A sector of CEPE aisbl

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

November 2011
(Replaces the September 2009 version)

1. Introduction

EuPIA member 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 consumers' health, and, through the years, has led to the publication of many recommendations.
Having regard to the fact that there is a Framework Regulation[1] applicable to all food packaging, but not yet any specific Community legislation concerning printing inks for food packaging, EuPIA have developed a Guideline for their members, based on current European legislation, which gives detailed recommendations as to how to formulate inks which will comply with this Regulation; this is 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 in their supplied form, there are some legislative instruments which impact on materials and articles intended for direct contact with food, whilst being printed on the non-food-contact side.

Regulation (EC) No 1935/2004[1] requires in Article 3 that materials and articles in contact with food 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.

Inks, once printed and dried/cured, on the non-food-contact side of a packaging material in contact with food become a component of this packaging and this packaging has to comply with the requirements of Article 3.

EuPIA recommends ensuring traceability during ink manufacturing analogous to the requirements as set out in Article 17:

- 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 .

[1] 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

Avenue E. Van Nieuwenhuyse 6 - BE-1160 Brussels
Tel: +32 (0)2 676 7480 - Fax: + 32 (0)2 676 7490 - E-mail: eupia@cepe.org - *Internet:* http://www.eupia.org/

Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film states that the printed surface of regenerated cellulose film must not come into contact with food, and therefore is relevant to printing inks for food packaging.

The main specific measure pursuant to the Framework Regulation is Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. It lays down an overall migration limit (OML) of 60 mg/kg food or 10 mg/dm² of surface area. In addition specific migration limits (SML) or maximum contents in the material or article (QM) are set for individual substances.

The Regulation contains a positive list (Union list) of substances authorised to be used in the manufacture of plastics. Packaging inks in their supply form are not in the scope of the Regulation, as they may be subject to other EU or national rules. Therefore, inks may be composed of other substances than those authorised at EU level for plastics. However, printed plastic materials and articles are within the scope of the Regulation. If there are ink components which are listed in the Union list, then the relevant restrictions such as specific migration limits (SML) or maximum content (QM) must be met and where there is the presence of dual use additives in the inks the legal provisions must also be followed.

Regulation (EC) No 2023/2006, applicable from 1st August 2008, sets out rules on Good Manufacturing Practice for the production of food contact articles. It has an Annex referring to printing inks applied to the non-food-contact surface of food packaging as well as to the storage of printed articles. In summary it can be concluded that the ink manufacturer does not have an independent responsibility for the formulation and application of the inks, but this remains ultimately with the downstream partners. To allow shared and final responsibilities to be met there needs to be cooperation between ink manufacturer and the rest of the supply chain. The cooperation between ink manufacturer and converter is best managed by requirement specifications, e.g. by detailed information about the substrate, type of food packed, printing and converting process parameters, storage and treatment conditions. When provided with this information the ink manufacturer is enabled to formulate inks that comply with the Regulation, if they are correctly used.

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 preparations (mixtures) manufactured from combinations of colorants (pigments, dyes), binders, solvents, 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, these include 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[2] 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 (categories 1A and 1B according to CLP, Regulation (EC) No 1272/2008).

Note: Category 3 substances (CLP Category 2) will only be used after a migration study has confirmed that migration levels are either within published SML or TDI values, or are below an intake (threshold of toxicological concern) of 0.15 µg/person/day[3]. Category 3 reproductive toxicants (R62, R63; H361f, H361d) without a published limit may be used if the migration levels are confirmed to be not detectable (with a detection limit of 0.01 mg/kg food);

(b) classified as toxic and very toxic;

(c) colorants based on and compounds of antimony[4], arsenic, cadmium, chromium (VI), lead, mercury, selenium;

(d) all substances identified in the REACH Regulation (EC) No 1907/2006, Title VIII and Annex XVII (restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles) and its amendments, if their use in a packaging ink 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 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 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 visible transfer (i.e. physical) 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 printing ink manufacturers' responsibility is to supply products that are fit for the intended purpose as defined between members of the packaging chain. They are not liable for any aspects of the production of food packaging once the packaging inks have left the

[2] 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.

[3] ILSI, Threshold of Toxicological Concern (TTC), Monograph, 2005, www.ilsi.org/Europe/Publications

[4] 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^+

manufacturing site. 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 complexity of the process all members of the packaging chain must exchange the relevant information - under appropriate confidentiality agreements if necessary - in order to ensure that products can be formulated to be fit for purpose, and thus be compliant with all legal responsibilities including the GMP Regulation 2023/2006. EuPIA members will supply a standard Statement of Composition for the use of these specific packaging inks; for plastic substrate converters this Statement will set out the levels of materials which are specified in the Plastics Regulation (EU) No 10/2011 with a limit value. Additionally it will indicate so-called dual use substances (in accordance with Regulation (EU) No. 10/2011) and ink manufacturers will disclose further potential migrants if necessary.
In the absence of current legal requirements for non-plastic substrates EuPIA members will assume further responsibility by supplying a Statement of Composition for all other uses. As outlined above this will likewise set out levels of materials which are specified in the Plastics Regulation, as well as indicating dual use substances and if necessary further potential migrants to be disclosed by ink manufacturers.

However, conformance with laid down migration limits must be assessed on the final print and/or package, and is the ultimate responsibility of downstream members of the packaging chain. The provision of a Statement of Composition is critical in this procedure.

Moreover information relating to usage and application constraints will be provided in Technical Data Sheets or other recommendation leaflets in order to enable the converters to meet their responsibilities for the printed food packaging.

6.3 It should be noted that the packaging ink manufacturers are not in a position 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 recommended laboratory practices 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 EuPIA Good Manufacturing Practices (see 5.1.2).

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 Regulation (EU) No. 10/2011, the Regenerated Cellulose Film Directive 2007/42/EC, 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 colorants

The term colorants is to be understood to include both pigments and dyestuffs. Whilst pigments are inorganic or organic coloured, white or black materials which are practically insoluble in the medium in which they are incorporated, dyes, unlike pigments, do dissolve during their application and in the process lose their crystalline or particulate structure.

All colorants 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 colorants in plastic materials intended to come into contact with food. However, non soluble barium based pigments can be used provided that 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-evaluated substances

Substance with molecular weight less than 1000 Da 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.

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

- 10 ppb, in case of insufficient toxicological data
- 50 ppb if the substance is demonstrated not to be genotoxic according to EFSA[5] Guidance
- a value higher than 50 ppb, if supported by favourable toxicological data and/or evaluation done in accordance with EFSA Guidance

For packaging scenarios which do not currently achieve this limit, an action plan between the printing ink manufacturer, the converter and other relevant members of the packaging chain should be generated that sets out a programme to ensure compliance within an agreed and manageable timescale.

In some instances when determining toxicity risk, the exposure concept may be used as an alternative to fixed migration limits.
Exposure can be calculated by the following generally accepted equation: µg/person/day = µg/6dm²
Not all of the data is available yet to estimate exposure to all migrants from inks and non-food contact coatings, but there is an EU funded 7th Framework research programme called FACET in progress to enable this situation to be addressed. The targeted completion date is 2012.

Continuous Improvement Strategy

The printing ink industry has set out a challenging continuous improvement programme that aims to control the presence and the potential level of migration of substances with MW < 1000 Dt present in packaging inks.

As part of this programme the European printing ink industry is working to collate toxicological data sets for chemical components used in food packaging, which are susceptible to migration. In order to do this they are working closely with CEFIC/FCA, National and European Regulatory Authorities and the many raw material suppliers to the printing ink industry. Aligned with this initiative a project has been finished, which aimed at collating a European Food Packaging Ink Raw Material Inventory (with inputs from EuPIA member companies), which is included in the Swiss “Bedarfsgegenstände-Verordnung”.

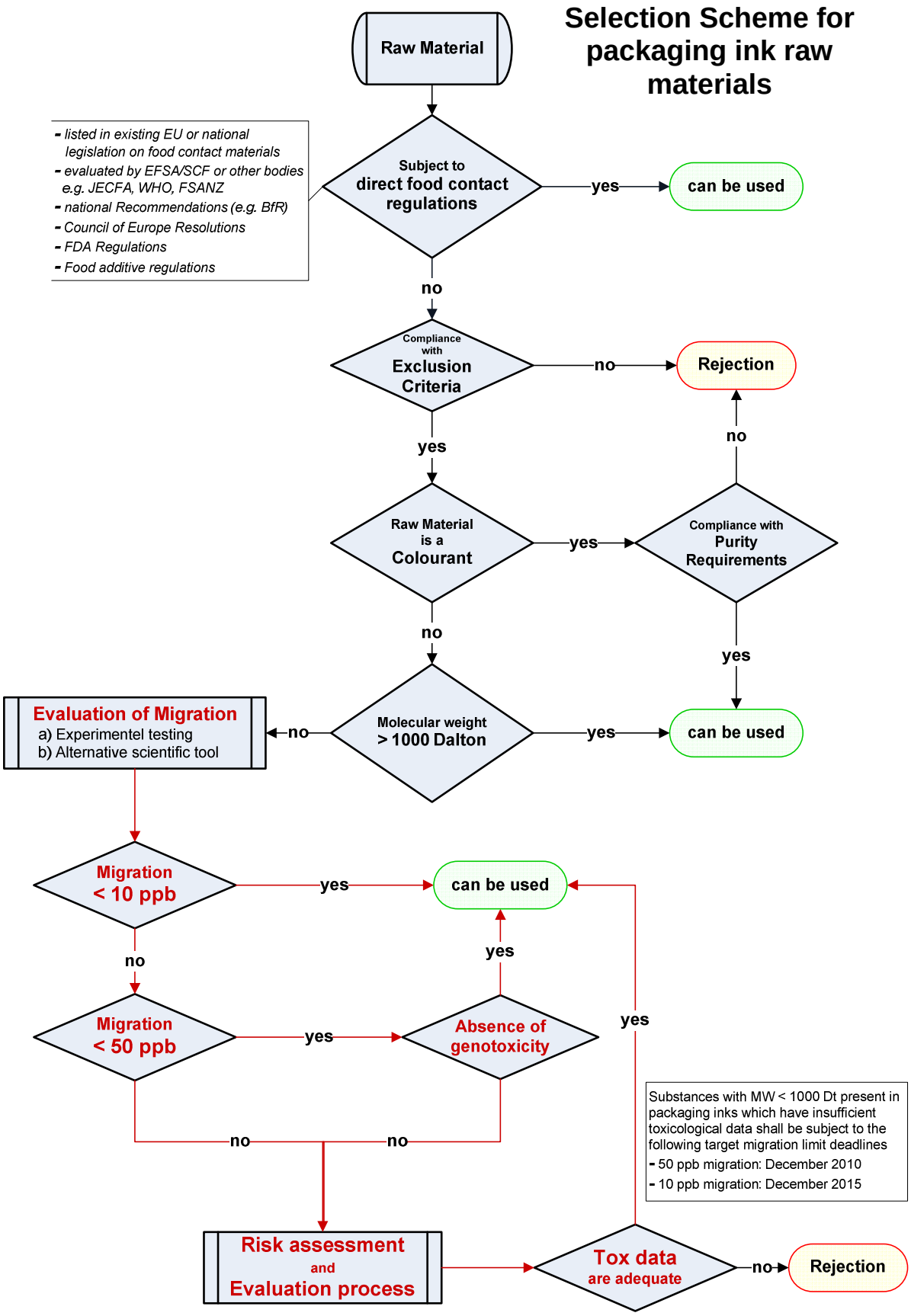
It is recognised that the printing ink industry uses a wide range of substances in the formulation and manufacture of packaging inks for the many current food packaging structures. The exercise to finalise all the individual action plans (described above) for all substances in all packaging scenarios will take a significant period of time.

It has therefore been agreed that substances used in food packaging inks without adequate SML/TDI data shall be subject to the following target migration limit deadlines to be monitored jointly by the converter and by the printing ink manufacturer:

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

[5] EFSA: European Food Safety Agency

There is a continuous use of new and innovative materials in food packaging, including inks. These new materials will need to be assessed for toxicology and migration potential in the same manner as is now to be applied to existing materials.


Selection Scheme for packaging ink raw materials
Raw Material
Subject to direct food contact regulations
yes
can be used
- listed in existing EU or national legislation on food contact materials
- evaluated by EFSA/SCF or other bodies e.g. JECFA, WHO, FSANZ
- national Recommendations (e.g. BfR)
- Council of Europe Resolutions
- FDA Regulations
- Food additive regulations
no
Compliance with Exclusion Criteria
no
Rejection
yes
no
Raw Material is a Colourant
yes
Compliance with Purity Requirements
no
yes
Evaluation of Migration
a) Experimentel testing
b) Alternative scientific tool
no
Molecular weight > 1000 Dalton
yes
can be used
Migration < 10 ppb
yes
can be used
no
yes
Migration < 50 ppb
yes
Absence of genotoxicity
yes
no
no
Substances with MW < 1000 Dt present in packaging inks which have insufficient toxicological data shall be subject to the following target migration limit deadlines
- 50 ppb migration: December 2010
- 10 ppb migration: December 2015
Risk assessment and Evaluation process
Tox data are adequate
no
Rejection

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

TABLE OF CONTENTS

1 Introduction
2 Definition of migration
3 Preparation of samples for indicative migration testing
4 Testing
4.1 General rules
4.2 Basic rules for migration testing
4.2.1 Plastic materials and articles
4.2.2 Paper and board materials and articles
4.3 Methods of migration testing and analysis
4.3.1 Food simulants
4.3.2 Migration testing conditions
4.3.3 Analytical methods
5. Worst Case Calculation

Annex A
Calculation of maximum possible migration; formula and example

Annex B
Calculation of maximum possible migration: Digital printing applications

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 to the non food contact side of 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 as well as further packaging components like adhesives and other packaging layers should be chosen accordingly. The sample for migration testing should reflect the final packaging structure as closely as possible.

In the absence of suitable specific results, the packaging ink manufacturer in conjunction with the converter shall evaluate available knowledge in terms of suitability for use in the proposed structure.

Size of printed sheets (test pieces)	sufficient for migration cell preferable DIN A4

Ink coverage	100 % for each colour (e.g. colour/white)

Ink film weight (dry) The ink film weight must be representative for the printing technology. Values given beside are only indicative.	Flexographic ink	1-1.5 g/m²
	Gravure ink	1-2 g/m²
	Offset ink	1-2 g/m²
	Dispersion varnish	2-3 g/m²
	White basecoat	12-16 g/m²
	Clear basecoat	1-2 g/m²
	UV varnish	4-7 g/m²

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

Storage/conditioning of print samples:

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

Print sample	Time	Temperature	Pressure	
Reel-fed materials (plastic film)	10 days	25 ℃	80 kg/cm²	8000 kPa
Reel-fed materials (paper)	10 days	25 ℃	40 kg/cm²	4000 kPa
Sheet-fed litho	10 days	25 ℃	0.02 kg/cm²	2 k Pa
Sheet-fed metal	10 days	25 ℃	0.3 kg/cm²	30 k Pa
Beverage end aluminium coil	10 days	25 ℃	0.3 kg/ cm²	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 Regulation (EU) No 10/2011 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.

Please note: The total extraction method is unlikely to provide analytical results which are representative of real food packaging storage/use scenarios, or even in line with indicative migration tests – great care and expert advice should be taken in to account when interpreting results.

4.2 Basic rules for migration testing

4.2.1 Plastic materials and articles

Regulation (EU) No 10/2011 covers migration testing for plastic materials intended to come into contact with food. Considering the printing ink as part of the plastic material, the migration testing procedures apply to printed plastic materials. .
There is a list of suitable food simulants provided in Annex III, and the rules for migration tests such as the conditions of contact times and temperatures are given in Annex V.

However, until 31 December 2012, the migration testing conditions described in Directive 82/711/EEC and in Directive 85/572/EEC are still applicable.
From 1 January 2013, the food simulants have to be chosen according to Annex III of Regulation (EU) No 10/2011.
From 1 January 2013 until 31 December 2015, the migration testing conditions (concerning time and temperature) can be carried out either according to Directive 82/711/EEC or according to Annex V of Regulation (EU) No 10/2011.
From 1 January 2016 all migration testing is to be based on the provisions of Regulation (EU) No 10/2011.

The Regulation, Directives and Standards mentioned are

- *Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with foodstuffs, and its amendments*
- *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, and its amendments.*

- *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, and its amendments.*
- *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 or Regulation. 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 Regulation (EU) No 10/2011 (for transitional provisions see chapter 4.2.1) 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[6]

According to Annex III of the Regulation (EU) No 10/2011, the best suited of the following food simulants shall be used for migration testing:

Food type	**Food simulant**	
Hydrophilic foods	Ethanol 10% (v/v)	Simulant A
Hydrophilic foods with pH below 4.5	Acetic acid 3% (w/v)	Simulant B
Alcoholic foods with up to 20% vol. and foods with relevant amounts of organic ingredients	Ethanol 20% (v/v)	Simulant C
Alcoholic foods with more than 20% vol. and oil in water emulsions	Ethanol 50% (v/v)	Simulant D1
Foods with free fats at the surface	Vegetable oil	Simulant D2
Dry foods	Poly(2,6-diphenyl-p-phenylene oxide)	Simulant E

4.3.2 Migration testing conditions[7]

Regulation (EU) No 10/2011 defines in Annex V, Compliance Testing, the specific migration conditions to be applied to the food simulants, concerning contact time and temperature.

Generally, the testing should apply those test methods that are recognized to reflect the most severe conditions of use.

<u>High temperature</u>
Temperatures above 100°C shall be used only for food simulants D2 and E. For applications heated under pressure, migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1, the test may be replaced by a test at 100°C (or at reflux temperature)

[6] Until 31 December 2012, the food simulants of Council Directive 85/572/EEC are applicable (see chapter 4.2.1).
[7] Until 31 December 2012, the testing conditions as described in Directive 82/711/EEC are applicable (see chapter 4.2.1).

for duration of four times of the expected contact time. The testing should take into account possible degradation products formed at elevated temperatures.

Low temperature / long storage time:
Examples for migration testing of frozen foods and/or long storage times:

Time	Temperature	Conditions covered
10 days	20℃	All storage times for frozen condition s
10 days	40℃	All storage times for refrigerated and frozen conditions
		2 hours at 70℃
		15 min at 100℃
10 days	50℃	≤ 6 months at room temperature
10 days	60℃	> 6 months at room temperature

Overall migration:
For analyzing the overall migration, again the worst foreseeable conditions are to be considered for the testing. Food simulants can be replaced, if, based on scientific evidence, the substitute food simulants overestimate the migration compared to the suggested food simulants.

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, for digital printing applications see Annex B.

Annex A
Calculation of maximum possible migration; formula and example

The “worst case calculation” assumes that migration of the actual substance into the foodstuff represents one hundred percent of the substance present. 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/m²] on the surface of the printed package or article.
C: concentration as a percentage of the substance in the dried ink.
S: actual area of package or article [dm²] being in contact with 1 kg foodstuff by default for all packaging for infants and young children and for all packaging sizes between 500 millilitres and 10 liters (Exceptions: According to Regulation (EU) No 10/2011, for packaging sizes below 500 millilitres or above 10 litres, for sheets and films that are not yet in contact with food and for articles for which the surface:volume ratio is impracticable to estimate, the value of migration shall be expressed in mg/kg applying a surface to volume ratio of 6 dm^2 per kg of food).
Q: quantity of food simulant [kg].

Example:
The ink weight 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 = 1 x 0.5 x 6 / 1 x 10 = 0.3 mg/kg
Consequently, the maximum possible migration, M is 0.3 mg/kg foodstuff

Annex B
Calculation of maximum possible migration: Digital printing applications

For Digital printing applications, it is often inappropriate to assume the printed article is fully printed with a given coat weight. Instead, the worst case migration calculation is based on the actual mass of ink deposited and the concentration of the potential migrant in the ink as well as the mass of the food product being printed. The mass of ink deposited is based on the number of drops deposited in the printed code and the mass of each drop, both of which are known for a given printing device.

$I = 4/3\ \pi r^3.n.1^9$

M= I.[pm]/mass of foodstuff in Kg

Where:
I is the mass of ink deposited in mg
M is the maximum migration possible from the ink in mg/Kg
r is the droplet radius in m
pm is the potential migrant concentration in the ink
n is the number of drops pinted
For a continuous inkjet printer a table may be prepared as below which allows the customer to work out the mass of code they are depositing. A table of maximum migration based on the concentration of the potential migrant, assuming a food product mass of 10 or 100g can also be supplied to help them with their risk assessment

Nozzle size	75µ (micron) nozzle	60µ (micron)	40µ (micron)
100 drop code (µg)	177	90	27
400 drop code (µg)	707	362	107
1000 drop code (µg)	1767	905	268

Appendix 3

Legislation References

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 (Framework Regulation)

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (Plastics Implementation Measure – PIM)

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

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm