured bases and additive varnishes), often through automated dispensing equipment.

When inks are manufactured by this procedure, the resultant inks have a reference number, description and batch number recorded, and the batch numbers of the constituents used to produce the finished inks also recorded.

If inks are returned from the print operation in their original state, they should be booked into stock under the relevant description and batch number.

Inks returned in a modified state should be checked for suitability for re-use. If found suitable then they are issued with a new description, reference & batch number.

If these modified inks are re-used or re-handled, the modifications should be recorded, the product tested and this new product labelled accordingly. Full traceability is required in the normal way.

TECHNICAL DOCUMENT No. 2

Part 2

CODE FOR GOOD MANUFACTURING PRACTICES FOR FLEXIBLE AND FIBRE-BASED PACKAGING FOR FOOD

A management tool for the prevention of migration, organoleptic changes and contamination and for compliance with the essential requirements for packaging and packaging waste

(prepared by FPE in co-operation with CITPA)

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Introduction

This Code for Good Manufacturing Practices is intended to be adopted by manufacturers of flexible and fibre based packaging materials for food. Its first goal is to provide certifiable certainty that excessive migration of components from the packaging into the food is prevented as intended by Art.3 of the EU Framework Regulation 1935/2004/EC.

It's other goals are to assure that the packaging will not cause organoleptic changes to the food, will be free of contamination and will be in compliance with the essential requirements of the packaging and packaging waste directive.

This code is a management tool: it provides the methods by which these goals can be attained. These methods can be adopted by the converter and their proper implementation can be audited. The code is not a stand alone document. It can only be implemented by converters who employ a good, independently audited, quality assurance system. It must be 'hooked on to' and 'embedded in' such a system. Before adoption of this code, the converter's technical processes must be organised in such a way, that they can be relied upon to produce only packaging materials in conformity with their specifications. The code also demands that a complete system for hygienic control be implemented.

With regard to the packaging products themselves, the code focuses on the design, development and specification stages in the manufacturing process. To 'design for compliance' is the short description of the chosen method. The choice of raw materials and production methods must be such, that product almost unavoidably answer to the goals of the code.

Traceability and certification of the raw materials are other important features. Certified compliance with legislation and conformity with the highest standards is demanded from the raw materials. The certification must be based upon an independently audited quality assurance system of the suppliers' manufacturing process.

The code, of necessity, fills the gaps that exist in European food contact legislation, mainly with regard to composite materials. It does so by indicating where national legislation, standards, recommendations or guidelines from authoritative bodies should be applied.

This GMP code was realised at the initiative of FLEXIBLE PACKAGING EUROPE, in close co-operation with CITPA. Drafts were put to other trade associations of manufacturers of flexible and fibre based packaging, to supplier trade associations and to large customers and their trade associations. Much valuable advise and numerous worthwhile comments were received; all of which could be incorporated.

International European trade federations of manufacturers of flexible and fibre based packaging materials are kindly invited to subscribe explicitly to this code and recommend the adoption to their members.

Industry support

The following trade associations subscribe explicitly to this code and recommend the adoption to their members:

FPE: Flexibe Packaging Europe
CITPA: International Confederation of Paper & Board Converters
FEDES: Federation Europeenne des Emballages Souples

Note to the reader

This is the version 2.0 of this Code for Good Manufacturing Practices. Remarks and suggestions for improvement are welcomed.

Please send them to the Flexible Packaging Europe Secretariat.

Presently several Flexibe Packaging Europe and CITPA member companies are introducing the code in production plants. In doing so they will collect valuable practical experience and identify points that may need to be clarified. Together with comments and suggestions received from other sources, this will lead to improvements to this code.

1. Scope

This code applies to the manufacture of flexible and fibre-based packaging that are intended to get into contact with food. These packaging materials are made of paper, board, regenerated cellulose, plastic film or aluminium foil and laminates of these materials. They may be printed, varnished, glued or made into boxes.

This code includes the preparation of inks, varnishes and adhesives, the extrusion of plastic film, metallizing of paper and plastic film and the corrugation of board, in so far as these activities take place at the converters premises.

2. Definitions

CEPE: Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art. (European federation of the paint and ink making industry)

CEPI: Confederation of European Paper Industries

CITPA: International Confederation of Paper & Board Converters

Composite packaging material: Packaging material which consists of more than one layer of material such as plastic, aluminium, paper or board. The layers may be of identical or of differing materials.

Contamination: All possible pollution of the finished packaging material, including microbiological contamination, contamination with insects, contamination with foreign substances such as lubricating oil, cleaning agents and waste water or contamination with foreign objects such as glass, knives and razorblades.

Corrugated board: A material composed of corrugated and non corrugated layers of paper that are glued together. Most common is a three layer board, with a corrugated layer of paper between two non corrugated layers.

Corrugation of board: The manufacture of corrugated board. This does not include the manufacture of the paper that is used.

Converter: The producer of the packaging materials or cardboard boxes who has adopted this code.

EAA: European Aluminium Association

EUPC: European Plastics Converters

FDA: Federal Food and Drug Administration (USA)

FPE: Flexible Packaging Europe

Fibre-based packaging: Packaging materials made of paper, solid board, corrugated board, carton board and composite materials on the basis of these materials.

Flexible Packaging: Packaging which is supplied in reel or sheet form or as pre-made bags or pouches, which has no volumetric dimension of it's own and will form around the product which is to be contained.

Food contact ink: An ink solely composed of substances listed as permitted for direct food contact, permitted as food or as an additive for the food that is to be packed in the packaging material that is to be printed with these inks.

Food product: The food product that is to be packed in the packaging material produced by the converter.

Functional barrier: Any integral layer of a composite packaging material which under normal and foreseeable conditions of use reduces the migration of components from any layer on the non-food side of the barrier into the food to 'acceptable' levels, where a level is considered 'acceptable' if it conforms with an SML or TORC-value or is analytically insignificant.

HACCP: Hazard Analysis Critical Control Points

ILSI: International Life Sciences Institute

Intended chemical reactions: Chemical reactions that take place in reactive raw materials such as two component inks, varnishes or adhesives when the supplier's instructions for use are followed correctly.

Laminate: Composite packaging material (see separate definition)

Packaging material: The packaging produced by the converter intended for the packing of food.

Principle of mutual recognition: The EU principle that a product that complies with the national legislation of one Member State must be permitted to circulate freely in any other Member State, even though it does not comply with the legislation of that Member States, unless it can be demonstrated that it represents a danger to public health.

QM: Maximum permitted quantity of residual substance permitted in a material or article. Expressed in mg/kg of finished packaging material.

QMA: Maximum permitted quantity of residual substance permitted in a material or article. Expressed in mg/dm² of finished packaging material.

Raw materials: All materials or intermediate products bought by the converter that are needed for the manufacture the packaging material.

Repeat order: Customer order for a packaging material with a required performance and technical specifications that are identical to those of a previously produced packaging material for the same customer.

Required performance: The whole of all functional requirements that the packaging material must be able to meet.

Residual solvent: Small amount of solvent that remains in dried layers of ink, varnish or adhesive. Generally expressed in mg/m²

SML: Specific Migration Limit generally expressed in mg/kg of food.

TORC: Threshold of Regulatory Concern for human health, generally expressed in µg/person/day.

Traceability: The possibility to retrieve reliable information with regard to composition, production methods, storage, shipment and other relevant features on packaging materials, their intermediate products and the raw materials that were used for their production. With this information the cause and extent of possible failures in the production and distribution chain and in the use of the packaging materials can be found whenever necessary.

Unintended chemical reactions: Chemical reactions that are not intended chemical reactions and reactions that take place where none was intended at all.

3. Objectives

3.1 Food safety objectives

The objectives with regard to food safety of this Code for Good Manufacturing Practice are to assure, under normal and foreseeable circumstances of use of the packaging material:

- the prevention of health hazards that may result from excessive migration of components of the packaging material into the packaged food product as intended by Regulation 1935/2004/EC,

- the prevention of unacceptable changes in the organoleptic characteristics of the food product that may result from the release of components from the packaging material, or from the withdrawal of components from the food by the packaging material, as intended by Regulation 1935/2004/EC,

- the prevention of health hazards and organoleptic changes that may result from contamination of the packaging material.

3.2 Environmental objective

The environmental objective of this Code for Good Manufacturing Practice is to assure,

- the necessary contribution of the converter to the attainment of compliance with the essential requirements for packaging materials that result from the EU Packaging and Packaging Waste Directive (94/62/EC), as amended.

Explanatory note: This environmental objective may be regarded as anomaly in this code, as it is not aimed at consumer protection. It is however included for practical reasons. Compliance with several of the essential requirements, demands a strict control of the design process of the packaging material and the composition of the raw materials. This is also the case for the food safety objectives. Inclusion in this code prevents the need for an additional system of control.

4. Method

The principal method by which the objectives of this Code for Good Manufacturing Practices are to be achieved, is 'Designing the packaging material for compliance'

'Designing' refers to all the decisions that need to be taken with regard to the final structure of the packaging material and the production techniques that are to be employed.

'Compliance' means compliance with legislation or official standards that cover the objectives of this GMP, and where these are incomplete or lacking, conformity with the best available guidelines and recommendations that fill the gaps.

'Designing the packaging material for compliance' means that the combination of:

- the choice of substrates
- the choice of other raw materials
- the composition of laminates
- the application of inks, adhesives, varnishes and other coatings
- and the choice of the production techniques

will be such, that protection against migration, organoleptic changes and contamination and compliance with the essential requirements is, as it were, 'built into' the finished product.

5.Migration

5.1 Achieving the objective

The objective of prevention of health hazards that may result from migration is achieved by:

- Continuous and full compliance of the packaging material with all relevant Food Contact Legislation or, where this is lacking or incomplete, with the best available guidelines and recommendations that fill the gaps, and

- Applying the above to each of the separate components of composite packaging materials, where legislation covering composite materials is lacking or where an efficient functional barrier cannot be applied.

The converter shall thus ensure that the Global Migration Limits, as well the Specific Migration Limits and other limitations when applicable, are fully respected. This shall be attained by either

- controlling the composition of the raw materials, or
- controlling the migration features of the raw materials, or
- the use of functional barriers, or
- testing directly the intermediate or finished products.

Explanatory note: For most composite materials European legislation is still missing. The legislation in the Member States is also to a large extent lacking in this respect. Only composite packaging materials composed entirely of plastic have been regulated so far by the European Union (2002/72/EEC, as amended). Most flexible and fibre-based packaging materials however are composed of more than only plastics and are therefore not regulated. Also it is yet not always clear under what circumstances a functional barrier can be considered sufficiently efficient.

As a result there are, in many cases, for the moment no clear rules to which the converter can abide. In cases where this problem occurs, this code resolves it by demanding compliance with food contact legislation separately of each individual component of the composite material.

This code therefore goes beyond existing legislation. In doing so, it ensures that the converter is taking all measures possible to fully control the composition of food contact materials, and thus ensure the highest degree of consumers protection.

5.2 Legislation

Where food contact legislation for the packaging material or for separate components of composite packaging material exists, this is complied with in the following order of preference:

- EU legislation on food contact and National Legislation resulting from the transposition of EU legislation.
- Where EU food contact legislation is found incomplete, national legislation of EU Member States. The national legislation that will be complied with is to be determined on a case by case basis, taking into account the following:

- The Member State where the converter is established
- The Member States where the packed product is to be marketed
- Appropriateness of the available legislation
- The principle of mutual recognition

Explanatory note: Where the packaging material is produced in the same Member State as where the product is marketed, evidently the legislation in that Member State will be complied with.

However, where packaging materials are manufactured in one Member State and the product is marketed in one or more other Member States the situation is not as simple; national legislations differ. Legally this should not pose a problem: any product legally marketed in one Member State can also be legally marketed in any other Member State.

In practice this principle is not always easily recognised by National authorities. The converter's customers therefore prefer to avoid situations, where it is necessary to resort to legal arguments to obtain acceptance of a packaging material. This implies that in some cases the National Legislation that is to be complied with, needs to be chosen with an eye for easy acceptance in the Member State where the product is to be marketed.

In situations where EU food contact legislation is found incomplete, but no practical problems with mutual recognition need to be expected preference is given to compliance with the national legislation of the EU Member States where the converter is established or with national legislation from yet another Member State if this legislation is more appropriate.

5.3 Guidelines and recommendations

Where both EU and national legislation are found incomplete, the packaging material will answer to the spirit of this legislation as phrased in Art.3 of the Framework Regulation 1935/2004/EC. To this end, in order of preference, conformity is sought with the most appropriate of the following:

- Recommendations in the Synoptic Document
- Opinions of the EU Scientific Committee on Food
- Council of Europe Resolutions
- Member State recommendations
- FDA regulations, however only insofar as these are not in conflict with the principles behind EU and EU Member States legislation
- Relevant and where possible officially recognised industrial policies established by European trade associations, such as the CEPE GMPs and exclusion lists, the CEPI guide for paper and board for food contact and the EAA GMP for aluminium alloy semi products intended to come into contact with foodstuff.

5.4 Non regulated components

In some cases components of flexible packaging materials may not be covered by any of the legislation, guidelines or recommendation mentioned in the sections § 5.2, Migration: Legislation and § 5.3, Migration: Guidelines and recommendations.
In those cases particular care shall be taken to identify the non regulated substance, in order to avoid the exposure of consumers to migrating substances at levels that could potentially pose a risk to consumer health.

In these cases, in order of preference, conformity is sought with following:

- Approval of the substances used in the component as direct food additives for the food for which the packaging materials is to be used, or

- The substance is not transmitted to the food in excess of a Threshold of Regulatory Concern (TORC) that is recognised by either the EU or the Council of Europe.

- Failing the availability of a TORC recognised by the EU or the Council of Europe, the toxicological threshold of no concern as recommended by Threshold of Toxicological Concern Task Force of ILSI Europe, in combination with a sufficiently conservative estimation of consumer intake of packaged food with the migrant under consideration.

Explanatory note: The use of a TORC should be a measure of last resort; to be used when no legislation, guideline or recommendation is available. There is at present however no TORC recognised by either the EU or the Council of Europe.

For the time being, lacking an officially recognised TORC, the ILSI recommendation for a toxicological threshold of no concern 1,5 µg/person/day is used. This threshold specifies a limit to the daily consumer intake of a substance.

In order to determine if a certain migration results in an intake below or over this limit, the daily consumer intake of packaged food with the migrant under consideration needs to be estimated sufficiently conservatively.

There is presently no widespread consensus on the toxicological threshold or on the manner in which daily intake should be estimated. There is however a need for this rule with regard to 'non regulated components', since gaps in legislation and official guidelines and recommendations still exist.

5.5 Export outside the European Union

Where packaging materials are exported to a country outside the European Union it may be necessary to deviate from the previous sections. Preference is however given to minimising these deviations as much as possible.

Where deviation is unavoidable, in order of preference, conformity is sought with the most appropriate the following:

- National legislation of the importing country
- FDA regulations
- Regulations as specified by the customer

6. Organoleptic changes

6.1 Achieving the objective

The objective of prevention of unacceptable changes in the organoleptic characteristics of the food, that may result from the release of components from the packaging material or the withdrawal of components from the food by the packaging is contributed to by the converter by either

- using raw materials that are certified or known from previous experience by the converter to be organoleptically inert for the specified food and specified use of the packaging material, or
- by testing the finished or intermediate products appropriately for the specified food and specified use of the packaging material

The objective of consumer protection against organoleptic changes is further achieved by the customer who is to assure that the packaging material is suitable for the intended purpose and is only used as specified.

Explanatory note: The prevention of organoleptic changes cannot be obtained by the use of appropriate materials and production techniques alone. Deviations from the specified use for which the packaging material was satisfactorily designed or tested, may unexpectedly result in organoleptic changes.

This code assures that the converter produces packaging material that under specified circumstance will not give rise to organoleptic changes. The customer must however also contribute by preventing use of the packaging material under other then the circumstances specified.

7. Contamination

7.1 Achieving the objective

Prevention of health hazards and organoleptic changes that may result from contamination of the packaging material is contributed to by the converter by

- Maintaining strict hygienic standards for production personnel

- Maintaining strict hygienic circumstances in factories, warehouses and during transportation

- Identification and control of potential sources of contamination during the production processes, storage and transportation

- Identification of raw materials that are potential sources of contamination and control of the composition and use of these materials.

Explanatory note: Consumer protection against contamination cannot be obtained by the converter alone. This code however assures that the converter produces packaging material that in itself is not contaminated.

8. Essential requirements

8.1 Achieving the objective

The objective of compliance with the essential requirements for packaging materials that result from the EU Packaging and Packaging Waste Directive 94/62/EC (as amended) is contributed to by the converter by:

- Within the constraints imposed by the required performance and other customer demands; designing the packaging material for minimum adequate weight and volume.

- Within the constraints imposed by the required performance and other customer demands; designing the packaging material such that it's material can be recycled or, where this is not possible, designing the packaging material such that it exceeds the minimum caloric value necessary for efficient incineration with energy recovery, or that it can be recovered in the form of composting, or that it can be biodegraded.

- Avoiding the use of raw materials that contain toxic heavy metals as mentioned in the directive over their maximum concentration levels.

- Avoiding the use of raw materials that contain substances that can give rise to noxious or hazardous emissions, ash or leachate when the waste of the product is incinerated or disposed of in landfill.

Explanatory note: The above includes all the essential requirements mentioned in Directive 94/62/EC (as amended) that practically may apply to flexible and fibre-based packaging materials. This means that the essential requirements that are specific to reusable packaging have not been included.

Explanatory note: Compliance with the essential requirements cannot be attained by the converter alone. Minimum weight, minimum volume and recyclability can only be attained in so far as this is possible within the constraints imposed by the required performance and other customer demands. Also noxious or hazardous emissions during incineration can only be avoided with certainty if the incineration takes place under well controlled circumstances.

Explanatory note: According to draft EN 13431 packaging composed of more than 50% (by weight) of organic materials and thin gauge aluminium foil (typically up to 50 µm thick) shall be considered recoverable in the form of energy. In practical terms this encompasses all the packaging materials to which this code applies.

Explanatory note: This GMP is only aimed at flexible and fibre-based packaging materials that are intended to get into contact with food. These can presently only be recycled, composted or biodegraded in exceptional cases. The possibilities mentioned in this section of designing the packaging material such that it's material can be recycled, recovered in the form of composting, or that it can biologically degraded are included mainly with an eye for the future.

8.2 Legislation, standards, guidelines, recommendations etc.

Legislation, standards or voluntary agreements concerning essential requirements are complied with in the following order of preference:

- Directive 94/62/EC (as amended)

- CEN standards related to the Essential Requirements

- National legislation or national voluntary agreements, where the legislation or agreement that is to be complied with, is to be determined on a case by case basis, taking into account the following:

    - The Member State where the converter is established
    - The Member States where the food product is to be marketed
    - The principle of mutual recognition and Art.18 of the directive 94/62/EC (as amended)

- National standards

Explanatory note: The CEN standards related to the Essential requirements are: EN13427, EN13428, EN13429, EN13430, EN13431, EN13432,

Explanatory note: Art.18 of the packaging and packaging waste directive states reads: 'Freedom to place on the market: Member States shall not impede the placing on the market of their territory of packaging which satisfies the provisions of this directive.'

9. Design for compliance

9.1 Preliminary remarks

The most important principle behind the GMp is ‘design for compliance’. See chapter 4, ‘Method’ for background information and a good understanding.

The GMP distinguishes between ‘product development’ and ‘adaptation to customer needs’, where it is assumed that the product is initially not developed for a specific customer, and later adapted to the specific requirements of different customers.

9.2 Product development

The converter will develop the products according to the principles of ‘design for compliance’. All developed packaging materials will

- be Fit-For-Use in accordance with its foreseeable applications and meet the required performance,

- either be composed of raw materials that, through their certified composition, migration features or barrier properties, make the packaging material fully compliant or in conformity with relevant legislation, guidelines and recommendations as described in chapter 5,

- or have been tested for such compliance or conformity appropriately

Explanatory remark: This bullet point gives a very concise reflection of GMP § 5.1, Migration: Achieving the objective. See this section for better understanding.

- either be composed of raw materials that are certified or known from previous experience by the converter, to be organoleptically inert for the specified food and specified use material,
- or have been tested appropriately for organoleptic changes.

Explanatory remark: This bullet point gives a very concise reflection of GMP § 6.1, Organoleptic Changes: Achieving the objective. See this section for better understanding.

- be of minimum adequate weight and volume, within the constraints imposed by the required performance and other customer demands,

- either be such that they allow, within the constraints imposed by the required performance and other customer demands, the material to be recycled

  or, where this is not possible, that the minimum caloric value necessary for efficient incineration with energy recovery is exceeded, or that it can be recovered in the form of composting, or that it can be biologically degraded

- not exceed the maximum concentrations of toxic heavy metals mentioned in directive 94/62/EC (as amended) or contain substances that can give rise to noxious or hazardous emissions, ash or leachate when waste of the product is incinerated or disposed of in landfill.

Explanatory remark: The last three bullet points give a very concise reflection of GMP § 8.1, Essential Requirements: Achieving the objective. See this section for better understanding.

Explanatory note: Where the composition of raw materials is mentioned, this is intended to mean the composition as delivered to the converter, except where during the manufacturing of the packaging material a chemical reaction has to take place. In these cases the composition refers to the material after the chemical reaction has taken place.

9.3 Development constraints

When developing packaging materials, the following will also be taken into account.
No unprotected ink is to be used on the food contact surface of the packaging material other than 'food contact ink'.

Explanatory note: Food contact inks are used very rarely. In some EU Member States, even the use of 'food contact ink' is not at all allowed in direct contact with the food.

- The choice of substrates, inks, varnishes, lacquers, other coatings and adhesives is to be such that no unintended chemical reactions can take place.

- The production process and specifically the preparation of all inks, varnishes and adhesives and the drying temperatures on production machines, are to be specified in such a way that:

- all materials are compatible and cannot undergo unintended chemical reactions

- in the case of intended chemical reactions, these reactions can not give rise to potentially hazardous by-products

- the level of residual solvent in inks, varnishes and adhesives will be such that it will not give rise to unacceptable organoleptic changes, unacceptable set-off or unacceptable migration

- the extrusion of plastic film can not give rise to unintended chemical changes to the plastic.

9.4 Required performance

To allow ‘design for compliance’, the required performance of the packaging material must be identified clearly during the development phase. In doing so, the following subjects shall at least be covered:

- the nature of the food product
- the expected maximum shelf life
- the filling, sealing and storage method to be used
- the heating, cooling, sterilisation and pasteurisation processes to which the packaging material and contents may be exposed

The required performance shall, wherever possible, be translated into technical specifications such as permeability, mechanical strength, barrier properties and specific organoleptic tests to be performed.

9.5 Adaptation to customer needs

When the original design of the developed packaging material is adapted to customer needs, the adapted design shall be rechecked in order to assure that the design for compliance remains intact.

To allow the ‘design for compliance’ to remain intact the performance required by the customer must be identified clearly. This shall at least cover the subjects as mentioned under § 9.4 'Required performance'.

All customer changes and additions to the originally identified required performance are to be checked against possible interference with the packaging material’s original design for compliance.

The required performance as adapted to customers needs shall be translated into technical specifications such as permeability, mechanical strength, barrier properties and specific organoleptic tests to be performed. Both converter and customer are to convince themselves of the correctness of this translation.

Customers will be required to report any changes in the use or requirements of packaging materials that would otherwise be produced as a repeat order. In the case where these changes may affect the required performance, the design shall be rechecked in order to assure that the design for compliance remains intact.

Explanatory note: Many possible changes in the use of the packaging material may necessitate a change in the design. It is most important that the customer reports these changes and allows the converter to recheck the original design. Even if at first sight the changes seem small and of limited relevance.

Translation of the required performance into technical specifications can be done by either the converter or the customer.

9.6 Changes to the packaging material

Where in the case of repeat orders, raw materials or production methods will be used by the converter that are different from those in previous production batches, the design of the packaging material shall carefully be rechecked for compliance.

Where such a change in raw materials or production method may influence the actual performance of the packaging the customer shall be informed of the change.

Explanatory note: Informing the customer of possible changes in the actual performance of the packaging material, is intended to prevent mishaps that may result from customer and consumer deviations from the originally identified use of the packaging material.

The actual performance of a packaging material may considerably exceed it's agreed required performance. Deviations from the originally identified use of the material will therefore not automatically lead to mishaps. However; in cases where such deviations do take place, a change in the actual performance of the packaging material may unwillingly provoke practical problems, even though the material still completely meets the required performance.

9.7 Changes in legislation, recommendations and guidelines (migration)

Where changes in legislation, recommendation or guidelines as referred to in chapter 5 'Migration' may affect the packaging material the design of the packaging material shall carefully be rechecked for compliance.

Where such a change in legislation, recommendation or guidelines may influence the regulatory status of the packaging the customer shall be informed of the change.

9.8 Changes in legislation, recommendations and guidelines (essential requirements)

Where changes in legislation, standards, recommendation etc. as referred to in chapter 8 ‘Essential requirements’ may affect the packaging material, the design of the packaging material shall carefully be rechecked for compliance.

Where such a change in legislation, standards, recommendation etc. may influence the regulatory status of the packaging the customer shall be informed of the change.

10.Raw materials

10.1 Purchasing and requirements

The purchasing of all raw materials shall be kept under strict control.

All raw materials shall be purchased only from suppliers who employ quality assurance systems that meet the requirements of section 12.3.

The converter will inform the supplier which legislation, other than legislation based upon EU directives, is relevant to the raw material purchased.

For materials purchased by the converter, the suppliers shall be required to

- assure complete traceability of the composition and the production method of these materials and intermediate products as well as the origin of the components. Intermediate products and raw materials should be traceable up to the point where for the first time in the production chain the material is earmarked to be used for food packaging. At this point in the chain it must have been made sure by an appropriate method that the material is indeed fit for this purpose

- certify compliance with relevant legislation

- where a change in legislation, recommendations or guidelines may influence the regulatory status of the raw material or packaging material made with that material, inform the converter of this change

- quantify the global migration of substrates and other food contact side materials under agreed standardised circumstances

- identify and quantify all components that have been allocated an SML, QM or QMA and provide evidence that the materials can be used without exceeding the SML, QM or QMA

- identify and quantify all components that are not covered by food contact legislation, guidelines or recommendations as mentioned in § 5.2 and 5.3 of this code and identification of the relevant parts thereof and provide evidence that the materials can be used safely in accordance with § 5.4 of this code

- identify and quantify all components to which restrictions apply due to the packaging and packaging waste directive such as toxic heavy metals and substances that can give rise to noxious or hazardous emissions, ash or leachate when the waste of the product is incinerated or disposed of in landfill and provide evidence that these materials can be used without exceeding these restrictions

- ensure that during production, handling, storage and transportation of the raw material it does not become contaminated and maintains it's required quality.

Explanatory remark: Traceability in the combination with quality assurance is an important feature in this GMP. It not only assures that the cause of possible mishaps can be found and remedied, but it also enables converters and their customers to rely on the previous steps in the production chain. Raw materials should be traceable up to the point where for the first time in the production chain the material is earmarked to be used for food packaging. At this point in the chain it should be made certain that the material is indeed fit for this purpose by an appropriate method.

10.2 Verification of migration requirements

Wherever in the production chain compliance with migration requirements needs to be verified this shall be performed by either

- suitable designed tests, or
- verification of the maximum permitted quantity of a substances in the material which correspond to the migration requirement, where the relation between quantity and migration has been established by adequate experimentation, or
- verification of the composition of a raw material which is known to comply with migration requirements and of which the relation between the composition and the compliance with migration requirements has been established by adequate experimentation, or
- the use of applicable and generally recognised diffusion models.

Testing procedures must be in accordance with the relevant EU directives. They will follow the relevant CEN standard whenever these standards are available, such as for Global Migration and a limited number of monomers in the case of Specific Migration.

Alternative testing methods that are known to be reliable and to lead to the same results may also be used.

Explanatory note: The use of alternative testing methods is in line with Directive 97/48/EC as specified in Chapter IV. Particularly the use of 'extraction tests' may be useful as results can be obtained much more quickly than with the conventional migration tests. Such tests may be used if they are generally recognised, on the basis of scientific evidence, to produce results that are equal or higher than those obtained with the equivalent official test.

Where relevant CEN standards are not available for testing for Specific Migration, the testing shall be demonstrated to have taken place with an appropriate analytical technique.

Where purchased materials, such as 2-component adhesives, are intended to react chemically, suppliers certification of migration requirements will regard the resulting material after the intended reaction.

Explanatory note: Of course the supplier of chemically reacting components is not responsible for the actual use of the product by the converter. Certification of compliance is therefore only asked after the reaction as intended by the supplier. It is up to the converter to assure that the actual reaction indeed takes place as intended by the supplier.

In cases where materials need to be purchased from a supplier who can not provide evidence of compliance with all relevant migration requirements, the supplier shall be required to provide the converter with all information necessary to enable verification of compliance with the migration requirements by or on behalf of the converter.

11. Production

11.1 Manufacturing

Explanatory note: This code is meant to be hooked on to an existing quality assurance system. Such a system must be in place before this code can be applied. This means that it must be possible to rely on the technical processes in the converter's plant to produce packaging materials in conformity with their specifications. For the purpose of this code it is therefore not necessary to describe in any detail how the production processes should be kept under control.

The manufacturing processes will be kept under strict control with the help of a quality assurance system. The control and quality assurance system will be such that it is assured that the packaging material that is produced answers to the technical specifications that apply to it and that these technical specifications are in conformity with the design of the packaging material.

If necessary the quality assurance system will be adapted in order to pay sufficient attention to subjects that are more important to the attainment of the objectives of this code than the attainment of the desired technical and aesthetic properties of the packaging material, such as:

- Traceability and therefore the use of the dedicated raw materials and proper record keeping during the production processes, and keeping track of intermediate and finished products till they reach the customers warehouse

- Correct setting of production parameters on production machines such as drying temperatures and reel tensions

- Chemical reactions to take place as intended.

Potential sources of contamination during manufacture shall be identified and analysed. Where necessary appropriate measures will be taken to prevent contamination. These measures are to include:

- the control of pests, insects and rodents

- the systematic cleaning of production departments and the maintenance of strict hygienic circumstances in these departments

- the removal of materials from previous use from all equipment used for the preparation of inks, coating or adhesives and from all production machinery such as presses, laminators and varnishing machines before starting the next production run.

11.2 Personal hygiene

Explanatory note: This code does not prescribe any particular method of hygienic control or quality assurance. It is meant to fit within existing control systems. The ISO 9000 series and industry specific hygiene systems, such as the EUPC ‘Guidelines for the hygienic production of plastic food packaging’, the 'Hygiene code for the Dutch corrugated board industry' or the Unites 'Guide des bonnes pratiques d'hygiene s'appliquant aux emballages en matière plastique et emballages souples complexes' are acceptable.

Strict hygienic standards will apply to production personnel. These standards shall at least include:

- dress
- the behaviour in case of infectious diseases
- personal cleanliness
- procedures regarding the maintenance of sanitary facilities
- refrain from keeping or eating food and smoking in production areas

11.3 Ware housing and transportation

Potential sources of contamination during warehousing and transportation shall be identified and analysed. Where necessary appropriate measures shall be taken to prevent contamination. These measures are to include:

- the control of pests, insects and rodents
- the systematic cleaning of warehouses and means of transportation
- the maintenance of strict hygienic circumstances in the warehouses and during transportation
- the training of drivers and fork lift truck operators in hygiene awareness
- the avoidance of mixed commodity loads on the same vehicle

Raw materials and packaging materials are identified, labelled and referred to in all documents in such a way that traceability is continuously assured.

Unless otherwise specified, raw materials are used on a first in first out basis and packaging materials are sent to the customer on a first in first out basis.

Certified and tested raw materials and packaging materials shall be clearly identified and be kept separate from other raw materials and products. Raw materials or packaging materials waiting for certification or testing shall be quarantined until approval or rejection.

Segregation shall be provided for the storage of rejected, recalled or returned raw materials or packaging materials.

Conditions during storage and transportation are such that deterioration of raw materials and packaging materials is prevented as much as possible.

12. Quality assurance

12.1 Converter quality assurance system

The converter shall maintain a quality assurance system capable of assuring the attainment of the objectives of this code through compliance with the policy listed in the chapters 3 (Objectives) and 4 (Method) and the sections 5.1 (Migration; Achieving the objective), 6.1 (Organoleptic changes; achieving the objective), 7.1 (Contamination; Achieving the objective) and 8.1 (Essential requirements; Achieving the objectives) and capable of meeting the requirements of chapter 12 (Quality assurance).

The converters quality assurance system shall be audited and certified periodically by an independent body.

The converters quality assurance system will be such that it can be verified by or on behalf of the customer, in order to check compliance with this Code for Good Manufacturing Practices.

12.2 Laboratory quality assurance system

Laboratories where migration tests and tests related to hygienic control or to essential requirements are carried out shall maintain a certified quality assurance system.

12.3 Supplier's quality assurance system

The suppliers shall maintain a quality assurance system capable of assuring compliance with the requirements as listed in chapter 10 (Raw materials).

The supplier's quality assurance system shall be audited and certified periodically by an independent body.

Where this is not the case, the supplier's quality assurance system shall be verified by, or to the satisfaction of, the converter before first delivery and periodically.

12.4 Subcontractor's quality assurance system

The converter shall only subcontract the manufacture of flexible and fibre-based packaging materials to converters that work in accordance with this or an equivalent Code for GMP and that have a quality assurance system in place capable of assuring this.

The subcontractor's quality assurance system shall be audited and certified periodically by an independent body.

Where this is not the case, the subcontractor's quality assurance system shall be verified by, or to the satisfaction of, the converter before first delivery and periodically.

12.5 Continuous compliance

Procedures will be in place to anticipate changes to legislation, guidelines and recommendations etc. with regard to food contact and essential requirements and to assure that these changes once in effect will find their way into all the relevant documents used for purchasing, manufacturing, etc.

These procedures will cover the legislation, guidelines and recommendations mentioned in

- § 5.2, Migration: Legislation,
- § 5.3, Migration: Guidelines and recommendations, and
- § 8.2, Essential requirements: Legislation, standards, guidelines and recommendations, etc

Procedures will be in place to assure that:

- packaging development engineers will regularly consult the available documentation to keep themselves informed on the most recent legislation, guidelines, recommendations, etc with regard to food contact and essential requirements.
- packaging development engineers will regularly consult the available documentation to keep themselves informed on the most recent insight with regard to organoleptic changes.
- in the case of changing legislation, guidelines and recommendations, existing packaging specifications and designs are checked for continued compliance.
- all changes find their way into all the relevant documents used for purchasing, manufacturing etc
- all changes trigger an update of regulatory status of the products

12.6 Procedures in case of failures at any stage

Complete traceability of the flexible and fibre-based packaging materials produced must be assured.

Where flexible and fibre-based packaging materials have been produced, that may have undergone an unintended chemical reaction, produced excessive set off or are in some other way not up to standard, these materials will be clearly identified and segregated.

Where these materials cannot be reworked, they will be rejected and disposed of in a controlled way, and in accordance with the national regulations.

A procedure shall exist which enables the converter, in the event of a failure at any stage of the process or a complaint, to find the cause, rectify the problem, and if necessary make the appropriate improvements to the manuals or other controls to prevent a repetition.

12.7 Certificate of conformity

A certificate of conformity, which reports the regulatory status of the material itself, shall be provided to the customers for all packaging materials upon delivery of the first batch that is produced after all test phases have been concluded. An entitled manager of the converter shall sign the certificate.

In the case of repeat orders the certificate shall be provided upon the customers' request.

13. Personnel and training

13.1 Commitment

The entire workforce, involving all levels of management, shall make a strong commitment to the objectives of GMP and management shall assure that appropriate responsibility, authority and resources is given, understood and applied at each level in the organisation.

13.2 Information and training

All personnel will be informed about the general concept of GMP, it's objectives and the policy by which these are attained.

The converter shall establish and maintain procedures for identifying the training needs and provide training of all personnel performing activities affecting compliance with this code of GMP.

Personnel performing specific tasks shall be qualified on the basis of appropriate education, training or experience as required.

Appropriate record of training shall be maintained.

TECHNICAL DOCUMENT No. 3

GUIDELINES ON TEST CONDITIONS FOR PACKAGING INKS APPLIED TO THE NON-FOOD CONTACT SURFACE OF FOOD PACKAGING MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

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GUIDELINES ON TEST CONDITIONS FOR PACKAGING INKS APPLIED TO THE NON-FOOD CONTACT SURFACE OF FOOD PACKAGING MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

1. Introduction

This technical document gives guidance on the test conditions to be used for testing packaging inks applied to non-food contact surface of food packaging materials and articles intended to come into contact with food. It should be read in conjunction with the specifications laid down in Resolution ResAP (2005) 2 on packaging inks applied to non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs and the corresponding Technical document No. 1 on requirements for the selection of packaging ink raw materials.

No specific methods of analysis are included in this document though some international standards for materials and articles in contact with foodstuffs are listed.

2. Sampling

The ink to be tested should be printed on the same substrate and by the same procedure that is intended for the final product.

N.B. The ink should not be tested as such as its composition may change during the printing process. Also the substrate greatly influences the migration properties of the components in the ink.

Tests pieces from printed samples should be chosen so that all components of the ink are represented at the same percentage composition as in the original material or article.

3. Testing for compliance with SML restrictions

3.1 General rules

In principle, testing for compliance with SML restrictions should be carried out by migration testing, using the conditions established in the EU Regulation on migration testing[1]. Extraction tests can 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 real foodstuffs.

Migration testing can be replaced by mathematical simulation or by calculation of the maximum possible migration. In both cases the amount of the actual substance must be either known or determined by exhaustive extraction. A formula and an example are given in the Appendix.

N.B. Transfer of a packaging substance from a packaging material or an article can take place either as diffusion through the substrate or as a result of so-called set-off. In migration or extraction tests the result will represent the sum of both transfer

[1] EU Directive 97/48/EC

mechanisms, but when using mathematical modelling, the transfer by set-off should be estimated separately.

3.2 Migration tests

When possible, testing should be carried out using the same kind of food that is to come into contact with the material or article. However, if this is not practical, a food simulant may be used.

The EU Regulation on migration testing should be used for guidance on the selection of appropriate simulants and exposure conditions (time and temperature). For those foodstuffs for which in the EU Regulation on migration testing 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 includes the type of foodstuff with which the printed material or article comes into contact, and the time and temperature of contact.

3.3 Mathematical simulation

Mathematical modelling can be used to predict the migration under real conditions of use and verify the compliance with the specific migration limits. For that purpose, recognised diffusion models based on scientific evidence should be applied. In order to apply modelling to a printing ink substance that contaminates the surface layer in contact with the foodstuff (set-off), the amount of this substance at the surface in contact with the foodstuff has to be known.

4. Special cases

4.1 Packagings and articles for use at high temperature

Migration testing should be carried out using only MPPO as a simulant regardless of the type of foodstuff, using the time and temperature of contact provided in EU Regulation on migration testing.

Testing should take into account possible degradation products formed at elevated temperatures. When carrying out extraction testing to determine compliance with the Resolution and the corresponding Technical document No. 1, the sample should, in principle, be preheated in a closed container, according to the time and temperature conditions given in the EU Regulation on migration testing.

4.2 Contact with dry food

As it is possible that migration occurs from a printed surface, either because of presence of volatile substances in the print or an intimate contact between substances in the print and the dry foodstuff (set-off), the print is subject to the limitations stated in the Resolution and in Technical document No. 1, though the printed material or article is in contact with dry foodstuffs only. In these situations, a

migration testing with the food itself under the worst foreseeable conditions or a simulant appropriate to that specific foodstuff shall be carried out.

5. Methods of analysis

There are no specific international standards for packaging inks dealing with determination of ink substances. The progress in chemical analysis is so rapid that any method may be considered obsolete after a limited number of years. It is therefore recommended that the reader search the literature in order to find an appropriate method. Special attention should be paid to the performance characteristics (trueness and precision) at the specified limit.

As some guidance may be found in the standards dealing with substances in paper and board and in plastics, some references are given below.

6. References and Standards

Note for Guidance to petitioners for authorisation of food contact substances and materials, EFSA document, update 21.02.2005.

CEN 14338. Paper and Board. Migration into modified polyphenylene oxide (MPPO)
EN 118613, parts 1 – 15. Materials and articles in contact with foodstuffs. Plastics
EN 13130, parts 1 – 28. Materials and articles in contact with foodstuffs. Plastic substances subjected to limitations.

APPENDIX

Calculation of maximum possible migration; formula and example

In this so-called “worst case calculation” it is assumed that migration of the actual substance into the foodstuff is one hundred percent. Also the amount of the actual substance in the print or in the package or article must be either known or determined by exhaustive extraction.

The maximum possible migration is calculated in accordance with the principle in the “Note for Guidance to petitioners for authorisation of food contact substances and materials” by the formula:

$$M = \frac{QxCxA}{10}$$

where

M is the maximum concentration of the substance in the foodstuff, expressed in mg/kg foodstuff;

Q is the surface weight of print on the surface of the package or article, in gram per square meter;

C is the concentration of the substance in the print, in percentage;

A is the area of package or article being in contact with 1 kg foodstuff. This is normally 6 dm^2.

Example: The quantity of print on a paper box is 1 g/m^2. The concentration of the actual substance in the print is 0,5 %.

The area of the paper box in contact with food is 6 dm^2.

$$M = \frac{1x0,5x6}{10} = 0,3$$

Consequently, the maximum possible migration, M is 0,3 mg/kg foodstuff.