

# **EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles**

**May 2007**  
**(Replaces the July 2006 version)**

## **1. Introduction**

EuPIA Companies have, for many years, followed a policy of Responsible Care / Coatings Care working for Sustainable Development, with a high level of Product Stewardship activity.

This is based on a strong commitment to protect consumer's health, and, through the years, has led to the publication of many recommendations.

Having regard to the fact that there is a Framework Regulation<sup>1</sup> applicable to all food packaging, but not yet any specific Community legislation concerning printing inks for food packaging, the present Guideline gives detailed recommendations to comply with the Framework Regulation, in line with the EuPIA strategy in the field of packaging inks.

It also takes into account the work done in cooperation with the Council of Europe Committee of Experts on Food Contact Materials.

## **2. Legislation**

Whilst European harmonised legislation does not specifically cover printing inks, there are some legislative instruments which impact on materials and articles intended for direct contact with food.

Regulation (EC) No 1935/2004<sup>1</sup> requires in Article 3 that materials and articles in contact with food, whether printed or not, shall be manufactured in accordance with good manufacturing practices, so that under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- endanger human health; or
- bring about an unacceptable change in the composition of the food; or
- bring about a deterioration in the organoleptic characteristics thereof.

Moreover it requires:

- the delivery of a declaration stating that the inks comply with the rules applicable to them and that appropriate documentation shall be available to demonstrate such compliance (Art. 16).
- the traceability of printed materials and articles at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility (Art. 17).

Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film, which states that the printed surface of regenerated cellulose film must not come into contact with food, therefore is relevant to printing inks for food packaging.

The main specific Directive pursuant to the Framework Regulation is Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. It lays down an overall migration limit (OML) of 60 mg/kg food or 10 mg/dm<sup>2</sup> of surface area. In addition specific migration limits (SML) or maximum contents in the material or article (QM) are set for individual substances.

The Directive contains a positive list of monomers and other starting substances as well as an incomplete list of additives allowed for use in the manufacture of plastic materials, which will become

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<sup>1</sup> REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJEU L338 of 13. 11. 2004

in future a positive list. Substances used only in the manufacture of printing inks are not listed, and thus packaging inks are not under the scope of this Directive. Ink components may contribute to the total quantity of substance(s) released by a material or article, and therefore shall be included in the determination of the overall migration (for plastic materials an OML of 10 mg/dm<sup>2</sup> respectively 60 mg/kg is set in the Plastics Directive); if there are ink components which are listed, the relevant restrictions such as specific migration limits (SML) or maximum content (QM) have to be met by the packaging in its finished state.

**Other legislative references** are set out in **Appendix 3**.

### 3. Field of Application

3.1. This Guideline applies to printing inks, coatings and varnishes (hereafter called 'packaging inks'), applied by an appropriate process to the non food contact surface of any material or article intended to come into contact with foodstuffs.

3.2. Printing inks in direct contact with foodstuffs are excluded from the field of application of the present Guideline.

### 4. Definitions

4.1. Packaging inks are any preparations (mixtures) manufactured from colourants (pigments, dyes), binders, plasticisers, solvents, driers and additives. They are solvent-based, water-borne, oleo-resinous or energy-curing (UV or electron beam) systems. They are applied by a printing and/or a coating process, such as flexography, gravure, letterpress, offset, screen, non-impact printing or roller coating.

4.2. Packaging inks layers, in their finished state, are thin dried or cured films of packaging ink on the non-food contact surface of substrates.

4.3. 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.

### 5. Requirements

Printed packaging materials and articles intended to come into contact with foodstuffs shall not, in their finished state - 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. In order to enable the printed packaging in its finished state to achieve the legal requirements the following specifications shall be met.

#### 5.1 Specifications regarding packaging inks

5.1.1 The raw materials<sup>2</sup> shall be selected in accordance with the **Appendix 1 "Selection scheme for packaging ink raw materials"**. They shall not belong to the following categories (exclusion criteria):

- (a) classified as "carcinogenic", "mutagenic" or "toxic for reproduction" categories 1 and 2, according to the provisions of Directive 67/548/EEC on dangerous substances<sup>3</sup>. Category 3 substances are also excluded with the exception of those substances which have been evaluated for risk by official third parties migration studies, or by having an SML or TDI value;
- (b) classified as toxic and very toxic;

<sup>2</sup> Raw materials may contain starting substances and/or components which are CMR or T, T+, but at levels which do not affect the classification of the raw material. Any migration of these into foodstuffs must comply with any relevant limit.

<sup>3</sup> OJ 196, 16.8.1967, p. 1 as last amended by 2004/73/EC (29<sup>th</sup> ATP)

- (c) colourants based on and compounds of antimony<sup>4</sup>, arsenic, cadmium, chromium (VI), lead, mercury, selenium;
- (d) all substances listed in Directive 76/769/EEC (relating to the restrictions on the marketing and use of certain dangerous substances and preparations) and its amendments, if their use in a Printing Ink for Food Packaging would lead to an infringement of Article 3 of the Framework Regulation.

5.1.2 The packaging inks shall be formulated and manufactured in accordance with the CEPE/EuPIA "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" ("GMP"), available at <http://www.eupia.org>

## 5.2 Specifications regarding the packaging material and article

- 5.2.1 The packaging inks shall be used and applied in accordance with a recognised converters' good manufacturing practices.
- 5.2.2 The printed or overprint varnished surfaces of food packaging shall not come into direct contact with food.
- 5.2.3 There shall be no, or negligible, visible set-off or migration from the printed or varnished non-food contact surface to the food contact surface.
- 5.2.4 Global and specific migrations from the packaging in its finished state or article shall not exceed the relevant limits.

## 6. Responsibility

- 6.1 The manufacturer of the packaging and the filler are responsible for the properties of the food packaging and its compliance with legal requirements.
- 6.2 The packaging ink manufacturers are responsible for the composition of the preparations in accordance with the requirements set out in paragraph 5.1. Moreover, due to the complex process all members of the packaging chain have to exchange the relevant information, under appropriate confidentiality agreements, aimed at the manufacture of tailor-made products fit for purpose, and thus ensure compliance with all legal responsibilities. In accordance with Article 16 of Regulation (EC) No 1935/2004 appropriate documentation shall be available to demonstrate such compliance. EuPIA members will supply a standard Declaration of Conformity for the use of these specific packaging inks.
- 6.3 The packaging ink manufacturers are not able to issue certificates or declarations of compliance which cover all the legal responsibility of the entire packaging chain.
- 6.4 To ensure conformity with current legal obligations the packaging ink manufacturer has to safeguard that
  - a) packaging inks are formulated in accordance with the Exclusion criteria defined in 5.1.1
  - b) the packaging inks are formulated in such a way as to minimise both potential migration through the substrate and set-off from the printed outer side to the food contact surface in the stack or the reel. In regard to this aspect it has to be noted that set-off and migration are also dependent on the processing conditions and barrier properties of the substrate. Appendix 2 describes laboratory practices for ink manufacturers to assess likely levels of migration. This will allow for an evaluation of the suitability of ink formulations for the intended purposes. This does not replace any of the converters' legal obligations for compliance of the printed packaging.
  - c) packaging inks are manufactured in accordance with the CEPE/EuPIA Good Manufacturing Practices (see 5.1.2).

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<sup>4</sup> 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\*

## Appendix 1

### Selection scheme for packaging ink raw materials

This appendix gives guidance on the selection process of raw materials used in the manufacture of packaging inks. Considering the fact that packaging inks are not intended to come into contact with food, the selection of raw materials according to this scheme will ensure adequate consumer safety.

#### Definitions

*“Raw materials”* used as components in the manufacture of packaging inks may be substances or preparations, which are defined according to the Directives 67/548/EEC and 1999/45/EC as follows:

*“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 derived from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

*“Starting substances”* are substances used in the manufacture of raw materials and are, following the chemical reaction, only present in raw materials as traces or impurities.

*“Preparations”* means mixtures or solutions composed of two or more substances.

#### Raw materials

Raw materials are selected according to the criteria set in section 5.1.1 of this Guideline and, when possible, from relevant listings such as the Plastics Directive 2002/72/EC and its amendments, the Regenerated Cellulose Film Directive 93/10/EEC and its amendments, or national legislation, including BfR (Bundesinstitut für Risikobewertung – German Federal Institute for Risk Assessment) Recommendations, Council of Europe Resolutions for direct food contact and US FDA regulations. They should comply with relevant restrictions of their use. Raw materials which are authorised food additives may be used.

Other raw materials can be used provided that the finished article fulfils Article 3 of the Framework Regulation (EC) No 1935/2004, on the basis of risk assessment described below.

#### Purity requirements for colourants

All colourants used in the manufacture of packaging inks have to comply with the specifications of the Council of Europe Resolution AP (89) 1 or national recommendations on the use of colourants in plastic materials intended to come into contact with food. However, non soluble barium based pigments can be used only if the packaging in its finished state meets the specific migration limit (SML) of 1 mg barium/kg food or food simulant.

#### Evaluation of migration

Data on migration should be obtained either by experimental testing in accordance with EU Directives or by other alternative scientific tools such as worst case calculation, migration modelling etc. , done in conjunction with the converter and the filler of the individual printed packaging material and article in its finished state, taking into account normal and foreseeable conditions of use.

#### Risk assessment of non listed substances

The substance (with molecular weight < 1000 Dt) should be subjected to appropriate risk assessment taking into account the fact that the same Raw Material may have a different suitability for use depending on many parameters, such as substrate, ink coverage, foodstuff etc in terms of exposure as well as toxicological and structure activity consideration. Appropriate evidence shall be provided by the packaging ink manufacturer in such a way as to allow compliance of the finished package with Article 3 of the Framework Regulation (EC) No 1935/2004, under conditions of correct use.

A target migration limit of no concern for non-evaluated substances of 10 ppb is the ultimate objective, to be consistent with other food contact materials. For packaging scenarios which do not currently achieve this limit, time is required either to modify the packaging designs, or to develop lower migration products, or to obtain additional toxicological data to demonstrate that the use is acceptable.

In particular, a substance is acceptable if its specific migration does not exceed:

- 10 ppb, in case of insufficient toxicological data
- 50 ppb if three negative mutagenicity tests requested by EFSA<sup>5</sup> Guidelines are available
- above 50 ppb, if supported by favourable toxicological data and/or evaluation done in accordance with the EFSA Guidelines

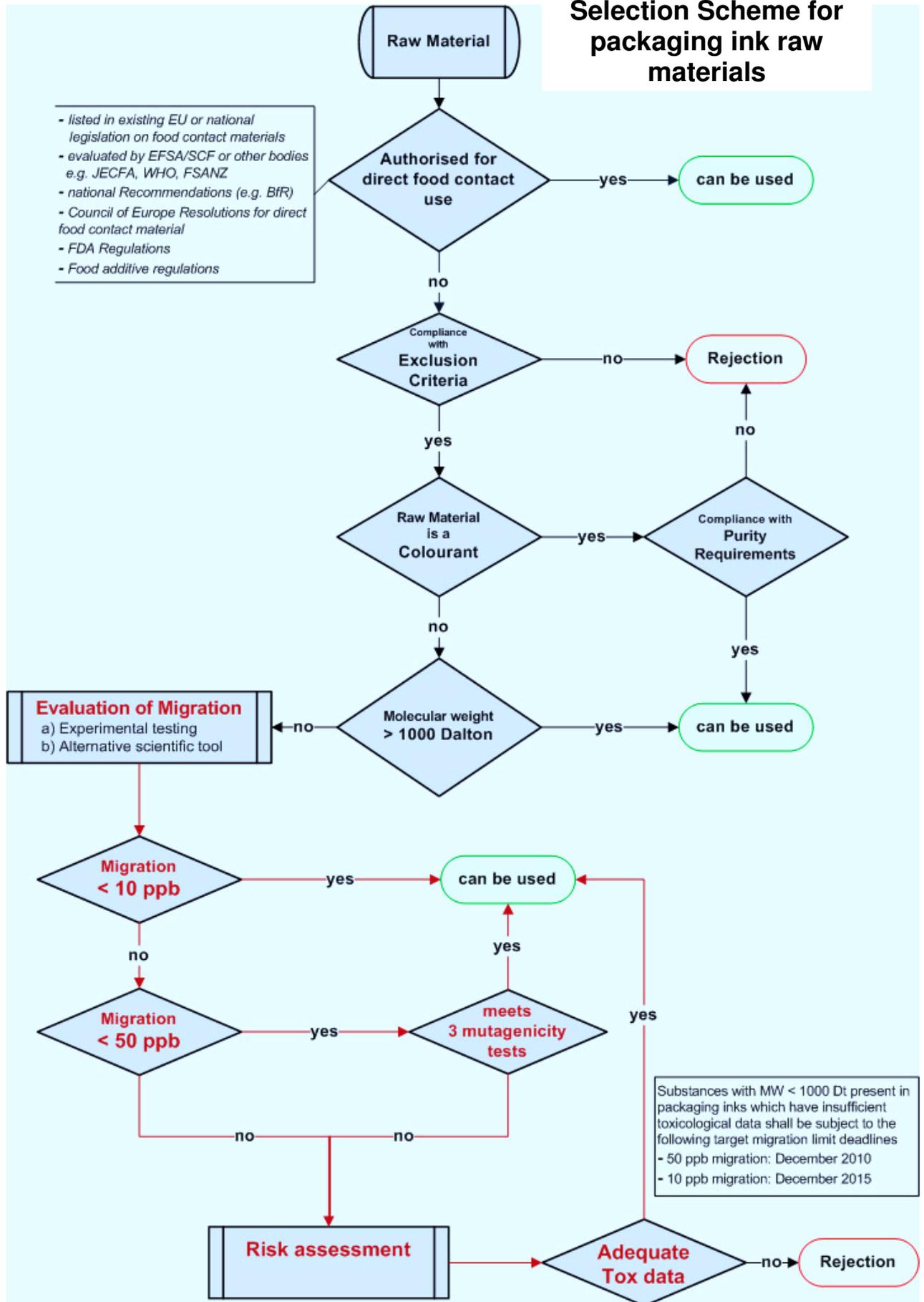
Substances with MW < 1000 Dt present in packaging inks which have insufficient toxicological data shall be subject to the following target migration limit deadlines:

- up to 50 ppb, to be achieved by December 2010
- up to 10 ppb, to be achieved by December 2015

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<sup>5</sup> EFSA: European Food Safety Agency

## Selection Scheme for packaging ink raw materials



## Appendix 2

# TEST METHODS 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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Calculation of maximum possible migration; formula and example

## TEST METHODS

### 1. Introduction

This Appendix 2 of the EuPIA Guideline gives guidance on the testing methods to be used for the evaluation of the migration of components of packaging inks applied to the 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 'EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles'.

The ink itself shall not be tested as such, since its composition may change during the printing process. In addition, the substrate greatly influences the migration properties of the components of the ink.

The specific methods of migration testing and analysis included in this document are described either in EC Directives on materials and articles in contact with foodstuffs or international Standards, with the exception of the preparation of printed samples.

### 2. Definition of Migration

From a physics point of view, migration is a partition and diffusion controlled transfer process of small molecules (approx. < 1000 Dalton molecular mass).

Transfer of printing ink components from a printed packaging material or article into food or food simulant may occur either directly as migration through the substrate, or via contact to the reverse side in the reel or stack, known as set-off migration, or by gas phase transfer.

### 3. Preparation of samples for indicative migration testing

To demonstrate that a packaging ink is likely to meet industry requirements, the ink should be applied on the relevant substrate in such a way as to reproduce, as far as possible, the printing and drying processes which are used in practice.

For the preparation of samples to complete migration testing the relevant substrates should be chosen accordingly.

In the absence of a specific substrate the following substrates are recommended for preparing test samples related to the various packaging types:

Packaging type	Substrate	
Flexible packaging	OPP	20 µm
	LLDPE	24 µm
	PET (Melinex <sup>®</sup> 813)	18 µm
	PA (Filmon <sup>®</sup> BX)	24 µm
Cardboard	Fresh fibre boxboard (e.g. Invercote <sup>®</sup> T or G)	220 g/m <sup>2</sup>
Metal packaging	Tin plate (internally lacquered, if appropriate)	
	Aluminium foil	8 µm

<b>Size of printed sheets</b> (test pieces)	sufficient for migration cell preferable DIN A4
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<b>Ink coverage</b>	100 %
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<b><u>Ink film weight (dry)</u></b>	Flexographic ink	1.3 g/m <sup>2</sup>
	Gravure ink	1.8 g/m <sup>2</sup>
	Offset ink	1.5 g/m <sup>2</sup>
	Dispersion varnish	2.5 g/m <sup>2</sup>
	White basecoat	15 g/m <sup>2</sup>
	Clear basecoat	1.5 g/m <sup>2</sup>
	UV varnish	6 g/m <sup>2</sup>

The average ink weight per unit area is required to calculate the maximum possible migration quantity of potential migrants caused by printing ink components.

In the case of flexographic and gravure inks the ink film layer weight is calculated by a gravimetric wash up method.

#### **Storage/conditioning of print samples:**

In each case 20 or more test pieces are to be wrapped in Aluminium foil and loaded with the following pressures which reflect practical conditions.

<b>Print sample</b>	<b>Time</b>	<b>Temperature</b>	<b>Pressure</b>	
Reel-fed materials (plastic film)	10 days	25 °C	80 kg/cm <sup>2</sup>	8000 kPa
Reel-fed materials (paper)	10 days	25 °C	40 kg/cm <sup>2</sup>	4000 kPa
Sheet-fed litho	10 days	25 °C	0.02 kg/cm <sup>2</sup>	2 kPa
Sheet-fed metal	10 days	25 °C	0.3 kg/cm <sup>2</sup>	30 kPa
Beverage end aluminium coil	10 days	25 °C	0.3 kg/cm <sup>2</sup>	30 kPa

## **4. Testing**

### **4.1 General rules**

Since there are no specific standards for packaging inks which deal with the determination of migration of ink components, migration testing, in principle, shall be carried out using the conditions established in EC Directives relating to plastic materials as well as in European and international Standards.

However, as a worst case method a total extraction test using a strong solvent could be carried out; if components are below the relevant limits, further testing is not required.

### **4.2 Basic rules for migration testing**

#### **4.2.1 Plastic materials and articles**

Regarding plastic materials, covered by Directive 2002/72/EC, there are basic rules for migration tests such as to the conditions of contact (time, temperature, food simulants) which are supplied in EC Directive 82/711/EEC and its amendments, while EC Directive 85/572/EEC gives a list of food simulants to be used in migration tests for the various types of foodstuffs.

The Directives and Standards mentioned are

- *Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs*  
(Official Journal of the European Communities L 220, p. 18, 2002-08-15)
- *Directive 82/711/EEC) laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.*  
(Official Journal of the European Communities L 297, p. 26, 1982-10-23)
- *Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.*  
(Official Journal of the European Communities L 372, p. /14, 1985-12-31)
- *CEN Standard EN 1186 parts 1-15 is a guide for the selection of conditions and test methods for overall migration from plastic materials and articles in contact with foodstuffs.*
- *CEN Standard EN 13130 Part 1: Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants*

#### 4.2.2 Paper and Board materials and articles

Paper and board food contact materials and articles are not yet regulated by a specific EC Directive. There is guidance in the Council of Europe Policy Statement concerning paper and board materials and articles intended to come into contact with foodstuffs (Version 2 dated 13.04.2005). It is recommended to apply test methods described in Directive 82/711/EEC (at last amended by Directive 97/48/EC) taking into account the technical nature of paper and board in comparison with plastics.

CEN has prepared Standard EN 14338 specific for paper and board.

- *EN 14338: Paper and Board intended to come into contact with foodstuffs. Conditions for determination of migration from paper and board using modified polyphenylene oxide (MPPO) as a simulant.*

#### 4.3 Methods of migration testing and analysis

The printed or coated samples prepared in the manner described in paragraph 3 above, are tested in suitable migration cells using appropriate exposure conditions and simulant(s).

##### 4.3.1 Food simulants

According to Directive 97/48/EC the following simulants shall be used:

Food type	Food simulant	
Aqueous food (pH > 4,5)	Distilled water	Simulant A
Acidic foods (pH ≤ 4,5)	Acetic acid 3 % (w/v)	Simulant B
Alcoholic foods	Ethanol 10 % (v/v)	Simulant C
Fatty foods	Modified polyphenylene oxide (MPPO, Tenax®)	Alternative test media as substitutes for Simulant D (rectified olive oil)
	Ethanol 95 %	
	Isooctane	

##### 4.3.2 Special cases

###### 4.3.2.1 Contact with dry food

Directive 97/48/EC does not require a simulant for dry food.

However, migration testing of either plastic or paper and board materials should be carried out using modified polyphenylene oxide (MPPO, Tenax®) as test medium under appropriate contact conditions.

#### 4.3.2.2 Packages and articles for use at high temperature

The testing of the migration of ink components from either plastic or paper and board materials should be carried out with modified polyphenylene oxide (MPPA, Tenax<sup>®</sup>) as simulant according to CEN Standard *EN 14338* regardless the type of foodstuff. The test conditions (time and temperature) should represent those the packages or articles are exposed to in practice.

Testing should take into account possible degradation products formed at elevated temperatures.

When carrying out extraction testing to determine compliance with the requirements of the EuPIA Guideline, the sample should, in principle, be preheated in a closed container, according to the time and temperature conditions given in the above mentioned references and standards.

#### **4.3.3 Analytical methods**

Analytical methods to determine quality and quantity of specific migrants in food simulants are described in the CEN Standards

- EN 13130, Parts 2-28.

The Community Reference Laboratory (CRL) for Food Contact Materials provides documents concerning overall migration and specific migration methods on their website <http://crl-fcm.jrc.it/>

#### **5. “Worst case” - calculation**

Migration testing can be replaced by calculation of the maximum possible migration. A formula and an example are given in Annex A.

## Annex A Calculation of maximum possible migration; formula and example

The “worst case calculation” assumes that migration of the actual substance into the foodstuff is one hundred percent. In addition, the amount of the actual substance in the print, package or article must either be known or determined by exhaustive extraction.

The maximum possible migration M is calculated by the formula:

$$M = W \times C \times S / (Q \times 10)$$

**M:** maximum concentration [mg/kg] of the substance in the foodstuff.

**W:** ink weight [g/m<sup>2</sup>] on the surface of the printed package or article.

**C:** concentration as a percentage of the substance in the dried ink.

**S:** area of package or article [dm<sup>2</sup>] being in contact with 1 kg foodstuff; conventionally set at 6 dm<sup>2</sup>.

**Q:** quantity of food simulant [kg].

### Example:

The ink weight on a paper box is 1 g/m<sup>2</sup>.

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<sup>2</sup>.

$M = 1 \times 0.5 \times 6 / 1 \times 10 = 0.3 \text{ mg/kg}$

Consequently, the maximum possible migration, M is 0.3 mg/kg foodstuff

## Appendix 3

### Legislation References

#### Framework Regulation

[Regulation \(EC\) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC \(L338/4\)](#)

Further information on food contact material, including legislation, is available on the following websites of the European Commission:

[http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/eu\\_legisl\\_en.htm](http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm)

[http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/legisl\\_list\\_en.htm](http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/legisl_list_en.htm)