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Food Packaging:
A Guide to Best Practice for Print

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FlintGroup

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FLINT GROUP – COMMITTED TO PROVIDING EXCEPTIONAL PRODUCTS AND EXPERTISE TO PACKAGING AND LABEL CONVERTERS WORLDWIDE ...

The aim of this guide

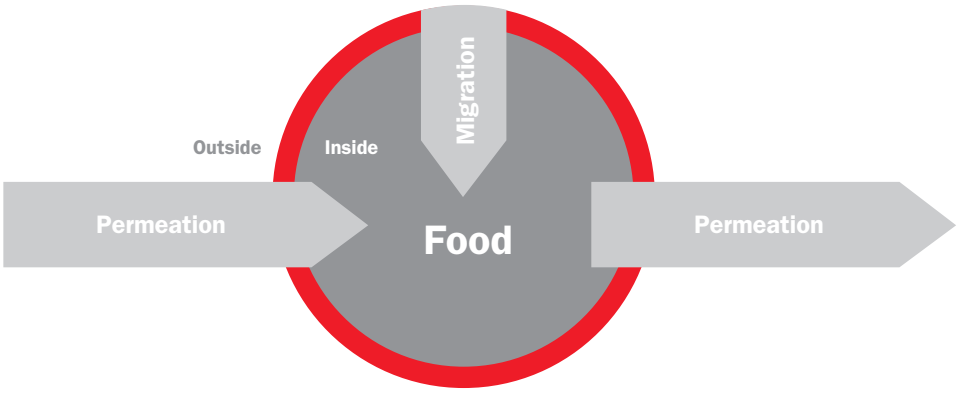
Flint Group is a dedicated supplier of printing inks for the packaging and label industry. Based on our expertise in this area we designed this guide as an overview of the macro issues related to food packaging regulations; providing printers and packaging converters with a sound understanding of the issues that can arise through the interaction of foods with their packaging. It highlights the most relevant legislation, and provides checklists and recommendations that can help promote best practices in the choice of inks for food packaging and other topics that need to be taken care of when printing packaging and labels for food applications.

Food packaging – naturally sensitive

Food packaging is a sensitive area, and manufacturers in this segment must focus on the highest levels of manufacturing controls in line with the imperative of protecting the consumer. This is naturally the subject of extensive legislation, which applies to all the packaging components of a packaged food – including the label. It is the responsibility of all suppliers in the food packaging value chain to ensure that their contributions do not in any way endanger consumer health – for example through the migration of harmful chemicals into the foodstuffs.

1 INTERACTION BETWEEN FOOD AND PRINTED PACKAGING: THE DANGER AREAS

There are three major ways where interaction between food packaging, its surroundings and its contents can arise, as the illustrations below demonstrate.



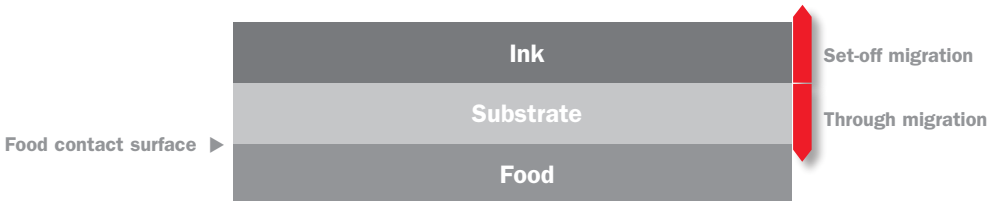
Reactions caused by food, its packaging, and its surroundings

Permeation

Permeation involves the transport of a substance of any kind through the walls of the packaging, both inwards and outwards. Changing environmental conditions in an extended logistical chain such as that for foods can aggravate such reactions.

Migration

The transfer of a substance from the packaging to the food, or vice versa, is the prime concern in the supply of materials (inks, packaging substrates, lamination adhesives, adhesives for labels etc.) for food packaging, and is subject to stringent controls. The diagram below shows the main methods of migration.



Main methods of migration

The concentration levels of migrants permitted by law are usually expressed as mg/6 dm^2 of the packaging, or mg/kg of the food content, sometimes also expressed in ppm (parts per million) or ppb (parts per billion) depending on the concentration. These traces may not always be detected in odour and taste tests, or when the food is consumed, but can be identified by sensitive chemical analysis.

Potential migrant candidates include:

- Plasticisers from plastics or inks
- Monomers from plastics or coatings
- Solvents, retained solvents from inks, washes and cleaning chemicals, oils and greases
- Low-molecular-weight components of inks, adhesives, etc.

Invisible set-off

Although it is not visible to the human eye, ink set-off can occur on the reverse side of printed labels, lids, cups and packaging film, either in a stack, or in the reel after printing. This creates a danger that low-molecular substances could be transferred to the unprinted surface of the packaging that makes contact with the packed contents. However, migration testing and/or Worst Case Calculations will define and quantify this particular phenomenon.

The container illustrated below demonstrates the areas of opportunity for set-off:

2 LEGISLATION AND CONTROL SYSTEMS

The long history of safe use of packaging demonstrates that the current controls already are effective in ensuring that the current products are fit for purpose, but it is sensible to review these. A number of common principles exist for the production of 'safe' food packaging, particularly in relation to migration issues.

Defining the principles

Firstly, responsibility for compliance of the packaging does not lie with one single individual member of the packaging supply chain. It is in the ownership of everyone concerned, including the printer, although ultimately it is the responsibility of the person placing the pack on the market who must ensure compliance.

The same printing ink system can be safe for use on food packaging or unsuitable depending on the packaging material it is printed on, the printing conditions, the food that is packed with the printed packaging, the conditions during the packaging manufacturing and filling (for example applied temperatures) and the way the food packaging is intended to be used (deep freeze, ovenable, microwavable etc.). For this reason the ink supplier alone can not take over responsibility for an ink being safe for any specific application.

Adulteration of a foodstuff by the packaging or its component parts is not permissible; nor is any unacceptable change in the quality, odour, or taste of the foodstuff caused by the packaging.

Migration of substances must remain below defined limits. Whether the packaging intended to bring to the market is safe with respect to migration can only be tested in the form of the final packaging arrangement.

Legislation of the European Union

Printing inks for food packaging are not directly covered by European legislation. There are, however, several regulations that are relevant to food packaging inks (see details in table p. 6).

The European Directive 2002/72/EC, for example, relates to plastic materials and articles intended to come into contact with foodstuffs. The Directive lays down an overall migration limit (OML) of 60 mg/kg food or 10 mg/dm^2 of surface area. In addition, specific migration limits (SML) or maximum contents in the material or article (QM) are set for individual substances. It also contains a positive list of monomers and other starting substances used in the manufacture of plastics intended for direct contact with food. Packaging inks that are not intended for direct food contact are not therefore under the scope of this Directive. However, if there are components used in the ink, which are listed, the relevant restrictions in this directive, such as specific migration limits or maximum content, have to be met. The requirement to issue a declaration of compliance also does not apply to packaging inks. In order to support packaging manufacturers to comply with this directive, Flint Group, as a member of the European Printing Ink Association EuPIA, provides the information on the substances appearing in the directive in a Statement of Composition.

The latest legislation affecting printing inks for food packaging is the Swiss Ordinance RS 817.23.21 from the Federal Office of Public Health, which came into effect on 1st April 2010. It requires that all inks used on food packaging must be composed of materials that have been made from substances which are listed in the Ordinance. Flint Group, as a member of EuPIA, has been heavily involved in making sure that all companies who supply raw materials for printing inks have registered the respective materials.

North American legislation

Within the United States the FDA regulates the materials which can be used in items (packaging) which will come into contact with food. There is a basic assumption that any materials used in food contact applications will become part of the food unless documented testing proves otherwise. The FDA provides a list of approved materials in title 21 CFR (Code of Federal Regulations). Inks and coatings that do not have direct food contact are not regulated; as long as there is a "functional barrier" between the food contact side and the ink or coating, and the inks and coatings do not migrate to the food contact side during various steps in the process. It is the responsibility of the packaging manufacturer to determine if the construction meets the definition of a functional barrier.

The prime general legal requirements

Region/Country	Relevant legislation	Main relevant aspects for the food packaging chain
European Union member states	Regulation (EC) No 1935/2004 of the European Parliament and of the Council	• No unacceptable change in food characteristics
	Commission Directive 2002/72/EC	• Setting out of migration limits for substances
	Commission Regulation (EC) No 2023/2006 (effective April 2010)	• Need to operate to Good Manufacturing Practices (GMP)
Switzerland	Ordinance of the FDHA on Materials and Articles (817.023.21) (only CH)	• *For Switzerland only:* All ink raw materials for food packaging have to be listed
USA	FDA, title 21 CFR	• Functional barrier required in case of direct food contact of the ink
Canada	CFIA & "Health Canada"	• Setting out of food packaging standards • Recommend "Letter of No Objection" for any packaging that may come in contact with food (unless functional barrier)
Australia/NZ	Australian Standard AS 2070–1999	• Strong reference to the EU approach
Japan	Food Sanitation Law	• Contamination of foodstuff by their packaging must be avoided
China	Legislation GB9685-2008	• List of materials that are allowed to be used in food packaging

Self regulations

In addition to the above mentioned regulations EuPIA (European Printing Ink Association) member companies, like Flint Group, are committed to a broad platform of self-control systems. As a principle Code of Practice agreed between all EuPIA members the use of carcinogenic, mutagenic, or reprotoxic substances is forbidden.

Region/Country	Relevant control	Key relevant aspects for ink producer
Europe	EuPIA	• Obey Exclusion List (incl. e.g. CMR and Toxic materials, heavy metals) • Follow Guideline when formulating inks for use on food packaging • Follow GMP when manufacturing inks for use on food packaging (> giving tracea-bility demanded by 1935/2004) · Should be documented · Ink modification on press needs to be recorded • Demonstrate compliance in ink store
USA	NAPIM	• No additional controls besides legislation

As a member of EuPIA and NAPIM, Flint Group complies with all self regulation set up by these associations in the relevant region.

3 PRACTICAL RECOMMENDATIONS FOR PRINTERS AND CONVERTERS TO MINIMISE MIGRATION RISK

There are several ways in which printers and converters can minimise the likelihood of migration. All involve an awareness and understanding of the nature and performance parameters of the packaging as a whole.

Inks and coatings for direct food contact

Surfaces in direct contact with food naturally bear the highest risk of unintended material transfer from the surface to the packed food. For printed surfaces that are intended to come in direct food contact, inks and coatings specially formulated for such applications must be used. Most printing inks and coatings are NOT formulated for direct food contact. If such applications are intended please inform your printing ink supplier accordingly and ask for suitable products. It is essential that manufacturing conditions, the type of food packed and intended use of the food pack (deep freeze, ovenable, microwavable etc.) are described in detail to the material supplier in order to enable them to recommend suitable products.

Printing inks and coatings for indirect food contact – barrier function of the packaging material

Where printing inks and coatings are indirectly applied – separated from the packed food by one or several layers of packaging material – the suitability of the ink or coating system is strongly depending on the barrier properties of the packaging material and the extraction properties of the packed food.
Containers such as metal cans and glass bottles represent an **absolute barrier**, and therefore make no special demands on the choice of printing ink, coating or printed label applied to the outside of the packaging.
However, there is lack of clarity in the packaging industry today on the permeability of plastic containers and film substrates as an infinite number of combinations of food type, packaging material and printing inks/coatings are possible where the packaging layer might always show different barrier functionality. To ensure that in such cases the packaging material acts as a **functional barrier**, preventing migration of components from the printed surface through the packaging material into the packed food, migration tests with the final packaging construction are recommended.
Conventional printing inks in many cases are a suitable choice for food packaging – most solvent based and water based packaging ink formulations do not give any reason for concern for use on most packaging constructions – the use of so called **low migration inks** is recommended when it comes to UV printing inks and conventional sheetfed inks, especially if thin film substrates are involved or paper or carton material with comparably weak barrier properties are used as the primary packaging material.
Low migration inks are based on formulations that are optimised with respect to their migration properties. They are tested under standardised migration test conditions to prove that under these conditions they do not migrate above defined acceptable limits. However, due to the fact that these tests can not simulate all possible food/ substrate combinations for which the low migration inks finally might be used, there can not be a 100% safety without a suitable risk assessment.

Risk assessment

It is helpful for every specific packaging and label application to assess the risk of migration through the use of practical investigations – this is particularly true for packaging where no absolute barrier exists. **Organoleptic testing**, for taste and odour; **migration modelling; practical migration tests on the printed packaging material**, both empty and full; and **calculation of possible 'worst case' scenarios** help to create a comprehensive analysis of a particular food packaging project and the inks that will best meet its needs. Flint Group is supporting its customers in their risk assessment by running worst case calculations and providing information about possible migrants to the analytical laboratory that is commissioned by the customer to conduct migration tests.

Recommended on-press enhancements

On press, converters working in food packaging are advised to install extra controls to ensure that not only does no visible set-off occur, but also the lowest possible levels of residual solvents and other volatile substances are used. Such controls could for example be processes ensuring that the drying being carried out is sufficient to meet these requirements.
Low odour and the elimination of any items that might have taint potential are important concerns; and the ink and press manufacturers' technical instructions should be followed in full.
Slow solvents are sometimes used to improve the printability of both solvent based and water based inks. Care must be taken in the choice of solvents used and the amount of slow solvents added. Slow solvents have a high potential to be retained in the printed product and subsequently migrate to the packaged food.

Material assessment and contamination prevention

When producing food packaging it is important to assess all materials that are used over the complete packaging manufacturing cycle. Special care must be taken to ensure that inadvertent use of materials unsuitable for food packaging is prevented. For example when printing with low migration printing inks only specially selected low migration ink additives including adhesion promoters, foam suppressors and others must be used. To avoid accidental use no other general ink additives should be in the press room close to the press.
Further, varnishes or additional graphic features that might be printed on top of the low migration ink design, for example by digital printing or thermal ribbon printing, all have to be based on materials that have proven low migration tendencies in order to ensure that migration from inks or coatings in the finished pack remains within legislatory limits.
It must be remembered that when setting up for a print job requiring a change from a conventional printing ink to a low migration ink system the press must be thoroughly cleaned to avoid any contamination from materials that have a higher migration tendency.

Energy curing: Recommendations to minimise migration

UV and EB curing present their own agenda of challenges for inks on food packaging and labels. Curing power and speed are critical. Lamp power must be sufficient for the thickness of the ink film applied and the print speed, and of course fully-functioning lamps are essential. It is important to use lamps within their specified lifespan, or a successful cure will not be achieved.
Process quality control is also the key to a good end result. Cure level should always be checked at the start of a print job, and again at regular intervals during the run. Correct colour strength is also a critical factor. Too strong (heavy ink film thickness) a colour can adversely affect the film weight and potentially deliver a reduced cure. Additionally, there are practical factors that should be taken into account for specific types of food packaging.

Microwaveable foods

Packaging for microwave use is a good example. Energy-cured labels should be checked to ensure that there is no adverse ink reaction under microwave conditions. Black inks may overheat; non-heat-stable pigments such as Fanals may discolour or fade; and the 'sparkle' of metallic inks can be adversely affected.

Shrink sleeves

In extreme cases it is possible that ink components can migrate through the layer of a printed shrink sleeve and the plastic wall of a beverage bottle below the shrink sleeves into the liquid in the bottle. Actual migration measurements are therefore recommended in case worst case calculations do show that migration risk above an acceptable limit can not be excluded.

Other special cases

Specific types of packaging make special demands in terms of migration prevention. Packaging for sterilisation or pasteurisation should employ an appropriate functional barrier such as aluminium foil. Where this is not possible, inks containing pigments specially chosen to withstand these processes should be used.
Baking and retort packaging make special demands on high temperature performance: request our information sheet on the use of diarylide pigments in printing inks at temperatures higher than 200°C. In addition, Nitrocellulose based inks should not be used for retort or ovenable packaging.
For labels on multi-layer packaging, it is important to clarify at the outset which supplier in the value chain will be responsible for conducting the testing to establish the correct choice of inks. In such situations, ultimate responsibility for migration performance lies with the company which places the finished pack on the market.

Quick checklist of packaging parameters affecting potential migration risk:

The design of the packaging

- amount of ink per surface unit
- substrate type and thickness
- functional barrier performance of the substrate
- size of pack/container and total print area

Other practical parameters for food packaging

- pack contents – food/liquid?
- time and pressure conditions in the stack or reel
- storage times and conditions
- length of time in contact with food packaging
- expected maximum shelf life
- special processing conditions for packs – e.g. sterilisation, pasteurisation, heating, cooling

In the printroom

- print process and type of press
- print speed
- achieving a true barrier
- conventional drying or energy curing?
  + choosing the right UV lamp
- surface print, reverse print, overlamination?
- likely level of residual solvents
- The use of additives

4 FREQUENTLY ASKED QUESTIONS ABOUT MIGRATION

What is migration?

Migration is the transfer of substances from the packaging to the packed food products. The presence of migrated substance traces may not always by detected in odour and taste tests, or when the food is consumed, but can be identified by sensitive chemical analysis.

How does migration occur?

Migration is caused by three different mechanisms: penetration through the substrate; set-off transfer to the reverse/package contact side of a stack or reel; vapour phase transfer (only for metal decoration).

How do you measure migration, and in what units?

Migration is measured by specialist accredited laboratories using sophisticated measuring cells and highly-sensitive chromatography or mass spectroscopy equipment. Migration measurement from printed packaging is much more complex than assessing odour or taint. It entails identifying and quantifying materials which have transferred from a packaging material sample vs a control sample – ideally a sample of the complete filled package. In practice, analysis of food samples is difficult, so food simulants are used to mimic the nature of the food concerned. Different analysis models are possible – e.g. area of print, weight of food simulant, contact time and temperature – and the results most usually expressed in parts per billion (ppb): in reality, mg per kg of food. The migration models for different foodstuffs are set out in EC regulations and are normally quoted from migration tests involving 600 cm^2 of print, 1 kg of food, and 10 days at 40°C. The EC regulations are subject to periodic review and updating.

What level of migration is acceptable?

The determination of an 'acceptable' maximum level of migration is based on the toxicological profile of the migrant material and, in some cases, the availability of toxicological data and its expert assessment. In every case, the migrants must first be identified in order to carry out a risk assessment.

Please also note that migration testing can take some weeks to complete due to sample preparation times before and after the period the sample spends in the migration cell.

The following table describes migration levels as widely accepted by toxicologists and various studies:

Measured level	Description	Note
< 10 ppb	No effect level	1
10 – 50 ppb	Evaluate test result	2
> 50 ppb	Full evaluation needed	3

Levels of migration

Note 1: Required for toxicologically unevaluated substances or substances where not enough toxicological data exists to judge their toxicity. Even if the level of migration is less than 10ppb, there must be no material detectable with potential carcinogenic activity.

Note 2: Acceptable for substances for which three mutagenicity tests exist (Ames an 2 in vitro tests) which are all negative (i. e. absence of genotoxicity).

Note 3: At this level of migration, the full toxicological profile must be evaluated by a competent expert and approved. For example, one of the migrants may be an approved food additive. Finally a dossier should be submitted to EFSA (European Food Safety Authority) for the development of TDI (Tolerable Daily Intake) and SML (Specific Migration Limit).

Is migration time dependent?

Migration is indeed a time-dependent phenomenon: the longer potentially 'migratable' components are in the proximity of the packaged goods, the greater the risk of migration. An ultimate equilibrium between the migrant level in the food and its packaging will, however, be established.

What migrates?

Potential migrants include plasticisers from plastics or inks; monomers from plastics or coatings; solvents, washes, cleaning chemicals, oils and greases; low-molecular-weight components of inks, adhesives, etc and low-molecular-weight ink additives (e.g. photo-initiators for UV curing); hydrocarbon distillates or mineral oils from conventional inks.

Why and how should we measure migration?

The protection of the consumer from food contamination is the prime concern in this respect, and has driven much legislation.

To comply with regulations, measurements undertaken by an accredited laboratory of fully-commercial, representative production packaging may be required. Depending on the result of a risk assessment from packaging design to filling line, migration testing at an appropriate frequency may form part of the necessary production protocol and specification.

A first step in achieving migration compliance may be to establish a relationship – and a mutual understanding of requirements – with an accredited local or regional laboratory.

What are 'low-migration'inks? Are they available from Flint Group?

Low-migration products are specifically formulated and tested for use in printing applications sensitive to migration issues. Essentially they are made from materials that, under normal or foreseeable conditions and when correctly used in the intended application, do not migrate into the finished package at levels above the current accepted limits.

Flint Group offers Low Migration (LM) Inks for most applications. While they fulfill the above functions, ultimate responsibility for the compliance of an item of printed packaging lies not with one individual within the packaging supply chain, but with all the partners in it. This supply chain partnership is critical for the reduction of the overall risk of migration, today and tomorrow. Flint Group is active in industry forums addressing the issue, and committed to continuous product development and improvement.

What is primary, secondary and tertiary packaging?

The Packaging and Packaging Waste Directive 94/62/EC has defined primary, secondary and tertiary packaging with the following definition (paraphrased):

a) Sales packaging or primary packaging, i. e. packaging conceived so as to constitute a sales unit to the final user.

b) Grouped packaging or secondary packaging, i. e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units.

c) Transport packaging or tertiary packaging i. e. packaging conceived so as to facilitate handling and transport of a number of sales units.

For migration studies the differentiation between primary- and secondary packaging is however not relevant. What must be considered relevant is that migration from the whole packaging (incl. primary, secondary and the label) into the food has to be in compliance with the framework regulation EC 1935/2004 article 3.

Consumer health and safety is of paramount importance where food packaging is concerned. Flint Group is committed to minimise the risks involved with the use of their products for food packaging applications.

Further information and technical support is available from Flint Group around the world. Please contact:

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