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Food Packaging: A Guide to Best Practices for Print

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FlintGroup
Narrow Web

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1. The Aim of this Guide

Flint Group is a dedicated supplier of printing inks for the food packaging and label industry. This guide is an overview of the macro issues related to food packaging regulations. It provides definitions, highlights the most relevant legislation, and provides checklists and recommendations that help promote best practices in the choice of inks for food packaging.

Manufacturers in the food packaging segment focus on the highest levels of manufacturing controls in line with the imperative of protecting the consumer. Naturally, food packaging is also 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 proper materials are chosen for each package they produce.

When considering the choice of inks to use on a package, a printer or brand owner should know if the ink will be used for Direct or Indirect Food Contact.

- Direct food contact - is defined as when packages have printed areas that are intended to have direct contact with the food stuff or whereby it can reasonably be expected the printed area will be brought into contact with food or it can be expected the printed area will transfer their constituents to food under normal or foreseeable conditions of use. In these cases, Direct Food Contact ink (known as DFC compliant) must be specified.

- Indirect food contact - If the foreseeable usage of the printed package does not result in direct contact between the foodstuff and the print, then a food packaging compliant printing ink can be used. Depending on the industry, these inks are also commonly known as 'Low Migration' products.

This guide focuses on definitions and best practices for use of food compliant inks in indirect food contact applications.



2. INDIRECT FOOD CONTACT - EXAMPLES OF MIGRATION

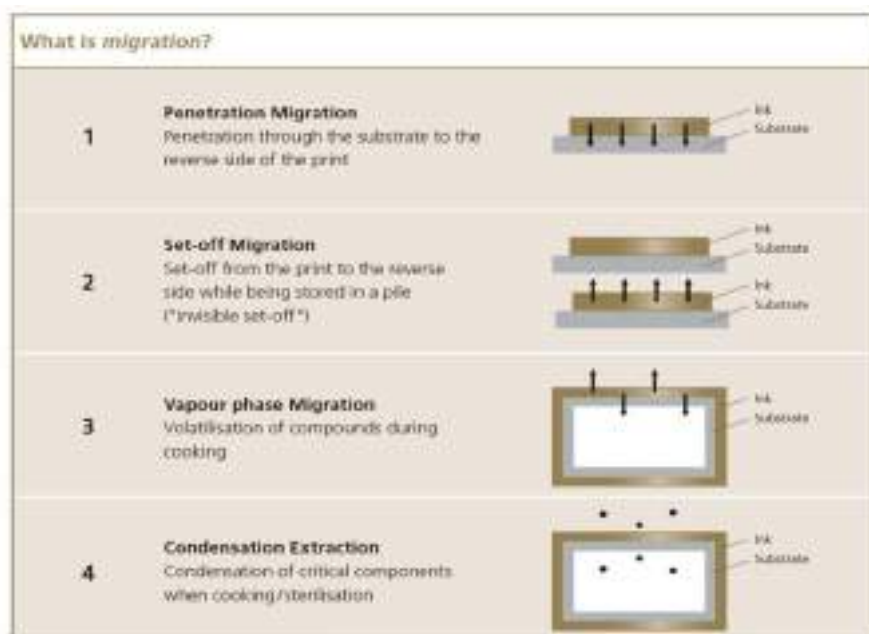
Indirect Food Contact

There are four primary ways where migration can be driven by the interaction between food packaging, its surroundings, and the food contents, as the illustrations below demonstrate. These are: penetration migration through the substrate; set-off transfer to the reverse package side of a stack or reel; vapour phase migration and; condensation extraction.

Migration Examples

The transfer of a substance from the packaging to the food, or vice versa, is called migration and is a prime concern for the food packaging supply chain. All materials in the package structure are evaluated for low migration (inks, packaging substrates, lamination adhesives, adhesives for labels, etc.)

The diagram below shows the main types of migration for inks used in indirect food contact applications.



Ink design not only takes into consideration the possible migration due to penetration migration, but also the unique circumstances that drive Set-Off Migration, Vapour Phase Migration and Condensation Extraction.

Set-off Migration

Although it is invisible 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 potential that low-molecular weight substances could be transferred to the unprinted surface of the packaging that makes contact with the packed contents. To prevent Set-off Migration, the use of food compliant inks for indirect food contact is recommended. Flint Group Narrow Web had designed these inks for low migration, and their efficacy has been tested by certified testing laboratories.

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

Aluminium lid

Full barrier properties but potential set-off to the reverse side, especially when printed reel to reel or stacked and stored.

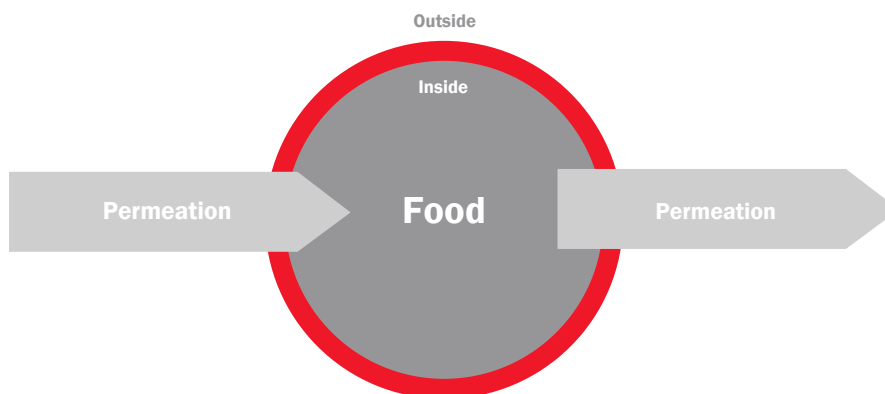
Container

Independent of barrier properties risk of potential set-off to the reverse side when stacked and thus bringing the printed outer surface in contact with the unprinted inner side of the container before filling.



Vapour Phase Migration - Driven by Permeation

Permeation involves the transportation of a substance of any kind through the walls of the packaging, both inwards and outwards. Changing environmental conditions (mostly temperature, humidity and pressure) can drive this transport.





3. SUMMARY OF REGULATIONS

The demonstrated and long history of safe food packaging indicates that the current regulations are effective in guiding packaging material choices and designs that are fit for purpose. Although the compliance of food packaging with regulations is ultimately the responsibility of the party placing the package on the market, all participants in the supply chain play a role in achieving the final compliance. (for example; raw materials providers, substrate and ink providers, printers, converters, package designers, and brand owners)

When it comes to inks, the same printing ink system can meet food packaging compliance or be unsuitable depending on the substrate type or thickness it is printed on, the printing conditions, the food that is packed within 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 (frozen, microwave safe, etc.). For this reason the ink supplier alone can not take over responsibility for an ink being safe for any specific application. This is also the reason regulations frequently define the migration limits of compounds that may migrate from the packaging. And this is a reason why regulations also define the test methods for measuring migration and migrants.

Ink Raw Materials Guided by the European Union

There are several regulations that are relevant to the materials that can be used to produce inks for indirect food contact. (see summary in table p. 6).

The Commission Regulation (EU) No.10/2011 and amendments, known as the Plastics Implementation Measures (PIM), relates to plastic materials and articles intended to come into direct contact with foodstuffs. The regulation 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. 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 regulation. However, if there are components used in the ink which are listed, the relevant restrictions in this regulation, such as specific migration limits or maximum content, have to be met. The requirement to issue a declaration of compliance (DoC) also does not apply to food 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 regulation and other potential migrants in an Enhanced Statement of Composition (e SoC).

Ink Raw Materials Guided by Swiss Ordinance

Additional legislation affecting printing inks for food packaging includes the Swiss Ordinance SR 817.023.21 from the Federal Office of Public Health, which came into effect on 1st April 2010, but is regularly amended. 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, together with the support of EuPIA, has been heavily involved in making sure that all companies who supply raw materials for printing inks have an understanding of the requirements, and register critical raw materials. Depending on the availability of toxicological data of the raw materials, determines the maximum migration limits that will be allowed.

Ink Raw Materials Guided by USA Regulation

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.

Quick Summary of Global Regulations

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	<ul style="list-style-type: none"> Article 3: Indicating minimum change in food characteristics from the food packaging
	Commission Regulation (EU) No.10/2011 and amendments	<ul style="list-style-type: none"> Indicates how run migration tests and which food simulants need to be tested, depending on the type of foodstuff and the temperatures and shelf life of the product
	Commission Regulation (EC) No 2023/2006	<ul style="list-style-type: none"> Defines the need for all steps in the food packaging supply chain to operate to Good Manufacturing Practices (GMP)
Switzerland	Ordinance of the FDHA on Materials and Articles (817.023.21) (only CH)	<ul style="list-style-type: none"> For Switzerland only: All ink raw materials for food packaging have to be listed either on Annex A or B
USA	FDA, title 21 CFR	<ul style="list-style-type: none"> Functional barrier required in case of indirect food contact of the ink
Canada	CFIA & “Health Canada”	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Strong reference to the EU approach
Japan	Food Sanitation Law	<ul style="list-style-type: none"> Contamination of foodstuff by their packaging must be avoided
China	Legislation GB9685-2008	<ul style="list-style-type: none"> List of materials that are allowed to be used in food packaging

Ink Raw Materials Guided by Industry Code of Practice

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. The principal Code of Practice agreed between all EuPIA members is summarised as followed:

Region/ Country	Relevant control	Key relevant aspects for ink producer
Europe	EuPIA	<ul style="list-style-type: none"> 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



4. PRACTICAL CONSIDERATIONS FOR PRINTERS AND CONVERTERS FOR THE CREATION OF FOOD COMPLIANT PACKAGING

Printing Inks and Coatings for Indirect Food Contact – Barrier Function of the Packaging Material

Where printing inks and coatings are 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 require no special 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 ability of a plastic container and/or filmic substrate to function as a barrier. This is due to the infinite number of combinations of food type, packaging material and printing inks/coatings that are possible where the packaging layer might show different barrier functionality. To ensure that 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 on the complete packaging construction are recommended.

A printer can choose from multiple types of printing ink chemistry, when looking for a food packaging compliant product. Traditionally, solvent based and water based packaging ink formulations have not given any reason for concern, as they have been used historically without any documented issues. When considering UV printing inks and conventional sheetfed inks, it is important to ensure that a compliant product is selected. This often has been referred to as “low migration” products.

Food Packaging compliant 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 printing inks finally might be used, there can never be a 100% guarantee or warranty that the products will always work, but instead the whole construction should be evaluated and a suitable risk assessment made.

Risk Assessment and Management Including Migration Testing

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; **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 able to support its customers in their risk assessment by running worst case calculations and providing information about possible migrants, as well as supporting external analytical laboratories with required information for them to complete accurate migration testing.

The choice of simulant for any migration test is determined by the end use of the printed package. The type of food to be packed combined with the shelf life of the product are the main determining aspects. Simulants are described in the Commission Regulation (Eu) No. 10/2011 and its amendments:

Type of Food	Simulant
Aqueous Food	10% Ethanol (simulant A)
Acidic Food (pH <4.5)	3% Acidic Acid (simulant B)
“Ethanollic” Food	20% Ethanol (simulant C)
Semi Fatty Food Products	50% Ethanol (simulant D1)
Fatty Food	Vegetable Oil (simulant D2)
Dry Food	TENAX (simulant E)

Traditionally 95% of Ethanol, or Tenax have been used as industry standards.

Controlling the Drying or Curing Process

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 that the printing inks or varnishes used are drying or curing to their full degree. For water based and solvent based inks, this means ensuring that the levels of residual solvents and other volatile substances are the lowest possible. Whilst for any UV curing product this means frequent calibration of the UV lamps to ensure that they will cure the printing inks and varnishes sufficiently. 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. In any printing ink chemistry, the use of press side additives needs to be carefully controlled and any additions made on press must be traceable according to Good Manufacturing Practices (GMP).

Avoidance of Contamination

Special care should be taken to ensure that inadvertent use of materials unsuitable for food packaging is prevented. For example when printing with food packaging compliant printing inks or varnishes, only specially selected compliant ink additives (adhesion promoters, foam suppressors and others) should be used. To avoid accidental use no other general ink additives should be in the press room close to the press. Additionally, other graphic features that might be printed on top of the printed package, for example by digital printing or thermal transfer ribbon printing, all have to be based on materials that have proven migration compliance in order to ensure that migration from inks or coatings in the finished pack remains within allowed limits.

It must be remembered that when setting up for a print job requiring a change from a conventional printing ink to a food packaging compliant ink system, the press must be thoroughly cleaned to avoid any contamination from materials that have a higher migration tendency. Generally speaking, it is appropriate to have dedicated printing presses for printing food packaging to avoid this uncertainty.

Additional Considerations: Energy Curing

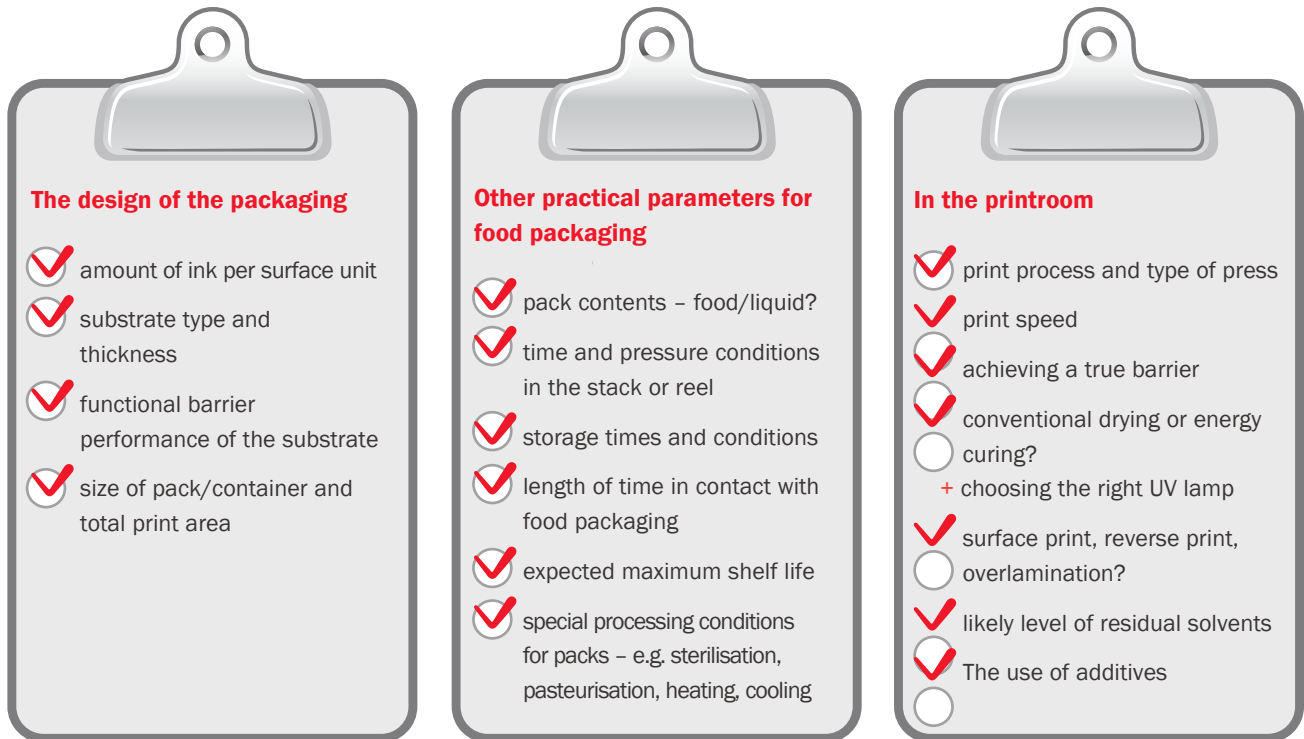
UV and EB curing technologies present a different set of challenges when printing food packaging materials. The key is to follow the recommendations in the ink manufacturers technical instructions. Correct colour strength is a critical factor. The wrong choice of anilox can result in too heavy ink film thickness, and hence higher colour strength, which potentially will deliver reduced cure. UV 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 life span, 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.

Additional Considerations: Shrink Sleeves

Dependant on the type of container used, it should be considered that many PET bottles do not always act as a barrier for migration. Therefore, in extreme cases, it is possible that ink components can migrate through the layer of a printed shrink sleeve and the plastic wall of the bottle, and into the liquid in the bottle. Therefore we also recommend that converters complete the appropriate testing to ensure that the risk for migration is evaluated fully.

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
-

5. 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 can be measured by chemical analysis. Regulation is interested in the migration of components that have a molecular weight of under 1000 Dalton, as any substance with a higher molecular weight will not enter the biobarrier in the human body, and is therefore considered not to be of concern.

How does migration occur?

There are four possible types of migration of indirect food contact ink compound into food: penetration through the substrate; set-off transfer to the reverse package side of a stack or reel; vapour phase migration and condensation extraction.

How do you measure migration, and in what units?

The migration potential of a printed article is measured by certified laboratories using sophisticated measuring cells and highly-sensitive analytical techniques, such as liquid chromatography or mass spectroscopy. Migration measurement from printed packaging is much more complex than assessing odour or taint. It entails identifying and quantifying materials which have transferred from the packaging material sample against 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 and these are defined in EC 10/2011 (PIM), and are dependant on the end use and type of foodstuff to be packed, as well as storage time and conditions. Migration results are usually expressed in parts per billion (ppb), which in reality means µg per kg of food. The EC regulations are subject to periodic review and updating, but are normally quoted from migration tests involving 600 cm² of print, 1 kg of food, and 10 days at 40°C.

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. This means that the analytical laboratory needs to have a close relationship with the printing inks manufacturer so that they have access to the formulations, and can accurately analyse any potential migration species. Migration testing can take some weeks to complete due to sample preparation times and the period the sample spends in the migration cell even before any data is collected.

The following table describes migration levels as widely accepted by toxicologists and various studies. However, it should also be noted that an increasing number of substances have enough data available that a Specific Migration Limit (SML) has been established. This implies that the component can be found at levels below the agreed SML, and is not considered to be of concern.

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: Generally accepted by EuPIA for substances for which three mutagenicity tests exist (Ames and two 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. This is why the PIM regulation takes storage time of the packed item into account when determining testing conditions.

What migrates?

Potential migrants include any substance with a molecular weight below 1000 Dalton. This includes (but is not limited to) plasticisers from plastics or inks; monomers from plastics or coatings; solvents, cleaning chemicals, oils and greases; photo-initiators, 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 'Food Packaging compliant' inks?

Food packaging compliant products are often referred to as "low migration" products. They have been specifically formulated and tested for use in food packaging printing. 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 Food Packaging compliant inks for indirect food contact 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 (including 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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