Packaging Printing

Designing Packaging with Certainty
A Best Practice Guide

A guide to printing food packaging and sensitive goods with UV & EB curing and conventional offset inks and coatings

working for you.

SunChemical®
a member of the DIC group

Introduction

With the increase in the number of food packaging migration alerts in recent times, highlighted by several high profile product withdrawals from supermarket shelves, Sun Chemical is pleased to provide this third edition of the Best Practice Guide to support the packaging development workflow in the production of safe packaging for food and sensitive applications such as tobacco and pharmaceutical applications. Market awareness of the issues surrounding migration from packaging has generally been increasing, and yet Sun Chemical has been promoting the use of low migration offset printing technology for use on packaging for more than 25 years. In 2004, Sun Chemical introduced the first edition of "Print for Packaging – A Printing Low Migration Best Practice Guide" which has proved to be a very useful and popular document for printer converters and end users alike over many years. Some 5000 copies of this document have been shipped to date. The guide was updated in 2007 and this third edition has now been prepared to reflect the current packaging market situation as it stands today.

This 3rd Edition Best Practices Guide represents a summary of the key challenges faced by the packaging development supply chain and has been prepared by Sun Chemical using in house knowledge and know-how, and after discussion with many industry experts in the printing and packaging industries.

The guide is laid out in a logical sequence to help readers understand the topic of how to design, produce and store packaging safely with respect to migration of unwanted contaminants, and provides practical ways to minimize the risks. We have tried to address the most important questions from our view as an inks and coating manufacturer and as a key stakeholder in the production of safe packaging through Good Manufacturing Practice (GMP).

Important Note:
A best practice guide such as this is no substitute for up to date information from the suppliers of equipment and consumables that are used in production of packaging or about the printed packaging itself, as sourced from converters. Our aim has been to help identify areas that warrant attention when seeking the best way to achieve a reduced risk of migration from printed packaging. Any comments and advice from readers would be greatly appreciated and can be sent to sheetfed@sunchemical.com.

Contents

For further information please see www.sunchemical.com or email sheetfed@sunchemical.com.

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Glossary of Terms

Measurements

ppb
parts per billion or 1 in 1 000 000 000

ppm
parts per million or 1 in 1 000 000

mg/dm²
milligrams per square decimetre

µg/kg
microgrammes per kilogram

Note: 1 µg/kg of food equates to 1 ppb, and 1mg/kg food equates to 1 ppm

Meanings

Low Odor –
Low Odor or to give good result in low odor testing. A low potential for causing an odor problem.

Low Taint –
Low Taint or to give good result in taint or taste testing. A low potential for causing an off taste or taint.

Low Migration –
A low potential to cause migration. Gives good results in migration testing and a low risk of migration to the packaged contents.

Definitions

Absolute Barrier / Functional Barrier
Any integral layer of a composite packaging material which under normal and foreseeable conditions of use reduces or prevents (Absolute Barrier) the migration of components from any layer on the non-food side of the barrier into the food to non-detectable levels. Where a level is considered 'acceptable' it conforms with an SML or TORC-value or is analytically insignificant.

BfR
The Federal Institute for Risk Assessment of Germany. The BfR has the statutory remit of providing information on possible, identified and assessed risks which foods, substances and products may entail for consumers. It seeks to present the entire assessment process in a transparent manner to the public at large. ***www.bfr.bund.de***

BRC
The British Retail Consortium is the trade association representing the retail trade in the UK and is directly involved in food safety, all forms for legislation and other important issues. ***www.brc.org.uk***

BRC/IoP Global Handbook (see Appendix II)
A procedure by which performance can be measured and validated to qualify production sites which supply food packaging. Is widely adopted in many European Countries.

CEPE
The European Council of the Paint, Printing Ink and Artists' Colors Industry. CEPE is a non-profit making organisation with the status of "association internationale sans but lucratif" (aisbl), which represents, promotes and protects the common interest of the European paint, printing ink and artists' Colors industries. ***www.cepe.org***

CEPI
Trade organisation for European manufacturers of kraft paper for the flexible packaging industry. ***www.cepi-eurokraft.org***

CIAA
Body that represents the food and drink manufacturing industry for the whole of the European Union. Many EU Member States also have similar bodies that represent their national interests. ***www.ciaa.be***

Contamination
All possible pollution of the finished packaging material, including microbiological contamination, insects, contamination with foreign substances such a lubricating oil, cleaning agents and waste water or contamination with foreign objects such as glass, knives and razorblades.

ECMA
Trade organisation founded in 1960 to promote the interests European Carton Makers and is today the established forum and officially approved umbrella organisation for national carton associations throughout Europe. ECMA represents 500 carton producers in nearly all countries in the European Economic Area, around 70% of the total carton market volume in Europe, and a current workforce of about 50,000 people. ***www.bfr.bund.de***

EFSA
The European Food Safety Authority is the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks. Before the formation of EFSA the Scientific Committee on Food (SCF) fulfilled this role.

EuPIA
Trade organisation composed of all printing ink manufacturer members of CEPE national associations and of affiliated companies. It is the forum for discussion and decision-making with a view to creating a responsible representation of the European printing ink business. EuPIA remains a group inside CEPE.

FDA
The Food and Drug Administration of the United States is a respected consumer protection agency which promotes and protects the public health by monitoring products in the marketplace and sets rules and approves materials. ***www.fda.gov***

Functional Barrier
As defined by the Plastics Implementing Measure, a functional barrier means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of the Regulation (EC) 1935/2004.

GMP
Good Manufacturing Practice: in this document GMP means Good Manufacturing Practice according to European Commission rules in the production of packaging materials.

HACCP
Hazard Analysis Critical Control Point. It is an internationally recognized and recommended system of food safety management.
www.haccpnow.co.uk

IFS
The International Food Standard (IFS) is a standard for auditing retailer and wholesaler branded food product suppliers and manufacturers. The food standard is designed for companies that undertake food processing, handling of food products and primary packaging activities. Those that meet the standard can achieve IFS Accreditation.

IoP
The Institute of Packaging, the professional membership body for the packaging industry for the education and training of those involved in the diverse packaging industry.

QM
Maximum permitted quantity of residual substance permitted in a material or article. Expressed in mg/kg of finished packaging material.

QMA
Maximum permitted quantity of residual substance permitted in a material or article. Expressed in mg/dm^2 of finished packaging material.

RASFF Portal
The European Commission "Rapid Alert System for Food & Feed" is a public domain portal tool put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed. See http://ec.europa.eu/food/food/rapidalert/index_en.htm

"Set-off"
Set-off is the transfer of unwanted components of the inks and/or coating components from one printed surface to another surface. In sheetfed printing, this is typically from the printed surface to the reverse side of the sheet above when the print is delivered into the stack at the end of the press. In web printing, the printed surface is wound against the reverse side during re-reeling. In both instances there is a risk of transfer of material due to the intimate contact of the printed surface with the reverse side of the substrate. As a result the potential for migration of components from the packaging to the packaged goods may be increased. In most instances this set-off is invisible to the eye and can only be detected by sophisticated analysis. Where food packaging is concerned, set-off should be kept to the absolute minimum.

SML & OML
The Specific Migration Limit (SML) is the maximum permitted amount of a given substance that can be released in food or an appropriate food stimulant. SML is generally expressed in mg/kg of food. Overall Migration Limit (OML) means the maximum total permitted amount of non-volatile substances released from a material or article into food or simulants, also expressed an mg/kg of food. The Overall Migration Limit is sometimes referred to as the Global Migration Limit.

Swiss Ordinance
An ordinance (regulation) on materials and articles in contact with food developed by the Swiss Authorities. A new chapter on packaging inks, which became applicable from April 2010, introduces a positive list of substances for inks and coatings that may be used for articles in contact with food.

TORC
Threshold of Regulatory Concern.

BfR

BRITISH RETAIL CONSORTIUM
for successful and responsible retailing

CEPE
The voice of paint, printing ink and artists' colours in Europe

cepi

EUROPEAN CARTON MAKERS ASSOCIATION

efsa
European Food Safety Authority

EuPIA
European Printing Ink Association

Institute of Packaging Professionals

What is Migration? Frequently Asked Questions

Why do I need to consider migration of inks and coatings components in packaging printing?

A migration risk may exist when printed inks, coatings or adhesives are in close proximity to a packaged food and where there is no functional barrier between the packaging and contents. Where the design, production, storage or use of a package includes a significant risk of transfer of unwanted chemicals to the packaged product, there is a need to minimize that risk by the use of best practices. Careful risk analysis can provide a measurement of the level of these risks and the lists in the "Designing Packaging with Certainty" section of this guide indicate a number of issues that need to be checked.

What is migration?

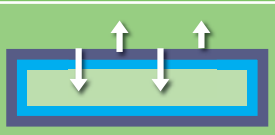
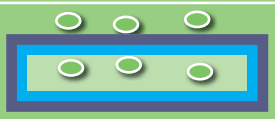
It is the transfer of substances from the packaging to the packaged goods. These substances may not always be detected in organoleptic testing (odor and taste tests) or when consumed, but may be found by sensitive chemical analysis.

How do you measure migration and in what units?

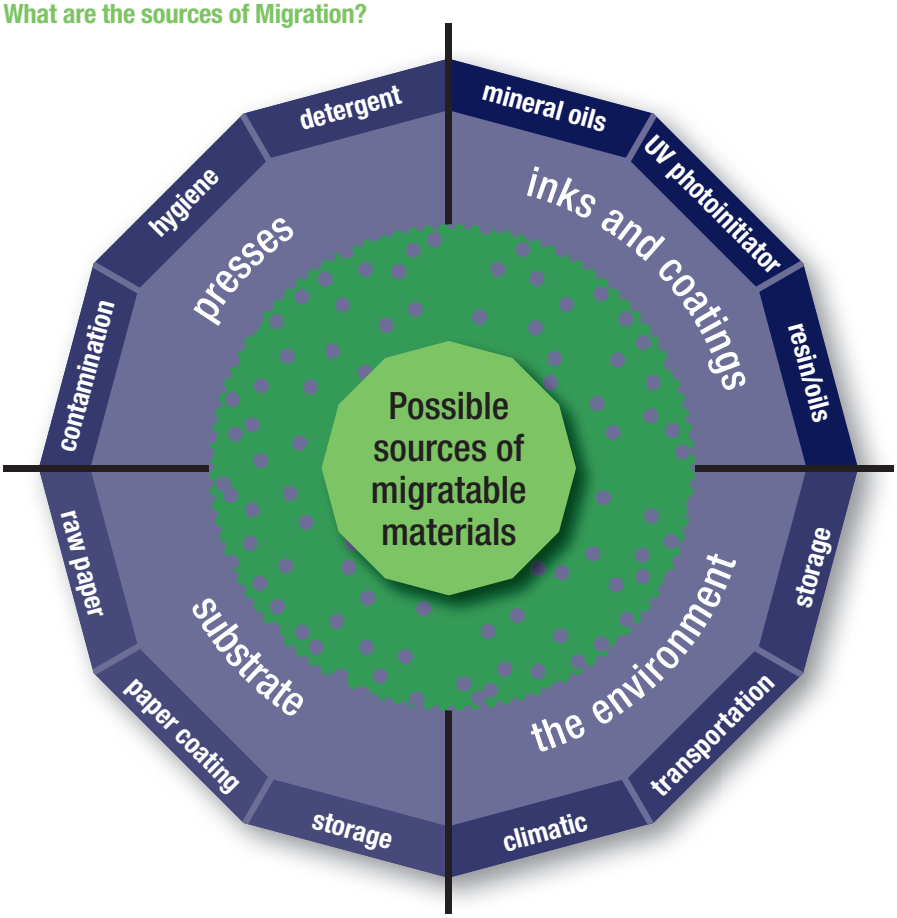
Migration testing is best undertaken by an expert accredited laboratory. Fully commercial and representative production packaging is usually required. Such laboratories use sophisticated migration cells and highly sensitive chromatography or mass spectroscopy equipment. Measuring migration from printed packaging is a much more complex task than assessing impact of odor or taint. Migration is measured by determining the identity of, and amount of, materials that transfer from the packaging sample, ideally into a control sample of the actual food. In practice, analysis of food samples is difficult and so food simulants are used to mimic the nature of the food itself.

Different models are possible (area of print, weight of food simulant, contact time and temperature) and the results are often quoted in parts per million (ppm), parts per billion (ppb) or actually microgrammes (µg) per kg of food.

HOW DOES MIGRATION OCCUR?

1.	Physical Migration	**PENETRATION MIGRATION** Migration from the printed side through the substrate onto the unprinted side.	 Penetration through the substrate
2.		**CONTACT MIGRATION** Migration from the printed side to the unprinted side of another sheet in a stack or roll (usually referred to as "Set-off").	 'Set-off' transfer onto the reverse side in the stack
3.	Gas Phase Migration	**EVAPORATION MIGRATION** Migration due to the evaporation of volatile materials by heating (e.g. cooking, baking, or boiling frozen products in their original packaging).	 Vapor phase transfer
4.		**CONDENSATION MIGRATION** Migration through steam distillation during cooking, baking or sterilisation.	 Condensation extraction

What are the sources of Migration?



The migration models for different food stuffs are set out in EC regulations* and are normally quoted from migration tests using the following model: 600cm^2 of print, 1kg of food, 10 days at 40°C.

Migration testing can take some weeks to complete due to sample preparation times before and after the period in the migration cell.

* Note: These 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 and expert assessment of the toxicological data. In all cases of migration the migrants must be identified in order to carry out a risk assessment.

Measured Level	Description	Note
< 10 ppb	No effect level	#1
10-50 ppb	Evaluate test results	#2
> 50 ppb	Full evaluation needed	#3

Note 1:
Even if the level of migration is less than 10ppb (the no concern level) there must be no material detectable with potential carcinogenic activity.

Note 2:
There are 3 mutagenicity tests (Ames and 2 In vitro tests) and all must be negative (i.e. absence of genotoxicity).

Note 3:
The full toxicological profile must be evaluated by a competent expert and approved at this level of migration. For example, one of the migrants may be an approved food additive.

What are 'low migration' products?

Low migration products for use in low migration printing applications are consumables (inks, coatings, founts, wash ups etc) that are specifically formulated and tested to minimize migration in use. Essentially they are made from raw materials that under normal, or foreseeable conditions of use, do not migrate.

How does "low migration" relate to "low taint and odor"?

"Low migration" systems by their very nature are low odor, low taint AND low migration and this represents a "Best Practice" solution to avoiding any unwanted organoleptic impact in packaging as well as avoiding problems in terms of any potential hazard to health due to chemicals from the graphic process.

"Low Odor" and "Low Taint" are expressions that have been well understood in the packaging industry for many years. There are methods and procedures for testing both printed packaging, and the various components used in their production, with respect to this issue, to ensure that under normal or foreseeable conditions of use, the organoleptic characteristics of the packaging are unaffected. Packaging suppliers can meet the demands of the packaging buyer, or end user in this respect, by using a suitable method and frequency of test. There are also published standards relevant for this, for example, EN1230-2:2001.

The availability of low migration materials does not mean that routine testing for odor and taint properties should be abandoned. Testing for freedom from organoleptic impact should still be an important part of product quality assessments programmes. Note also, that a material described as "low taint" and "low odor" doesn't necessarily have low migration properties

Is migration time dependant?

Yes, migration is a time dependant phenomenon. However, there are many factors that affect the rate and extent of migration including the type of packaged foodstuff, the temperature at which the packaging is stored and the nature of the packaging itself.

What migrates?

The following is a non-exhaustive list of typical potential migrants:

- Solvents, washes and cleaning chemicals
- Oils and greases
- Plasticisers from plastics or inks
- Residual monomers from plastics, inks or coatings
- Breakdown products from inks and/ or coatings following curing or drying
- Low molecular weight components from substrates or other raw material sources such as adhesives
- Hydrocarbon distillates, mineral oils and vegetable esters from conventional inks
- Non reacted materials in the case of insufficient UV or EB curing

Why measure migration?

To ensure consumer safety and that packaging complies with the relevant regulations, in line with Good Manufacturing Practice and Risk Assessment practices.

How do I ensure prevention of health hazards that may result from migration?

By ensuring continuous and full compliance of the packaging materials used with all the relevant Food Contact Legislation. Alternatively, where the legislation is currently incomplete, the best available guidelines and recommendations should be used. These guidelines should be applied to each of the separate components of composite packaging materials, where legislation covering composite materials is lacking or where an efficient functional barrier cannot be applied.

The converter must ensure that the Overall Migration Limit, as well as the individual substance Specific Migration Limit (SML) and other limitations when applicable are fully respected. This can be achieved by:

- Appropriate pack design
- Controlling the composition of the raw materials
- Controlling the migration features of the raw materials
- The use of functional barriers
- Testing directly the intermediate or finished products
- Controlling the process (working hygiene)

For reference, additional information on the relevant legislation is included later in this document.

Designing Packaging with Certainty

In general terms, legislation on food packaging covers the guiding principle that food packaging should not transfer materials to the packaged food in quantities that could bring about a change in the nature, substance or quality of the food and must not be injurious to health. (EU Framework Regulation 1935/2004/EC)

Design and production of packaging is becoming more complex with the emergence of new regulations. Finding a clear path to "compliance" and safe production may not be easy and require expert guidance.

Responsibilities

The objective of achieving safe packaging requires all stakeholders in the packaging design and production chain to work together as outlined in the Good Manufacturing Practice (GMP) regulation (EU Regulation EC 2023/2006/EC). This regulation details the overall requirements regarding selection and use of materials and articles intended to come into contact with food. It introduces a framework of rules for all stakeholders involved in the development of packaging and provides recommendations that working specifications, quality assurance and control mechanisms and traceability are established and maintained.

Where the design, production, storage or use of packaging includes a significant risk of transfer of unwanted chemicals to the packaging product, there is a need to minimize that risk by the use of "best practices". A risk may exist when inks, coatings or adhesives are in close proximity to the packaged foodstuff and where there is no functional barrier between the packaging and the contents. Careful risk analysis can provide a measurement of the level of these risks. Even if not exhaustive, the checklists provided in the Designing Packaging With Certainty section of this guide suggest a number of issues that may be addressed.

"Low Migration" production means paying attention to and acting in a proactive way towards these issues. A wide range of potential sources of migratable materials or contaminants is listed, but each packaging production scenario is different so needs to be assessed independently. Use of qualified experts, as well as following guidance from your trade association, can assist in understanding and establishing processes and procedures to meet the requirements of the appropriate legislation.

For more information on Good Manufacturing Practice (GMP) please contact www.eupia.org and reference the "EuPIA Position on Regulation EC No 2023/2006 of 22.12.2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food".

Brand owners and end users of packaging may also wish to review their printer/converters Good Manufacturing Practice procedures and protocols to assure themselves that appropriate measures are in place to produce fit-for-purpose packaging.

The Ink Makers' Responsibilities

Sun Chemical, in common with the other members of EuPIA, is committed to full compliance with the "EuPIA Guideline on Printing Inks applied to the non-food contact surface of Food Packaging & Articles".
All substances used by Sun Chemical in the formulations of printing inks and coatings designed for food packaging comply with the EuPIA Exclusion List as published on www.eupia.org.

In summary, specifically excluded materials are those that are:

1. Classified as carcinogenic, mutagenic or reprotoxic Category 1 or 2 (GHS Category 1A or 1B), according to the provisions of Directive 67/548/EEC and EC Regulation 1272/2008 on dangerous substances. Please note that Category 3 (GHS Category 2) substances will only used after a migration study has confirmed that the migration levels are within published SML or TDI values and that Category 3 reprotoxic substances without a published limit may be used if migration levels are confirmed to be not detectable, with a detection limit of 0.01mg/kg food.
2. Classified as toxic or very toxic.
3. Colorants which are based on and compounds of antimony, arsenic, cadmium, chromium, lead, mercury or selenium.
4. Substances listed in the REACH EC Regulation 1907/2006, Title VIII & Annex XVII and its amendments, if their use in packaging ink would lead to an infringement of Article 3 of the EC Framework Regulation 1935/2004.

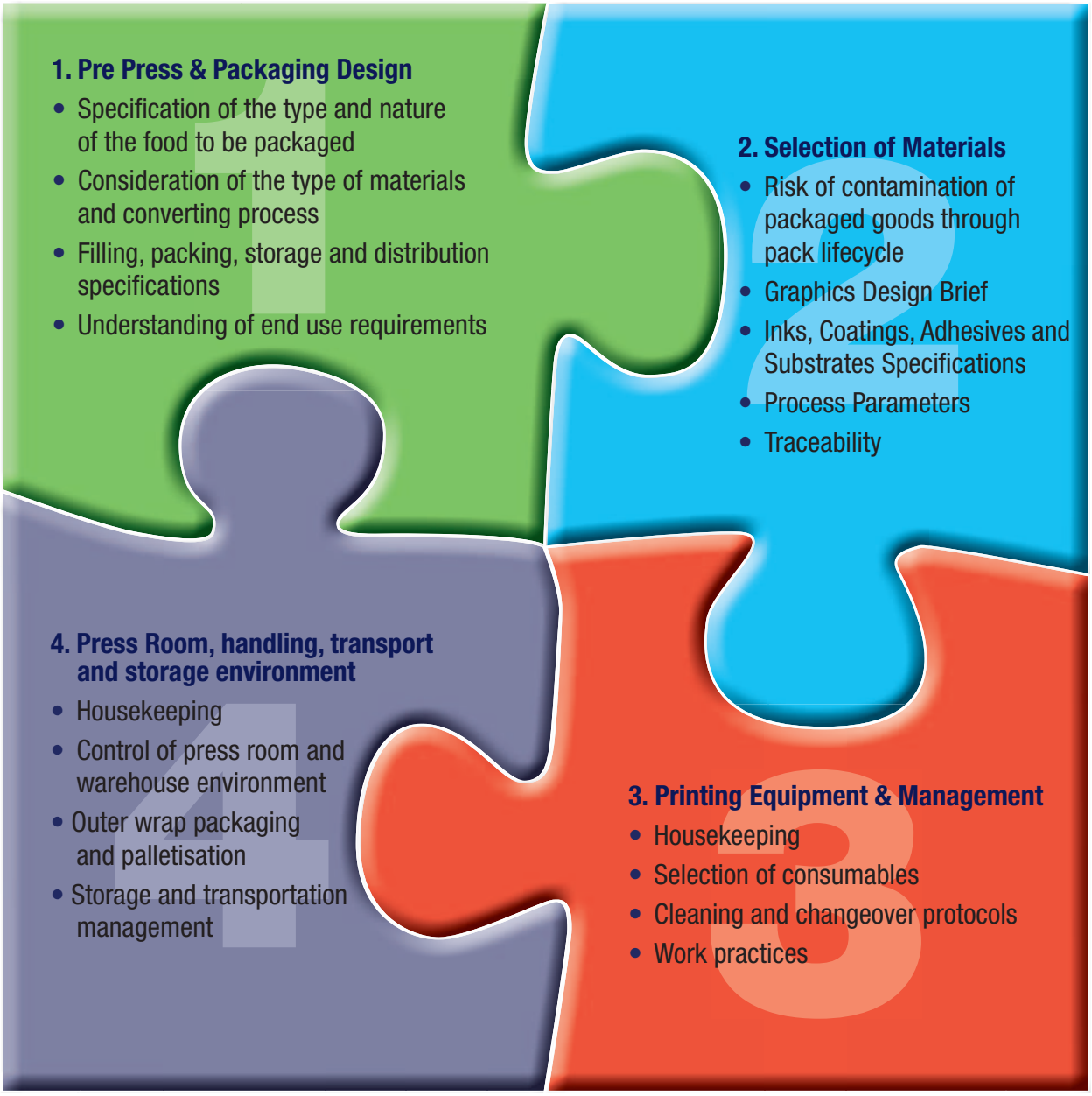
Sun Chemical's packaging inks are manufactured in accordance with the requirements of Good Manufacturing Practice. Raw materials are carefully selected and our packaging inks formulated so that the levels of heavy metals and environmentally hazardous substances are minimized to allow the printed packaging to meet the requirements of the Packaging and Packaging Waste Directive.

Please note Substances of Very High Concern (SVHC) are not used.

Sun Chemical takes its product stewardship responsibility very seriously and works hard to keep abreast of all current and future legislative changes and support customers in managing their compliance on a continuous basis.

Four Step Model to Designing Packaging with Certainty

The role of designing compliant packaging can be split into four main areas of focus:



The guidance and checklists on the following pages are designed to raise awareness of the key issues associated with each area.

Packaging Definitions

The overriding objective is to find an appropriate, safe, secure and economic solution for each print job.

When producing packaging, it is assumed that high quality printing is a must, along with excellent graphic reproduction and handling properties that satisfy end use demands. However, when reviewing how that packaging is to be used, it is quickly apparent that what is a requirement for one job may not be important for another.

Different types of packaging require different design solutions. Those that are suitable for the packaging of food and sensitive goods may not be relevant, for example, for packaging destined for luxury packaging e.g. cosmetic boxes or liquor cartons, or for cleaning or household goods.

Today, primary packaging has been defined in the Packaging and Packaging Waste Directive (94/62/EC as amended) and these new definitions are those used by most brand owners and packaging designers. Essentially, any packaging that the consumer touches, that will eventually find its way into the waste stream is now considered primary packaging, irrespective of the number of layers of packaging material involved.

Within this generic definition, packaging can be split into different categories, depending on how it is designed and used, as follows:

1. Primary Packaging ("Direct Packaging")

Packaging where the packaged goods are in prolonged direct contact with the non-printed side of the packaging material.

2. Primary Inner Wrap ("Food Containment Packaging")

Where a two-piece packaging solution has been designed, the inner wrap (for example, a tray or a flow wrap material) is designed to be in direct contact with the packaged goods. The inner wrap is not normally printed and, if plastic will be subject to additional regulation from the Plastics Directive.

3. Primary Outer Wrap ("Secondary or Indirect Packaging")

Outer wrap packaging, which is usually printed, where the packaged goods are retained within some form of primary inner wrap such that the printed material is not in direct contact with the contents.

Primary Outer Wrap
Folding Carton

Primary Inner Wrap
Flow Wrap

4. Non-Food Packaging

Packaging that contains contents not intended for human or animal consumption e.g. household cleaning products, white goods, garden products etc.

Designing Packaging with Certainty Part I – Pre-Press and Package Design

CONSIDER POTENTIAL MIGRATION OF PACKAGING COMPONENTS AT THE CONCEPTION OF THE PACKAGE AND PRODUCT DESIGN

Printing inks, coatings and adhesives, unless specifically designed for the purpose, should not under normal circumstances come into direct contact with packaged foodstuffs.

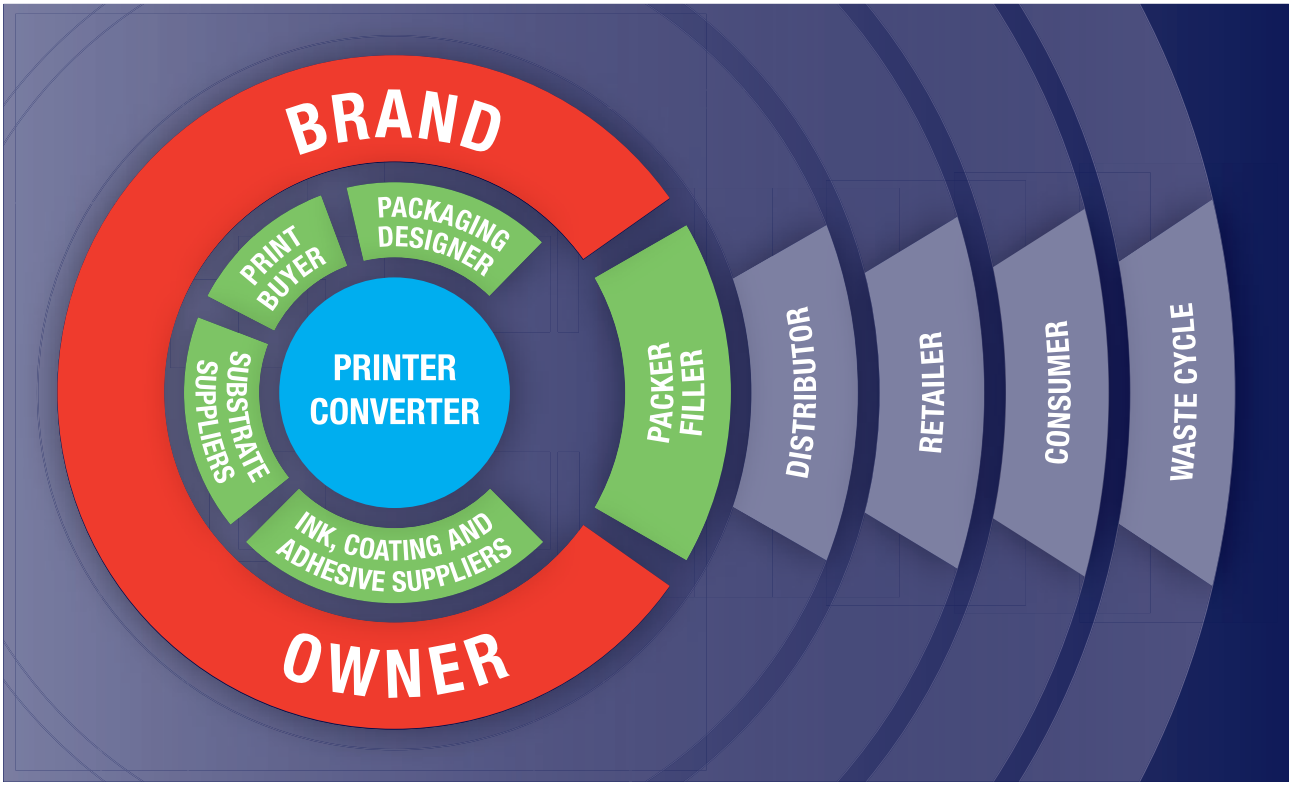
Therefore printed food packaging should be printed in such a manner that set-off (see glossary for definition) during and after the printing process is avoided as far as is practically possible in order to ensure that the surface of the packaging in contact with the packaged product is free of printing inks and coating.

If it is to be fit for purpose, designing packaging that is suitable for the food requires specific information to be known. As required by Good Manufacturing Practice, the chances of success are greatly improved if all the stakeholders in the production of the packaging are connected. That is not always straightforward as some of the steps between the Brand Owner specifying the packaging and the consumer receiving the packaged goods may not be directly connected.

The nature of the foodstuff dictates how it must be packaged and once that is determined the choice of substrate, inks and coatings can be reasonably assessed. The flow chart on pages 18 &19 details some of the questions that need to be considered, with some suggestions of answers.

However, every package is different, so the outcomes may differ according to the perceived risk of transfer of material from the packaging to the food and the barrier properties of the packaging materials used. End use properties may also influence the choice, for example if the food is to be hot filled or heated in the packaging, which might lead to additional risks of migration.

The ink film on a package is extremely thin (of the order of 1-3 g/m^2) and consequently the total quantity of ink involved is likewise very small indeed. Inks and coatings for food and sensitive packaging are specially made for this purpose and are based on materials guidance issued by the European industry bodies representing printing inks: EuPIA and C.E.P.E. (See Glossary for explanation).



Where there is a risk of "set-off" on the reverse side of the print, a functional barrier should be included in the package design. Unless using a specially designed coating, use of a coating or over-print varnish will not normally prevent migration. Set-off can be controlled to some extent by adopting simple procedures, and by ink and coating selection. When conventional oil based inks are used spray powder and/or water-based coating can help reduce the risk. With UV curable inks and coating, the best possible cure should be achieved. Reducing the temperature in the stack will also reduce the risk of volatile component migration, which may be reduced further by "fanning" or airing the stack. Reducing the pressure by creating smaller stacks may also be helpful. In web printing, ensuring the maximum drying or curing and keeping the temperature as low as possible before re-reeling can help reduce the risk of set-off. If practical, lowering web tension to minimize pressure in the reel may also help reduce set-off.

A finished package is produced from >97% substrate and about 0.5% ink and up to 1.5% of coating. The consequence of this is that the substrate plays a key role in both the organoleptic performance of the package and the potential result in migration testing. In general terms for carton board based packaging for food 'pure' cellulose-based board (GZ type) is usually preferred to those containing ground-wood or some recycled material content (GC, GD, GT) but the substrate supplier should be consulted for definitive information and advice.

Reverse Side Carton Board Printing

Under normal circumstances, printing on the inside of the packaging (that is to say printing to the 'non-printing' side of the substrate) should be avoided. In most cases this is undesirable on technical grounds as the reverse side of many folding carton substrates is uncoated and not intended as a printing surface. There is pressure from 'marketing' in some cases to increase the appeal of the packed product by introducing text or images on the normally non-printed side, for example, for competitions or special offers, etc…

Any intentional printing on the inside of a carton or box increases the risk of migration by putting the packed product in very intimate contact with print and/or coating in a confined space. In addition, the ink will penetrate the reverse side of the board during the printing process, more than the outer surface, which is designed for printing. When printing on the uncoated surface, a part of the ink vehicle normally included in the dried or cured matrix (conventional or UV curing) will be preferentially absorbed into the body of the board and so become available for transfer by migration. Partly dried or cured ink greatly increases the risk of migration and can lead to organoleptic changes in the packaged goods.

If reverse printing cannot be avoided, use of low migration inks and coatings is recommended, and the location of the print within the pack should be such that the risk of migration is minimized. Furthermore, it should be noted that the smaller the printed area, the lower the risk. The print should always be as fully dried or cured as possible. Some substrate suppliers now offer two-side printing board, which helps overcome issues of ink and coating absorption, thus reducing the risk of migration.

Direct Food Contact Inks

In rare instances the print on the packaging is intended to be in very close or direct contact with the packaged goods. In these circumstances, it is worth considering whether the printing should be conducted using the same type of ink as used for printing food itself. Such products are specifically designed and formulated from materials that are edible, though the Color range is somewhat limited. These inks may be sourced from specialist suppliers, who also manufacture them in food production compliant conditions.

Microwave & Ovenable Packaging

A key packaging design trend emerging in recent years has been the development of convenience packaging. "Ready meals" that are microwaved or oven cooked in their original store packaging, retail and home use of "cook-in-the-tray" bakery items and even the development of heated airline meals, are growing in popularity.

An increasing proportion of this packaging is now printed in some way and there are growing concerns about the design of such packaging and particularly the risk of potential impact of the packaging on the contained foodstuffs during the cooking process.

It is always a minimum and mandatory requirement to ensure consumer safety when selecting materials for packaging. An additional cooking process being included in a pack design adds to that demand. Foodstuffs packaged in boxes or trays, that are to be cooked by microwaving or in an oven, can be assumed to be subject to a number of conditions, including:

- Close proximity of print to foodstuff
- Long-term storage (extended shelf-life products)
- A wide variety of (uncontrollable) cooking times and temperatures
- Exposure to temperatures in excess of 200°C when cooked in an oven (Note also, the potential effect of air circulation in a fan oven)
- Localized heating in a microwave oven, especially if the packaging includes a susceptor*

Under these conditions, careful attention must be given to packaging design and selection of materials, since there is increased potential for migration from the packaging due to the high temperatures which can be attained during microwave and oven cooking. Potential migrants include thermal breakdown products from pigments, volatile components from the ink and coating vehicle systems, low molecular weight components of inks, coatings, adhesives and the substrate and by-products from the UV curing process. To minimize risk, carefully selected low migration inks and coatings are recommended for these applications. Furthermore, minimising the amount of print on the carton will also help to limit any risk.

*Please note that if the packaging construction includes a susceptor, excessive localized heating can lead to breakdown of materials used in the packaging with currently unknown consequences; printing on, or close to, the susceptor should be avoided.

Selecting Colors With Care

Please note that not all Colors are applicable for high temperature applications and only those based on heat stable pigments are recommended. Even then, exposure to temperatures above 200°C for periods in excess of 30 minutes should be avoided. Low Migration coatings should be used with the inks where gloss, controlled slip properties and print protection are required. In some cases, a cross-linkable water-based coating may be used, but standard water-based coatings should be avoided as they can both melt and break down in elevated temperature conditions.

Watch for potential hazards

There have been a small number of reported instances of a potential fire hazard when containers printed with a printing in incorporating carbon black pigment are heated in a microwave oven. Although these incidents appear to be rare, they have not been subjected to definitive technical evaluation. Consequently, Sun Chemical advises that products printed with carbon black containing inks, intended for microwave applications, should be assessed under appropriate conditions of use to ensure they are fit for that specific purpose. If necessary a trichromatic black blend can be used in place of a carbon black based ink. Please contact your local Sun Chemical representative for more information.

Packaging Safety Responsibilities

Knowledge regarding the performance of different types of printed material in elevated temperature applications is far from complete. It is always recommended that packaging produced for elevated temperature applications is tested to ensure that it complies with legal requirements. It is the printer converters' and packaging distributors' responsibility to ensure the packaging has been fully assessed for risk and that the packaging produced meets regulatory requirements for its end use. Therefore, migration testing under appropriate conditions of use is strongly recommended before proceeding with commercial printing of packaging for microwave or ovenable applications.

Packaging Design Checklist

✓	What	Rationale	How
☐	Define the product to be packaged	Identifies likely packaging requirements	Brand Owner to communicate appropriate information (maybe print buyer if outsourced)
☐	Primary or Primary Outer Wrap (also known as secondary or indirect) packaging?	Defines material requirements and directs selection of materials	Determine if packaged goods are susceptible to migration of components from the packaging as a result of pack design
☐	Supplier packaging brief	Provides pack designer with specific information on packaging requirements	Details essential elements, including substrate type and graphic decoration requirements
☐	Does the packaged foodstuff have any specific characteristics that need special consideration?	High sugar and high fat content foodstuffs and high fibre content drinks, for example, all have a greater tendency to attract migratory materials	Understand foodstuff characteristics and risk assess against the type of packaging chosen
☐	Will the foodstuff be contained in some form of Primary Inner Wrap packaging, e.g. flow wrap or a tray?	Barrier properties of the containment material directs ink and coating selection	Define containment material and risk assess for barrier or migratory performance
☐	How will the product be printed and assembled?	Enables selection of appropriate inks, coatings and adhesives and contamination risk assessment during the production process	Perform risk assessment based on knowledge of package construction and working environment
☐	Any reverse side printing?	Brings ink and coating into close proximity with the packaged food, increasing the risk of migration, and substrate surface may not be suitable for printing (absorbent)	Minimize amount of print and ensure placement to minimize the risk of migration. Always use Low Migration inks and coatings. Check substrate suitability
☐	Ink or coating on glue flaps?	Non-drying conventional inks must be coated in order to avoid set-off or transfer to the reverse side of the package. Adhesives can also be a source of migratory components.	Look carefully at graphic lay out
☐	Microwave or ovenable packaging?	Identifies specific product requirements	High temperature resistant low migration inks and specific types of coating required

Designing Packaging with Certainty Part II – Selection of Materials

SELECTION OF MATERIALS DEPENDS ON THE NATURE OF THE PACKAGED FOODSTUFF AND IS ULTIMATELY THE RESPONSIBILITY OF THE PACKAGING PRINTER CONVERTER

Material selection depends very much on the packaging end use requirements. For example, is the packaging intended for food or non-food applications? If for food, is it Primary Packaging, where the packaged goods are in prolonged direct contact with the non-printed side of the packaging? Alternatively, is it designed for Primary Outer Wrap (also known as secondary or indirect) packaging, where the goods are retained within some form of primary packaging, such as a flow wrap or tray? Is that primary packaging a barrier to migration? Will the packaging undergo some form of secondary processing, for example, in an oven or microwave? Does the packaged food contain materials that make it a higher risk for migration, for example due to high sugar or fat content?

Within GMP, all the stakeholders in the production and distribution of the packaging need to communicate with each other to ensure the packaging complies with relevant regulations and ultimately to ensure consumer safety. This includes all elements of specification and traceability, as well as what is to be packed and how.

When printing primary packaging, low migration inks, coatings and other consumables should be used.

Low migration UV curing inks and coatings are based on proprietory raw materials including in particular high molecular weight oligomers and polymers, together with polymeric photo-initiators, which are multi-functional and non-migrating. Formulations are normally 100% solids and:

- Avoid the use of low molecular weight raw materials including solvents
- Use polymeric photoinitiators
- Are fast curing with a high cross-link density

Low Migration EB curing inks and coatings are formulated using similar principles to UV curable products, but with careful selection of materials to provide optimized EB curing. The key difference is that EB curing formulations do not contain photoinitiators as the energy provided by electron beam irradiation is sufficient to promote curing. Curing usually takes place in an inerted chamber, with a Nitrogen atmosphere preferred when producing food packaging.

Conventional Oleoresinous Inks designed for food packaging are normally based on proprietary raw materials such as specially modified resins, high molecular weight polyesters or vegetable oil derivatives. Unlike UV curing inks and coatings, where a cross linking process is used to “lock in” potential migrants, conventional inks designed for food packaging, are based on high molecular weight and high boiling point vehicles which, under normal circumstances, do not migrate. They are therefore fit for applications requiring a low migration performance.

Vegetable oil esters, the “liquid” and therefore the potential migratory component of “Low Migration” Conventional inks, have been assessed toxicologically by the European Food Safety Authority (EFSA). Due to the low toxicological concerns European Food Safety Authority did not assign a Specific Migration Limit so the Overall Migration Limit (OML) should apply. Many of these types of materials have a proven metabolic route to innocuous substances if consumed and a Global Migration Limit (GML) of 60ppm applies. As a consequence, they are regarded as low risk materials.

Note: The oxidation drying process normally used in non-low migration conventional ink products can produce oxidation bi-products. Low migration conventional inks are therefore designed as non-drying products and a suitable in-line coating MUST be used to avoid set-off and marking during finishing.

Low migration water-based coatings are specially formulated for use over conventional and UV curing inks. These formulations avoid the use of ingredients that have been identified as potential migrants. Water-based coatings are made from specially selected polymers but also contain coalescing solvents, slip control agents, anti-corrosion and anti-microbial additives in order to be fully effective. In low migration water-based coatings, great care is taken in the selection of all the raw materials to maintain effective print performance, along with appropriate results in low migration testing.

Other consumables for ‘low migration’ packaging printing need to be considered, including:

- Fountain solutions
- Press washes

Fountain solution concentrates are used at 2.5-5% in the fountain and can often contain potential migrants such as:

- Wetting agents
- Alcohol replacements (for low IPA printing)

Your consumables supplier can provide guidance for and instruction on use of a suitable fount concentrate for low migration printing.

Note: Isopropyl Alcohol (IPA) is a highly mobile potential migrant commonly used at 5-15% in the damping solution fountain. IPA is also highly volatile (VOC) and is therefore unlikely to be a persistent migrant in the print, even though levels could be high immediately after printing. Replacing it is often a high priority for many printers, although this is not always simple. The use of fount concentrates with high alcohol replacement content should be avoided, as these may be ‘persistent’ migrants.

Note: Normal press washes can also be a potentially significant source of unwanted migration. They are by nature both volatile (mobile) and liquid. Contact your supplier to obtain a suitable replacement press wash and follow the guidance given.

A clean press is an essential best practice in low migration packaging printing. A low migration press wash is unlikely to be as economic or efficient as a normal wash and great care must therefore be taken to change procedures to take account of this. It is best practice to wipe the roller and blankets dry to remove all traces of solvent wash after cleaning to reduce the risk of migration.

Note: Don’t forget adhesives used in the folder gluer or laminator. Ask your supplier for suitable products for low migration package production and ask for guidance in best practices in the use of the product. Most manufacturers provide

a 'food grade' product but it is still necessary to ask them for re-assurance that the composition not only meets the appropriate food packaging regulations but also provides good results in package migration testing. Follow the manufacturers guidance.

When printing primary outer wrap packaging where a barrier of unknown properties is present, the printer converter is faced with multiple options.

Evaluating the choices

The checklists and flow charts in the following pages identify some of the questions that need to be asked to aid material selection.

Some choices can be quickly resolved. If, for example, the inner wrap packaging is determined to have no barrier properties, then low migration inks and coatings should be used. The difficulty arises when it is unclear if components of the packaging can find their way into the packaged foodstuff, a situation that can only be resolved by having greater knowledge of the construction of the pack and the application of risk assessment.

Note, however, that producing low migration packaging is not simply achieved by moving to low migration inks and coatings. Migration from many sources can affect the packaged goods and the whole process from concept to distribution needs to be considered.

Where there is difficulty in finding the required information, two certain solutions are either to use low migration inks and coatings with appropriate work practices, or to use standard (non-low migration) inks and coatings and replace the inner wrap with an absolute or functional barrier. Even then, the risk that migration can occur by a different mechanism should be assessed.

Absolute Barriers

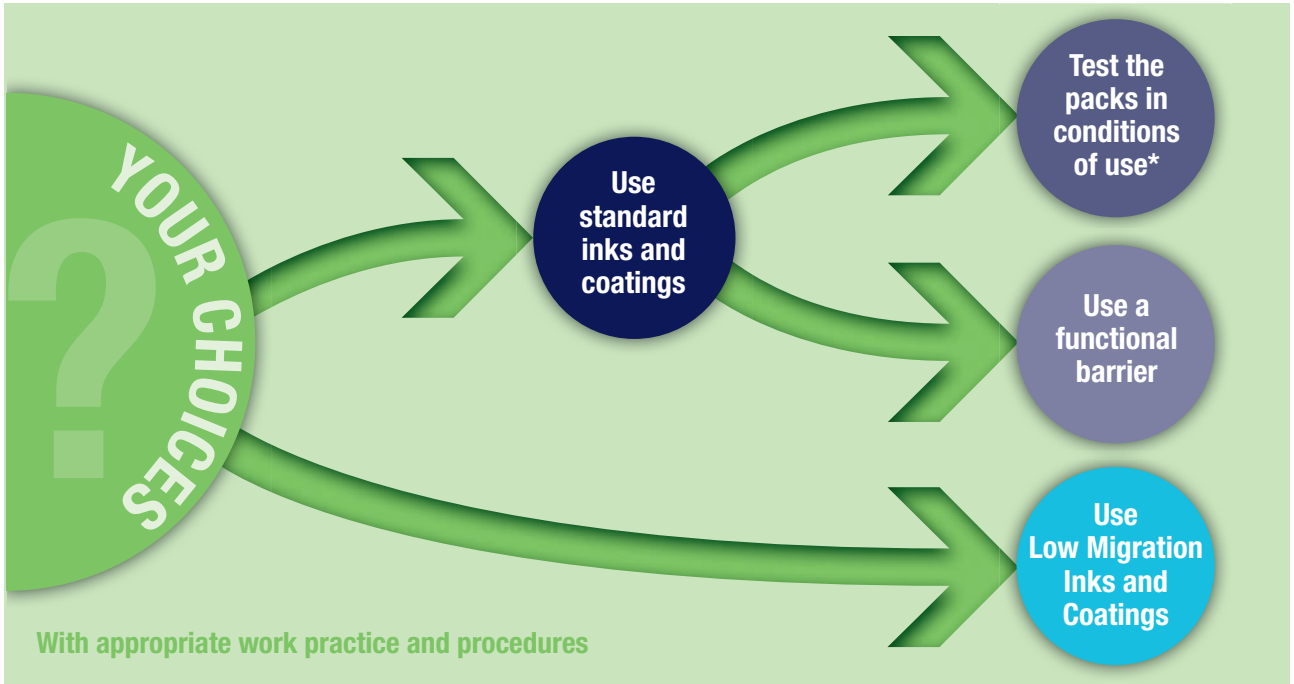
Examples of absolute barriers include glass bottles, metal cans and pouches or cartons that contain a continuous layer of aluminium. Some films, e.g. PET and to a lesser extent OPP, may have barrier properties, depending on thickness. In general olefin films such as PE or HDPE, unless specially treated, have poor barrier properties to many chemical migrants, even though they function well as moisture barriers. However, whilst these options provide a certain outcome, they are also the most expensive options and may not be necessary in practice.

The alternative is to print with standard (non-low migration) inks and coatings and to test the packaging in conditions of use. Ideally, the packaged foodstuff should be tested but, as that is often very difficult, prescribed simulants (see below) for the particular foodstuff are normally used. In general, whilst results from this type of testing are usually reported as "global migration" and represent a "worst case scenario" they provide a good basis for risk assessment.

Testing is best conducted in an expert third party accredited laboratory that specializes in this type of work. Under normal circumstances Sun Chemical, as the ink and/or coating supplier, will provide compositional information to the test house or analytical laboratory, under non-disclosure agreement, to allow effective testing and reporting of results.

Sun Chemical has extensive knowledge in this area, built up over more than 25 years, and can provide an ISO 17025 accredited testing service, the highest level of accreditation for analysis in this area. Sun Chemical also has close working relationships with a number of external migration testing laboratories.

ITS ALL ABOUT SIMPLE CHOICES



* Review results and select appropriate materials.

Migration Testing Interpretation

Once the testing results are received, it is necessary to evaluate them carefully, to understand what has actually been tested, the outer packaging itself (printed or non-printed side), or the whole packaging as it will be used, that is including the inner wrap layer. This information is essential, as the results could be misleading, depending on the test used and how the results are calculated.
In particular, tests made on the non-printed side of the primary package are a good indicator for risk assessment, but the same test run on primary outer wrap material, whilst giving an indication of the level of material that is available to migrate, is not representative of the conditions of use as it does not take into account the properties of the inner wrap.

Additionally, migration results are usually reported according to a standard model, which assumes that 1kg of food is wrapped in 600 cm^2 of print. Calculating to this model can give misleading results if the pack has a high printed surface area and the weight of packaged goods is small. For example, a typical cereal box containing 500g of foodstuff may be supplied in a package that has a surface area of 2000cm^2, i.e. half the weight in the EU model, and more than three times the area. The migration risk is therefore a factor of around six times higher than if calculated using the standard model. Depending on the properties of the inner wrap, this increase in risk may be sufficient to prescribe a change in ink and coating selection to lower migration options, as it is possible that a package construction previously considered as safe may no longer conform to regulations as migration limits are exceeded. As every packaging scenario is different, risk assessment for each is necessary to produce packaging with certainty.

Responsibilities

It is the responsibility of the packaging designer, the printer/converter that manufactures the packaging and the distributor of the product to ensure that the packaging produced meets the requirements of the Regulations and selection of appropriate materials for the end use of the packaging.

Within GMP, the ink and/or coating maker is obliged to formulate packaging inks so as to avoid transfer to the food contact surface though set-off or through migration.
Sun Chemical, along with the other members of EuPIA, subscribe to the position that only low migration offset inks and coatings are recommended for primary food packaging applications, and that ink and coating makers are unable to take any responsibility for the use of non-low migration for primary outer wrap (secondary or indirect) packaging applications. Further, ink and coating manufacturers can not guarantee compliance of inks and coatings in application due to the large number of variables in the pack design, printing and converting processes, over which they have no control. The printer/converter that applies the inks and coatings is responsible for the process of manufacture in order to produce compliant packaging.

Food Simluants

Food simulants and their use are prescribed in a number of EU Directives and Regulations including 85/572/EC, 82/711/EC and (EU) No 10/2011. Simulants A, B, C, D1 & D2 and E are designated as suitable for testing of food contact materials, depending on the nature of the foodstuff that is to be packaged. The following are commonly used:

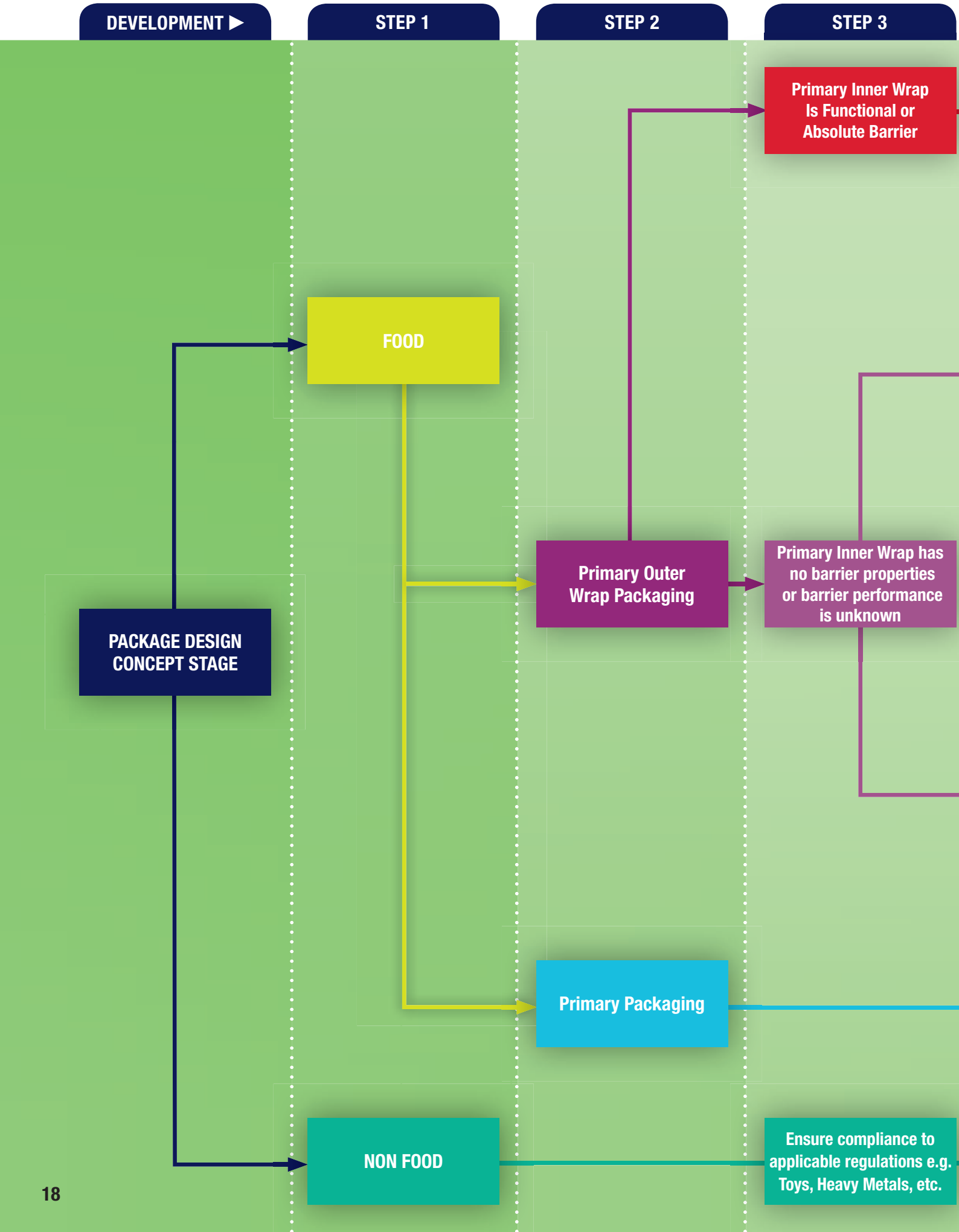
- 3% aqueous acetic acid, for acidic foods.
- Aqueous ethanol at varying concentrations, e.g. 20% to simulate clear drinks, 50% for dairy products and 95% for fatty foods. Isooctane and olive oil may also be used, with the latter chosen to represent all vegetable oil products.
- Tenax®, Poly (2,6-diphenylphenylene oxide) is a highly porous polymer resin that is used as a stimulant for, especially dry, food as it is a very effective absorbent for volatile or semi-volatile materials.

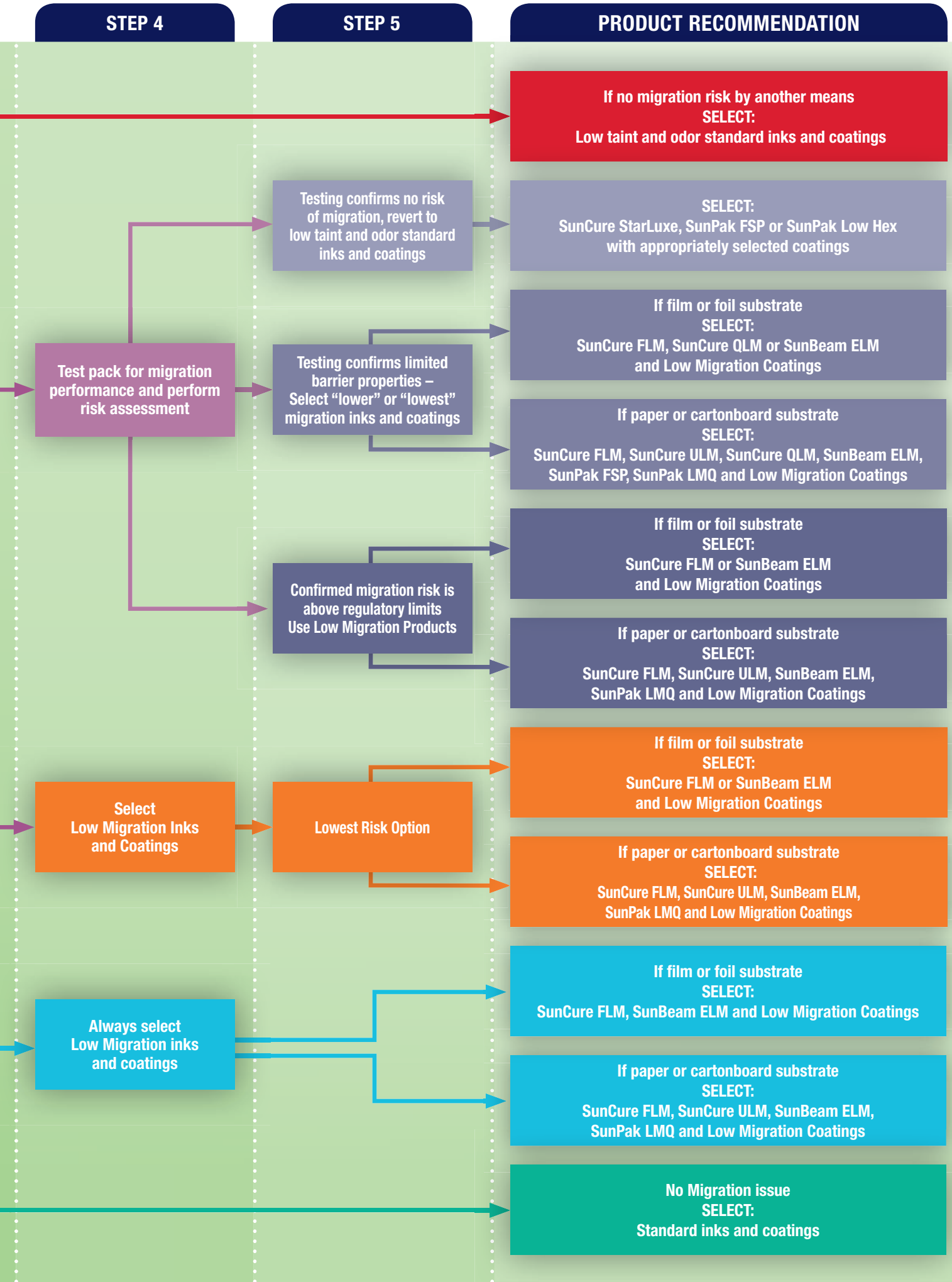
Analytical methods to separate, detect and identify migrants include, in particular, gas and liquid chromatography, with a variety of detectors, including UV and mass spectroscopy. Results are usually calculated to an EU standard model, whereby 1kg of food is assumed to be wrapped within 600 cm^2 or 6 dm^2 of print.

Selection of Materials Checklist

✓	What	Rationale	How
☐	Food or non-food packaging	Different ink and coating choices are available, depending on end-use requirements	No special requirements for non-food packaging, standard products usable, noting other regulatory needs, e.g. CONEG, Toys Regulations etc…
☐	Primary packaging? Is the foodstuff in prolonged direct contact with the non-printed side of the packaging?	Need to minimize the risk of set-off onto the contact side, e.g. milk or juice cartons	Always a low migration application
☐	Primary Outer Wrap, also known a secondary or indirect packaging?	Choice of ink and coating depends on what else is used in the package construction	Check composition and properties of the primary inner wrap or containment layer, e.g. flow wrap or tray
☐	Primary inner wrap is a known absolute or functional barrier to migration	If there is no migration risk from other sources, standard low odor inks may be used	Confirm barrier properties and risk assess. Select appropriate standard inks and coatings
☐	Primary inner wrap has unknown barrier properties	Risk exists that migration may exceed regulatory limits with standard inks and coatings	Use LM products OR test in conditions of use, assess results and select appropriate inks and coatings
☐	Primary inner wrap has no known barrier properties	Selection of inks and coatings depends on testing and risk assessment	Most times, use LM inks and coatings
☐	Primary inner wrap has known limited barrier properties	This scenario opens up more options in selection of inks and coatings	Ensure the use of products that give levels of contamination below regulatory limits. Test to confirm compliance in conditions of use before commercial printing
☐	Package will be used to cook contents in an oven or microwave	Requires special inks and coatings	LM products based on heat resistant pigments must be used. Coatings need to be specially selected. Note that Microwave cartons that contain a susceptor should not be printed
☐	Package will contain reverse side print	Risk of migration greatly increased due to proximity of ink and coating to food. Substrates may not be suitable as not designed for printing (absorbent)	Minimize amount of print and ensure placement to minimize the risk of migration. Always use Low Migration inks and coatings. Check substrate suitability
☐	Ink and/or coating will be in direct contact with food	Printing inks, unless specially designed for the purpose, are not suitable for direct food contact	Obtain specialist products, e.g. edible inks

Designing Packaging with Certainty – Route Finder




STEP 4
STEP 5
PRODUCT RECOMMENDATION
If no migration risk by another means
SELECT:
Low taint and odor standard inks and coatings
Testing confirms no risk of migration, revert to low taint and odor standard inks and coatings
SELECT:
SunCure StarLuxe, SunPak FSP or SunPak Low Hex with appropriately selected coatings
Test pack for migration performance and perform risk assessment
Testing confirms limited barrier properties – Select "lower" or "lowest" migration inks and coatings
If film or foil substrate
SELECT:
SunCure FLM, SunCure QLM or SunBeam ELM and Low Migration Coatings
If paper or cartonboard substrate
SELECT:
SunCure FLM, SunCure ULM, SunCure QLM, SunBeam ELM, SunPak FSP, SunPak LMQ and Low Migration Coatings
Confirmed migration risk is above regulatory limits Use Low Migration Products
If film or foil substrate
SELECT:
SunCure FLM or SunBeam ELM and Low Migration Coatings
If paper or cartonboard substrate
SELECT:
SunCure FLM, SunCure ULM, SunBeam ELM, SunPak LMQ and Low Migration Coatings
Select Low Migration Inks and Coatings
Lowest Risk Option
If film or foil substrate
SELECT:
SunCure FLM or SunBeam ELM and Low Migration Coatings
If paper or cartonboard substrate
SELECT:
SunCure FLM, SunCure ULM, SunBeam ELM, SunPak LMQ and Low Migration Coatings
Always select Low Migration inks and coatings
If film or foil substrate
SELECT:
SunCure FLM, SunBeam ELM and Low Migration Coatings
If paper or cartonboard substrate
SELECT:
SunCure FLM, SunCure ULM, SunBeam ELM, SunPak LMQ and Low Migration Coatings
No Migration issue
SELECT:
Standard inks and coatings

Designing Packaging with Certainty Part III – Printing Equipment & Management

COMPLIANT FOOD PACKAGING PRINTING CANNOT BE ACHIEVED BY SIMPLY SWITCHING TO LOW MIGRATION INKS AND COATINGS

If a printing press can be dedicated to low migration printing, this is the ideal situation offering several advantages:

- Reduced downtime in changeovers
- Reduced cleaning
- Reduced waste
- Allows optimized dedicated working practices

However, normal circumstances dictate that this is not the case and therefore the starting point for any food packaging printing is to ensure that the identified press is free from materials that could affect the migration properties of the print.

Trace amounts of contamination from the printing press itself can adversely affect the packs' migration performance. Therefore the whole design process from pack design, selection of materials, press and pressroom environment as well as appropriate storage also needs to be in place.

Transitioning to low migration printing

The following list relates to offset presses and is **not exhaustive**, but should provide the basis for a code of practice in the changeover from normal to low migration production.

☐	Fully instruct all operatives on the objectives of the job and potential risks for contamination.
☐	Empty all ink and coating ducts and pipes.
☐	Wash the press thoroughly including all rollers, blankets and coater aniloxes.
☐	Clean with copious amounts of water.
☐	Change the fount to one recommended for use with the ink system and clean the mixing and storage tanks, filters and pipes in the process.
☐	Change the coating using plenty of water and rinse the supply pipes*.
☐	Clean all ink knives. NB: On Heidelberg presses change all duct foils.
☐	Check that all consumables being used are the correct grade for low migration printing.
☐	Fix new plates.
☐	Fill the duct with the low migration inks.
☐	If required use only supplier recommended additives, respecting the maximum level of addition.
☐	For the first print, run a large quantity of run up sheets (ideally 3000+) should be printed as a way of removing any last traces of 'non-LM' materials.
☐	If ink is supplied to press from a drum, make sure there is no contamination from previously used inks by using a clean pump and pipes.
☐	If a 'bag' is used in lining the drum, ensure that the liner is suitable for use with low migration inks.
☐	Leave the pile of print with the printed material open and unwrapped (or use a pile turner) for a short while after printing to let any volatiles evaporate.
☐	Cover the pile of print before any transport to print finishing or subsequent processing.
☐	Ensure all subsequent processes are free of the risk of migration from: • Solvents • Plasticisers • Oils and greases • Other potential migrants

*Cleaning the coating supply system with water applies to water based coatings only. For UV coatings, follow the same procedure as UV inks by using a wash specifically formulated for the task.

Press Rollers

Press rollers retain quantities of ink and wash solvents in normal use. When moving to low migration printing these retained migrants may come out of the rollers and adversely affect results in migration testing. Whilst it is unlikely that, under normal conditions of use, unwanted migration from wash-up and fount materials will result, if the packaging is to be used at high temperatures, such as when used in a cooking process, then some risk exists. During the production of low migration printing, when cleaning the rollers and blankets, always wipe them dry before recommencing the print run to minimize any contamination of the first prints.

Rollers should be correctly set to minimize misting which can be a source of air-borne contamination. High roller train temperatures can also lead to misting, so use of cooling rollers and correct setting of oscillating rollers can also help to minimize air-borne particles.

Flexo units and coaters

As with offset printing, it is necessary to ensure operatives understand the risks associated with and the working practices required for the safe production of print intended for food packaging. In particular, the following need to be considered:

- Ink/coating pans should be changed before printing with low migration products and should be thoroughly clean.
- Ink/coating pick up rollers should be thoroughly clean, or ideally replaced with ones dedicated to printing with low migration products.
- New plates are recommended, to avoid contamination with inks previously used.
- Dedicated or thoroughly clean aniloxes are recommended.
- If pumping inks and/or coating to press, a separate set of pipes is recommended, dedicated to printing with low migration products.
- Ensure the pump itself is thoroughly clean.
- Ensure in-line tooling is free from contamination from print previously produced.

In summary, all rollers and equipment throughout the press that can come into contact with the substrate should be checked, cleaned or replaced as necessary.

Ink mixing and Color matching

Many of the inks needed in packaging printing are mixes, spot Colors or brand Color matchings. Care must be taken to use all components of the blend from the same series of low migration inks. Even a small amount of a ‘non-LM’ or standard ink can have an effect compromising the low migration and low odor performance.

Press and Printing Checklist

✓	What	Rationale	How
☐	Press is free from materials that could affect migration properties of print	Trace amounts of material from previously used inks and coatings can migrate into new inks and coatings. Machine oils and cleaning materials can also cause problems	Develop an effective change over procedure, washing and reconditioning of rollers, use new blankets and check fount, dual piping for coaters etc…
☐	Use of Press washes	Washes are a source of odorous and low molecular weight chemicals that can affect taint, odor and migration	Check composition with supplier, develop a procedure for washing to ensure full removal, flush off with water
☐	Rollers	Rollers absorb materials that are retained, but may come back out into fresh inks, even long after use	Ensure cleanliness, recondition with fresh ink extender or transparent white, if problem is persistent the only solution may be to replace the rollers
☐	Aniloxes	Anilox cells may retain materials from previously used inks coatings that may come back out into fresh inks, even long after use	Ensure aniloxes are thoroughly cleaned. Where possible, for critical work, dedicated aniloxes may be preferred
☐	Use of maintenance chemicals	Potentially full of materials that can migrate to cause taint and odor problems	Check suppliers literature or with supplier. Ensure good cleaning after use
☐	Use of oils and lubricants	Usually based on hydrocarbon materials, so a migration risk	Check that none of these materials become co-mixed with consumables during the printing process
☐	Use of fountain solutions	Source of potential migrants, especially if there is a build up of ink in the filter system	Check supplier data. For critical work, dump old fount and start with freshly made material. Note that some Heidelberg presses have reserve tanks, check
☐	Duct foils	Old ink can build up or be retained, so may be a potential source of unwanted contamination	Change if in doubt!
☐	Spray powder	Excess causes housekeeping problems, including damage to lamps and reflectors in curing systems	Minimize use, check suppliers information to ensure suitability
☐	UV lamps	Output efficiency deteriorates with use, reflectors can become dirty, both leading to reduced potential for cure	Monitoring of the curing system is essential, with lamp replacement when required and regular, careful cleaning of reflectors
☐	EB unit	Cure is inhibited by Oxygen, leading to poor crosslinking and film properties	Ensure EB curing chamber is effectively inerted and Nitrogen knives are correctly set
☐	Extraction units	These remove volatile materials and dust and must be working effectively	Routine inspection, maintenance and repair. Ensure any recycled air is free from particulates or Vapors

Designing Packaging with Certainty Part IV – Press Room, Handling, Transport & Storage Environment

NON PRINTING ACTIVITIES CAN CONTRIBUTE TO THE CONTAMINATION OF PRINTED PACKAGING

A number of housekeeping and work place best practices need to be considered regarding the general handling and storage of materials and printed packaging.

Avoid strong smells in all storage areas

There are storage or waiting periods at various points in the process of package production. At each stage perform a risk assessment to identify any potential sources of contamination and take appropriate action.

Paper and board in particular, are very receptive to airborne migration of volatile materials and are very absorbent both to Vapors and liquids such as those from press washes or conventional inks in the pressroom atmosphere. In particular storage conditions of >60% R.H. should be avoided to help prevent the growth of micro-organisms, and keeping unprinted substrates stored in plastic wrap helps to avoid exposure to airborne volatiles from other work in progress or cleaning or painting, etc…

From substrate delivery through to the finished goods warehouse, the package is open to possible contamination by airborne or other pollutants such as vehicle exhaust fumes. An audit of each potential or actual storage or transit area, looking for potential migrants, can help in implementing preventive and corrective actions to avoid contamination of packaging in production.

Floor cleaning

It is recommended to either clean the floor and then ventilate the area thoroughly or use cleaning processes free of volatile components capable of migrating to stacks of work in progress. Dust covers on stacks serve a useful purpose to exclude particulates but even fully shrink wrapped stacks are not free from potential contamination by migration if the area contains volatile solvents in the air.

Painting (building infrastructure and signage)

Ensure careful choice of paints and coatings to avoid possible contamination from solvents or oxidation by-products coming from the paint or coating which could adversely affect the package in all stages of production. Where high resistance paint and coatings are essential (floor and metal beam coatings for example) it is best to ensure complete drying and airing before using the area. Some paint and coating manufacturers can give good advice on products suitable for use in sensitive applications such as food processing, including acceptable thinners and application methods.

Fumes and Pollution

Exhaust fumes from any diesel or petrol driven vehicles should not be allowed to impact on work in progress or print stored in warehouses. The hydrocarbons found in fossil fuels are particularly problematic concerning volatility and potential migration or transfer. Exhaust fumes can contain non-burned hydrocarbons and sulphur compounds, with potentially significant adverse impacts on migration performance. Check any area at risk and ensure good ventilation.

Migration is time and temperature dependant

If potential migrants exist in a package, then the risk of unwanted transfer to the packaged food or other goods can increase with time. This can be a two way process with volatile materials being lost from the package through evaporation as well as the reverse. From a temperature perspective, generally speaking, the rate of migration of volatile and mobile unwanted migrants increases 2-fold for each increase in temperature of 10°C. Normally migration is only a problem with liquids and gases (Vapors). Those materials with significant Vapor pressures at normal temperatures are the most likely to migrate…they are also the materials most likely to evaporate and to be lost during the airing process.

Packaging work in progress needs to be stored and transported at normal temperatures. Maintaining stable normal temperatures during the whole process is not only important for dimensional stability of the package but also important in minimising migration.

Working Environment Checklist

✓	What	Rationale	How
☐	Cleanliness/Housekeeping	Avoids contaminant materials	Assessment and good working practices
☐	Warehouse	Wide variety of materials may be stocked, including volatile solvents and other contamination risk items	Review storage conditions and segregate high risk materials
☐	Substrate storage	Substrates, especially carton board, can readily absorb volatile materials	Minimize exposure to the working environment up to the point of use
☐	Transport	Exhaust fumes are readily absorbed into substrates. Mixed loads may introduce the risk of contamination	Avoid exposure to exhaust fumes and check groupage when transporting to ensure risk of contamination is minimized
☐	Packing	Can be a good protective mechanism against contamination, but may also be a contributor, e.g. plasticizer from film	Risk asses and ensure use of appropriate materials
☐	Airborne dust, work in progress	May carry contaminants and affect low migration properties, also may affect printability of inks and coatings	Good hygiene and work environment, extraction with filters where air is re-circulated
☐	Pallets	Slime and mould control agents have been shown to migrate and can cause taint and odor problems, even in very small quantities (parts per trillion)	Ensure freedom from mobile chemicals from wood treatment
☐	Cleaning chemicals	Contain a wide variety of materials that could cause contamination of print	Suppliers data checked by competent person to verify suitability, plus good working practices
☐	Building works / Construction activities near or on site	Particulate materials can cause printing problems and reduce curing equipment efficiency. Paints and varnishes contain volatile solvents	Project manage to take account of risks
☐	Traceability	Essential component of Good Manufacturing Practice	Develop and implement easy to use recording systems

Legislation

RELEVANT TO PRODUCTION OF LOW MIGRATION PACKAGING

In general terms food packaging legislation covers the guiding principle that food packaging should not transfer materials to the packaged food in quantities that could bring about a change in the nature, substance or quality of the food and must not be injurious to health.

This can be a difficult area and outside advice can be useful. Best practice would indicate following appropriate legislation using trained personnel and to contact your trade association or qualified experts for help and assistance whenever needed.

Food Contact Materials Framework Regulation EC 1935/2004

This regulation has legal status in all Member States and covers all materials in contact with food, including packaging. Additionally the Plastics Regulation (EU) No. 10/2011 (formerly the Plastics Directive 2002/72/EC) covers plastic food contact materials and articles and contains a positive list of component monomers and additives. Many of these components have been assigned SML's. The migration limits also apply to migration from the printed plastic packaging, but the printing inks and coatings are not themselves directly covered. There are no measures yet specifically for paper and board. Some member states have national regulations in addition to the Framework Directive, for example, France, Germany, Greece, Italy and The Netherlands.

- In the USA the food supply chain must comply with 21 CFR parts 170-189.
- In Europe the Council of Europe expert groups has developed resolutions for several food contact materials in the absence of harmonized legislation.

Council of Europe Resolutions for food packaging and food packaging ink

These take the form of Resolution AP(2002)1 on paper and board materials intended to come into contact with food and Resolution AP(2005)1 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with food, together with technical annexes that provide a policy statement concerning paper and board and printed food packaging. However, the technical annexes are not complete even after many years. The future status remains unclear such that very few packaging inks can be produced according to AP(2005)1 and the Resolution in its current form is widely regarded as unworkable.

Swiss Ordinance SR 817.023.21

In 2005, the Swiss Federal Department of Home Affairs (FDHA) published an Ordinance on Foodstuffs & Utility Articles. In March 2008, an amendment to this legislation was adopted that dealt with Packaging Inks and Materials used in their manufacture. The amendment stated that the new requirements would become law after 31st March 2010 and this is now known as the "Swiss Ordinance". This regulation demands that packaging inks for packaging articles coming into contact with food can only be manufactured from lists of permitted substances set out in Annex documents to the legislation.

- There are two Annex documents:
  - Annex 1 (Lists I and II) – monomers and additives authorized for use in food contact plastics, taken from EU 'Plastics Directive' 2002/72/EC + amendments
  - Annex 6 – all other packaging ink raw material substances
- Substances in Annexes are categorized (by chemical type) then split as:
  - List A: Evaluated i.e. those substances having verified toxicological data, SML etc
  - List B: Non-Evaluated i.e. those substances requiring toxicological evaluation

List B Substances automatically have a migration limit of 10 ppb (0.01 mg/kg food) imposed until an evaluation has been completed. They may then move to List A. All substances included in the Ordinance, that is in List A or List B status are permitted in the production of food packaging. Substances not listed are not permitted.

The 'Swiss Ordinance' also requires that the EC Food Contact Materials Framework Regulation (EC 1935/2004) be met and that migration limits for substances listed in Annex 1 and Annex 6 must be met and that good manufacturing and printing practices must be used.

The Swiss Ordinance only applies to packaging materials for foodstuffs that are:
i) Manufactured in Switzerland, or
ii) Imported into Switzerland

It has no legal status in any other country, including EU member states at the time of writing. However, multi-national companies may require that their packaging conform to the requirements of the Ordinance wherever it is manufactured on a global basis.

Note, some substances are not required to be listed, for example polymers made from listed monomers, pigment additives, certain salts of listed acids, etc.

The Swiss Ordinance legislation is aimed at controlling what is used in, and can migrate from food packaging. The requirements are summarized as follows:

- The duty to comply with the migration components of the Swiss Ordinance lies with the printer, packaging converter and end user and not with the ink manufacturer because ink makers cannot control migration from the final package.
- The ink maker has the responsibility to select materials that are listed in Annex 1 & 6.
- To comply the packaging converter or end user must ensure that:
  - Materials used to formulate the inks on the packaging only contain substances listed in the Ordinance.
  - Remember, materials from both A and B status can be used, but materials in List B can only migrate at the 10 ppb level (0.01 mg/kg food).
  - Migration of all listed substances migrating from the packaging, into the foodstuff must be below the limits specified.
- There is therefore a clear duty of care upon the ink manufacturer on how their inks are formulated.

Originally, it was intended that all packaging made on or after 1st April 2010, must use inks that are in line with the requirements of the Swiss Ordinance, but due to the incompleteness of the raw material listings, enforcement will not begin until the Swiss Authorities provide a new deadline. At the time of writing, this is expected to be from the start of 2012.

Also, at the time of writing, the German and Spanish Authorities are in the process of developing similar regulations.

In particular, the German Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) have published a draft proposal to amend the German Commodities Regulation in include printing inks and printed food contact materials. This "German Inks Ordinance" is structured along similar lines as the Swiss Ordinance, with a list of substances allowed to be used in the manufacture of food packaging inks, and migration limits for substances migrating from the printed packaging. It should be noted that the draft released for stakeholder consultation has a different set of evaluated substances, and with some different migration limits, as compared to the Swiss Ordinance. This German proposal may become the basis of EU-level legislation in the longer-term.

REACH EC 1907/2006

New EU Legislation known as REACH (the Registration, Evaluation and Authorization of Chemicals Regulation) EC No. 1907 / 2006 came into force on June 1st 2007. It is introducing major changes into the way chemicals, including inks and pigments, are managed throughout the European Union and presents a significant challenge to chemical supply chain management.

The key objective of the legislation is to improve protection of human health and the environment, through placing the onus onto industry, to show within a specific timeframe, that the chemicals it uses are safe. For example, manufacturers and importers are responsible for developing exposure scenarios and communicating these via extended Safety Data Sheets. Downstream users have a right to communicate their use of a substance up through the supply chain to ensure appropriate exposure scenarios and assessments can be made. In addition, safe use and handling measures for a particular application or use must be communicated by the suppliers down the supply chain and information regarding the presence of certain very hazardous materials in finished products ("articles") must be provided. Finally all existing substances are treated under the same regulatory framework as new substances. Pre-registered existing substances are known as "phase in" substances; other substances will be considered "new substances".

REACH applies to all EU countries and will be enforced on a national basis within each EU member state.

REACH demands that any chemical substance produced or imported into the EU in quantities of 1 Tonne or more per year must pass under the scrutiny of the specific requirements detailed in the legislation. The responsibility for compliance with the legislation resides with any company responsible for manufacturing, importing, using or placing a substance, preparation or article into the EU market. This includes suppliers, distributors, downstream users and retailers. The whole supply chain is required to be involved in communication along the supply chain, and according to position in the chain, responsibilities will vary.

Phase 1	**1st June 2007 REACH Legislation came into force**
	1st June 2008 Pre-registration of chemicals begins (for existing phase in substances)
	1st December 2008 Pre-registration ends (for existing phase in substances) 30th November 2010
	Registration deadline for substances in quantities >1000 T/year and certain substances of very high concern
Phase 2	**31st May 2013 Registration deadline for substances in quantities >100 T/year**
Phase 3	**31st May 2018 Registration deadline for substances in quantities > 1 T/year**

Sun Chemical has been actively working in this area since 2001 and has committed significant resources to support our customers through this process and will provide technical support on an ongoing basis to ensure success for our customers and all our partners in the print industry.

Other Considerations

Traceability

Regulation 1935/2004 provides for traceability and came into force on 27/10/2006. In the preface to HACCP for food packaging (see glossary) the regulation EC178/2002 on traceability is quoted. In summary, the Regulations on traceability can be summarized as follows:

- The traceability of materials and articles shall be ensured at all stages to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.
- With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials and articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.
- The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

GMP Good Manufacturing Practice EC 2023/2006

Regulation 1935/2004 demands production by GMP, which has been elaborated in the subsequent Regulation on Good Manufacturing practice EC No. 2023/2006. CEPI has developed a GMP guide that is included in CoE paper resolution Technical document #4. There are questions about the use of recycled fibres and Technical document 3 allows the use of 3 groups of fibres. Both visible and invisible set-off must be prevented in the print process.
See documents in www.eupia.org on this subject. (go to publications, then GMP)

Migration

Specific Migration Limit (SML) restrictions are defined by EFSA (see Glossary) for some substances based on toxicological evaluations. Maximum Quantities (QM) are also defined for heavy metals for example. Measurements are commonly made using food simulants.

Sensory (Organoleptic) Properties

Regulation EC 1935/2004 demands that packaging must not change the organoleptic properties in an unacceptable way. Measurements are made in accordance with EN1230-1 and EN1230-2. At the time of writing, the European Standards Agency (CEN) is preparing a technical report for calibration of sensory testing, so changes may be enacted in this area.

Confirmation of compliance

Compliance must be checked on the final packaging. Ink makers cannot guarantee the compliance of ink products due to the large number of variables in printing.
A third party evaluation may be necessary to cover composition, additives, migration, and micro-biological safety. To avoid costly mistakes and claims, getting up-to-date expert advice in this area must form part of the business plan to print low migration packaging.

Sampling for migration testing

Print samples for testing in low migration printing may need to be collected and transported to a suitable testing station periodically or on specific demand.
The sampling process is crucial in getting the correct results on which to base important decisions.
Communicate with all involved to agree:

- How many samples
- Size of samples
- Unprinted reference samples
- Packaging of samples for transport (to avoid contamination)

The following samples may be needed:

1. Unprinted samples from the in-feed stack
2. Unprinted samples after being passed through the press with the inkers off and coating off
3. Unprinted samples after being passed through the press with the inkers off but coating on
4. Printed sample uncoated
5. Printed sample coated

Samples should be taken 12-24 hours after printing. 10-15 sheets of A4 size should be taken and made up into 5 identical packs of 3 sheets and should be packed individually in thick unwashed aluminium foil.

It is not the role of the material supplier to act as a forensic laboratory. Detailed results for migration testing can only be relied upon if provided by an accredited expert laboratory.

Order of Legislative Responsibility

Where food contact legislation for the packaging material or for separate components of composite packaging material exists, this should be complied with in the following order of preference:

EU legislation on food contact and national legislation resulting from the transposition of EU legislation.

Where EU food contact legislation is found incomplete then national legislation of EU Member States should be followed. The national legislation that must be complied with is to be determined on a case by case basis, taking into account the following:

- The Member State where the converter is established
- The Member States where the packed product is to be marketed
- Appropriateness of the available legislation
- The principle of mutual recognition

Export outside the European Union

Where packaging materials are exported to a country outside the European Union it may be necessary to deviate from the previous sections. Preference is however given to minimising these deviations as much as possible.

Where deviation is unavoidable, in order of preference, conformity is sought with the most appropriate from the following:

- National legislation of the importing country
- FDA Regulations
- Regulations as specified by the customer

APPENDIX I – A GUIDE TO SUN CHEMICAL INKS & COATINGS SOLUTIONS

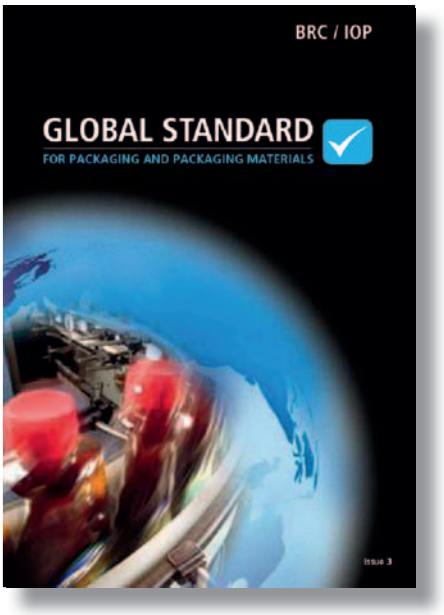
Brand Name	Curing Technology	Process	Application	Expected Migration*&**
SunCure® ULM	UV	Offset	Paper & Board	<10ppb
SunCure® FLM	UV	Offset	Films, Foils, Paper & Board	<10ppb
SunCure® QLM	UV	Offset	Films, Foils, Paper & Board	<50ppb
SunCure® Starluxe	UV	Offset	Non Food Packaging	>50ppb
SunBeam® ELM	EB	Offset	Films, Foils, Paper & Board	<10ppb
SunPak™ LMQ	Conventional Oil Based	Offset	Paper & Board	<10ppb
SunPak™ Diamond	Conventional Oil Based	Offset	Paper & Board	<60,000ppm
SunPak™ FSP	Conventional Oil Based	Offset	Paper & Board	100-<500ppb***

* In correct conditions of use ** Based on standard EU Food Model 600cm^2 wraps 1kg of food *** OML applies of 60,000ppb (60ppm)

Note: SunCure Starluxe is only suitable for outer wrap food packaging if the food is contained within an inner wrap that is an absolute or functional barrier to migration.

Although the data supplied above is believed to be correct, the data is presented without any representation or warranty concerning the suitability, performance or correctness of the product for a particular application or use. Significant variations can occur between test results and the results obtained in actual use. We strongly advise that before purchase the buyer test the product in the specific intended application under conditions expected during use. Suggestions made by Sun Chemical are our opinion only and there is no warranty of the results to be obtained.

APPENDIX II – THE BRC / IOP GLOBAL STANDARD FOR FOOD PACKAGING AND LOW MIGRATION



THE BRC/IoP GLOBAL STANDARD - FOOD PACKAGING AND OTHER PACKAGING MATERIALS

This well known standard has become a benchmark by which evaluations of companies supplying packaging are undertaken, not only in the United Kingdom but in many parts of Europe including Denmark, Sweden and Germany.

Note: This short summary is introduced here to make the reader aware of the Standard and is not intended in any way to replace or supplement the Standard. The Standard is essential reading for anyone intending to produce low migration packaging.

The benefits of complying with the Standard are:

- A single standard and procedure that allows an evaluation by a third party certification body accredited to European Standard EN45011.
- A single verification commissioned by the manufacturer or supplier (at an agreed frequency) provides an excellent status report to meet the needs of food retailers and other organisations.
- The Standard is comprehensive in scope covering quality, hygiene, and product safety throughout the packaging industry.
- The Standard addresses part of the due diligence requirements of the packaging manufacturer or supplier, the packer/filler, and the retailer. Packaging manufacturers may also use this Standard to ensure their suppliers are following good hygiene practices and so help to complete the due diligence chain.
- The Standard is so prepared as to be part of continuous improvement processes. It includes a requirement for ongoing surveillance and the check steps for corrective actions on non-conformance in quality, hygiene and product safety.

The Standard applies to the manufacture of converted packaging used in food packaging and filling. It is also intended to apply to:

- Prior converting operations.
- The supply of packaging from stock where additional processing is required.
- Disposables such as paper plates, cups, aluminium foil, cling film and plastic cutlery.

There are 2 categories of compliance, A and B, based on risk. The lower risk category is A. In a simple case, if the packaging is for direct packaging of food but there is an adequate barrier then the correct procedures can be found in Category A. If the packaging has the potential to contaminate the food then the Category is B.

Note: The Standard also includes a valuable Glossary of Terms and many Best Practices.

A partner who transforms with you.

Today's environment requires more than change. It demands transformation—and a partner who's willing to transform with you. As the world's leading producer of inks and pigments, Sun Chemical gives you 9,500 people working in 250 locations in 56 countries. And every one of those people is working every day to create new solutions for the increasing challenges in packaging, publication, coatings, plastics, electronics, brand protection, and product authentication. We are committed to meeting your needs, while never losing sight of the business essentials: reliable, on-time delivery, consistent product quality, dependable service, and ground-breaking innovation. As you move forward into a world of stiffer competition, faster turnarounds, more complex printing demands, and sustainable products, count on Sun Chemical to be your partner.

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