# EuPIA Guidance on Migration
# Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials

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# 1. Introduction

This EuPIA Guidance document is to be used in conjunction with food packaging regulations to help select appropriate testing methods 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. Testing methods for the evaluation of direct food contact applications will be dealt with in a separate document.

This document should be read in conjunction with other EuPIA documents on printing inks for food packaging, for instances the EuPIA GMP [1] and the EuPIA Guidance on the Risk Assessment of NIAS and Non-Listed Substances [2].

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.

Regulation (EC) No. 1935/2004 requires that the finished article for food contact materials must be tested and / or evaluated under real conditions of use. Screening tests can be based on experimental-analytical testing methods or on theoretical migration estimations via calculation or migration modelling. Testing the inks, coatings and varnishes with model systems and conditions can only be considered as a screening tool and should be used only when the worst-case calculation or migration modelling cannot be conducted due to missing information, or the results of these calculations exceed the specific migration limits (SML) associated with components of the inks, coatings and varnishes.

The specific methods of migration testing and analysis are described either in EU Regulations [3] on materials and articles in contact with foodstuffs or international Standards [4] [5] [6], with the exception of the preparation of printed samples. For this purpose, substrates and simulants are recommended to check the migration behaviour of components of packaging inks, coatings and varnishes under worst-case conditions.

The draft JRC guideline on compliance testing [7] states: “As a matter of principle, screening approaches need always to be at least as conservative as the verification method. Therefore, test conditions which are at least as severe, should be applied. For an estimation of migration conservative theoretical considerations which overestimate migration are needed. **As a logical consequence, screening tests can only be conclusive in that they demonstrate compliance but they cannot demonstrate non-compliance.** In the event of exceeding a migration limit by screening, compliance may be checked then by using a more appropriate verification test using food simulants or even foodstuffs. Since, from experience, screening results will be in most cases conclusive concerning positive compliance declaration, screening tests offer advantages over verification methods with regard to time and costs.”

The JRC guideline provides detailed information on compliance testing, however, it is only applicable to plastic materials and articles in the scope of this regulation [3]. In the absence of harmonised regulations on other Food Contact Materials (FCMs) the conditions used in the Plastics Regulation are often also applied to non-plastic FCMs. However, plastic simulants and/or conditions may cause physical damage or changes to the non-plastic FCM leading to erroneous results. This is also true for printing inks (see below). Hence, testing conditions better suited to the specificity of each FCM needs to be proposed [8]. This document is aimed at providing specific guidance for printing inks for FCMs.

# 2. Definitions

**Printing Ink**

The term “printing ink”, or in short just “ink”, in this paper includes:

(a) Mixtures of colourants with other substances which are applied on materials to form a graphic or decorative design together with

(b) Other coloured or uncoloured overprint varnishes/ coatings or primers which are normally applied in combination with (a) in order to enable the printed design to achieve specific functions such as ink adhesion, rub resistance, gloss, slip/friction properties

Printing inks do not include coatings which are applied with the prime objective of enabling the material or article to achieve a technical function such as heat sealing, barrier, corrosion resistance, as opposed to a graphic effect, even though they may be coloured.

**Migration**
In the printing industry, when we refer to migration this concept in its simplest form is the transfer of components from the FCM into the foodstuff itself.
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, via contact to the reverse side in a reel or stack (known as “set-off migration”) or by gas phase transfer.
As there are several different mechanisms of migration taking place, the assumption that the degree to which a printing ink component will migrate directly relates to the component’s molecular weight cannot be relied upon. Smaller molecules **will likely** migrate more readily than larger molecules, and molecules with a mass greater than 1000 Daltons (or 1500 Daltons for Fluoropolymers) **are generally** considered to be of no concern as they are too large to be absorbed from the gastro-intestinal tract. However, there may be exceptions where a substance with a molecular weight of greater than 1000 Daltons will readily migrate and accordingly will have a Specific Migration Limit (SML) which will limit the acceptable level of migration.

**Intentionally Added Substances in printing inks for FCMs (IAS)** [2]
IAS in inks are all chemical substances which are intentionally added in the production and use of the printing ink. They have an intended and specific function within the final ink and without which the performance of the inks would change. These substances may be added as single components or as mixtures of various substances. The term “use” of raw materials or substances in inks in this paper means always that these raw materials or substances are added intentionally.

**Non-Intentionally Added Substances in printing inks for FCMs (NIAS)** [2]
NIAS are all chemical substances which are not IAS and do not have an intended and specific function within the ink formulation. Such NIAS may come from impurities in used raw materials from former production steps or could be created due to contamination in ink production or handling or during the application process of the inks (e.g. unintended side reactions during crosslinking, curing, drying or decomposition).

**Non-Listed Substances (NLS)** [2]
NLS are intentionally added substances, which are not required to be listed. An example for printing inks with regard to the Swiss Ordinance (SR 817.023.21) would be pigment additives.

## 3. Recommended methods

### 3.1. “Worst case” – calculation and migration modelling

Migration testing can be replaced by the calculation of the maximum possible migration. A formula and an example for “Worst case” calculations are given in Annex A. For digital printing applications see Annex B.

The FCA (“Food Contact Additives” Sector Group of Cefic) guidance on the risk assessment of NIAS and NLS states “For predicting the migration of substances, mathematical modelling can be applied, which has been significantly developed in recent years. These tools have been validated for some of the commonly used plastics and provide an over estimation of the possible actual migration. For guidance on migration modelling JRC (Joint Research Centre) issued a guidance document” [9].
“Modelling on plastics has been accepted by EFSA as an option to calculate migration [10]. Modelling is only applicable under “non-swelling” conditions. For other materials, like paper and paperboard, the development of a modelling tool is in progress” [8].
There are a few companies who offer software systems for migration modelling (non-exhaustive list of tools) such as: INRA Safe Food Packaging Portal version 335, FABES MIGRATEST Software or AKTS-SML Software, FACET, among others.

## 3.2. Accelerated migration testing

### 3.2.1 Preparation of test samples

***Printing and drying***

For testing, printed samples should be used preferentially, which have been produced and dried under typical conditions of industrial practice. This is especially true if converting and/or drying has a considerable influence on the composition of the printing inks or varnishes, as for instance in reactive (UV, EB, 2-component systems) or solvent-based systems.
Printed three-dimensional objects can also be tested (cups, in-mould-labelled plastic containers).
Alternatively, the ink can be applied to the substrate under laboratory conditions, so that the printing and drying process resemble the reality as much as possible.
To demonstrate that a packaging ink is likely to meet industry requirements, the ink should be applied to the relevant substrate in such a way as to reproduce, as far as possible, the printing and drying processes which are used in practice. In addition, where the final packaging application is known the composition of the resulting print (i.e. the identity/type of individual ink layers applied and their associated relative film weights) should reflect that application as closely as possible.
For a generic test, where the worst case print scenario is not known, a representative film weight hast to be used (see Table 1). Care should be taken when selecting the substrate used for the test sample, which should by preference be the material chosen for the actual application. In case this is not available, a worst-case substrate such as OPP (30 - 40 µm thickness) for plastic applications or fresh-fibre cardboard (200-300 g/m²) for typical cardboard, paper and corrugated fibreboard applications would be suitable, as neither are a sufficient barrier for most migratable substances.

***Storage and conditioning***

Conditioning of printed samples to be subjected to chemical analysis is dependent on how the material is delivered; typically, the printed samples are either on a roll, as a stack of sheets or as three-dimensional objects. Printed samples originating from a roll or coming from a stack of sheets should be, upon arrival to the laboratory, cut to a suitable size (typically A4), stacked (print to non-print side, containing preferably 20 or more test specimens) and the stack should then be wrapped in Aluminium foil. The Aluminium foil should not contain any coating that can interfere with the subsequent analysis. Ideally, a “blank” stack of material should be wrapped separately in Aluminium foil and should be subjected to the same conditioning and analysis as the printed samples under scrutiny. Samples originating from a roll of material do not need further conditioning if the roll of material has already been subjected to conditions typical of production. If possible, three dimensional objects should be stacked and wrapped in Aluminium foil in a manner like two-dimensional objects. If this is not possible, the printed samples should be wrapped in Aluminium and subjected to temperatures and humidities either typical of production (if not already subjected to such) or as defined in Annex C.

When sampling for further analysis of a stack, the top and the bottom 5 layers should be discarded (for stacks containing more than 20 layers). Sampling is then done from the middle of the remaining substrates.

### 3.2.2. Selecting migration parameters

***Selection of migration cells***

Assorted designs of migration cells are shown in EN 13130-1:2004. The surface area to volume ratio is a crucial factor where there may be reduced migrant solubility. Therefore, a minimum ratio of 1ml:1cm2 is recommended. For 95% ethanol, a reduced area to volume ratio can be used, as it is a stronger solvent for typical migrants. Ethanolic solutions used over 10 days at 60°C can result in leakage from the migration cell; this leakage is mainly evaporative in nature. Minimum recovery should be 80%.

***Selection of testing conditions***

Table 1 lists model systems of printing inks, substrates, simulants and film weights. These models represent a major part of all typical practical applications. For plastics, Ethanol 95%(v/v) serves as an universal simulant, since it represents the worst case for most of the practical cases listed in the regulation 10/2011 [7].
For paper and cardboard Poly(2,6-diphenyl-p-phenylenoxide) (Tenax®) is the appropriate simulant, since paper and cardboard can only be used for dry and/or fatty filling goods. Liquid simulants are not applicable for paper and cardboard.

In case of plastic laminated paper and cardboard liquid simulants are also appropriate when they are suitable for wet or fatty food.

Tenax is also recommended as simulant for high-temperature applications [7]. However, Tenax is known to overestimate migration of some migrants compared to real food, and a reduction factor or measurement in real food might be needed for compliance measurements [11] [12].

Print samples which have been produced and dried according to their typical industrial application may also be produced using other substrates and be tested with other simulants, as long as the model system is equivalent and represents the major part of the practical application of the respective ink system.

Table 1: Model systems of printing inks (for 100% coverage). When the coverage is different, a factor should be applied accordingly.

| **Printing ink or varnish system** | | **Substrate** | **representative film weight, dry [g/m²]** | **simulant** | **Remark** |
|---|---|---|---|---|---|
| Oil-/resin-based | Conventional offset (absorption) | Cardboard | 1 – 2 | Tenax® | Printed with water-based overprint varnish |
| UV/EB-curing | UV/EB-offset | Cardboard<br>PP-cup | 1 – 2<br>1 – 2 | Tenax®<br>95% EtOH | |
| | UV/EB-flexo | BOPP | 1 – 2 | 95% EtOH | |
| | UV/EB-coating | Cardboard | 4 – 7 | Tenax® | |
| | UV/EB-screen printing | PP | 10 – 20 | 95% EtOH | |
| | UV/EB-ink-jet | Cardboard<br>BOPP | not applicable* | Tenax®<br>95% EtOH | |
| Solvent- or water-based | Gravure | BOPP<br>Cardboard | 1 – 2 | 95% EtOH<br>Tenax® | |
| | Flexo | BOPP<br>paper or cardboard | 1 – 1.5 | 95% EtOH<br>Tenax® | |
| | 2-component-systems, solvent-based | BOPP | 1 – 2 | 95% EtOH | |
| | Overprint varnish offset, water-based | Cardboard | 2 – 3 | Tenax® | |
| | Screen printing, solvent-based | PP | 10 – 15 | 95% EtOH | |
| | Ink-jet | Cardboard<br>BOPP | not applicable* | Tenax®<br>95% EtOH | |

*For continuous inkjet (CIJ), it is recommended that the end user prints a sample which reproduces as typically as practicable the ink coverage required for the application. When considering a generic test, in which no particular end use is defined, it is recommended 'test' samples be printed consisting of forty individual "8" figures of 7 drops high using a 75 µm nozzle. This corresponds to a mass of printed code: 0.0012 g. For a 100% coverage, the film weight is typically 1 - 5 g/m².

If there is evidence that the simulants given in table 1 do not represent worst-case conditions for specific migrants, a more appropriate simulant should be used e.g. use of 3% acetic acid for Primary Aromatic Amines (PAA).

Regulation (EU) No. 10/2011 specifies three different testing regimes (10 days at 40°C, 10 days at 50°C and 10 days at 60°C) dependent on product storage conditions. The regulation also states that substrates should not be altered by the applied conditions [13]. Therefore, it is recommended to use 10 days at 40°C and extrapolate to 10 days at 60°C where required using migration modelling. Higher temperatures can be used for migration testing, if the substrate is not altered.
Alternatively, the Arrhenius equation can be used as a screening approach to calculate different time-temperature conditions as also mentioned in section 2.1.4 of Annex V of the Regulation (EU) No 10/2011. The Arrhenius equation can only be used for plastics where the migration is controlled by diffusion and the polymer properties are not greatly affected by increasing temperatures for accelerated test conditions.

Applications, which are not covered by the models in Table 1 must be tested with appropriate formulations and testing conditions. It must be ensured that all elements of the production process are considered to allow for an accurate risk assessment (e.g. drying, curing conditions, stacking, wrapping, shaping, pasteurizing, sterilization, etc.). Applications such as metal printing, cup printing, or printing inks for packaging and food contact materials which are intended for higher temperatures or differing storage conditions fall into this category. Test conditions for monitoring migration using food simulants have been proposed for materials and articles intended for use in high-temperature applications (ovenable cookware, ovenable packaging and microwave-active packaging) and may vary depending on the food, the packaging structure and the method of heating (e.g. aqueous food 100°C, unrestricted microwave use 150 °C and unrestricted dual-oven use 175 °C). Microwave-active materials (susceptors) in contact with ready-prepared foods frequently reached local spot temperatures above 200°C [14].

### 3.2.3. Analytical identification and quantification

#### *Targeted analysis (IAS/NLS/NIAS)*

The analytical approach to determine specific migration will depend on:

- the volatility of the substance(s)
- the polarity of the substance(s)
- the nature of the food or food simulant (e.g. aqueous or fatty)
- the level of determination (e.g. high or low)
- the functional groups of the substance(s) (considered to define the detection method)

Table 2: Examples of analytical techniques to determine specific migration

| Type of substance | Example | Predominant technique |
|---|---|---|
| Volatile organics (bp < 150°C) | Monomers, solvent residues (e.g. styrene) | Headspace, SPME, purge & trap, and GC with mostly FID or MS |
| Semi-volatile organics (bp < 300°C) | Plasticisers, glycols, additives, PIs mol. wt. < 400 – 500 g/mol | Liquid injection GC (split, splitless, PTV, on-column etc.) with FID or MS |
| Non-volatile organics | Antioxidants, polymeric plasticisers and PIs, additives with mol. wt. >400-500 g/mol | LC, with diode array, fluorescence or MS detection |
| Metals | Al, Ba, Co, Cu, Fe, Li, Mn, Zn | ICP-MS, ICP-OES, AAS |

**Glossary:** GC, Gas Chromatography; FID, Flame Ionization Detector; ICP, Inductively Coupled Plasma; mol. wt., molecular weight; MS, Mass Spectrometer (detector); PTV, Programmable Temperature Vaporizer; SPME, Solid Phase Micro Extraction; bp, boiling point; PI, Photoinitiator

Some 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 on their website (http://crl-fcm.jrc.it/) a collection of more than 400 analytical methods concerning overall migration and specific migration.

For targeted analysis of known organic compounds gas chromatography or liquid chromatography, both with a mass spectrometric detector (GC-MS and LC-MS), are recommended for the majority of migrants.

***Non-targeted analysis (NLS/NIAS)***

This section deals with non-targeted NLS/NIAS screening. For the risk assessment of identified NIAS, please refer to the corresponding EuPIA Guidance [2].

When testing for NIAS there are 2 important questions that must be answered: what is the NIAS and how much is present? In determining the significance of a NIAS both are important and interrelated, as the potential risk of a NIAS in a food packaging scenario is ultimately the risk to human health and this is determined by both the type and amount of the compound.

A NIAS is defined as a compound that is not intentionally added: this does not mean that it is unknown. A NIAS may be a compound that is expected to be present due to the production process, or a known common contaminant, but equally it may be a compound that has not been observed before and is truly unknown.

Consequently, the analysis for NIAS is complex, as the precise identity of the material may be difficult to confirm and reference standards may not be available for calibration. Analysis of raw materials can be helpful in the identification of NIAS for further migration testing.

Screening for non-intentionally added substances is routinely conducted by GC-MS. This is because the technique is specific, sensitive and contains data that can be used to help identify the components detected.

The routine method for identification using GC-MS is by comparison of acquired component mass spectra to either “in-house” user generated libraries or commercially available libraries. Different types of mass spectrometer can give rise to spectral variation in the resultant mass spectrum and therefore the use of a quadrupole mass spectrometer is recommended. The spectrometer scan range employed also influences spectral properties and therefore a range of m/z 20-650 is proposed (reference to DIN EN 15768 (2015)).

For confident identification of a “known” NIAS, the following guidance is appropriate: for full scan and selective ion monitoring (SIM) data the relative intensities of the detected ions, as a percentage of the most abundant ion, should correspond to those of the reference standard at comparable concentrations measured under the same conditions (SANCO/2007/3131).

Recommended maximum tolerances are:

| Relative intensity (% of base peak) | EI-GC-MS (relative) |
|---|---|
| > 50 | ± 10 |
| > 20 to 50 | ± 15 |
| > 10 to 20 | ± 20 |
| ≤ 10 | ± 50 |

A general guidance for library matching using the NIST MS Search Program is as follows: >900 – excellent match, 800-900 – good match, 700-800 – fair match. However, it should be noted that the library match alone is insufficient to confirm identity and should be double-checked by an experienced analyst with knowledge of substances found in the printing ink industry.

Quantitation by GC-MS should be conducted by preparing a calibration curve with a reference sample of the NIAS. Where this is not possible, a quantitative estimation of the NIAS is usually conducted by reference to the response of another known compound deliberately introduced to the test solution at a known concentration i.e. an internal standard. There can be a significant error as a result of this type of calculation however, as compounds can respond quite differently to one another in mass spectrometry. The associated error can be as

much as a factor of 10. If a mass spectrometer is used for quantification of unknowns by relative response it is recommended to use full scan data.

There are standard methods that use multiple internal reference compounds to try to correct for these differences in MS response. It is recommended that if agreement between laboratories upon migration figures is required, then efforts should be made to harmonise procedures and a common internal standard solution such as deuterated compounds should be adopted. Examples of such standards include, but are not limited to, d-Tridecane or d-Nonadecane.

An alternative to GC-MS quantitation is to use GC-FID. Flame Ionisation Detectors (FID) are universal detectors which do not exhibit the large variation in response from chemical to chemical observed via MS detection, therefore the errors using this technique are more likely to be reduced.

For non-volatile NIAS it is necessary to evaluate samples using LC-MS, but this technique suffers from a number of disadvantages. LC-MS is a relatively “noisy” technique: it suffers from short term baseline instability due to instrument operating parameters which could potentially mask the presence of low concentration NIAS. As a result, any samples may require a significant concentration procedure before analysis. In addition, the variety of employed ionisation techniques and the solvents and additives used in chromatography raises the potential for variable ionisation (and therefore detection) of NIAS. Finally, some NIAS may not respond to ionization at all and therefore will remain undetectable via LC-MS.

In order to confidently screen samples for NIAS by LC-MS it may be necessary to run the sample multiple times using a combination of Electrospray Ionisation (ESI) & Atmospheric Pressure Chemical Ionisation (APCI), and using both positive and negative ion detection.

Identification by LC-MS is more complex than via GC-MS and might require the use of high-resolution and/or hyphenated techniques, such as MS-MS. As a result, LC-MS is better suited to the detection of “known” NIAS, as looking for and identifying unknowns could be a very protracted exercise and many laboratories are not equipped to deal with this.

Quantitation using LC-MS is also prone to much larger variation than GC-MS due to unpredictable ionisation efficiencies, therefore calibrating the system with the correct compound or a compound chemically very similar is essential to avoid extreme overestimation or underestimation.

An alternative to LC-MS quantitation is to use LC-CAD. Charged Aerosol Detectors (CAD) are universal detectors which provide significantly greater consistency of response from chemical to chemical: errors from using this technique are estimated to be considerably lower than those from LC-MS.

### 3.2.4. Justified deviations from the recommended methods

#### *Changes which do not occur under worst foreseeable conditions of use*

The aim of the methods in this document is to provide a guideline reference for the execution of worst-case tests to assess whether a product is fit for purpose. However, whenever a method effectuates a physical or other change to the test sample, the test must be carried out under the worst foreseeable conditions of use in which these changes do not occur [13].

Situations in which the recommended methods are not suitable can be divided into (i) physical changes to the test substrate, and (ii) chemical changes to the migrating compounds. Known examples are given below.

#### *Examples of physical changes to the test substrate*

- Ethanolic solutions used with Polypropylene substrates (≤ 35µm thickness) at 60°C can result in penetration of the film by the solvent, producing an extraction rather than migration testing. Similar changes are known to occur when other plastics when are subjected to ethanolic solutions at 60°C.

- Acetic acid solutions cannot be used with Aluminium foils due to the formation of Aluminium acetate and resulting damage to the substrate.
- Olive / vegetable oils contain components which can penetrate silicone elastomer matrices, which results in an overestimation of migration compared to real food when using these substrates; the same applies to the simulants Isooctane and 95% Ethanol. A proposed solution is to use Tenax which does not penetrate silicone elastomer matrices.
- For Polyamide substrates, Isooctane is the preferred worst-case simulant: 95% Ethanol solutions have the same polarity range as Polyamide, leading to substrate damage.
- Swelling effects can occur e.g. when iso-octane is in contact with polyolefins or when food simulants with high ethanol contents (50% or 95%) are in contact with polyesters, in particular at elevated temperatures (60°C).

***Examples of chemical changes to the migrating compounds***

- Cases of the degradation or further reaction of photo-initiators during exposure to simulant solutions have been reported. For example, Irgacure 819 (CAS No. 162881-26-7) yields TPO-L (CAS No. 84434-11-7) in Ethanolic solutions. Such conversions may cause false positive and/or false negative results if the chosen solution poorly simulates the properties of the real food.
- Deuterated Benzophenone internal standards are known to undergo exchange reactions with non-deuterated species in some solutions.
- Acrylates may be transesterified in alcoholic solutions.
- Thermal decomposition of ink/coating components during analysis has been reported, producing detectable artefacts: notable examples include some pigments/pigment additives, polyurethanes, photoinitiators and ATBC/tributyl aconitate.

## 4. References


[1] EuPIA, *Good Manufacturing Practices (GMP) : Printing Inks for Food Contact Materials.*

[2] EuPIA, *EuPIA Guidance for Risk Assessment of Non Intentionally Added Substances (NIAS) and Non Listed Substances (NLS) in printing inks for food contact materials.*

[3] *Regulation (EU) No 10/2011*.

[4] *CEN standard EN 1186 series.*

[5] *CEN standard EN 13130 series.*

[6] *Methods from the European Union Reference Laboratory for Food Contact Materials (http://crl-fcm.jrc.ec.europa.eu/ or https://ec.europa.eu/jrc/en/eurl/food-contact-materials/test-methods ).*

[7] Joint Research Center, *Technical guidelines for compliance in the framework of regulation (EU) No 10/2011 on plastic food contact materials - draft.*

[8] Food Contact Additives - Cefic Sector Group, *Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under the requirements of Article 3 of the Framework Regulation (EC) 1935/2004,* 2016.

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[13] *Annex V, 2.1.3, Regulation (EU) No 10/2011*.

[14] L. Castle, S. M. Jickells, J. Gilbert and N. Harrison, "Migration testing of plastics and microwave-active materials for high-temperature food-use applications," *Food Additives & Contaminants*, vol. 7, pp. 779-796, 1990, doi: 10.1080/02652039009373940.

[15] „IVLV Merkblatt No. 104/2010: Abklatschlagerung (Set-Off) von Lebensmittelkontaktmaterialien".

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1st amendment, 2018-10-31

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

The formula below is intended for calculations

- near the specific migration limit of compounds which are present at ppm levels in a coating
- in worst-case scenarios
- that are not limited to the Euro cube convention
- independent of the area used in the migration experiment

The formula can be rearranged to calculate the maximum tolerable content in an ink or coating from a given SML.

$$c_{max} = m_{ink} \cdot c_{ink} \cdot a_{spec} \cdot 0.01$$

| | |
|---|---|
| $c_{max}$ | maximum content of a migrant in foodstuff in the worst case, in [µg/kg] i.e. [ppb] |
| $m_{ink}$ | mass of liquid ink or coating applied to packaging in [g/m$^2$] |
| $c_{ink}$ | content of migrant in ink or coating in [ppm] i.e. [µg/g] |
| $a_{spec}$ | specific surface area of foodstuff in [dm$^2$/kg], is 6 dm$^2$/kg for the EU cube |

The factor 0.01 comes from conversion of dm$^2$ to m$^2$, with 1 dm$^2$ = 0.01 m$^2$ or 100 dm$^2$ = 1 m$^2$.

**Example.** Does the content of compound A in ink or coating comply with the SML (worst case)?

compound A (not evaluated toxicologically) — working quantification limit = 10 µg/kg (ppb)

4 g of ink or coating applied per m$^2$ — $m_{ink}$ = 4 g/m$^2$

compound A content in ink or coating is 40 ppm — $c_{ink}$ = 40 µg/g

packaging complies with Euro cube — $a_{spec}$ = 6 dm$^2$/kg

$c_{max}$ [µg/kg] = $m_{ink}$ [g/m$^2$]* $c_{ink}$ [µg/g] * $a_{spec}$ [dm$^2$/kg] * 0.01

= 4 * 40 * 6 * 0.01 [µg/kg]

= 9.6 [µg/kg] (ppb)

In the worst case, the maximum content of compound A in foodstuff would be slightly lower than the SML.

## Annex B: Calculation of maximum possible migration: Digital printing applications

For digital printing applications producing articles with full ink coverage (many graphical and industrial end uses) the treatment outlined in Annex A is appropriate, with ink weight calculated as a function of film thickness (known for a given printing device) and ink density.

$$m_{ink} = f_{ink} \cdot \rho_{ink}$$

| | |
|---|---|
| $m_{ink}$ | mass of liquid ink or coating applied to packaging in (g/m$^2$) |
| $f_{ink}$ | film thickness of coating (µm). |
| $\rho_{ink}$ | density of liquid ink or coating applied (g/cm³) |

However, for some applications (e.g. continuous inkjet printing where the coverage of the ink on the substrate is limited), the mass of ink deposited per m$^2$ ($m_{ink}$) is calculated from the number of drops deposited in the printed image and the mass of each drop, both of which are known for a given printing device.

$$m_{ink} = (\frac{4}{3}\pi r^3 \cdot n \cdot \rho_{ink})/A$$

| | |
|---|---|
| $m_{ink}$ | mass of liquid ink or coating applied to packaging in (g/m$^2$) |
| $r$ | droplet radius (cm) |
| $n$ | number of drops printed |
| $\rho_{ink}$ | density of liquid ink or coating applied (g/cm$^3$) |
| $A$ | area of packaging (m$^2$) |

The calculated mass can then be applied via the treatment in Annex A.

## Annex C: Storage/Conditioning of print samples

**Time / Temperature / Air humidity:**
As described, conditioning of the aluminium wrapped stacks of printed substrates should preferably be conducted at the customer's premises under realistic conditions. Alternatively, storage carried out in the laboratory should be conducted either according to the customer's requirements, at ambient humidity for 6-10 days at 23±2 °C or according to conditions relating to real applications.

**Pressure:**
Preferably, a uniform pressure should be applied to the stack of two-dimensional substrates wrapped in aluminium foil. If no other data is available a minimum pressure of 1 kg/dm² should be applied to the stack, such that the substrates are in intimate contact – thus the whole area of the printed substrates to be analysed should be subjected to pressure [15]. It has been shown that pressure does not have a major influence on the set-off. Higher pressure can be applied if deemed appropriate.

For stacks of three dimensional objects, a pressure should be applied typical of real-life conditions without deforming the three-dimensional structure. A realistic contact between each substrate/object should be ensured.