ILSI Europe
Report Series

Packaging Materials
8. Printing Inks for Food Packaging Composition and Properties of Printing Inks

Report

ILSI Europe
International Life Sciences Institute

Commissioned by the ILSI Europe Packaging Materials Task Force

About ILSI / ILSI Europe

Founded in 1978, the International Life Sciences Institute (ILSI) is a nonprofit, worldwide foundation that seeks to improve the well-being of the general public through the advancement of science. Its goal is to further the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment. ILSI is recognised around the world for the quality of the research it supports, the global conferences and workshops it sponsors, the educational projects it initiates, and the publications it produces. ILSI is affiliated with the World Health Organization (WHO) as a non-governmental organisation and has special consultative status with the Food and Agricultural Organization (FAO) of the United Nations. By bringing together scientists from academia, government, industry, and the public sector, ILSI fosters a balanced approach to solving health and environmental problems of common global concern. Headquartered in Washington, DC, ILSI accomplishes this work through its worldwide network of branches, the ILSI Health and Environmental Sciences Institute (HESI) and its Research Foundation. Branches currently operate within Argentina, Brazil, Europe, India, Japan, Korea, Mexico, North Africa & Gulf Region, North America, North Andean, South Africa, South Andean, Southeast Asia Region, as well as a Focal Point in China.

ILSI Europe was established in 1986 to identify and evaluate scientific issues related to the above topics through symposia, workshops, expert groups, and resulting publications. The aim is to advance the understanding and resolution of scientific issues in these areas. ILSI Europe is funded primarily by its industry members.

This publication is made possible by support of the ILSI Europe Task Force on Packaging Materials, which is under the umbrella of the Board of Directors of ILSI Europe. ILSI policy mandates that the ILSI and ILSI branch Boards of Directors must be composed of at least 50% public sector scientists; the remaining directors represent ILSI's member companies. Listed hereunder are the ILSI Europe Board of Directors and the ILSI Europe Task Force on Packaging Materials industry members.

PACKAGING MATERIALS
8. PRINTING INKS FOR FOOD PACKAGING COMPOSITION AND PROPERTIES OF PRINTING INKS

By Josef Sutter,
Vincent Dudler, Roger Meuwly

REPORT

COMMISSIONED BY THE ILSI EUROPE PACKAGING MATERIALS TASK FORCE

DECEMBER 2011

For more information about ILSI Europe, please contact

ILSI Europe a.i.s.b.l.
Avenue E. Mounier 83, Box 6
B-1200 Brussels
Belgium
Phone: (+32) 2 771 00 14
Fax: (+32) 2 762 00 44
E-mail: info@ilsieurope.be
www.ilsi.eu

Printed in Belgium

D/2011/10.996/22

ISBN 9789078637257

CONTENTS

FOREWORD 4

INTRODUCTION 5

CHARACTERISTICS AND PROPERTIES OF PRINTING INKS 6

COMPOSITION OF PRINTING INKS 7
- Offset printing 8
- Gravure and flexographic printing 10
- UV-curing inks and lacquers 13
- Screen printing 16
- Digital printing (non-impact printing) 17
- Overprint coatings and lacquers 17
- Summary of available ink systems 18

INTERACTION BETWEEN PACKAGING AND CONTENTS 19

INTERNATIONAL REGULATIONS AND GUIDELINES ON PRINTING INKS 21
- Regulations 21
- Guidelines 25

CONCLUSIONS 29

REFERENCES 30

Authors: Josef Sutter, hubergroup (DE), Vincent Dudler, Swiss Federal Office of Public Health (CH), Roger Meuwly, Swiss Federal Office of Public Health (CH)
Scientific reviewers: Andy Boon, Sun Chemical (UK), Konrad Grob, Official Food Control Authority of Canton of Zurich (CH)
Report Series Editor: Kevin Yates (UK)
Coordinators: Tanja Wildemann, ILSI Europe (BE), Massimo Ambrosio ILSI Europe (BE)

All the figures used in this publication belong to hubergroup (DE)

FOREWORD

The present report is the eighth in the report series on food packaging materials, which was commissioned by the ILSI Europe Packaging Materials Task Force. The report series aims at giving a concise overview on specific packaging materials with regard to their uses as packaging material, their basic chemistry, safety and toxicology, regulation and environmental fate. The reports mainly address an audience in the packaging-producing and packaging-using sectors.

Earlier reports have been published on the following topics and can be obtained as a hard copy via publications@ilsieurope.be or downloaded from http://www.ilsi.org/Europe/Pages/PM_Series.aspx.

- PET Packaging Materials (2000)
- Polystyrene for Food Packaging Applications (2002)
- Polypropylene as a Packaging Material for Foods and Beverages (2002)
- Polyethylene for Food Packaging Applications (2003)
- Polyvinyl Chloride for Food Packaging Applications (2003)
- Paper and Board for Food Packaging Applications (2004)
- Metal Packaging for Foodstuffs (2007)
- Multilayer Packaging for Food and Beverages (2011)

INTRODUCTION

Printed food packaging is used to provide information to the final consumer and plays an important role in the presentation and advertising of foodstuffs. Some of this information is legally required, such as weight, vendor details, information about composition, presence of allergens and nutritional details, etc. In addition, printing is carried out for decorative and protective purposes.

There are exceptional instances where printing inks are applied to the inner side of the packaging or on inserts, e.g. for promotional purposes, and intentionally have direct food contact. Direct food contact inks represent a special case and comprise less than 1% of food packaging applications. Such inks are subject to different requirements and will not be treated in this report. This report mainly deals with printing inks applied on the non-food contact surface of food packaging (packaging inks) as outlined in the information leaflet of the European Printing Ink Association (EuPIA, 2009b).

CHARACTERISTICS AND PROPERTIES OF PRINTING INKS

The printing inks and coatings must cope with a multitude of different requirements:

- Ink production: The requirements related to colour and gloss are only met if the pigments used are dispersed as finely as possible. The quality of the dispersion process depends very much on the components used.
- Printability: Continuous improvement of the ink formulations is required to satisfy requirements of increasing press speed, use of new substrates, etc.
- Substrate: Inks need to be customised for their best performance for each substrate they are printed on.
- Finishing: Finishing processes include coating, foil embossing, laminating, gluing, etc. and each has different requirements.
- Packaging: The choice of ink will be influenced by the packaging processes employed, e.g. heat sealing, speed of packaging machines, necessary slip, packing at low temperatures, etc.
- Storage of goods: Temperature and humidity have an impact.
- Package contents: The characteristics and properties of the food have an impact on ink choice (and subsequent formulation).
- Recovery of packaging: Inks are to be considered in the recovery processes for potential impacts in the recovered materials.

COMPOSITION OF PRINTING INKS

The composition of printing inks can be described in terms of their generic components, irrespective of the printing process. However, the type and composition of these components can be significantly different depending on the printing process and on the substrate. The main constituents of printing inks are:

- *Colourants*: insoluble organic and inorganic pigments, soluble dyes
- *Vehicle*: transport medium for carrying pigments through the press and fixing or binding them to the substrate. Vehicles comprise binders (polymers/resins) and different solvents
- *Additives:* (see list below)

Colourants in printing inks

- *Coloured organic pigments*: Classification according to colour index, e.g. PY13, PR57:1; PB15:3; PG7, PB61, PV23
- *White pigments*: Titanium dioxide
- *Black pigments*: Carbon black
- *Metallic effect pigments*: Powdered aluminium or brass
- *Fillers*: Kaolin, chalk

Types of additives used in printing inks

- Acid catalyst
- Adhesion promoter
- Amine solubiliser
- Antifoam agent
- Antimist
- Antistatic
- Biocide
- Chelating agent
- Dispersing agent
- Flow agent
- Jellifying agent
- Inhibitor
- Ink stabiliser
- Optical brightener
- Photoinitiator
- Plasticiser
- Siccative agent
- Slip agent
- Suspension agent
- Thickener
- UV stabiliser
- Waxes
- Wetting agent

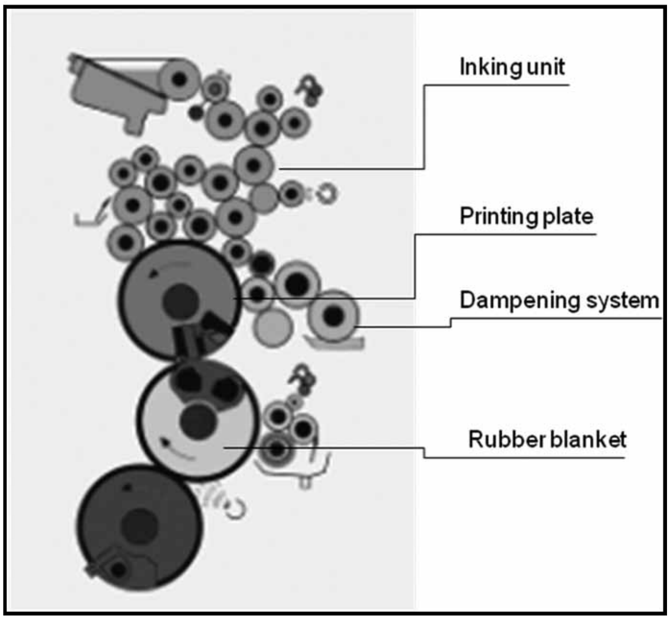
CAS numbers for all ink constituents are listed in Annex 6 of the Swiss Ordinance on articles and materials SR 817.023.21 (FOPH, 2005) and in the EuPIA inventory list (EuPIA, 2011b).

Offset printing

Offset printing remains largely used for paper and board applications. In the offset printing process, the image and non-image areas lie on the same plane and differ only by their wetting characteristics. The non-image areas are hydrophilic and can be readily wetted with water or a mixture of water and alcohol. The image areas (ink-receptive areas) are hydrophobic.

In the printing process, the hydrophilic areas are wetted with the aqueous solution (fountain solution). Inks, by contrast, are transferred only to the hydrophobic part of the printing plate according to the image wanted. A further transfer to the substrate takes place by means of a rubber blanket acting as an intermediate image carrier. The wet ink film has an approximate weight ranging from 0.8 to 1.8 g/m².

Figure 1. Printing unit offset printing



The offset inking unit is made up of a system with a large number of rollers that transport the ink from the ink duct to the printing plate, distributing the ink uniformly and creating a thin film on the rollers. To guarantee a proper flow of ink by this "transport system", the inks have to be of high viscosity. Because of the temperature in the inking unit (approximately 25–40°C), the solvents used must have a high boiling point so that they do not evaporate as the ink is transported through the inking unit. The solvent must have the following properties:

- Able to dissolve the resins used
- Stable in the inking unit
- Ensure good drying of the ink

The following solvents are commonly used in offset inks:

- Mineral oils
- Vegetable oils (linseed oil, soy bean oil, wood oil)
- Fatty acid esters

Mineral oils are mixtures of hydrocarbons and differ by their boiling point and solubility properties (proportion of aliphatic/alicyclic/aromatic compounds).

Solvent boiling point (°C)	Printing process	Means of drying
240–290	Heatset	Solvent evaporation
>320	News printing	Slow setting
280–310	Sheet-fed offset	Setting

Mineral oils used in low-odour inks are generally free of aromatics, because such oils – and therefore inks – fulfil the organoleptic demands for neutrality. Mineral oils are not suitable for food packaging materials and should be replaced by other solvents. These "traditional" mineral oils have nevertheless to be differentiated from "white oils", which are also hydrocarbons, but highly refined and authorised as food additives.

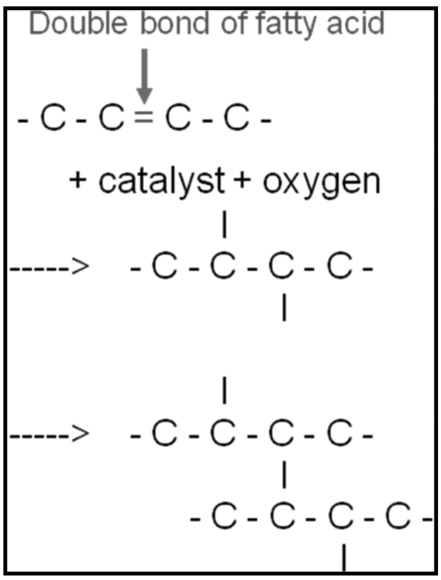
Offset printing is typically used in heatset, coldset and sheet-fed processes. The first technique involves a heat-induced evaporation process and the second uses natural evaporation and subsequent penetration of the solvent in the substrate. These two processes are used for news printing and will consequently not be discussed here.

In the sheet-fed offset segment, vegetable oils and vegetable oil esters are used as alternatives to mineral oils. Their purpose is, on the one hand, to optimise wetting of the pigments but more importantly, to facilitate oxidative crosslinking. Offset vehicles contain 35–50% of hard resins, which are complex rosin esters typically obtained by polymerising combinations of rosin, maleic anhydride, formaldehyde, alkylphenol and pentaerythritol.

Drying of sheet-fed offset inks

Sheet-fed offset printing inks dry either physically by means of setting and/or chemically by crosslinking the vehicle components under the influence of oxygen (oxidative drying). In the case of drying by means of "setting", the liquid components of the ink penetrate the surface of the substrate and the ink film solidifies, leaving the solid components on the surface (pigments, resins). This also means that the solvent remains in the material for long periods of time.

Figure 2: Principle of oxidative drying



The setting mechanism presupposes an absorbing substrate and an adequate quantity of low-viscosity components (e.g. vegetable oil ester). Hence, typical substrates for sheet-fed offset are coated and uncoated paper and board. Plastic films and metal foils do not enable inks to dry by setting. Vegetable oils are viscous and only have a low capacity for setting. Ink films that dry solely by means of the setting mechanism are not very stable mechanically and thus typically require an over-print varnish to provide adequate resistance properties.

Oxidative drying leads to a chemically crosslinked, mechanically stable ink film. Vegetable oils contain double bonds that can trigger a crosslinking reaction when exposed to catalysts (siccatives, i.e. drying agents) and oxygen in the ambient air. These inks dry by free radical auto-oxidation and polymerisation. It generally means that the chains of the vegetable oils link with one another and also with the hard resin. The higher the crosslink density, the more stable the ink film becomes.

Note that during the course of oxidative drying, decomposition products that are strong-smelling (e.g. low molecular weight aldehydes) may be generated. The same process is involved in rancidity of fats. For this reason, oxidative drying is not used when low-odour inks are required.

Important components in offset inks

- Pigments (1–20%)
- Binders (40–65%): rosin resins, maleic resins, hydrocarbon resins, alkyd resins
- Solvents and diluents (5–25%): mineral oils, vegetable oils (soy bean oil, linseed oil, wood oil), fatty acid esters
- Additives (3–6%): waxes (PE/PTFE waxes), siccative agents (cobalt, manganese, zirconium compounds), inhibitors

Sheet-fed offset inks for food packaging

Printing inks produced for food packaging must be formulated in compliance with the EuPIA Guideline, which means that inks are only formulated using food contact approved substances or using substances that do not migrate. For example, the solvents used in low-migration sheet-fed offset inks are typically special fatty acid esters that have been evaluated by the European Food Safety Authority (EFSA) with respect to contact with foodstuffs for which no limit has been set, or which have low or no detectable level of migration. Mineral oils are not intentionally used for sheet-fed offset inks for food packaging. Nevertheless, contamination can happen and the level of mineral oils [especially the aromatic fraction "MOAH" (Mineral Oil Aromatic Hydrocarbons) and saturated fraction "MOSH" (Mineral Oil Saturated Hydrocarbons) of lower molecular weight (<C24)] in the final packaging solutions may need to be monitored.

To prevent deterioration in the organoleptic characteristics of the package contents, offset inks for food packaging must form a film of ink that is organoleptically neutral. In practice this can be achieved by:

- Using rosin-based resins
- Avoiding hydrocarbon resins (with their characteristic odour)
- Using minimised quantities of vegetable oils (with few double bonds)

As low-odour and low-migration inks dry purely by means of setting, it is absolutely essential to apply a suitable overprint varnish to the packages for protection purposes.

Gravure and flexographic printing

Flexographic printing is a direct, rotary process employed to print web substrates. The printing form consists of a flexible relief printing plate made of rubber or photopolymer. The image areas are inked by means of a screen ("anilox") roller into which millions of tiny cells are engraved, which transfer the ink to the printing plate. The size and depth of these cells determine how much ink is applied to the printing plate. The ink is usually applied to the screen roller using closed chambered doctor blade systems. The printing plate transfers the ink directly onto the substrate.

The printing cylinder in the gravure process consists of a thin copper layer into which the image areas are engraved or etched as small cells. The cylinder is inked by being dipped directly into the ink and the excess ink is then wiped off the surface with a steel blade. The ink that remains in the cells is then applied directly to the substrate. Gravure presses are normally also set up for printing web substrates.

In the gravure and flexographic processes, the ink is metered by a screen roller. The cells of the screen roller have to be filled from the ink duct or chambered doctor blade, respectively, and then subsequently emptied onto the printing cylinder or substrate. This means that the ink has to be of low viscosity and not tacky.

The dry ink-film weights applied in the gravure and flexographic processes are between 1.5 and 3 g/m². This equates to a wet film weight of 5–9 g/m² for gravure and 3–6 g/m² for flexographic processes.

For most substrates, solvent-based inks are used, to allow adequate wetting and adhesion. Water-based ink is the usual choice for paper and board, due to the absorbency, and can also be used on non-porous substrates to a limited extent.

Figure 3: Flexographic printing unit

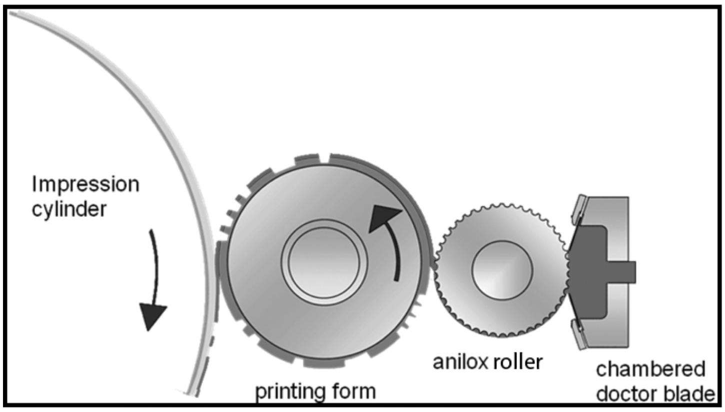
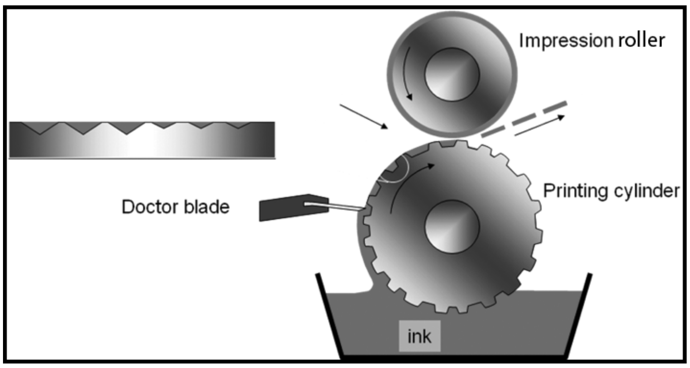


Figure 4: Gravure printing unit



Solvent-based systems

Nitrocellulose (NC) is the most important and most widely used vehicle for inks and coatings. It is soluble in organic solvents such as acetone, ethyl acetate, ketones and alcohols. Most flexographic and gravure packaging inks contain nitrocellulose. Depending on the intended use of the packaging and the substrate, maleic resins and other synthetic resins, such as polyvinyl butyral (PVB), polyamide (PA) and polyurethane are also used.

Solvent release, compatibility and drying are the most important criteria for resins and solvents. In solvent-based systems, the resins are dissolved in the solvent. When the solvent evaporates, a homogeneous film of resin with dispersed pigment particles remains on the surface. This results in a mechanically stable print.

Smaller quantities of slowly evaporating solvents, such as glycol ethers (e.g. methoxypropanol and ethoxypropanol) are used in solvent-based inks as "retarders" to prevent too rapid drying on the press cylinder.

Important components in solvent-based inks
- Pigments
- Binders: nitrocellulose, maleic resin, polyvinyl butyral, polyamide, polyurethane
- Solvents: alcohols (ethanol, isopropanol), esters (ethyl acetate, isopropyl acetate), ethoxypropanol
- Additives: plasticisers (no phthalates), slip additives (lubricants), adhesion promoters

Water-based systems

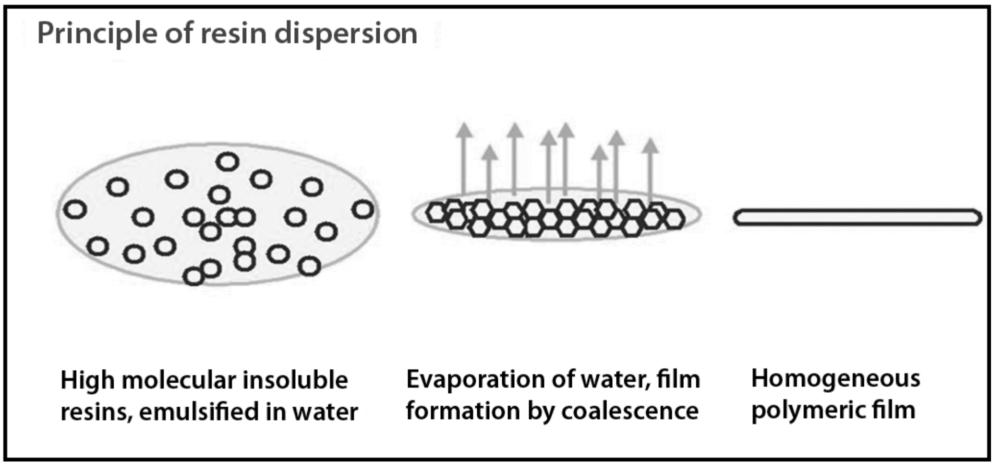
Compared with solvents, water evaporates at a considerably slower rate, and drying a water-based print requires a lot of energy. This is why water-based inks are usually used when the substrate facilitates the setting mechanism (absorption). As a rule, water-soluble resins are not used as the sole binder in water-based systems because the resulting prints are not water resistant.

Polymers containing acid groups can be used to prepare aqueous solutions and dispersions by using a volatile neutralising agent, typically an organic amine, to form an amine salt. This agent evaporates during the drying process so that a water-insoluble print is formed.

Resin dispersions (i.e. colloidal dispersions of fine polymer particles stabilised in the liquid phase) can also be used. Binders used in water-based systems are usually copolymers of acrylic acid and its esters, with styrene and similar vinyl-containing substances, prepared by emulsion polymerisation.

Drying (evaporation and absorption of the water) reduces the space between the "polymer clusters" until they are fused together and form a film. The polymer film consists of a homogeneous polymer composite with correspondingly good resistance properties. This process can be assisted by film-forming agents that promote the "merger" of the individual polymer particles.

Figure 5: Drying of water-based inks by resin dispersion



Dispersions dry rapidly by means of setting (absorption) or evaporation of the water. Small quantities of "retarders", such as propylene glycol or glycol ethers may be used to modify the rate of evaporation. Water-based inks generally contain a mixture of resin solution and a polymer dispersion depending on the requirements for drying, gloss and rub resistance.

Important components in water-based inks

- Pigments
- Binders: styrene-acrylic co-polymers, acrylic co-polymers, maleic resins
- Solvents: water, isopropanol, glycol ether, propylene glycol
- Additives: amines, biocides, defoamers, wetting agents, waxes (PE, PTFE), slip agents

Gravure and flexographic inks for food packaging

Solvent-based inks are needed to print onto a wide range of plastic substrates. Good adhesion and resistance properties on a wide range of plastic films are not easily achieved with water-based inks. Hence, water-based inks tend to be used on porous substrates (e.g. paper, carton board) unless crosslinking agents are used.

In contrast to conventional sheet-fed offset inks, the solvents (and water) used in flexographic and gravure inks are volatile and generally evaporate when the prints are dried. It is important to control this process since too much retained solvent in the dried print not only affects the organoleptic properties of the packaging, but also acts like a plasticiser, increasing the potential for migration and set-off of components from the printed packaging.

Some of the less volatile solvents (retarders), plasticisers and other additives have the potential to migrate from printed packaging into foodstuffs, in the absence of a functional barrier. Evaluated substances must not exceed their specific migration limit (SML); substances not yet evaluated should not migrate above the limit that can be derived from the available toxicological data.

If calculation with the worst case scenario (i.e. 100% migration) demonstrates that potential migrants from a printed food packaging exceed the applicable migrations limits, experiments (migration tests) will be required to demonstrate that the packaging is suitable for food contact application.

UV-curing inks and lacquers

UV-curing systems are used with offset and flexographic printing processes. UV radiation allows the ink or varnish to instantly form a three-dimensionally crosslinked stable film. Crosslinking is triggered by defined UV radiations. Photo-initiators (catalysts) are required to start the reaction. The UV light emitted by the lamps transforms the photo-initiators into free radicals, which instantly react with the double bonds of the acrylate oligomers (UV ink vehicle).

Figure 6: Principle of UV curing

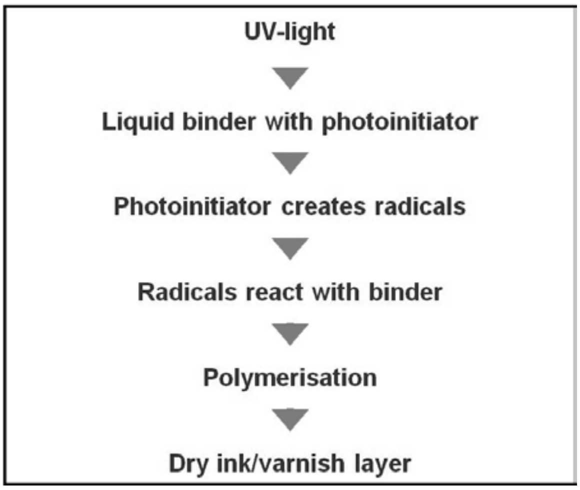


Figure 7: Examples of acrylate oligomers used (from Papilloud and Baudraz, 2002)

Abbreviation	Name	Formula
GPTA	propoxylated glyceryl triacrylate	$(H_2C{=}CH{-}C({=}O){-}O{-}CH(CH_3){-}O)_3CH$
NPpGDA	propoxylated neopentyl glycol diacrylate	$H_2C{=}CH{-}C({=}O){-}O{-}CH(CH_3){-}O{-}CH_2{-}C(CH_3)_2{-}CH_2{-}O{-}CH(CH_3){-}O{-}C({=}O){-}CH{=}CH_2$
TPGDA	tripropylene glycol di-acrylate	$H_2C{=}CH{-}C({=}O){-}O{-}CH_2{-}CH(CH_3){-}O{-}CH_2{-}CH(CH_3){-}O{-}CH_2{-}CH(CH_3){-}O{-}C({=}O){-}CH{=}CH_2$
DPGDA	dipropylene glycol di-acrylate	$H_2C{=}CH{-}C({=}O){-}O{-}CH_2{-}CH(CH_3){-}O{-}CH_2{-}CH(CH_3){-}O{-}C({=}O){-}CH{=}CH_2$
PETA	pentaerythritol tetra-acrylate	$(H_2C{=}CH{-}C({=}O){-}O{-}CH_2)_4C$
TMPTA	trimetylol propane tri-acrylate	$(H_2C{=}CH{-}C({=}O){-}O{-}CH_2)_3C{-}CH_2{-}CH_3$
TMPeoTA	ethoxylated trimetylol propane tri-acrylate	$(H_2C{=}CH{-}C({=}O){-}O{-}CH_2{-}CH_2{-}O{-}CH_2)_3{-}C{-}CH_2{-}CH_3$
HDDA	hexane diol di-acrylate	$H_2C{=}CH{-}C({=}O){-}O{-}(CH_2)_6{-}O{-}C({=}O){-}CH{=}CH_2$
TMPpoTA	propoxylated trimetylol propane tri-acrylate	$(H_2C{=}CH{-}C({=}O){-}O{-}CH_2{-}CH(CH_3){-}O{-}CH_2)_3{-}C{-}CH_2{-}CH_3$

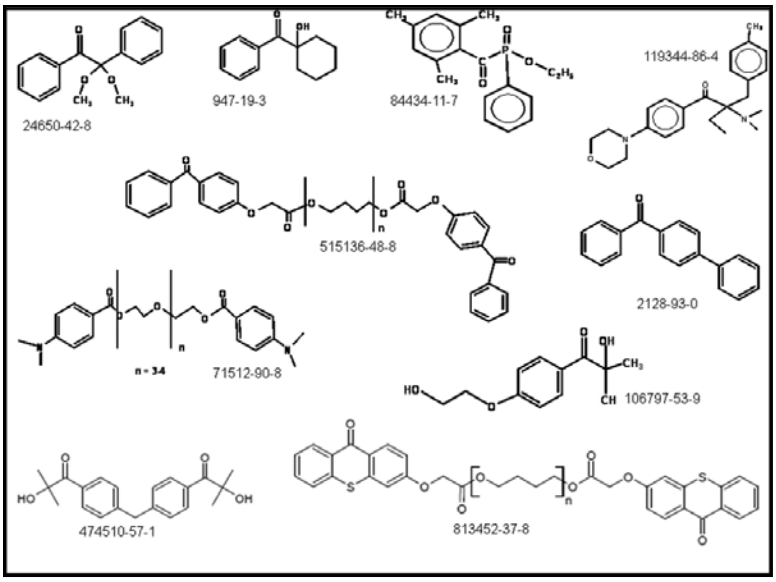
These oligomers are very viscous polymers and prepolymers containing reactive acrylate groups. They are usually subdivided according to the chemistry used in their manufacture or polymer structure (e.g. epoxy acrylates, polyester acrylates, urethane acrylates). They are the skeleton of a UV ink and ensure its important properties such as adhesion, resistance and flexibility.

Multifunctional acrylates are used as reactive diluents (often referred to as "monomer") and act as a kind of solvent. They influence the curing speed and give the ink the viscosity required for printing. They control the crosslinking density of a UV ink.

In addition to the reactivity of the vehicles and monomers, the pigments and their UV absorption also have an important influence on the reaction rate of the inks.

Generally speaking, standard UV-curing systems using low molecular weight photo-initiators continue to be strong-smelling even after curing and are consequently not suitable for food contact applications. Many photo-initiators or monomers are not, or only partially, trapped in the cured ink film and still remain capable of migration to foods, depending on their molecular weights. Likewise, decomposition products that are formed during the curing reaction and that are not trapped in the ink film may be a source of migrating chemicals. The majority of photo-initiators have not been toxicologically evaluated for food contact applications.

Figure 8: Examples of photoinitiators



Important components in UV inks

- Pigments
- Oligomers: epoxy acrylates, polyester acrylates, polyether acrylates, urethane acrylates
- Monomers/reactive diluents: di-, tri- and tetrafunctional acrylates
- Photoinitiators: benzophenone derivates, alpha-hydroxy ketones, amine synergists, polymeric photoinitators
- Additives: waxes (PE/PTFE waxes), silicone oils, stabilisers.

Cationic UV-curing inks

Cationic UV-curing inks use photo-initiators that generate a cationic species to initiate an acid-catalysed polymerisation. Triarylsulphonium salts, diaryliodonium salts and their derivatives are typically used as cationic photo-initiators. The vehicle usually comprises a mixture of di-epoxide compounds and vinyl ethers. Cationic systems tend to be used on more difficult substrates and where adhesion is a problem.

Low-migration UV-curing systems

By taking great care when selecting photo-initiators, oligomers and monomers, it is possible to formulate UV inks and varnishes with very low levels of migration once sufficiently cured. The following parameters should be considered when developing inks for food packaging materials:

- Relevant selection of photo-initiators with low migrating potential (e.g. high molecular weight or specific chemical structure)
- Use of highly reactive oligomers and diluents to ensure that almost all the substances used are completely crosslinked
- Relevant selection of additives (low migration potential and use of evaluated substances)
- Inks and lacquers are formulated in compliance with good manufacturing practice (GMP)

Low-migration UV inks and lacquers are only low-migration systems once professionally cured. This is the reason why ink composition is not the only factor to take into account to ensure low migration. Further to an appropriate ink formulation, complete curing must be guaranteed. This requires that the printing equipment (e.g. lamps and reflectors) are adequately maintained and worn parts replaced when the intensity of UV energy declines below acceptable limits. Furthermore, the substrate must possess a very low level of absorbency, to avoid quick-setting monomers being absorbed onto the surface. Finally, the press speed and the time interval between the printing unit and the dryer are crucial points in obtaining perfect curing results.

Electron beam-curing inks

Electron beam-curing inks (EB inks) do not require photo-initiators to trigger the curing process, because the electron beams act directly on the reactive vehicles. Thick ink films can be efficiently cured because the electron beams penetrate deeply into the ink layer and the pigments have little influence on the curing process. The vehicles and additives (with the exception of photo-initiators) are comparable to those used in UV-curing inks.

Screen printing

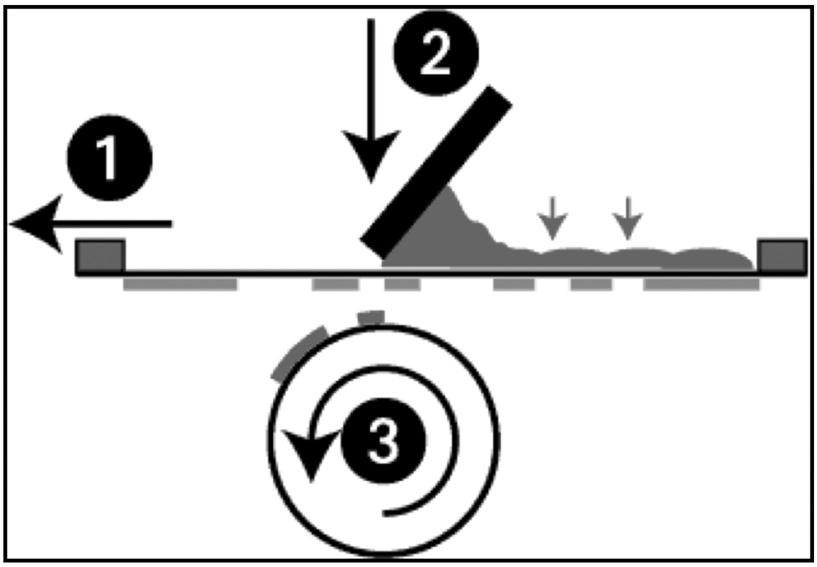
The screen (1) is filled with ink from above. The substrate or article to be printed is positioned a few millimetres below the screen (off-contact printing). A blade made of hard rubber (2), is drawn sideways across the screen, pressing the screen onto the substrate (3) and forcing the ink through the open mesh onto the substrate. Following the printing stroke, the blade returns to its starting position, spreading the ink on the screen again in the process (flooding). The screen then swivels upwards and the print can be removed.

Rotary screen printing presses also enable cylindrical objects to be printed round their entire circumference.

Due to the slow production speeds, screen printing is only used for jobs with very small runs.

Typical wet film thicknesses with screen printing are between 15 and 30 µm.

Figure 9: Printing unit for screen printing



Screen printing has the widest range of applications as regards substrates. Almost all materials can be printed and these materials can be laid flat or preformed, large or small, thick or thin, soft or hard, with textured or smooth surfaces. This wide range of potential substrates may be used with a broad variety of inks:

- Oxidative-drying, vegetable-oil-based inks
- Solvent systems
- Water-based inks
- UV-curing systems

Digital printing (non-impact printing)

Digital printing is a method of printing from a digitally based image directly to the substrate. So far, digital printing has played only a very small role in the manufacture of packaging. It is typically used for date stamping and printing other variable information onto food packaging or for producing small editions. It is nowadays envisaged to be used for small customised runs.

Inkjet printing

Inkjet printers use solvent-, UV- or water-based inks of low-viscosity, or inks based on waxes. The printhead generates small ink droplets and then propels them onto the substrate. Both soluble dyes and, to an increasing extent, pigments are used as colourants. A range of different carrier fluids is used (water, solvent, UV monomers, molten waxes) depending on the type of the inkjet process and the substrate being printed. The print films produced with water- or solvent-based inks are very thin (<0.5 µm). They are thicker for hot-melt and UV inks (>10 µm), because they contain practically no evaporating components.

Electrophotographic principle – dry toner

An optical system (laser or LED) projects an image onto an electrically charged, photosensitive, rotating drum and removes charge from the areas exposed to light. The fine toner particles are then electrostatically picked up by the charged areas, transferred onto the paper and fused by a heat source (IR lamp or hot rollers).

Dry toner consists of carbon black or chromatic pigments that are embedded in resins (styrene acrylates, polyester) and which, with the aid of iron oxide particles acting as the carrier, are transferred electromagnetically to the imaging drum. Charge controllers (metallic salts) and waxes are added to the toner. The thickness of a toner film on paper is between 6 and 15 µm after fusing. The range of substrates that can be printed is limited compared with the offset process.

Electrophotographic principle – liquid toner

In the case of laser printers using liquid toner (ink), the imaging areas on the exposed printing belt pick up the electrostatically charged ink and transfer it to a rubber blanket, from which it is then transferred to the paper. The chromatic pigments are comparable to pigments of offset inks. They are suspended in a carrier fluid. Liquid toners are less common than dry toners.

Overprint coatings and lacquers

A large proportion of packaging materials has an overprint coating. Packaging materials are coated not only for graphical reasons (gloss or matt effects) but also to provide protection and possibly some other kind of functional layer (primer coating for further finishing). Such coating must be fit for the final application and be fully compatible with the ink layers underneath. The following overprint coatings/ lacquers are used for packaging:

- Water-based coatings
- Solvent-based lacquers
- UV-curing lacquers
- Crosslinking, reactive two-component systems

The coating/lacquer is generally applied by means of suitable flexo printing units (e.g. lacquering unit on offset presses), gravure printing units, rollers or curtain coaters. Overprint coatings and lacquers have the same composition as the corresponding inks, but without the pigments. However, unlike the printing inks, the applications rates are far higher.

Coating or lacquering system	Wet film thickness (µm)	Dry film thickness (µm)
Water-based coatings	3–6	1–3
Solvent-based lacquers	3–10	1–3
UV-curing lacquers	2–5	2–5
Crosslinking, reactive two-component systems	2–10	1–3

Summary of available ink systems

The table below summarises the basic differences between the principal packaging ink systems. The pigments and their concentration are similar in all ink systems. Differences exist with respect to the vehicles and solvents employed when it comes to setting the viscosity.

Constituent	Percentage composition of different ink systems			
	Solvent-based	Water-based	Offset	UV
Pigments[a]	0–20	0–20	0–20	0–20
Binders	10–30	15–35	30–60	55–80[b]
Additives	1–10	1–5	3–6	3–10
Solvents	Up to 70	0–5	–	–
Water	–	45–70	–	–
Mineral oil; vegetable oil/ester	–	–	0–40	–

[a] Could be up to 40% by weight for white inks, which use titanium dioxide as the pigment (due to the enhanced density compared with typical organic pigments)

[b] Includes reactive diluents

INTERACTION BETWEEN PACKAGING AND CONTENTS

Transfer of packaging constituents into foodstuffs must be minimised and components that may endanger human health must not be used in food packaging inks (see also the section "International Regulations and Guidelines on Printing Inks").

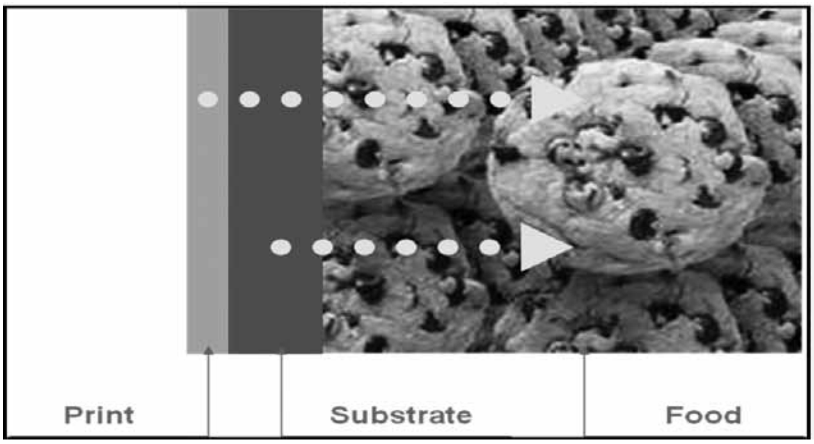
Migration is a mass transfer from the packaging materials into the packed food. This transfer between packaging and the contents can happen via:

- Migration through materials
- Invisible set-off
- Migration through gas phase

Migration through materials is influenced by the following parameters:

- Diffusion coefficient in the film
- Partition coefficient of the migrating substance in the respective packaging layers and the food
- Molecular weight of the migrating substance
- Temperature during life of the packed product
- Time of contact

Figure 10: Interaction of packaging and foodstuff – migration`



During the production process, packaging materials are stacked or rolled onto a reel. This causes the printed side of the packaging to be in contact with the food contact side. This means there is a possibility of (invisible) transfer. This transfer is known as "invisible set-off". These substances can transfer to the food once the packaging has been filled.

Finally, volatile substances of the packaging can transfer to the food through the gas phase. This type of migration generally relates to absorbing foods such as dry foods. Such transfer requires evaporation into the gas phase and recondensation into the food, which only occurs with substances of a significant vapour pressure.

Figure 11: Interaction of packaging and foodstuff – invisible set-off

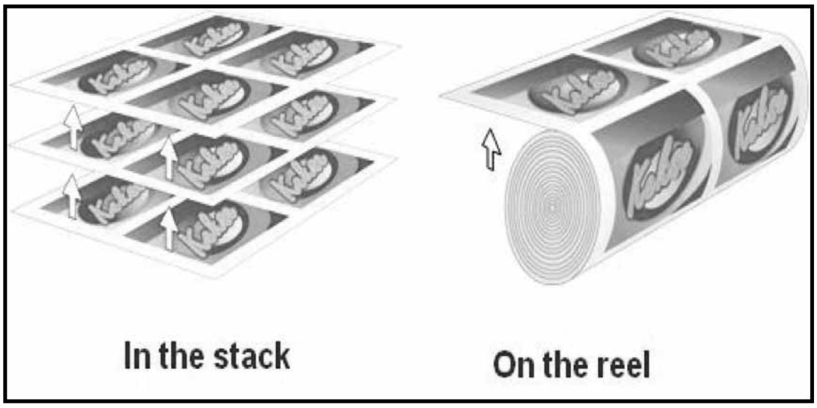
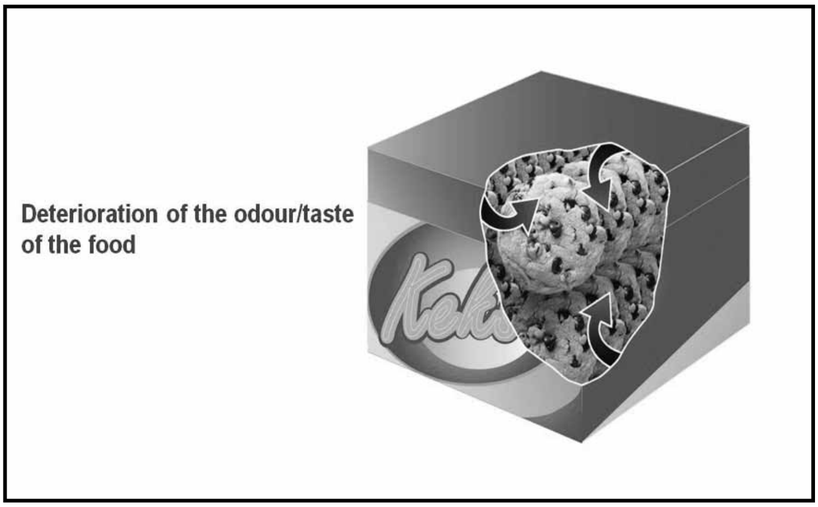


Figure 12: Substance transfer through gas phase



Migration is measured in accordance with relevant norms, e.g. using food simulants (standards EN 1186 and EN14338). Nevertheless, these simulants have their limitations, and, though complex, analyses will be more and more carried out in the food matrices.

The potential for migration and deterioration of organoleptic characteristics depends not only on the individual composition of the packaging ink but also on the substrate and on the printing conditions (e.g. printing speed, temperatures), which are under the control of the converter.

Some important factors affecting migration and deterioration of organoleptic properties of packaged foodstuffs

- Packaging design and construction
- Substrate selection and barrier properties
- Print design, ink coverage and film weight
- Choice and composition of printing ink
- Type and speed of printing press and drying conditions
- Lamination adhesive and curing conditions and effects of other layers
- Storage conditions (time, temperature, pressure in the reel or stack)
- Nature and composition of the packaged foodstuff and effects of further processing

INTERNATIONAL REGULATIONS AND GUIDELINES ON PRINTING INKS

This section provides information on current laws, regulations, recommendations or voluntary guidelines in place in Europe and in the USA for printing inks applied to food contact materials (FCMs).

Regulations

European Union (EU)

Framework Regulation (EC) No 1935/2004

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

This Regulation is applicable to all food contact materials and articles. Printing inks are mentioned in Annex I in the list of materials and articles, which may be covered by specific regulation, but no such legislation has been issued so far. Article 5 of *Directive 2007/42/EC, relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs* (CEC, 2007) states that the printed surface must not come into contact with the foodstuffs.

The final food contact material, including the print (ink film and coating) as an integral part, must fulfil the requirements of Article 3 of the Regulation (EC) No 1935/2004:

> *1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:*
>
> *(a) endanger human health; or*
> *(b) bring about an unacceptable change in the composition of the food; or*
> *(c) bring about deterioration in the organoleptic characteristics thereof.*

In accordance with Article 17, manufacturers are required to implement traceability and product recall measures. Traceability must be ensured at all stages of the supply chain in order to facilitate the control, the recall of defective products, consumer information and the attribution of responsibility. Business operators must be able to identify the company from which and to which the materials, articles, products and substances are supplied.

Plastics Implementing Measure Regulation (EU) No 10/2011

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

The Plastics Implementing Measure is an updated consolidation of EU legislation on plastic food contact materials and articles going back to 1978. Although it does not specifically apply to printing inks, it does cover materials consisting exclusively of plastics and plastic multilayer materials that are printed and/or coated. Printed plastics materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I of the Regulation. A generic SML of 60 mg/kg food applies to substances listed in Annex I without restrictions.

This Regulation recognises that substances other than those authorised at EU level for plastics can be used in printing inks; however, migration of such substances from printed plastic materials should comply with Article 3 of Regulation (EC) 1935/2004, using risk assessment in accordance with internationally recognised scientific principles taking exposure into account. Printing inks are not subject to the requirement for a declaration of compliance, although adequate information should be provided to the manufacturers of the final plastic article to enable them to ensure compliance for substances with migration limits.

Regulation (EC) No 2023/2006 ("GMP Regulation")

Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

This Regulation lays down the rules on GMP for the groups of materials and articles intended to come into contact with food listed in Annex I of the Regulation (EC) No 1935/2004, including combinations and recycled materials used in those materials and articles. It introduces general rules for all business operators in the supply chain and specifies that quality assurance and control systems are to be established and implemented. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing that are relevant to compliance and safety of the finished material or article. Detailed rules on processes involving the application of printing inks are now set in the Annex:

Detailed rules on good manufacturing practice

Processes involving the application of printing inks to the non-food contact side of a material or article

1. Printing inks applied to the non-food contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food contact side:

(a) through the substrate or;

(b) by set-off in the stack or the reel,

in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

2. Printed materials and articles shall be handled and stored in their finished and semi-finished states in such a manner that substances from the printed surface are not transferred to the food-contact side:

(a) through the substrate or;

(b) by set-off in the stack or reel,

in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

3. The printed surfaces shall not come into direct contact with food.

The GMP Regulation expands on Article 3 of the European Framework Regulation (EC) No 1935/2004, which states that compliance with the basic requirements, such as the safety of the migration, must be assured through GMP. The term "GMP" was introduced in the preceding legislation from 1976 and must be understood in the meaning of GMP at that time. It primarily implies that each step of the manufacturing process must contribute to the compliance work.

A more specific interpretation of GMP was provided by German authorities (BVL, 2009). It clarifies responsibilities within the manufacturing chain, simplifies compliance work and avoids unnecessary tests.

The cooperation and communication between ink manufacturers and their suppliers on the one side and the customers on the other has to ensure that the compliance work for the final material or article is complete, i.e. covers all potential migrants (introduced as such, including the impurities, or formed by reaction). This may presuppose specifications, such as the intended food contact material, type of food, printing and converting process parameters, use restrictions, treatment and storage conditions.

Responsibility is a key. In the first place, a manufacturer introducing a substance into a product intended for food contact is responsible for compliance of this substance, its impurities and the reaction products it may form. If the manufacturer is unable or unwilling to carry this responsibility (e.g. since migration cannot be predicted at this stage), the work can be delegated to the customer. This delegation must be specific and provide the customers with the information needed to take over this work. General disclaimers without an adequate disclosure of the information needed to ensure compliance of the material are no longer tolerated. Undelegated compliance work automatically means that the supplier carries the responsibility. It is not up to the customer to find out about the migration of critical substances: it is the duty of the one introducing the substance to inform him. The customer not only buys the product, but also accepts the compliance work burdened on it, and the final costs are not only determined by the price of the materials, but also by the compliance work it involves.

Only components may be used that were produced according to GMP in this legal sense. This implies a declaration accompanying the product that confirms GMP in the meaning of the food contact material legislation. This declaration may include restrictions in the use for which compliance is guaranteed and must specify delegated compliance work. In-house documentation (supporting documentation) is legally required recording the compliance work and demonstrating compliance in all aspects for which compliance work has not been delegated. This documentation must be disclosed to the competent authorities only. However, due diligence of the customer, including the food manufacturer, also requires some control by industry. As an example outlined in the GMP Regulation, the printing ink manufacturer has to ensure that the printer can rule out problems regarding set-off. Either the manufacturer can rule out health risks even in case of severe set-off or must inform the printer about the critical substances, enabling the latter to perform adequate tests. The manufacturer cannot delegate responsibility to the printer without giving information about how to carry out the corresponding compliance work.

Switzerland
Ordinance of the FDHA on articles and materials (SR 817.023.21) of 23 November 2005

The new Swiss regulation for packaging inks (FOPH, 2005) is based on the Council of Europe Resolution ResAP(2005)2 on packaging inks (CoE, 2005) and was a result of a collaboration between the Swiss Federal Office of Public Health (FOPH) and the EuPIA, representing ink manufacturers throughout Europe, in updating the list of the Technical Document No. 1 of the Resolution ResAP(2005)2. The Regulation entered into force on 1 April 2010 and states that packaging inks may be manufactured only from the substances listed in Annex 1 (lists I and II) or Annex 6 (lists I to V) subject to the requirements set out therein. The ink industry can notify new substances in accordance with the process defined in Article 26h of the ordinance.

Lists I and II of Annex 1 comprise substances authorised for use in the manufacturing of plastics. Annex 6 is specifically concerned with packaging inks and is available in electronic format on the Swiss Federal Office of Public Health (FOPH) website (http://www.bag.admin.ch/packaging_inks).

Annex 6 lists substances authorised for use in the manufacturing of packaging inks in five sections:

- I List of binders (monomers)
- II List of dyes and pigments
- III List of solvents (including the "energy curing monomers")
- IV List of additives (without the additives used in the preparation of pigments)
- V List of photoinitiators

The list of additives IV does not include substances that directly influence the formation of polymers (e.g. catalysts) and the substances used in the preparation of pigments. The substances were subdivided into Part A evaluated substances, and Part B non-evaluated substances, which must not be detectable in a migration test at a detection limit not exceeding 0.01 mg/kg foodstuff or food simulant. In Part A, the specific migration limit (SML) or maximum permitted content (QM) in the material or article are set for individual substances. The SML or QM values of substances listed both in Annex 6 (packaging inks) and in Annex 1 (plastics) were taken from Annex 1 (plastics), which in turn is derived from the Plastic Directive 2002/72/EC (CEC, 2002) and its amendments, repealed with Commission Regulation (EU) No 10/2011.

Layers of packaging inks in direct contact with foodstuffs are excluded from the scope of this regulation but have to comply with the general requirements of Article 34 of the *Ordinance on Food and Commodities* (SR 817.02), which is analogous to Article 3 of the Regulation (EC) No 1935/2004. Inks used behind a functional barrier, such as in glass bottles and metal cans, are also excluded, provided that a set-off or transfer via the gas phase can be ruled out.

The FOPH maintains contact with industry and other authorities to constantly update this new regulation with respect to the substances used and the toxicological data available for classification of the substances in Parts A or B.

Germany

Germany is in the process of introducing a national regulation for printing inks (available as a draft when printing this document).

USA

In the United States, the laws and regulations published by the US Food and Drug Administration (FDA) have to be considered when using printing inks on food packaging materials. Substances used in packaging that, under circumstances, migrate into the food are regulated as direct (intentionally added to food) or indirect (substances that end up in food but that are not intentionally added) food additives.

As formulated printing inks are not covered by a single specific regulation, each printing ink and intended use is a unique situation with respect to its FDA status. One of the few FDA regulations for inks is in Chapter 21 of the Code of Federal Regulations (21CFR) section 73.1, a direct "colour additive" clearance that covers colour additive diluents. Another regulation is in section 176.130 Anti-offset substances of Part 176 Indirect Food Additives: Paper and Paperboard Components (FDA, 2010). Substances named in this section may be safely used to prevent the transfer of inks employed in printing and decorating paper and paperboard used for food packaging in accordance with the provisions cited therein. Some ink components have now been cleared via the Food Contact Notification (FCN) system to avoid the time-consuming FDA food additive petition.

The FDA generally permits the use of the following ink components:

- Food additives that are listed in relevant parts of 21CFR 170.189, including GRAS (generally recognized as safe) substances and some direct food additives such as flavourings. It is important to note that some of these listings only apply to specific categories of material and there may be limitations with particular food types
- Substances that are subject of an approval (prior sanction) issued by the FDA or the US Department of Agriculture before 1958
- Substances that are separated from food by a "functional barrier", or otherwise are not reasonably expected to become components of foods

The FDA regulations require that the materials be manufactured under GMP. There are three GMP general concepts that apply to inks and coatings:

1. The quantity that is used is not more than is reasonably required to accomplish the intended physical or technical effect and does not exceed any limitations
2. The material must be of a purity suitable for the intended use
3. The methodology for production and use should ensure compliance with the regulations

Guidelines

Council of Europe

The documents elaborated by the Council of Europe (CoE) may be considered as reference documents in the field of some food contact materials and are intended for use as the basis for a transposition or preparation of a national or EU regulation, but are not regulations on their own. A joint group of experts from authorities and industry formed by the CoE elaborated *Resolution ResAP(2005)2 on Packaging inks applied to the non-food contact surface of food packaging and articles intended to come into contact with foodstuffs*, and published it in September 2005 (CoE, 2005). It requires:

Printed materials and articles intended to come into contact with foodstuffs, should not, in their finished state and under normal and foreseeable conditions of use, transfer their constituents to foodstuffs in quantities which could endanger human health or bring about unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof, in accordance with Article 3 of Regulation (EC) No 1935/2004.

The Resolution includes an incomplete list of substances used for the manufacture of packaging inks (Technical Document No. 1), guides for good manufacturing practice (Technical Document No. 2) and guidelines on test conditions for packaging inks (Technical Document No. 3). The list in Document 1 is an "inventory list", i.e. a list of substances declared by industry to be used. Substances that are listed but not toxicologically evaluated can be used if they do not migrate into the food:

They shall not be detectable at the lowest concentration at which a substance can be measured with statistical certainty by a validated method of analysis. This limit expressed as concentration shall not exceed 0.01 mg/kg of food or food simulant.

Substances and raw materials for packaging inks must be selected taking into consideration the inventory list and exclusion criteria defined in the Technical Document No. 1 and GMP developed by industry in Technical Document No. 2. Verification of the compliance with the quantitative restrictions should respect the rules set out in Technical Document No. 3.

EuPIA Guideline

In October 2005, EuPIA published guidelines relating to printing inks for food packaging (latest version November 2011): *Guideline on printing inks applied to the non-food contact surface of food packaging materials and articles* (EuPIA, 2011c).

The most important pronouncements of the Guideline are:

- Raw materials are to be selected in accordance with the selection scheme specified
- Ink production is to be conducted in accordance with EuPIA GMP (EuPIA, 2009c)
- The printed and/or coated surfaces must not come into direct contact with food
- Visible set-off must be prevented
- The overall migration limit of the finished packaging and SML of the individual substances must be complied with

The following criteria apply when selecting the raw materials in accordance with the selection scheme laid down in the Guideline:

- Colourants (pigments) must comply with Resolution AP(89)1 of the Council of Europe (CoE, 1989)
- Raw materials must not belong to one of the following categories:
    - o CMR substances (substances classified as carcinogenic, mutagenic or reprotoxic Category 1 or 2)
    - o Substances classified as “toxic” or “very toxic”
    - o Raw materials based on antimony, arsenic, cadmium, chromium (VI), lead, mercury or selenium
    - o All restricted substance uses according to EU Directive 76/769/EEC restricting the marketing and use of certain hazardous substances and preparations (Council of the European Communities, 1976)
- Limit values apply for the migration of substances with a molecular weight < 1000 Da, as given in the Table below:

Migration limit (ppb)	Circumstance
< 10[a]	In case of insufficient toxicological data
< 50	When three negative mutagenicity test results are available (in accordance with EFSA guidelines)
> 50 up to SML value	If supported by favourable toxicological data and/or evaluation done in accordance with EFSA guidelines

[a] The migration limit cited is subject to the following deadlines: up to 50 ppb to be achieved by December 2010, up to 10 ppb by 2015

There are some instances where there is intentional contact with the foodstuff due to printing on the inside surface of food packaging (e.g. printing inks, protective coatings, heat-seal coatings, cold-seals and release lacquers, anti-fog coatings or slip coatings). In comparison with non-food contact prints, there is an increased risk of migration into the food. In the absence of specific legislation concerning printing ink products intended for direct food contact, only raw materials that are included in positive lists and/or have been evaluated by a recognised expert body are used (EuPIA, 2009b). Transfer to the foodstuff should not exceed any specific restriction and be in accordance with Article 3 of Regulation (EC) No 1935/2004.

EuPIA Good Manufacturing Practice (GMP)

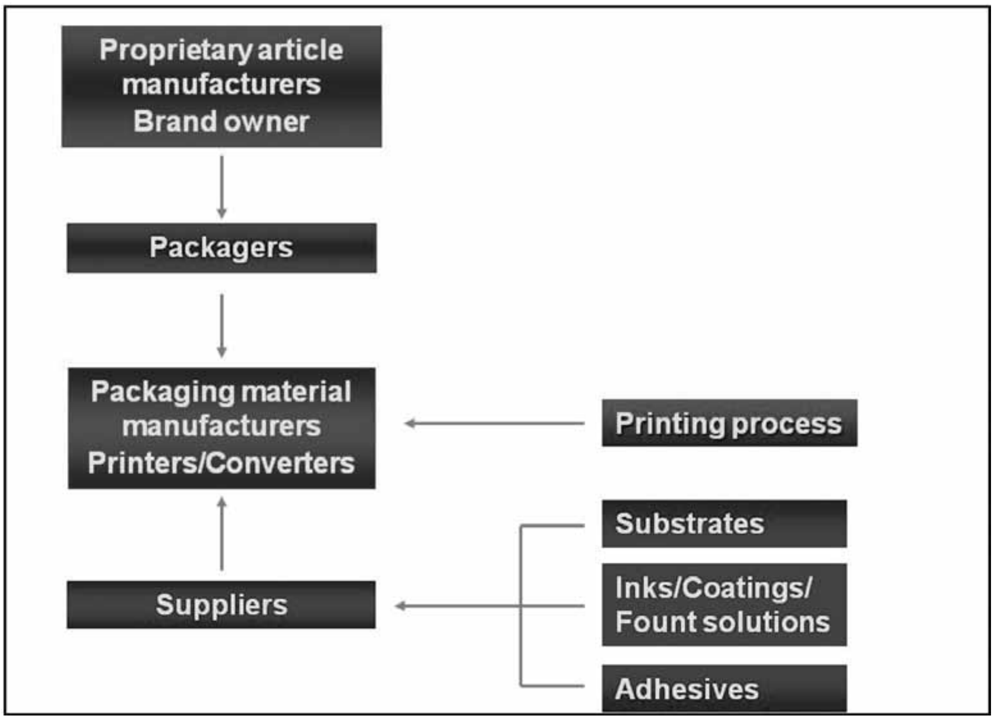
With respect to the production of food packaging, the regulations and guidelines demand that migration, organoleptic changes and contamination be prevented and that compliance with the most important requirements laid down with regard to packaging be ensured.

This can only be achieved if all of the processes in the entire process chain function hand-in-hand and/or are optimised so as to prevent illegitimate interactions from taking place. This must be guaranteed by:

- An unbroken, end-to-end flow of information within the process chain
- Monitoring of the individual production steps with the aid of a suitable quality assurance system that also takes into account contamination of the products (this is covered in the relevant GMP recommendations)

At one end of the supply chain is the customer (proprietary article manufacturer), possibly via a packer, to the packaging manufacturer and/or printer. At the other end of the chain are the suppliers, above all the suppliers of substrates, adhesives, inks, coatings and fount concentrates. Another important process step is, of course, the printing process itself, whereby the wet ink is applied to the packaging substrate and dried as part of the production of the printed packaging.

Figure 13: Supply chain



What is GMP?

According to the official definition (the legal framework for GMP is laid down in European Commission Regulation (EC) No 2023/2006, Article 3), "good manufacturing practice (GMP)" means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof (CEC, 2006).

For printing-ink manufacturers, a GMP guideline has been developed by EuPIA as part of its guideline: *Good manufacturing practices for the production of packaging inks formulated for use on the non food contact surfaces of food packaging and articles intended to come into contact with food* (EuPIA, 2011c). The most important points in this GMP guideline are:

- Requirements for the formulation of inks
  - Raw materials are selected in accordance with the EuPIA guidelines
  - The packaging design, production and package contents are taken into consideration during ink formulation (printing process, substrate/composite material, package contents, package filling process, package-shaping processes, specifications of the end user)
  - Adequate adhesion of the ink films on the substrate
  - Adequate resistance to chemical and physical stresses
  - Adequate resistance to the package contents
  - No visible set-off
  - No deterioration in the organoleptic characteristics
  - Potential migration – including invisible set-off – must be kept to a minimum
  - All regulatory requirements must be complied with
- Production of the inks
  - Traceability of all raw materials used must be guaranteed
  - Production must be controlled and monitored
  - Conformity with the product specifications must be checked as part of quality assurance
  - Test equipment must be monitored
- Product information (data sheets)
- Correct racking into clean containers

The EuPIA GMP for packaging ink has to be combined with the GMPs covering the other stages in the production process, such as substrate manufacture (CEPI, 2010; PlasticsEurope, 2008) and the printing/converting process (FPE, 2009; ECMA, 2011).

CONCLUSIONS

There is a wide selection of different ink and overprint varnish formulations to meet the requirements of the printing processes, substrate types and food packaging specifications. For the manufacture of food packaging, a number of specially formulated and manufactured low-migration inks and overprint varnishes are available for offset printing onto paper and carton board. For flexographic and gravure printing, there are also many options available.

Provided that inks and varnishes are processed on suitable substrates in accordance with GMPs, it is possible to produce food packaging that is compliant with Regulations (EC) No 1935/2004, (EC) No 10/2011 and with the Swiss Ordinance on Articles and Materials (SR 817.023.21).

In contrast to these carefully formulated food packaging inks, standard inks and standard overprint varnishes have not been designed for the manufacture of food packaging. Most of them will contain substances that are not suitable or have not been evaluated for food contact and that may be transferred to the foodstuff in amounts above legal limits, either by migration through the substrate, via the vapour phase, or by set-off from the printed outer side to the food contact surface in the stack or the reel.

REFERENCES

BVL (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) (2009). Amtliche Mitteilungen. *Journal für Verbraucherschutz und Lebensmittelsicherheit* 4(3): 411–419.

CEPI (Confederation of European Paper Industries) (2010). Good manufacturing practice for the manufacture of paper and board for food contact. issue 1- September 2010. Available at http://www.cepe.org

CoE (Council of Europe, Committee of Ministers) (1989) Resolution ResAP(1989)1 on the use of colourants in plastic materials coming into contact with food (adopted by the Committee of Ministers on 13 September 1989). Council of Europe, Strasbourg.

CoE (Council of Europe, Committee of Ministers) (2005). Resolution ResAP(2005)2 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs (adopted by the Committee of Ministers on 14 September 2005). Council of Europe, Strasbourg.

CEC (Commission of the European Communities) (2002). Commission Directive 2002/72/EC of 7 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs. *Official Journal* L220, 15.08.2002, p. 18.

CEC (Commission of the European Communities) (2006). Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. *Official Journal* L384, 29.12.2006, p. 75.

CEC (Commission of the European Communities) (2007). Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. *Official Journal* L172, 30.06.2007, p. 71.

Council of the European Communities (1976). Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. *Official Journal* L262, 27.09.1976, p 201.

ECMA (European Carton Makers Association). Good manufacturing practice guide, v 1.0; September 2011. Available at www.ecma.org

EuPIA (2009a). Customer information note regarding the use of sheetfed offset inks/varnishes (setting and/or oxidative drying, or UV/EB curing) and water-based coatings for the manufacture of food packaging made from paper and board; PIFOOD 05 February 2009, amended 30 June 2011. EuPIA, Brussels. Available at http://www.eupia.org

EuPIA (2009b). Information leaflet: Printing inks for food packaging; PIFOOD 2009-02-05. EuPIA, Brussels. Available at http://www.eupia.org

EuPIA (2009c). Good manufacturing practices for the production of packaging inks formulated for use on the non-food contact surfaces of food packaging and articles intended to come into contact with food, 3rd revised version; PIFOOD 2009-03-01. EuPIA, Brussels. Available at http://www.eupia.org

EuPIA (2011a). Exclusion list for printing inks and related products, 7th revised edition; April 2011. EuPIA, Brussels. Available at http://www.eupia.org

EuPIA (2011b). Inventory list – version January 2011 comprising of packaging ink raw materials applied to the non-food contact surface of food packaging; 11/01/2011. EuPIA, Brussels. Available at http://www.eupia.org

EuPIA (2011c) Guideline: EuPIA guideline on printing inks applied to the non-food contact surface of food packaging materials and articles; September 2009. EuPIA, Brussels. Available at http://www.eupia.org

European Commission (2011). Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. *Official Journal* L012 15.01.2011, p. 1.

European Parliament and Council of the European Union (2004). Framework Regulation 1935/2004/EC of the European Parliament and of the Council of 27 October 2004 on articles and materials intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. *Official Journal* L338, 13.11.2004, p 4.

FDA (US Food and Drug Administration) (2010). 21CFR176.130 Anti-offset substances of Part 176 Indirect Food Additives: Paper and Paperboard Components. FDA, Silver Spring, MD.

FOPH (Swiss Federal Office of Public Health) (2005). Ordinance of the FDHA on materials and articles (SR 817.023.21) of 23 November 2005. FOPH, Bern. Available at http://www.bag.admin.ch/packaging_inks

FPE (Flexible Packaging Europe) (2009). Code for good manufacturing practices for flexible and fibre-based packaging for food, version 5.0; June 2009. FPE, Düsseldorf and CITPA, Brussels. Available at http://www.flexpack-europe.org

Kipphan, H. (2000). Handbuch der Printmedien (Manual of print media). Springer, Berlin.

NAPIM (National Association of Printing Ink Manufacturers USA) (2009). Printing inks for food packaging – FAQ. NAPIM, Woodbridge, NJ. Available at http://sho.lunariffic.com/~kusto7/wp-content/uploads/2011/07/NAPIM-Food-Packaging-FAQ.pdf

Piringer, O.G. and Baner, A.L. (2008). Plastic packaging interactions with food and pharmaceuticals, 2nd edn. Wiley-VCH, Weinheim.

PlasticsEurope (2008). Guidelines for good manufacturing practice for plastic materials and articles intended for food contact applications; 18 April 2008. PlasticsEurope, Cefic-FCA and EuPC, Brussels. Available at http://www.plasticseurope.org/document/guidelines-for-good-manufacturing-practice-for-plastic-materials-and-articles-intended-for-food-contact-applications.aspx

Siegwerk (2010). Know how – Customer guidance: Printing inks for food packaging. Siegwerk, Siegburg. Available at http://www.siegwerk.com/fileadmin/user_upload/pdf/download_center/Customer_Guidance_E.pdf

Papilloud, S. and Baudraz, D. (2002). Analysis of food packaging UV inks for chemicals with potential to migrate into food simulants. *Food Additives and Contaminants* 19(2): 168–175.

Sun Chemical (2007). Print for packaging – A printing low migration best practice guide, 2nd edition; December 2007. Sun Chemical, Parsippany, NJ.

Other ILSI Europe Publications

Concise Monographs

- Alcohol – Health Issues Related to Alcohol Consumption
- A Simple Guide to Understanding and Applying the Hazard Analysis Critical Control Point Concept
- Calcium in Nutrition
- Carbohydrates: Nutritional and Health Aspects
- Caries Preventive Strategies
- Concepts of Functional Foods
- Dietary Fibre
- Food Allergy
- Food Biotechnology – An Introduction
- Functional Foods – From Science to Health and Claims
- Genetic Modification Technology and Food – Consumer Health and Safety
- Healthy Lifestyles – Nutrition and Physical Activity
- Microwave Ovens
- Nutrition and Genetics – Mapping Individual Health
- Nutrition and Immunity in Man
- Nutritional and Health Aspects of Sugars – Evaluation of New Findings
- Nutritional Epidemiology, Possibilities and Limitations
- Oral and Dental Health - Prevention of Dental Caries, Erosion, Gingivitis and Periodontitis
- Oxidants, Antioxidants, and Disease Prevention
- Principles of Risk Assessment of Food and Drinking Water Related to Human Health
- The Acceptable Daily Intake – A Tool for Ensuring Food Safety
- Threshold of Toxicological Concern (TTC)
- Type 2 Diabetes – Prevention and Management

Reports

- Addition of Nutrients to Food: Nutritional and Safety Considerations
- An Evaluation of the Budget Method for Screening Food Additive Intake
- Animal-Borne Viruses of Relevance to the Food Industry
- Antioxidants: Scientific Basis, Regulatory Aspects and Industry Perspectives
- Applicability of the ADI to Infants and Children
- Application of the Margin of Exposure Approach to Compounds in Food which are both Genotoxic and Carcinogenic
- Approach to the Control of Entero-haemorrhagic Escherichia coli (EHEC)
- Assessing and Controlling Industrial Impacts on the Aquatic Environment with Reference to Food processing
- Assessing Health Risks from Environmental Exposure to Chemicals: The Example of Drinking Water
- Beyond PASSCLAIM – Guidance to Substantiate Health Claims on Foods
- Campylobacters as Zoonotic Pathogens: A Food Production Perspective
- Considering Water Quality for Use in the Food Industry
- Consumer Understanding of Health Claims
- Detection Methods for Novel Foods Derived from Genetically Modified Organisms
- Emerging Technologies for Efficacy Demonstration
- Evaluation of Agronomic Practices for Mitigation of Natural Toxins
- Evaluation of the Risks Posed in Europe by Unintended Mixing of Food Crops and Food Crops Developed for Non-Food Uses
- Exposure from Food Contact Materials
- Foodborne Protozoan Parasites
- Foodborne Viruses: An Emerging Problem
- Food Consumption and Packaging Usage Factors
- Food Safety Management Tools
- Food Safety Objectives – Role in Microbiological Food Safety Management
- Functional Foods in Europe – International Developments in Science and Health Claims
- Functional Foods – Scientific and Global Perspectives
- Guidance for the Safety Assessment of Botanicals and Botanical Preparations for Use in Food and Food Supplements
- Impact of Microbial Distributions on Food Safety
- Markers of Oxidative Damage and Antioxidant Protection: Current status and relevance to disease
- 3-MCPD Esters in Food Products
- Method Development in Relation to Regulatory Requirements for the Detection of GMOs in the Food Chain
- Micronutrient Landscape of Europe: Comparison of Intakes and Methodologies with Particular Regard to Higher Consumption
- Mycobacterium avium subsp. paratuberculosis (MAP) and the Food Chain
- Nutrition in Children and Adolescents in Europe: What is the Scientific Basis?
- Overview of the Health Issues Related to Alcohol Consumption
- Overweight and Obesity in European Children and Adolescents: Causes and consequences – prevention and treatment
- Packaging Materials: 1. Polyethylene Terephthalate (PET) for Food Packaging Applications
- Packaging Materials: 2. Polystyrene for Food Packaging Applications
- Packaging Materials: 3. Polypropylene as a Packaging Material for Foods and Beverages
- Packaging Materials: 4. Polyethylene for Food Packaging Applications
- Packaging Materials: 5. Polyvinyl Chloride (PVC) for Food Packaging Applications
- Packaging Materials: 6. Paper and Board for Food Packaging Applications
- Packaging Materials: 7. Metal Packaging for Foodstuffs
- Packaging Materials: 9. Multilayer Packaging for Food and Beverages
- Recontamination as a Source of Pathogens in Processed Foods – A Literature Review
- Recycling of Plastics for Food Contact Use
- Safety Assessment of Viable Genetically Modified Micro-organisms Used in Food
- Safety Considerations of DNA in Foods
- Salmonella Typhimurium definitive type (DT) 104: A multi-resistant Salmonella
- Significance of Excursions of Intake above the Acceptable Daily Intake (ADI)
- The Safety Assessment of Novel Foods
- The Safety Assessment of Novel Foods and Concepts to Determine their Safety in use
- Threshold of Toxicological Concern for Chemical Substances Present in the Diet
- Transmissible Spongiform Encephalopathy as a Zoonotic Disease
- Trichothecenes with a Special Focus on DON
- Using Microbiological Risk Assessment (MRA) in Food Safety Management
- Validation and Verification of HACCP
- Water Use of Oil Crops: Current Water Use and Future Outlooks

To order

ILSI Europe a.i.s.b.l.
Avenue E. Mounier, 83, Box 6
B-1200 Brussels, Belgium
Phone: (+32) 2 771 00 14 • Fax: (+32) 2 762 00 44
E-mail: publications@ilsieurope.be

ILSI Europe's Concise Monographs and Report Series can be downloaded from: www.ilsi.eu

ISBN 9789078637257