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

September 2009
(Replaces the April 2008 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 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\(^1\) 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.

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 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/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 Directive contains a positive list of monomers and other starting substances as well as a Community list of additives which will become a positive list as from 1 January 2010. Packaging inks are not under the scope of this Directive and thus substances used only in the manufacture of printing inks are not listed. However, if there are ink components which are listed therein, 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. In order to allow for assuming shared and final responsibilities there needs to be cooperation between ink manufacturer and the rest of the supply chain. Specific to the cooperation between ink manufacturer and converter it is recommended that this 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 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, 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 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 and Regulation (EC) No 1272/2008 on dangerous substances.

Note: Category 3 substances will only be used after a migration study has confirmed that migration levels are within published SML or TDI values, or below 10 ppb;

(b) classified as toxic and very toxic;

(c) colourants based on and compounds of antimony, arsenic, cadmium, chromium (VI), lead, mercury, selenium;

(d) all substances listed in the REACH Regulation (EC) No 1907/2006, Title VIII (relating to manufacturing, placing on the market and use of certain dangerous substances, preparations 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 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 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 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 -

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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 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+
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 Directive (2002/72/EC and its amendments) with a limit value. Additionally it will indicate so-called dual use substances (in accordance with Directive 2002/72/EC and its amendments) 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 directive as well as it will indicate dual use substances and if necessary further potential migrants will 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 CEPE/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 Directive 2002/72/EC and its amendments, 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 colourants

The term colourants 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 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 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 three negative mutagenicity tests requested by EFSA Guidelines are available
- above 50 ppb, if supported by favourable toxicological data and/or evaluation done in accordance with the EFSA Guidelines

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: \( \mu g/\text{person/day} = \mu g/6 \text{dm}^2 \)

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 with no formal 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, to be completed by December 2010
- up to 10 ppb, to be completed by December 2015

\(^4\) 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.
EuPIA Guideline on Printing Inks applied on the non-food contact surface of food packaging materials and articles – September 2009

Selection Scheme for packaging ink raw materials

1. **Authorised for direct food contact use**
   - yes → can be used
   - no → Compliance with Exclusion Criteria

2. **Compliance with Exclusion Criteria**
   - yes → Raw Material is a Colourant
   - no → Rejection

3. **Raw Material is a Colourant**
   - yes → Compliance with Purity Requirements
   - no → Evaluation of Migration

4. **Evaluation of Migration**
   - Molecular weight > 1000 Dalton → can be used
   - no → Migration < 10 ppb

5. **Migration < 10 ppb**
   - yes → can be used
   - no → Migration < 50 ppb

6. **Migration < 50 ppb**
   - yes → meets 3 mutagenicity tests
   - no → Risk assessment

7. **Risk assessment**
   - yes → Adequate Tox data
   - no → Rejection

- listed in existing EU or national legislation on food contact materials
- evaluated by EFSA/SCF or other bodies (e.g. IJECFA, WHO, FSANZ)
- national Recommendations (e.g. BfR)
- Council of Europe Resolutions for direct food contact material
- FDA Regulations
- Food additives regulations

Substances with MW < 1000 Da 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
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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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.

<table>
<thead>
<tr>
<th>Size of printed sheets (test pieces)</th>
<th>sufficient for migration cell preferable DIN A4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ink coverage</td>
<td>100 % for each colour (e.g. colour/white)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ink film weight (dry)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexographic ink</td>
<td>1-1.5 g/m²</td>
</tr>
<tr>
<td>Gravure ink</td>
<td>1-2 g/m²</td>
</tr>
<tr>
<td>Offset ink</td>
<td>1-2 g/m²</td>
</tr>
<tr>
<td>Dispersion varnish</td>
<td>2-3 g/m²</td>
</tr>
<tr>
<td>White basecoat</td>
<td>12-16 g/m²</td>
</tr>
<tr>
<td>Clear basecoat</td>
<td>1-2 g/m²</td>
</tr>
<tr>
<td>UV varnish</td>
<td>4-7 g/m²</td>
</tr>
</tbody>
</table>

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 unlaquered Aluminium foil and loaded with the following pressures which reflect practical conditions of stack or reel.

<table>
<thead>
<tr>
<th>Print sample</th>
<th>Time</th>
<th>Temperature</th>
<th>Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reel-fed materials (plastic film)</td>
<td>10 days</td>
<td>25 °C</td>
<td>80 kg/cm²</td>
</tr>
<tr>
<td>Reel-fed materials (paper)</td>
<td>10 days</td>
<td>25 °C</td>
<td>40 kg/cm²</td>
</tr>
<tr>
<td>Sheet-fed litho</td>
<td>10 days</td>
<td>25 °C</td>
<td>0.02 kg/cm²</td>
</tr>
<tr>
<td>Sheet-fed metal</td>
<td>10 days</td>
<td>25 °C</td>
<td>0.3 kg/cm²</td>
</tr>
<tr>
<td>Beverage end aluminium coil</td>
<td>10 days</td>
<td>25 °C</td>
<td>0.3 kg/cm²</td>
</tr>
</tbody>
</table>

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.

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

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, 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. 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 82/711/EEC and its amendment Directive 97/48/EC, as well as Directive 85/572/EEC (last amended by Directive 2007/19/EC), the following simulants shall be used:

<table>
<thead>
<tr>
<th>Food type</th>
<th>Food simulant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous food (pH &gt; 4.5)</td>
<td>Distilled water</td>
</tr>
<tr>
<td>Acidic foods (pH ≤ 4.5)</td>
<td>Acetic acid 3 % (w/v)</td>
</tr>
<tr>
<td>Milk products</td>
<td>Ethanol 50 % (v/v)</td>
</tr>
<tr>
<td>Alcoholic foods</td>
<td>Ethanol 10 % (v/v)</td>
</tr>
<tr>
<td>Fatty foods</td>
<td>Modified polyphenylene oxide (MPPO, Tenax®)</td>
</tr>
<tr>
<td></td>
<td>Ethanol 95 %</td>
</tr>
<tr>
<td></td>
<td>Isooctane</td>
</tr>
<tr>
<td></td>
<td>Alternative test media as substitutes for Simulant D (rectified olive oil)</td>
</tr>
</tbody>
</table>

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®) 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/](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 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:

\[
M = \frac{W \times C \times S}{Q \times 10}
\]

- **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**: area of package or article [dm²] being in contact with 1 kg foodstuff; conventionally set at 6 dm².
  n.b. Should other factors apply – such as known variation from this standard package area:foodstuff ratio - then these must be taken into account when carrying out the calculation.
- **Q**: quantity of food simulant [kg].

Example:
The ink weight on a paper box is 1 g/m². The concentration of the actual substance in the print is 0.5 %. The area of the paper box in contact with food is 6 dm².

\[
M = \frac{1 \times 0.5 \times 6}{1 \times 10} = 0.3 \text{ mg/kg}
\]

Consequently, the maximum possible migration, \( M \) is 0.3 mg/kg foodstuff.
Appendix 3

Legislation References

Framework Regulation


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