INK, HEART & SOUL

KNOW HOW
Customer Guidance: Printing Inks for Food Packaging
Scope: Worldwide Regulations
Considerations on packaging safety should always be of utmost importance for the formulation and supply of printing inks for food packaging. Brand owners and consumers expect safe food packaging which does under no circumstances contaminate the packed food or impair their health.

The ITX crisis of the year 2005 has alerted the food packaging chain as well as authorities about the fact that there might be food contamination risks originating from printing ink components. In some countries, this has led regulators to believe that the market needs tightened legislation on food packaging and on top of that specific regulations on printing inks for food packaging. As a result, we see on a global scale changes towards more and more harmonized food packaging legislation. Within these activities, the European legislation concept for food packaging is considerably influencing international food packaging legislation, no matter whether we look at Asia (China) or Latin America.

It is one objective of this Customer Guidance to bring global food packaging regulations to light, with a specific focus on printing inks. We would like to show that formulating and supplying inks and later on printing them on food packages is covered by food packaging regulations existing in most countries all over the world which address the basic principles for safe packaging.

Specific regulations dealing with printing inks for food packaging are however still rare.

We are convinced that by observing the essential steps mentioned in this Guidance and additionally by sticking to open mutual information influencing food safety, a major milestone will be taken for the production of safe and compliant food packaging. It is without discussion that this Guidance cannot and shall not substitute the bilateral discussion with Siegwerk’s experts both by the Technology team as well as by the Product Safety and Regulatory team. I sincerely invite you to challenge our expertise and utilize it for your benefit. We are looking forward to hearing from you!

Dr. J.-P. Langhammer Vice President Global HSE + Sustainability
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1. Migration

1.1 History and importance of migration

Early cases of migration

Long before the public became aware, a number of scientific publications had already revealed the migration potential of substances present in prints. The transfer of low molecular plasticizers from flexible packaging printed with solvent-based inks into fatty snack foods was published in 1989, and into confectionery, chocolate bars, biscuits, potato crisps and similar in 1993. Beverage cartons printed with water-based inks were shown to transfer a low molecular surfactant in detectable quantities to mineral water (1998). Migration of the very low molecular photoinitiator ‘benzophenone’ was measured in shelf-stable, refrigerated, frozen and microwaveable food packed in cardboard printed with UV inks (2000, 2003). In the US, the 1999–2000 National Health and Nutrition Survey detected phthalate metabolites in more than 75 percent of the US population.

A migration study with UV inks containing ‘benzophenone’ and other low molecular photoinitiators was conducted in 2002. It became evident that packaging printed with the widely used, so-called standard, UV inks – which were typically based on low molecular photoinitiators – could not be regarded suitable for food packaging.

All this knowledge about the migration of low molecular substances from printed layers did not spread. Instead, it remained largely unnoticed by the decision-makers in the packaging chain. However, it prompted Siegwerk to adapt formulations of solvent-based and water-based inks in order to achieve lower migration potential. Equivalently, for UV and sheetfed offset inks, new, first generation ‘low migration’ products were proposed to converters. Because of the persisting wide unawareness of the migration issue, these calls for change received, at that time, only little attention by most users of ink and printed packaging.

A series of incidents

That attitude changed with the first big migration scandal in 2005: Findings of isopropyl thioxanthone (ITX, a low molecular photoinitiator used in UV inks) in baby milk and other liquid foodstuffs (the ‘ITX case’) were reported, all over Europe, in the year 2005 and caused several product recalls. This food scandal alerted the packaging chain about the migration potential of substances from printing inks. The stakeholders within the packaging chain realized that substance transfer from printed and/or varnished layers, even if not intentionally brought into direct food contact, can happen nevertheless. The transfer of ITX to food could be described by a set-off in the reel (due to reel-to-reel printing).
As a consequence of the ITX case, the European Commission was prompted to take action and issued the so-called Regulation (EC) 2023/2006 on Good Manufacturing Practice, which addresses processes involving the application of printing inks (also see chapter 2.1). It was the first time that printing inks were explicitly regulated in the European food packaging legislation.

The Rapid Alert System for Food and Feed (RASFF) was 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. The legal basis of the RASFF is Regulation EC/178/2002. Starting mainly with entries related to the food itself (e.g. salmonella and aflatoxins), packaging-related hazards also became increasingly reflected in the RASFF later on. In the year 2013, 3137 entries were made by the member states, of which 203 were migration issues. In early 2009, new findings of the two UV curing photoinitiators ‘4-methylbenzophenone (4-MBP)’ and ‘benzophenone’ above the acceptable thresholds in breakfast cereal packed in polyethylene pouches included in cardboard boxes were entered into the RASFF. The issue gained huge media coverage, including evening TV news all over Europe. Food and packaging was recalled on a broad scale, bringing considerable financial losses to the affected companies and a negative image to the food production industry as a whole.

In June 2014, the RASFF consumers’ portal was launched. This is an internet tool providing latest information on food recall notices. As it is especially designed for consumers, it also includes public health warnings issued by food safety authorities and food companies.

Mineral oils
Following analytical investigations by enforcement labs in Switzerland and Germany on cardboard packaging made of recycled fibers and/or printed with standard (non ‘low migration’) oleoresinous sheetfed offset inks, again, at the end of 2009 and in 2010, prime-time TV broadcasts brought wide attention to the migration of mineral oils into foods. In particular, they were detected in dry, non-fatty foods like rice and flour, which so far had not been widely perceived to be able to accumulate migrants. The prevention of the first source, i.e. recycled fiberboard containing mineral oils...
The worldwide awareness of migration from food packaging is still increasing – and all companies in the supply chain will be affected!

from newspaper prints, has proved to be an issue with many causes and several possible solution approaches; at present, it is still under debate within the complex production chain and between the concerned industry and the regulators. However, the second source, sheetfed offset inks based on mineral oils, raised once more the fact that the existing ‘low migration’ sheetfed offset proposals by Siegwerk and other inkmakers had not resulted in large-scale use by converters and food companies.
1.2 Mechanisms of migration

Migrants are substances which, due to their chemical characteristics and molecular size, move from a printed layer into the packed food.

Polymeric materials are generally large molecules without migration potential, thus they are usually not regarded as migrants. In addition, if ever ingested, polymeric substances with molecular weights above 1000 Daltons are not absorbed by the gastrointestinal tract and thus are not considered by the European Food Safety Authority (EFSA) to present a toxicological risk. Inorganic materials (such as white titanium dioxide pigment, calcium carbonate fillers, silica matting agents) are crystalline particles and therefore not migrants. Unlike the soluble dyes (basic dyes, acid dyes) which were sometimes used as colorants in the past, today’s organic pigments commonly used as colorants in inks are generally not regarded as being migrants, either.¹

There are different types of migration:

1) Set-off migration
Migrants can migrate from one layer to another, such as a surface printed layer to the non-printed food-contact surface which is later on brought into contact with food. If these are in direct or close contact like in a reel or a stack after printing, set-off migration can occur due to the pressure existing in the reel or stack.

2) Diffusion migration
Small and mobile molecules can easily penetrate into and diffuse across packaging material layers. This can occur even if the printed material has not yet been converted into a food package and filled with food, or later on when the printed package is filled with food and the food starts to ‘extract’ the migrants from the packaging material.

¹However, see chapter 5.2 for information on the bleeding properties of certain organic pigments.
The following upper figure illustrates set-off migration in a reel or stack, demonstrating that migration can occur even if an aluminum foil (indicated as ‘barrier’) prevents diffusion migration across the packaging material layers. It also shows that set-off migration can take place even if the ink layer as such is not in direct contact with the inner (food contact) PE layer, but another PE layer lies in between. The lower figure illustrates a situation where both diffusion migration and set-off migration take place. The situations shown are situations for liquid food cartons and demonstrate the cause and effect of the ‘ITX case’.

3) Gas-phase migration
Migrants can also migrate from a cardboard (the ‘releasing reservoir’) via the gas phase within the pack, to end up in food which acts as ‘recipient reservoir’ (gas phase migration). This can, for example, occur with migrants such as mineral oils or some UV photoinitiators that might not be generally known as being volatile such as organic solvents.

High temperature applications
High temperature treatments enhance the release of migrants from the printed layers. Typical cases are boiling the food in the bag, pasteurization, autoclave sterilization of packed foods under increased pressure, or food in microwaveable and ovenable packaging.

Furthermore, high temperature increases the mobility of migrants in the material layers through which they diffuse. Hot water and hot water vapor will add to this effect, because migrants are strongly driven out of a printed layer and, if not hindered by barriers, may be quickly carried into food by streams caused by steam distillation and condensation.

Additionally, the possibility should be considered that, in particular if high temperature exposure is involved, all food contact materials, including printed layers, may form small but potentially relevant quantities of breakdown products. These may consist of new low molecular substances, which were not present in the ink itself.

Drying process
Equivalently, in printed layers obtained via oxidative or UV curing, breakdown products, i.e. as formed from photoinitiators during the photo-induced hardening process, might be present. For printed layers from UV and electron beam curing (EB) inks, attention is also to be paid to minimize residual oligomers or monomers from incomplete polymerization. Finally, if the drying process is not sufficiently driven to be complete, in printed layers from solvent-based and water-based inks, relevant amounts of residual solvents or retarders might be present as potential migrants.
Food packaging is primarily intended for the protection of food. It is printed for product presentation and advertising as well as to provide information to the final consumer in accordance with, e.g. in Europe, the Regulation (EU) No 1169/2011 relating to the labeling (concerning contents, food ingredients and nutrition facts). In addition, printing is carried out for decorative and protective reasons.

There are exceptional instances where printing inks are applied on the inner side of the packaging or on inserts, e.g. for promotional purposes, and intentionally have direct food contact. These cases are only negligible in volume, and therefore this chapter mainly deals with printing inks applied to the non-food surface of food packaging.

The definition of packaging inks also includes primers, lacquers and overprint varnishes applied by a printing and/or coating process, such as flexography, gravure, letterpress, offset, screen, non-impact printing or roller coating.

2. Legal requirements and responsibilities

Packaging regulations worldwide

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European Union

In the European Union, currently comprising 28 member states, legislation on food packaging materials is harmonized and thus equally applicable in each member state. The Framework Regulation (EC) No 1935/2004\(^2\) related to materials and articles intended to come into contact with foodstuffs provides the basis for the assurance of a high level of protection of human health and of consumers’ interests in relation to food packaging, whether printed or not. The manufacturer of the final packaging is responsible for the compliance of the material and the article with the legal requirements laid down in Article 3:

\[
\text{Materials and articles […] shall be manufactured in compliance with Good Manufacturing Practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: a) endanger human health; or b) bring about an unacceptable change in the composition of the food; or c) bring about a deterioration in the organoleptic characteristics thereof.}
\]


2.1 Europe

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- endanger human health;
- bring about an unacceptable change in the composition of the food;
- bring about a deterioration in the organoleptic characteristics thereof.

The GMP Regulation (EC) No 2023/2006\(^3\) lays down rules on Good Manufacturing Practice for materials and articles intended to come into contact with food. It introduces general rules for all business operators in the supply chain, and specifies that quality assurance and control systems are established and implemented. All printing inks intended for use on food packaging are within the scope of this regulation. The Annex introduces detailed rules which relate to processes involving the application of printing inks to the non-food side of a material or article\(^4\):

\(^3\) 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, OJEU L384 29.12.2006

\(^4\) For more information, see the “EuPIA Position on Regulation (EC) No 2023/2006 of 22 December 2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food”, www.euapia.org

01

Printing inks applied to the non-food 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:

- through the substrate or;
- 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.

02

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:

- through the substrate or;
- 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.

03

The printed surfaces shall not come into direct contact with...
There is today no specific EU legislation concerning printing inks for food packaging. The main specific regulation pursuant to the Framework Regulation is the Regulation (EU) No 10/2011\(^{5}\) with its subsequent amendments on plastic materials and articles intended to come into contact with foodstuffs. It lays down an overall migration limit (OML) of 60 mg/kg food. In addition, specific migration limits (SMLs) or maximum content in the material or article (QM) are set for individual substances. The regulation contains a positive list of monomers and other starting substances as well as of additives. Substances used only in the manufacture of printing inks are not listed, and thus packaging inks are not under the scope of this regulation. However, ink on printed plastic packaging is covered if it contains components which are listed (thus are so-called evaluated substances), therefore the relevant restrictions, such as specific migration limits (SMLs) or maximum content (QM) have to be met by the final packaging (which includes the possible effect of certain ink substances). Finally, Article 8 provides for substances used for plastic layers in plastic food contact materials that they shall be of a suitable technical quality and purity. This requirement does not directly cover substances used for inks, however, it appears advisable to observe it in the light of Article 3 of the mentioned Framework Regulation (EC) No 1935/2004, which includes printed layers as part of the final packaging (for Siegwerk’s commitments on quality and purity of raw materials, see chapter 4.1).

Council of Europe (CoE)
The CoE covers, with currently 47 countries, an area which is bigger than the EU (www.coe.int). For decades, in an attempt to harmonize regulations in Europe, expert committees representing officials from the member countries have been working on food contact materials to issue proposals for regulations which are mostly based on positive lists. However, the CoE itself cannot issue laws; furthermore, it is a fact that member countries have only partly used these models (called ‘Resolutions’) for writing their own regulations and guidances for industry in the field of food contact materials. In the field of colorants, the CoE issued, in 1989, a document which was widely recognized as a workable standard. Resolution AP(89)1 “on the use of colorants in plastic materials coming into contact with food” was established with the support of the European pigment and dye manufacturers; consequently, it became an integrated part of industry standards and processes. Its specifications for limits for impurities in the colorants (see chapter 4.1) are regarded to be the benchmark for ink pigments as well despite the fact that its intended scope is restricted to mass coloration of plastics which are, in contrast to printed layers, in direct contact with food.

In fact, with its comprehensive list of potentially hazardous impurities, on a global level, it is currently the most demanding official standard for food contact materials. As presented in chapter 4.1, Siegwerk has even added its own expertise to these official purity specifications, by also including strong

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\(^{5}\)Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ L 12 of 15.01.2011
preventive measures (on dioxins and equivalent impurities) which aim to exclude any risk of transfer of hazardous impurities from pigments to food. The CoE also published, in 2005, Resolution AP(2005)2 on ‘Packaging Inks Applied to the Non-Food Contact Surface of Food Packaging’. It includes a positive list of substances allowed for use in inks. However, since it is largely incomplete and does not reflect current practices, it is not usable, either by regulators or by industry.

Switzerland
Switzerland was the first country to issue specific ink legislation. Switzerland’s amendment on the “Ordinance on Materials and Articles” (quoted as ‘817.023.21’) came into force on 1st April 2008 with a transitional period of two years, hence the requirements became applicable as of April 2010. This ordinance introduced a positive list (‘list of permissible substances’) with provisions on food packaging inks. It does not cover direct food contact inks. The positive list contains in Part A more than 1000 substances that are toxicologically evaluated. These are listed with specific maximum migration limits (SMLs) or without a specific limit, in which case the overall migration limit of 60 ppm applies. These substances may be used in the manufacture of inks, given that the SMLs are not exceeded for the final packaging.

For another almost 4000 substances in Part B, the Swiss Ordinance imposes an explicit threshold ‘not detectable’ (as a rule equivalent to 10 ppb) for the specific migration of non-evaluated substances. The authority processes notifications by requestors from the industry for toxicological evaluation and determination of an SML. Notifications must include appropriate data provided in toxicological dossiers with all necessary study reports. In the majority of the cases, this evaluation can result in thresholds which are higher than the default threshold ‘not detectable’. Siegwerk has ensured and continues to ensure, in Europe, that all raw materials used in printing inks and varnishes intended for food packaging are included in this positive list.

Despite the fact that the regulatory obligation is only legally binding for Switzerland and relevant for the packaging market in Europe, Siegwerk has safeguarded that the large majority of all raw materials used worldwide are listed as well; where currently some raw materials are missing, a global completion plan is running (see chapter 4.1).

Germany
Germany might be the first EU country to issue specific ink legislation. The draft of the so-called German Ink Ordinance is an amendment to the German regulation...
on materials and articles intended to come into contact with food (‘Bedarfsgegenständeverordnung’). After four years of discussion, the fifth draft was issued on July 14th, 2014 by the Federal Ministry of Food and Agriculture (BMEL). The Ordinance will regulate the formulation and application of printing inks for food packaging. It addresses printing inks and applications for indirect as well as for direct and foreseeable food contact and outlines exclusion criteria, substance use and migration limits.

There is a mandatory positive list (Annex 14) comprising about 1000 chemical substances including gliding references to the positive list of the Plastics Regulation 10/2011 (amongst them monomers for binders, solvents, additives, pigments, photoinitiators), some of which may be restricted with specific migration limits. Additions of substances to this positive list will require validation by the Federal Institute of Risk Assessment (BfR). Substances not on this positive list (= non-evaluated substances) may be used as well, unless they are ‘CMR’ substances (carcinogenic, mutagenic, reprotoxic = classes 1A, 1B and 2 acc. to the CLP Regulation) and as long as they are not migrating > 10 ppb.

Inks for direct food contact uses must be manufactured exclusively from materials which are on the positive list of Annex 14. This requirement refers to inks for foreseeable transient food contact as well. For these applications, additional pigments (Table 2 of Annex 14) may be used for two years after the Ordinance becomes applicable. There will be no inventory list of non-evaluated materials attached to the Ordinance (like in the Swiss Ordinance), but the BMEL aims to implement a separate inventory list managed by the Federal Institute of Consumer Safety and Food Safety (BVL), the legal status of such a list still being unclear. Furthermore, there is a mandatory requirement for issuing a Statement of Conformity upon first market introduction for raw materials, printing inks and printed products.

The use of nanomaterials is only permitted if explicitly allowed in the positive list of Annex 14 or if there is no migration detectable in the food (simulant). Most of the common pigments used in food packaging inks would fall under this category. However, the ink industry has proved via a publicized analytical study\(^8\), which has been acknowledged by BMEL and BfR, that currently there is no concern from nanomaterial (= pigment) migration into foodstuff. So current pigment uses in inks for front and lamination print are not affected. The Ordinance will enter into force with a transitional period of two years. However, at the date of print of this Guidance, the Ordinance is still at draft stage, and the positive list as well as the text is still subject to changes.

Siegwerk has already provided substantial input, covering this fifth draft, in the official association statements forwarded to the BMEL in order to safeguard that current products will continue to be compliant with the envisaged legislation.

Nordic countries (Denmark, Finland, Iceland, Norway, Sweden)

In May 2012, based on the perception that in the EU there is no regulation on inks yet, the Nordic Council of Ministers, representing the Nordic Cooperation, has issued the publication “Food contact materials and articles: Printing inks. Check lists [sic] for compliance in industry and trade and control by food inspection” (www.norden.org).

\(^8\) Nanoscale Pigment Particles: Analysis of the migration behaviour from printing ink layers of printed food packaging into the food (DLR, April 2013)
Know how

The Food and Drug Administration (FDA) is the regulatory body in the United States that regulates food additives. The FDA does not approve specific products, such as printing inks, for direct or indirect food contact. Their sole concern is with materials that may become, either by default or design, food additives. They rely on properly designed extraction studies before determining the food additive status of a printing ink. Food additives are divided into direct and indirect food additives.

Direct food additives are not naturally a part of the food but are approved by the FDA for direct addition to food in order to perform a specific function. Indirect food additives are also referred to under the umbrella term ‘food contact substances’ (FCSSs), which, mixed with other substances will form a food contact material (FCM). Indirect food additives are not approved for direct addition to food. There is no intent that they have a functional effect on the food, however, they may reasonably be expected to migrate into food, that is, become a component of the food.

2.2 North America

These checklists are not strict law, however they represent enforceable guidance to the packaging chain in order to ensure compliance; they set a frame with minimum requirements to all responsible parties in the supply chain, from producers to food industry and trade. All the communication and the measures presented in this Siegwerk Customer Guidance are in line with all provisions of these ‘checklists’.

Turkey
Turkey has implemented the relevant EU regulations on food contact materials in a national regulation, the “Turkish food codex regulation on materials and articles which are intended to come into contact with foodstuffs” (www.tarim.gov.tr), therefore the same migration control principles, positive lists and thresholds are in place.

Russia
In 2013 the Russian Federation issued a draft Technical Regulation on the Safety of Materials in Contact with Food. In this regulation, for example, there is no general positive list approach. However, for many polymers, Permissible Quantities of Migration (PQMs) have been established. These lists are not exhaustive, as there are no PQMs for starting monomers or for most additives. A declaration of conformity is obligatory for all materials in contact with food products. The migration of harmful substances emitted by materials in contact with food products made of composite materials is investigated only for the layer directly in contact with food products. Regarding inks, it can be concluded that those not in direct contact with food are not included in the scope of the regulation today.

USA
The Food and Drug Administration (FDA) is the regulatory body in the United States that regulates food additives. The FDA does not approve specific products, such as printing inks, for direct or indirect food contact. Their sole concern is with materials that may become, either by default or design, food additives. They rely on properly designed extraction studies before determining the food additive status of a printing ink. Food additives are divided into direct and indirect food additives.
Printing inks or coatings on food packaging materials may be potential indirect food additives. Food packaging substrates like plastics, paper or board as well as other materials like adhesives or coatings are regulated by 21 CFR parts 174-177, which provide positive lists of authorized (‘evaluated’) substances that are approved for use up to a fixed level. Similar regulations for food packaging inks do not exist.

Additionally, for several years, individual manufacturers of substances intended for food contact material have been able to obtain evaluation and approval of their commercial product for a defined use via a Food Contact Notification (FCN) process whose data requirement for chemical composition, toxicology, migration data and consumer exposure is very demanding.

The Food and Drug Administration (FDA) does not have specific guidelines for printing inks or coatings applied on the non-food contact surface of food packaging. The FDA is solely concerned that a barrier to migration is sufficiently in place and that the ingredients of inks and coatings will not become food additives. This type of contact does not require compliance with the indirect food additive guidelines (21 CFR 170-190) must be complied with. The converter is responsible for ensuring that the barrier is sufficient to prohibit migration.

Migration testing and analytical test data may be needed to support a claim of no migration. A conclusion of no migration can be based on extraction testing, 100% migration calculations and diffusion calculations that model testing conditions. The FDA has determined that up to 50 ppb limits in migration is “negligible”, but it is dependent on the dietary exposure of the material along with known risks of the migrating material/ substance (Ramsey Proposal).

Canada

The Canadian Food Inspection Agency (CFIA) and the Health Products and Food Branch (HPFB) of Health Canada are both responsible for food packaging issues. Health Canada sets standards and evaluates food packaging against these standards. Packaging requirements at federally regulated packaging facilities are enforced by the CFIA. As a best practice, Health Canada recommends that food-packaging companies obtain a Letter of No Objection from the Health Protection Branch for any packaging that may come into contact with food. (It is important to note that a Letter of No Objection does not absolve the packer from liability, should there be a failure in package design leading to the contamination of the food product.) To obtain a Letter of No Objection, detailed information about the printing and packaging processes is required, along with representative extraction test data, where possible. If the food package has a functional barrier between the food and the printed ink film or, if the ink is completely dry and there is no ink set-off during stacking/nesting of the packages, then the packaging is considered to have “no direct food contact” with the ink film and a Letter of No Objection is not required. More information can be found in the Canadian Food Inspection Agencies Guidelines for Submissions, Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products.
China

Food contact materials and articles are regulated by Standard GB 9685-2008 ‘Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials’. Article 3 provides the following principles for the management of substances (called ‘additives’) with regard to all materials and layers, including printed layers:

- Migrating additives shall not impose any harm to the health of human beings;
- Migrating additives shall not cause any changes in food properties (such as ingredients, structure, color, smell or flavor);
- Use level of additives in food containers and packaging materials should be as low as possible;

- Additives must comply with relevant quality specifications/standards.

In Annex A of the Standard GB 9685-2008 the ‘additives’ are allocated to the scope of use and sometimes also to specific types of materials. For many of them, maximum usage levels per type of material are fixed, partly based on the European Regulation (EU) No 10/2011, and many are restricted by SMLs that are predominantly identical to those in Europe. **Inks:** There are also few ‘additives’ listed to be used in printing inks. Less than 200 substances are explicitly allowed for printing inks, thus the listed ‘ink additives’ are only a minute part of all substances that are today necessary to produce packaging inks. Therefore, these listings cannot be considered complete. There is a Government announcement (2013) No. 241, which mentions that a clean-up project for food related standards is ongoing. As part of this project, the GB9685 will be revised. Currently, a second draft is available. Furthermore, several national Standards are planned, including one specifically for printing inks. Today, there is no official information as to when the new Regulations will enter into force or what their concrete content will be. Therefore, to offer compliant and safe inks, Siegwerk’s approach today is:

Wherever listed substances are used in the manufacture of an ink for food packaging, the ink is designed so that given restrictions can be met. For all substances that are not explicitly listed, an internal risk assessment is performed to ensure a high level of safety of all our inks.

Taiwan

Under the “Act Governing Food Sanitation”, Art. 13 states: Food utensils, food containers, food packaging or food cleansers under any of the following circumstances shall not be manufactured, sold, imported, exported or used:

1. those that are toxic;
2. those that tend to cause unfavorable chemical reactions; or
3. those that are otherwise harmful to health.

The related “Sanitation Standard for Food Utensils, Containers and Packages” provides migration limits (overall migration and SMLs) for food contact materials. In particular, some plasticizers for plastics, which are also usable or used in printing inks, are restricted with the same SMLs as in Regulation (EU) No 10/2011.
Singapore
The ‘Food Regulations’ are based on Chapter 283, Section 56 (1) of the ‘Sale of Food Act’. Part II, section 37 deals with ‘Containers for food’. In addition to providing limits for the vinyl chloride monomer, this section prohibits “any package or container” which “yields, or is likely to yield, to its contents any compounds known to be carcinogenic, mutagenic or teratogenic or any other poisonous or injurious substance”.

Malaysia
Based on the Food Act of 1983, Packages for Food are regulated in Part VI of the ‘Food Regulations 1985’. In particular, point 27 “Use of harmful packages prohibited”, bans any package “which yields or could yield to its contents, any toxic, injurious or tainting substance, or which contributes to the deterioration of the food”. A new Draft Regulation 27B (amending the 1985 Food Regulations) was notified to the WTO in March 2015. This Draft includes migration limits for certain metals and other substances (15 substances, including formaldehyde, phthalates or epoxidized soybean oil) from plastic food contact materials and articles that come into contact with food.

Indonesia
BPOM’s (Indonesia Food and Drugs Administration) regulation number HK.00.05.55.6497 on Food Packaging Materials, Annex 1, chapter 1.2 specifically restricts the formulation of packaging inks and varnishes. It is an exclusion list of toxic substances (i.e. colorants, stabilizers, solvents), which is of course met by Siegwerk’s inks as they have long been compliant with the more stringent and comprehensive substance bans of the ‘Negative List (NL) Regulations’ of the Japanese Printing Ink Manufacturers Association (JIPMA) as well as the EuPIA Exclusion List. Regulation number HK.00.05.55.6497 on Food Packaging Materials also provides positive lists of authorized substances for plastics and several other food contact materials (but not for printing inks), and lays down maximum permissible amounts of extractives for the specific food contact material which are equivalent to those applicable in the USA and (as an overall migration limit) in the EU. Furthermore, the regulation contains a positive list for additives for food packaging as well as some specific migration limits with the respective migration test methods. These limits are only valid for the packaging materials, but not including the effect of printing inks.

Thailand
Food packaging in Thailand is regulated by the Food Act, B.E. 2522 (1979). Section 26 of the ‘Food Act B.E. 2522’ states: “Food of the following description shall be deemed impure; (1) Food which contains anything likely to be dangerous to health […] (5) Food in containers made of materials which are likely to be dangerous to health.” Food containers must be clean and free of germs, must not emit any heavy metals or other substances that contaminate food at levels that may be harmful to health, and must not emit any color to food, according to the Ministerial Notification No 92, B.E. 2528 (1985).

Philippines
Food safety in the Philippines is regulated by the Republic Act No. 10611 (an act to strengthen the food safety regulatory system in the country to protect consumer health and facilitate market access of local foods and food products, and for other purposes), shortly known as the ‘Food Safety Act of 2013’. In Section 18 a) it is stated that “The DOH (Department of Health) shall ensure the safety of all food processing and product packaging activities.” There are several standards proposed by the Thai Industrial Standards Institute (TISI) regarding packaging material, as for example the TISI 1069-2549 (Colorants for plastics for food contact use). These standards are voluntary, merely the standard of Sterile pharmaceutical product is a compulsory standard.

India
In India, the Food Safety and Standards Authority of India (FSSAI) is responsible for protecting and promoting public health through the regulation and supervision of food safety. FSSAI has been established under the Food Safety and Standards Act, 2006.

Packaging components that may become part of the food are regarded as food additives and regulated by Bureau Circular No. 2006-016 (Updated List of Food Additives). This list contains several tables of permitted food additives with maximum allowed amounts in different food categories.
Food packaging:
The ‘Food Safety and Standards Act’ (FSSA, No. 34 of 2006) introduces regulation on food contaminants, in particular including contaminants from packaging. Specific provisions on packaging are detailed out in the ‘Food Safety and Standards (Packaging and Labelling) Regulations, 2011’. Section 2.1.1 (2) regulates plastics in contact with food, stating generally that “containers made of plastic materials should conform to the following Indian Standard Specification (IS)” (followed by a list of 10 Indian Standards on 10 different plastic types previously issued by the Bureau of Indian Standards). These Standards include overall migration limits (identical to those in the EU) and/or positive lists of authorized substances for the 10 plastic types (but not for printed layers), with maximum concentration limits.

Ink:
The voluntary Indian Standard IS 15495:2004 ‘Printing Ink for food packaging – Code of practice’ prescribes guidelines for printing inks for use on food packages. The standard differentiates between four categories of printing inks:

1) Printing inks on external (secondary) food packaging. They can be formulated freely, but must not contain substances from the exclusion list.

2) Printing inks on direct food packaging (immediate food wrappings). Those must be applied to the outside of the food wrapper, comply with the exclusion list and must not contain toxic substances. Inks are to be printed in such a manner as to avoid set-off.

3) Printing inks for direct food contact. They must be formulated only with food additives.

4) Printing inks for disposables (e.g. paper plates, drinking straws, or table napkins). Those must not contain substances from the exclusion list and they shall be formulated to avoid bleeding onto food.

The exclusion list in Annex A comprises pigments and compounds based on antimony, arsenic, cadmium, chromium (IV), lead, mercury and selenium as well as several dye colorants, solvents, plasticizers and other compounds (e.g. dioxines, nitrosamines and others). It is less demanding than the JPIMA and EuPIA exclusion lists – in particular, toxic phthalate ester plasticizers usable in solvent-based inks are not banned.

With regard to converter’s obligations, in the case of immediate food wrappings, printing inks must be applied only on the outside of the wrapper, and are to be printed in such a manner as to avoid set-off. Finally, IS 15495, No. 5.4, generally states that “where the nature of the food packaging is such that migration or bleeding from dyes or other soluble coloring agents is likely to occur, printing inks shall not be formulated with such coloring agents.”

Japan
Under the Food Sanitation Law, Chapter III “Apparatus and Containers and Packaging”, Article 16, the inertness of food packaging must be ensured. Packaging which contains or “is covered” with toxic or harmful substances and involves a risk for human health, and food contact materials that “have a harmful effect on food” and involve a risk for human health, are banned. The Japanese Printing Ink Manufacturers Association (JPIMA) has issued the Voluntary Regulations Concerning Printing Inks (Negative List (NL)). All of Siegwerk’s inks for food packaging are in accordance with the exclusion criteria of the NL.

Siegwerk’s inks and varnishes are compliant – and even safer – in any case.
Korea

In Korea, the Food Sanitation Act is the basic law dealing with potential risks to human health caused by foods.

The Food Code is issued by the Ministry of Food and Drug Safety (MFDS). (Before March 2013 it was the Korean Food and Drug Administration (KFDA), however, the transition seems to be not entirely finished yet). The Food Code contains the relevant information regarding the quality and safety of foods covering specific maximum levels for contaminants, heavy metals, pesticide residues, veterinary drug residues, etc. The provisions contained are applicable to all foods under the Food Sanitation Act.

There are some specific packaging ink requirements in the Korean law. “Korea Standards and Specifications for Utensils, Containers and Packaging for Food Products” (formerly Article 7, Standards & Specifications for Equipment, Containers and Packaging) states the following:

*The food contact surface shall not be printed in the manufacture of utensils, containers and packaging. Printing inks applied to the non-food side must be sufficiently dried and in this case the benzophenone as ink compounds shall not migrate more than 0.6 mg/L. In case of flexible packaging, among synthetic polymer packaging with printing non-food side, residual toluene as ink compounds shall not be more than 2 mg/m².*

It is also to be noted that di-(2-ethylhexyl)phthalate (DEHP) shall not be used in the manufacture of packaging (even though not explicitly stated, this seems to apply to printing inks as well – unless it is safeguarded that no migration into the food takes place).

Hong Kong

Food packaging materials in Hong Kong are currently not required to comply with Chinese food law. Food contact materials are regulated in a shared responsibility of the Food and Environmental Hygiene Department (FEHD) and the Customs and Excise Department (C&ED).

The basic food law in Hong Kong is laid down in Part V of the Public Health and Municipal Services Ordinance (Chap. 132). It stipulates that all food for sale in Hong Kong must be fit for human consumption. The migration of packaging components that may render food injurious to health is prohibited.

Mercosur

Mercosur or Mercosul (Spanish: Mercado Común del Sur, Portuguese: Mercado Comum do Sul) is an economic and political agreement among Argentina, Brazil, Paraguay, Uruguay and Venezuela. Expert committees from the Mercosur countries are working on proposals for regulations on food contact materials, the so-called GMC Resolutions (‘Grupo Mercado Comun’). The regulations were created on the basis of the current EU and U.S. regulations. GMC Resolutions must be incorporated into national legislations in order to become effective. In Brazil, the Agência Nacional de Vigilância Sanitária (ANVISA) incorporates the GMC Resolutions into national Resolutions, in Argentina the Ministry of Health is responsible, in Uruguay it is the Ministry of Public Health and in Paraguay the Ministry of Public Health and Social Welfare. The basic document is GMC Framework Resolution 3/92 which provides general criteria for all food contact materials. It is required that all substances used in packaging materials intended to come in contact with foodstuffs must fulfill the positive list principle and must comply with the given migration limits. At present, there are 27 GMC Resolutions in force dealing with packaging materials intended to come into contact with food, of which 10 are related to plastic materials (including varnishes and coatings). GMC 56/92 provides general criteria for plastic packaging and articles. With regard to migration thresholds, i.e. the Overall Migration Limit and the Specific Migration Limits (SMLs), it is similar in its structure and content to Regulation (EU) No 10/2011.

2.4 Latin America
Nevertheless, restrictions differ, e.g. the overall migration limit in Mercosur countries is 50 mg/kg food, whereas in Europe it is 60 mg/kg. Several follow-up GMC Resolutions have published proposals with the positive list of polymers and monomers of plastics, and in particular of additives for plastics (GMC Resolution 32/07), which harmonizes with the list and SMLs of Regulation (EU) No 10/2011. In the Mercosur states, there is no specific regulation for printing inks intended for non-food contact. Nevertheless, a plastic outside-printed food packaging material that falls under the scope of GMC Resolution No. 56/92 must meet migration limits when it is tested for compliance. As the printing ink becomes part of the plastic packaging, the migration of substances which are both part of the plastic packaging and at the same time also used in the printing ink must be considered with their combined effects. In this respect, non-food contact inks are indirectly covered by Mercosur legislation and must not contain potential migrants in amounts that would possibly lead to exceedance of the given migration limits. Furthermore, coatings intended for direct contact with food would fall under Resolution GMC 56/92 and would have to be produced using only substances of the positive lists. Additionally, printed materials for direct food contact must comply with specific metal migration limits as described in Resolution GMC 15/10.

Andean Community / CAN

The Andean Community (Spanish: Comunidad Andina, CAN) is a customs union consisting of four South American countries: Bolivia, Colombia, Ecuador and Peru. The community only recently began adopting common measures, i.e. the common legislation has only been rudimental. Andean food packaging regulations are principally based on the Mercosur legislation.

Chile

The Ministry of Health of the Chilean government issued Decree No. 977/1996, the Sanitary Food Regulations. These Regulations contain articles that cover food packaging. The requirements are not very specific and similar to the basic requirements in most of the world. E.g. Article 123 states that packages must not transfer toxic substances to food, nor lead to sensory or nutritional changes of the food. However, there are no specific regulations on food packaging materials or on inks for food packaging.

Mexico

Until now, there has been no specific legislation in Mexico on food packaging material or on printing inks for food packaging. It is expected that there will be new standards put in place by the Mexican Organization for Standardization and Certification – Normex – which will be based on the U.S. regulations.

Central America

The seven states of Central America (Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama) do not (yet) have common or single legislation on food packaging materials in place nor on inks for food packaging.

The following table gives, as a summary, an overview on the type of Regulations in the different countries.

<table>
<thead>
<tr>
<th>Country</th>
<th>Food Packaging Legislation</th>
<th>Negative lists</th>
<th>Positive lists</th>
<th>Migration limits</th>
<th>Printing Ink Legislation</th>
<th>Positive lists</th>
<th>Negative lists</th>
<th>Migration limits</th>
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</tbody>
</table>

9 Implicit limits by substrate regulations, see respective chapter
10 Draft “German Ink Ordinance”
Positive list principle
For direct food contact materials, in particular for plastics, there are regulations in place which demand that only those substances be used in the manufacture of these materials that are approved for this purpose (positive list principle). In many cases, the affected industry compiles comprehensive toxicological data on substances of interest to obtain this approval. The evaluation of substances is performed by toxicologists of the authorities. In case of EU legislation it is done by the experts from the European Food Safety Authority (EFSA) based on a very demanding and comprehensive set of data on toxicity focusing on the chronic effects from lifelong exposure to the substances in question.

Migration (EU)
Depending on the quality of the toxicological data, acceptable exposure levels from food intake (to which the consumer can be exposed lifelong) are determined with high safety margins. The legislator compiles these final toxicological evaluations in the positive lists which are part of the packaging regulations. Thus these positive lists provide the data for acceptable transfers into food for each individual substance (specific migration limit, SML). While many substances are restricted by an SML, it should be understood that for those substances without an SML the food packaging regulations specify an upper limit for the substance transfer, which is defined as the sum limit of all substances migrating into food (overall migration limit, OML).

Migration (USA)
In the USA, the positive lists for food contact materials issued by the Food and Drug Administration (FDA) are equivalently based on very demanding industry notifications and toxicological evaluations. The substances listed therein are authorized (having been “evaluated”) for the respective food contact materials and, in many cases, are subject to further limitations such as maximum use concentrations which shall safeguard that migration will be lower than quantities of concern. As well, the overall migration is limited.
Printing inks
While in Europe (except for Switzerland – and Germany in the future) and in the USA, as well as in almost all other parts of the world, printing inks on food packaging are currently not regulated via positive lists, it is by coincidence that many evaluated substances for food contact materials are also in current use for printing inks. According to the European Plastics Regulation, if evaluated substances are contained in a printing ink printed on plastic packaging, the entire packaging, including the printed layer, must comply with these limits. In addition, the OML (in Europe normally 60 mg/kg food, equivalent to 60 ppm), will also be applied for the entire packaging, including the printed layers. Both provisions require attention from the ink manufacturer and the converter.

All substances which are used in printing ink formulations but which are not officially approved by a national authority, and thus not explicitly and positively listed as evaluated in regulations and guidelines, are principally to be regarded as ‘non-evaluated’.

It is common sense amongst legislators worldwide that substances without or with only a small amount of toxicological data are not considered safe, by default. Relevant regulations in Europe, Switzerland, and in the USA determine that non-evaluated substances should not be detectable in food. It is important to be aware that this requirement is compulsory, and it is enforceable by food control authorities.

3.2 Non-evaluated substances

Europe
There is a general understanding in Europe – and in Switzerland an undisputable legal provision (and the same will hold true for Germany in the future) – that ‘not detectable’ means that a default migration threshold of 10 μg/kg (=10 ppb) for all of these substances is applicable. However, for substances with carcinogenic and/or mutagenic properties, the legally enforceable threshold will be lower, i.e. correspond to the most sensitive, reliable analytical method available.

USA
In the USA, although not backed up by the FDA’s official consent, there has long since been a general consensus in the scientific community that, for claiming absence of migration of non-approved substances, a default detection limit of 50 ppb is, as a rule, deemed sufficient. However, control authorities are entitled to assess on a case-by-case basis at which concentration in food a non-approved substance would be tolerated, respectively at which action level an enforcement measure would be imposed. As outlined above, this threshold can only be ignored if favorable toxicological data supports a higher safety margin. The resulting new threshold would have to be determined by recognized toxicologists and according to the criteria established by EFSA for Europe, or respectively by the FDA for the USA.
3.3 Acceptable migration is very low

The packaging chain should be aware of the minute amounts of substances which can, in case of migration, lead to noncompliance:

Sugar cube (2.5 g) dissolved in...

Specific migration limits for evaluated substances: some ppm down to ppb

Threshold for non-evaluated substances: 10 ppb

Examples of values

- 10 grams per kilogram (1%)
- 1 gram per kilogram (1‰)
- 1 milligram per kilogram (1 ppm)
- 1 microgram per kilogram (1 ppb)

- Alcohol in drinks
- Alcohol in blood
- Nitrate in water
- Heavy metal in water

3.4 Migration assessment via worst-case calculation

The following table gives an idea about the maximum amounts that can theoretically migrate into food from the printed layers. These calculations are based on ‘100% migration’ also known as ‘worst-case’ migration. These worst-case calculations are immediately applicable in Europe, Mercosur and China.

Of course, migration into conventionally packed food is not likely to occur to this maximum extent as the majority of practically observed migration cases do not even come close to the worst-case assumptions. This is substantiated by public studies and many observations made in industry which indicate that under normal conditions only a minor or even a minuscule part does actually migrate into the food-stuff. However, regulations stipulate that this assumption must be verified on the packaging in its finished state (or by software-aided migration modeling).
### Content of migrant in dried ink layers, applied at 100% area coverage

<table>
<thead>
<tr>
<th>Evaluated substances</th>
<th>Max. migration with 6 dm²/kg food</th>
<th>Max. migration with small package</th>
<th>SML (Europe)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With 3 g/m² dry ink</td>
<td>With 5 g/m² dry ink</td>
<td></td>
</tr>
<tr>
<td>25% ATBC (plasticizer, solvent-based inks)</td>
<td>45 mg/kg</td>
<td>75 mg/kg</td>
<td>187 mg/kg</td>
</tr>
<tr>
<td>10% DEHA (plasticizer, solvent-based inks)</td>
<td>18 mg/kg</td>
<td>30 mg/kg</td>
<td>75 mg/kg</td>
</tr>
<tr>
<td>2% Erucamide (lip agent, solvent-based inks)</td>
<td>3.6 mg/kg</td>
<td>6 mg/kg</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>1% Di-2-ethylhexylphosphoric chloride (surfactant, water-based inks)</td>
<td>1.8 mg/kg</td>
<td>3 mg/kg</td>
<td>7.5 mg/kg</td>
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<tr>
<td>0.02% Benzotriazolzone (biocide, water-based inks)</td>
<td>0.036 mg/kg</td>
<td>0.06 mg/kg</td>
<td>0.15 mg/kg</td>
</tr>
<tr>
<td>5% Benzophenone (photoinitiator in UV inks not intended for food packaging)</td>
<td>9 mg/kg</td>
<td>15 mg/kg</td>
<td>37 mg/kg</td>
</tr>
</tbody>
</table>

### Typical example

**Max. migration with 6 dm²/kg food**

- EU cube 10×10×10 cm, 1 kg food

**Max. migration with small package**

- Case 40 g food in pouch 10×3×1.5 cm = 1 dm², 25 dm²/kg

### SML (Europe)

- With 3 g/m² dry ink
- With 5 g/m² dry ink

### Non-evaluated substances

<table>
<thead>
<tr>
<th>Non-evaluated substances</th>
<th>Max. migration with 6 dm²/kg food</th>
<th>Max. migration with small package</th>
<th>SML (Europe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25% Mineral oil (oleoresinous offset inks not intended for food packaging)</td>
<td>45 mg/kg</td>
<td>75 mg/kg</td>
<td>187 mg/kg</td>
</tr>
<tr>
<td>5% Low molecular photoinitiators (UV curing ink not intended for food packaging)</td>
<td>9 mg/kg</td>
<td>15 mg/kg</td>
<td>37 mg/kg</td>
</tr>
<tr>
<td>0.5% Low molecular photoinitiators (UV curing ink not intended for food packaging)</td>
<td>0.9 mg/kg</td>
<td>1.5 mg/kg</td>
<td>3.7 mg/kg</td>
</tr>
</tbody>
</table>

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*Overall migration limit Europe (SML)*
If the quantity of all potential migrants in all components of a certain food packaging is known, the so-called ‘worst-case’ calculation is a reliable method to verify the maximum migration possible. Siegwerk has a ‘worst-case calculator’ available for customers on www.Siegwerk.com/en/customer-segments/customer-service/food-packaging-safety.

European regulations explicitly allow the verification of compliance via this method. If the results of the worst-case calculation for the packed food unit are lower than the applicable thresholds, no further measures, such as practical migration testing, are required. However, it must be noted that the permissible migration is not stipulated for average packed food in average packaging; in fact, authority control labs ultimately examine actual packed food in the actual packaging unit. Therefore, all potential factors of influence, such as the ratio of surface to volume of food and the other parameters as specified in chapter 6.2 have to be carefully considered. In case of any doubt, the real migration should be determined by the printer and the food packer using official analytical methods stipulated by the regulations.

It is to be noted that, depending on the nature of the packed food unit and the individual migrant, the European regulations provide certain additional checks of migration results (normally conversions which are alleviations) such as, for some migrants, multiplication with a ‘fat reduction factor FRF’ before comparison with legal limits, or application of a default surface/volume ratio (EU cube) instead of the actual one in case of low volume packaging. Particular attention is required with regard to the verification of compliance of non-evaluated substances, as the following table demonstrates.

### EFFECT OF THE POTENTIAL PRESENCE OF NON-EVALUATED SUBSTANCES

<table>
<thead>
<tr>
<th>Content of migrant in dried ink layers</th>
<th>Migration risk of the packaging structure</th>
<th>Migration rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worst case = 100%</td>
<td></td>
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<tr>
<td>0.005% = 50 ppm</td>
<td>10 ppm</td>
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<td>0.05%</td>
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<tr>
<td>0.5%</td>
<td>1000 ppm</td>
<td>5%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Migration risk of the packaging structure</th>
<th>Migration rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worst case = 100%</td>
<td></td>
</tr>
<tr>
<td>0.005% = 50 ppm</td>
<td>50 ppm</td>
</tr>
<tr>
<td>0.05%</td>
<td>100 ppm</td>
</tr>
<tr>
<td>0.5%</td>
<td>1000 ppm</td>
</tr>
</tbody>
</table>

Considering the minute amounts which can lead to noncompliance, examination of the individual material combinations and their migration risk is indispensable!
Siegwerk’s efforts to supply the safest inks in the world go far beyond legal requirements. Siegwerk is committed to full compliance with the EuPIA guidelines, amongst these the EuPIA GMP. Food packaging inks are formulated and manufactured taking into consideration many individual and varying parameters relating to substrate, application and end use. Not only are toxic substances excluded based on unequivocal exclusion criteria but moreover all food packaging inks are designed to minimize the potential for the transfer of ink components of concern into food, whilst meeting the high end-use requirements.
4.1 Pharma, cosmetics and hygiene packaging inks

Not only food packaging can lead to an exposure of the consumer to chemicals used in the ink – there are several other scenarios that show potential for an uptake of such chemicals. For example, printed pharmaceutical packaging: like in food packaging, there is a risk that migratable substances can end up in the pharmaceutical products which are then ingested by the patient. Thus there is a responsibility of the packaging chain to ensure the safety of pharmaceutical packaging. Cosmetics: even though cosmetics are not typically eaten, there are several exposure scenarios which highlight the importance of the use of safe printing inks on the packaging. Cosmetics are usually applied to the outside of the body (skin, nails, hair, lips) and can be (partially) absorbed into the body. Thus, there is an exposure scenario that is not as critical as with food packaging, yet it is to be addressed. The same holds true for hygiene products. The most sensitive application is the printing of diapers (especially on the landing zone but also on the outside). There is a long term direct contact of the printed material with the skin and the mucous membranes of a baby, which must be evaluated to determine the potential risk. But also in less sensitive applications, like the printing of tissue packaging, there is a potential exposure of the consumer to substances from the print – and therefore risk assessment is needed.

Today, there are almost no specific regulatory requirements for the above mentioned applications, and therefore each job has to undergo a specific risk assessment. However, Siegwerk has chosen to be more restrictive in order to safeguard very high safety standards. At Siegwerk, we require all of our inks for pharma, hygiene and cosmetics to be as safe as our food packaging inks! As on the one hand, for food packaging there are specific regulations available, and on the other hand, the human exposure via food packaging is by far higher than through other applications, we choose to be on the very safe side for all pharma, hygiene and cosmetics inks.
4.2 Selection of raw materials

All raw materials used by Siegwerk in the formulation of printing inks are selected, by Siegwerk subsidiaries worldwide, in accordance with the EuPIA GMP. Consequently, raw materials do not belong to any of the following categories (exclusion criteria)\(^1\):

a) classified as ‘carcinogenic’, ‘mutagenic’ or ‘toxic to reproduction’ categories 1 and 2, according to the provisions of Directive 67/548/EEC on dangerous substances (categories 1A and 1B according to CLP, Regulation (EC) No 1272/2008). Note: Category 3 substances (CLP Category 2) will only be used after a migration study has confirmed that migration levels are either within published SML or TDI values, or are below an intake (threshold of toxicological concern) of 0.15 μg/person/day. Category 3 reproductive toxicants (R62, R63; H361f, H361d) without a published limit may be used if the migration levels are confirmed to be not detectable (with a detection limit of 0.01 mg/kg food);

b) classified as ‘toxic’ and ‘very toxic’;

c) colorants which are based on and compounds of antimony\(^13\), arsenic, cadmium, chromium (VI), lead, mercury, selenium;

d) all substances identified in the REACH Regulation (EC) No 1907/2006, Title VIII and Annex XVII (restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles) and its amendments, if their use in a packaging ink would lead to an infringement of Article 3 of the Framework Regulation.

Furthermore, Siegwerk packaging inks worldwide are formulated without raw materials excluded by the Japanese Negative List (NL) Regulation of JPIMA\(^14\). Conformity is covered as well with the Indonesian exclusion list of toxic substances by BPOM (see chapter 2.3).

The same holds true for Siegwerk’s global compliance with relevant voluntary industry standards, such as the Indian Standard IS 15495 ‘Printing Ink for food packaging – Code of practice’, as well as with the China Standards HJ/T 371-2007 ‘Technical requirement for environmental labeling products – gravure and flexible printing inks’, QB 2920.2-2008 ‘Limits and determination method of certain toxic elements in printing inks, Part 2: Lead, Mercury, Cadmium, Chromium (VI)’ and QB 2930.1-2008 ‘Limits and determination method of certain toxic elements in printing inks, Part 1: Soluble elements’, whose core provision is also a negative list of toxic substances (see chapter 2.3).

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\(^{12}\)Raw materials may contain starting substances and/or components which are CMR or T, T+, but at levels which do not affect the classification of the raw material.

\(^{13}\)Any migration of these into foodstuffs must comply with any relevant limit.

\(^{14}\)Voluntary Regulations Concerning Printing Inks (Negative List (NL) Regulations), current Edition May 1, 2014 (available on request). Definitions and terms of this document from the Japanese Printing Ink Manufacturers Association apply.
Control of raw materials:
Siegwerk has implemented a comprehensive raw material introduction process. It is based on a centrally coordinated approval via Global HSE which is operated on a worldwide basis:

- **Sample request**
- **Lab tests**
- **Trial preparation**
- **Global HSE approval**
- **Business approval**
- **New raw material**

**Checklist for approval**

- Exclusion criteria (e.g. no carcinogenic, mutagenic, neurotoxic or toxic substances)
- Defined purity standards and full understanding of existing impurities
- Compliance with chemical registration
- Full understanding of chemical composition for food packaging

**Process steps in the responsibility of Global HSE**

With this process Siegwerk strives to even further achieve complete knowledge of the chemical composition of all raw materials intended for food packaging inks, down to traces of 100 ppm and less. Thus, Siegwerk’s risk assessment is based on full knowledge of the identity, the positive lists status, the migration threshold and the quantity of every potential migrant present in ink layers. This is important in particular for Siegwerk’s risk management of non-evaluated substances, which must not be detectable in food (default threshold 10 ppb).

How Siegwerk ensures the control of deliveries of raw materials after the approval:
A risk assessment of supplied raw materials is performed to determine potential non-consistency of raw materials with Siegwerk’s specifications. As an example, an internal Siegwerk ‘Formulation Guideline – Instruction for Analytical Testing’ safeguards via practical measurements that all batches of certain commercial pigments deemed critical meet Siegwerk’s very strict dioxin purity specifications.

**Organoleptic properties (odor and taste)**
Siegwerk carefully chooses all raw materials to ensure that printing inks, if correctly selected and processed by the printer, do not inadvertently affect foodstuffs in terms of odor and taste. Siegwerk maintains two sensory panels with at least 12 qualified panelists each. They perform routine checks (e.g. quality controls of prints) as well as checks during product development (e.g. assessment of sensory behavior of raw materials and inks). The tests comprise a Robinson test (gustatory) and a Sniff test (olfactory) and are usually performed as triangular tests. With these measures, Siegwerk maintains a very high quality with respect to the odor of inks.

Whenever a risk is identified, the respective deliveries are monitored to ensure constant quality.
4.3 Ink formulation towards low migration

Siegwerk inks and varnishes for food packaging are formulated, worldwide, to minimize potential migration of concern to the food. All packaging inks are formulated and manufactured in accordance with Good Manufacturing Practice. Requirements for any ‘low migration ink’ are laid down in the ‘Explanatory Note on the assessment of migration potential from food packaging inks and its dependency on the packaging structure’ of the Packaging Ink Joint Industry Task Force. The PIJITF encompasses all members of the food packaging chain in Europe, and includes representatives from the printing ink industry, packaging manufacturers and food producers.

Any Siegwerk ink intended for food packaging is a low migration ink, which is described by PIJITF as “…designed for use on food packaging that is formulated using selected components which should ensure that migration from the resultant printing ink film will be within accepted migration limits, provided that the packaging structure is suitable, and the packaging ink is applied under Good Manufacturing Practices [sic] in accordance with guidance given by the ink supplier for the intended application.”

UV and sheetfed inks
In the market segment of UV and sheetfed offset printing technology, for years, Siegwerk has been offering a complete global portfolio of explicitly termed ‘low migration’ UV curing and oleoresinous sheetfed offset inks. They have been successfully introduced into the market in Europe as a replacement of the respective standard inks. Aimed to proactively increase food safety in other regions, Siegwerk strives to promote the change on a global scale as well. Finally, Siegwerk’s ‘low migration’ UV curing inks and varnishes are exclusively formulated using only photoinitiators of Group 1A of the ‘EuPIA Suitability List of Photoinitiators for Low Migration UV Printing Inks and Varnishes’, thus these low migration photoinitiators have both low migration potential and are supported by toxicological data, they have recognized migration thresholds and are listed in Annex 6, Part A of the Swiss Ordinance 817.023.21. In accordance with the industry practice indicated in the PIJITF document, Siegwerk’s liquid inks (solvent-based and water-based) are not explicitly termed ‘low migration’, but of course meet, and have long met, the low migration requirements.
How Siegwerk achieves control of its formulations:
Siegwerk has implemented global control of its formulations of inks intended for food packaging – that is, ‘low migration’ inks – via its Formulation Guidelines. A Formulation Guideline gives a detailed overview on the status of all raw materials used in the production of our inks. They are established, implemented and audited by Global HSE. Raw materials are only permitted for use, worldwide, if they are explicitly listed on these Siegwerk Positive Lists; a maximum allowed percentage in formulations is fixed where necessary to meet the SML. Global HSE performs positive listings only if worst-case calculations or representative migration tests have demonstrated that each substance will safely meet its migration threshold. All data, including results of risk assessments and/or migration data, and all reasons for the positive listing are transparently documented for easy, science-based backtracking. The negative listings reliably safeguard that no nonconforming raw materials are used.

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Migrants
It goes without saying that an ink supplier’s full commitment is necessary to make the converter’s risk evaluation and verification work as targeted and easy as possible. The main commitment of Siegwerk is to identify the migrants present in an ink layer as well as their maximum content in percent. This filtering process, done by Siegwerk’s Global HSE experts, has as input the high number of substances of which the formulations consist, which are mostly not migrants, and results in putting the focus only on those migrants which can potentially transfer to food and need to be controlled by the user. Based on the excellence in knowledge on chemical composition of ink layers acquired by Siegwerk’s Global HSE experts, this simplifies, to the maximum extent possible, the converter’s own work for compliance and packaging safety, which is due under his own responsibility.

4.4 Information provided by Siegwerk

Migrants
It goes without saying that an ink supplier’s full commitment is necessary to make the converter’s risk evaluation and verification work as targeted and easy as possible. The main commitment of Siegwerk is to identify the migrants present in an ink layer as well as their maximum content in percent. This filtering process, done by Siegwerk’s Global HSE experts, has as input the high number of substances of which the formulations consist, which are mostly not migrants, and results in putting the focus only on those migrants which can potentially transfer to food and need to be controlled by the user. Based on the excellence in knowledge on chemical composition of ink layers acquired by Siegwerk’s Global HSE experts, this simplifies, to the maximum extent possible, the converter’s own work for compliance and packaging safety, which is due under his own responsibility.

Statement of Composition
Siegwerk provides, under European regulations, information on evaluated and non-evaluated migrant substances in a ‘Statement of Composition’ (SoC) for packaging inks. This information is based on EU and Swiss regulations. The SoC indicates per single ink, the chemical identity of the migrants (that is the unequivocal chemical name and all related identification data in the relevant positive lists including SMLs, as well as their maximum percentage in the dried ink film. Additionally, the SoC provides results of worst-case calculations for relevant migrants. In any case, Siegwerk is committed to disclosing, worldwide, all information fit for the purpose which is necessary for the identification and quantification of evaluated and non-evaluated migrants. In certain cases, signature of a confidentiality agreement may be requested. In preparation of a practical migration test and in cooperation with Siegwerk, the printer shall select the facility with the required analytical capability and regulatory expertise. The migration testing lab must be able to reliably measure potential migrants from packaging printed with Siegwerk products. Further information can be found in the Customer Information “Analytical Institutes recommended for migration testing of food packaging printed with Siegwerk inks and varnishes”, which is available on request.

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Siegwerk’s Technical Data Sheets and related communication provide data on the intended use, such as substrates to be printed on, conversion process and application conditions. With regard to the safety of the food packaging for the consumer, they further specify the intended use: either ‘Food Packaging: Yes’ or ‘Food Packaging: No’. Siegwerk advises customers to follow the associated conditions of use:

### Intended Use

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Conditions of Use</th>
</tr>
</thead>
</table>
| 1 Food packaging | **Yes** This ‘Know How’ has to be observed as a whole, in particular:
|                | • The measures recommended to the printer in the table of chapter 5.1.1
|                | • The correct application and the verification of compliance laid down in chapter 6. |
| 2 Food packaging | **No** For non-food packaging only
|                | Exception: for food packaging under the condition that its manufacturing process rules out any possibility of set-off and that a functional barrier prevents migration through the material. Chapter 5.1.2 provides guidance. |

Furthermore, Siegwerk provides information on the resistance and fastness properties of each individual ink. They have to be checked for applications which involve unintended but foreseeable short-term and/or low-area direct contact with food, as per chapter 5.2.1. With this information and with the following tables, Siegwerk makes it easy for the printer to align with the most advanced benchmark standards in Good Manufacturing Practices for food packaging, which specify that the converter is required to assess the migration potential of packaging inks case by case. In particular, printers worldwide are advised to align with the above-mentioned “Explanatory Note on the assessment of migration potential from food packaging inks and its dependency on the packaging structure” of PIJITF.
5.1 Categories of food packaging and their migration risk

5.1.1 Categories with migration risk

The following table gives a non-exhaustive overview on the major packaging categories with risk of migration, set-off and/or organoleptic deterioration, as well as recommendations with regard to the selection of ink types and validation measures by the printer.

In case of packaging with an identified migration risk, only inks and varnishes explicitly intended for food packaging should be used.

Special attention must be paid to applications subject to high temperature exposure, such as pasteurization, sterilization and Parameters which potentially trigger non-compliance (sic) (migration, organoleptic effect)” for verifications (see chapter 6.2.1).

Packaging intended for particularly sensitive consumer groups (such as infants and small children) requires formal qualification in any case.

### FLEXIBLE PACKAGING

<table>
<thead>
<tr>
<th>Application</th>
<th>Example</th>
<th>Potential migration risk of the packaging structure</th>
<th>Procedure</th>
<th>Remarks</th>
<th>Measurements</th>
<th>Parameters which potentially trigger non-compliance</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandwich print in laminates or surface print on monofilms</td>
<td>Cheese, meat products, tea bags, confectionery, bakery products, butter wrappers</td>
<td>Yes, migration via diffusion across the layers and via set-off.</td>
<td>Qualification via migration testing order upon previous Siegwerk disclosure to intended lab.</td>
<td>Calculating migration of actual combination of products on specific packaging using Siegwerk Statements of Composition: Consider qualification via migration testing order upon previous Siegwerk disclosure to intended lab.</td>
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<td>Consider Siegwerk Statements of Composition.</td>
</tr>
<tr>
<td>Thermally treated packed food</td>
<td>Ready meals, bakery, pasteurized dry or in an autoclave, boil-in-the-bag, microwave, baking oven</td>
<td>Yes, migration via set-off to high absorbance layer (heat-seal varnish, PE ...).</td>
<td>Qualification via migration testing order upon previous Siegwerk disclosure to intended lab.</td>
<td>Calculate migration of actual combination of products on specific packaging using Siegwerk Statements of Composition: Consider qualification via migration testing order upon previous Siegwerk disclosure to intended lab.</td>
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<td>Consider Siegwerk Statements of Composition.</td>
</tr>
</tbody>
</table>
**Measures**

Adjustments to printing order upon previous Siegwerk disclosure to intended lab.

**Potential migration**

Recommended to risk of the printer packaging structure to intended lab.

**Siegwerk disclosure**

Order upon previous Siegwerk disclosure to intended lab.

- **Measures**
- **Potential migration**
- **Siegwerk disclosure**

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**PAPER & BOARD PACKAGING**

<table>
<thead>
<tr>
<th>Application</th>
<th>Examples</th>
<th>Requirements for migration testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>UV curing</td>
<td>Only products intended for food packaging</td>
<td>General migration ('low migration'). By default, no UV curing product should be used.</td>
</tr>
<tr>
<td>Water-based, solvent-based, UV curing, electron beam curing</td>
<td>Only products intended for food packaging. (UV: low migration). By default, no UV curing product should be used.</td>
<td></td>
</tr>
<tr>
<td>Water-based overcoatings</td>
<td>Only products intended for food packaging. (low migration)</td>
<td></td>
</tr>
<tr>
<td>Sleeve or label will be applied onto the container and become a primary food packaging which is stacked before filling</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**RIGID LIQUID FOOD PACKAGING**

<table>
<thead>
<tr>
<th>Application</th>
<th>Examples</th>
<th>Requirements for migration testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE-coated board packaging</td>
<td>Only products intended for food packaging. (UV: low migration). By default, no UV curing product should be used.</td>
<td></td>
</tr>
<tr>
<td>UV curing</td>
<td>Only products intended for food packaging. (low migration)</td>
<td></td>
</tr>
</tbody>
</table>

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**SELF-ADHESIVE LABELS, CUPS, TAGS, SLEEVES, TUBES**

<table>
<thead>
<tr>
<th>Application</th>
<th>Examples</th>
<th>Requirements for migration testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>UV curing</td>
<td>Only products intended for food packaging. (low migration)</td>
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<tr>
<td>Sleeve or label will be applied onto the container and become a primary food packaging which is stacked before filling</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Examples**

**Application**

- **UV curing**
- **Water-based, solvent-based, UV curing, electron beam curing**
- **Water-based overcoatings**
- **Sleeve or label will be applied onto the container and become a primary food packaging which is stacked before filling**

**Requirements for migration testing**

- **General migration ('low migration'). By default, no UV curing product should be used.**
- **Only products intended for food packaging. (UV: low migration). By default, no UV curing product should be used.**
- **Only products intended for food packaging. (low migration)***
- **Only products intended for food packaging.**

---

**Materials**

- **Paper bags for bakery, flour, fruits, vegetables, cheese, meat.**
- **Paper bags for bakery, confectionary, super flour, fruits, vegetables, snap-off or without PE or varnish coating for fast food, mues, mues.**
- **Some use for microwave.**
- **Migration can be enhanced by temperature and water/steam absorption.**
- **Migration both via diffusion across the layers, via set-off and gas phase.**
SELF-ADHESIVE LABELS, CUPS, TAGS, SLEEVES, TUBES

**Glued or PSA labels for primary packaging and lidding**

- Shrink sleeves on PET bottles
- Shrink sleeves on PMP/PPD bottles
- Tubs, cups

**Examples**

- Labels applied on filling line to preformed and filled packaging of all types of food.
- Soda, mineral water, dairy food, fruit drinks.
- Mayonnaise, mustard, dairy products.

**Potential migration risk of the packaging structure**

- Yes, depending on barrier properties to migration of the primary packaging: migration via diffusion (set-off not possible).
- Minor, studies show that PET is quite a barrier to migration from printed layers.
- Yes, migration via diffusion across PE/PP/OPS is possible.
- Yes, depending on point in time of tube formation and on presence of barrier: migration via diffusion and/or set-off.

---

**About inks for this application**

**UV curing**

- Products intended for food packaging (‘low migration’) highly recommended. In any case, odor optimized products (‘low odor’) recommended.
- UV curing (cations, UV flexo, radical UV offset and flexo) Products intended for food packaging (‘low migration’) highly recommended. In any case, odor optimized products (‘low odor’) necessary.
- UV curing Only products intended for food packaging (‘low migration’).
- UV curing Only products intended for food packaging (‘low migration’).

---

**Measures recommended to the printer**

- Formal qualification via migration testing order upon previous Siegwerk disclosure to intended lab.
- Sensorial issues to be considered.

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5.1.2 Categories without migration risk

In cases where the converter can avoid set-off and can prove the existence of an efficient functional barrier, inks and varnish es not intended for food packaging may be used. This may also apply to certain labels or sleeves applied to non-packed vegetables, fruits or equivalent foodstuffs which are peeled by the consumer before eating, thus potential migrants in the peel are eliminated. The following table provides some examples:

<table>
<thead>
<tr>
<th>PAPER &amp; BOARD PACKAGING</th>
<th>SELF-ADHESIVE LABELS, SLEEVES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigid packaging</td>
<td>PSA labels for primary packaging and lidding</td>
</tr>
<tr>
<td>WITH the inner wrap being a barrier to migration</td>
<td>Shrink sleeves on glass bottles</td>
</tr>
<tr>
<td>PSA labels for primary packaging and lidding</td>
<td>Shrink sleeves on glass bottles</td>
</tr>
<tr>
<td>WITH the inner wrap or the lidding being a barrier to migration</td>
<td></td>
</tr>
<tr>
<td>Shrink sleeves on glass bottles</td>
<td></td>
</tr>
<tr>
<td>Glass is by default a recognized functional barrier.</td>
<td></td>
</tr>
</tbody>
</table>

---

UV Curing, oleoresinous offset, water-based

- In any case, odor optimized products (‘low odor’) necessary.

---

UV Curing, oleoresinous offset, water-based

- In any case, odor optimized products (‘low odor’) necessary.

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UV Curing, oleoresinous offset, water-based

- In any case, odor optimized products (‘low odor’) necessary.
5.2 Cases of unintentional and intentional direct food contact

5.2.1 Particular cases of unintentional but foreseeable direct food contact of the printed ink layer

There are cases where unintentional but foreseeable direct contact of the printed and dried or cured ink and/or varnish layer to the food is possible. This is associated with a higher risk for the consumer as there is no barrier function of the packaging material between ink and food.

Some examples:

- Lamination print job where the printed layer may be exposed to food at the cutting edges, or
- a packaging line where wrappers of food packages are partly folded so that a small area of the printed surface is turned inside (e.g. butter wrappers), or
- food that could be spilled onto a surface print upon opening of the package by the consumer (who may lick it off), or
- articles with transient food contact like napkins, placemats, tea tags and others.

In accordance with Good Manufacturing Practice principles, Siegwerk recommends precautionary measures to the converter to minimize the risk of migration. Otherwise, colored matter could end up in food (so-called 'bleeding'), and/or non-visible migration could occur via solubilization of the printed layers. To prevent any risk of bleeding and solubilization, the resistances of the printed layers to the relevant foods are to be guaranteed as measured by the relevant fastness standards:

- ISO 2836 (Assessment of print resistance to various agents; in particular with regard to water, oils and fats, cheese and spices),
- ISO 11628 (Determination of print resistance to acids)
- EN 646 (Paper and board intended to come into contact with foodstuffs – determination of color fastness of dyed paper and board) for towels and napkins.

The printer is responsible for the selection of printing inks and varnishes which are resistant to the respective foodstuff. To the extent that the information is not already declared in Siegwerk’s Technical Data Sheets and related documentation, the required typical fastness data is available on request. As a further measure, Siegwerk recommends the assessment of potential migration of the relevant migrants via a worst-case calculation or – preferably – via a practical migration test.

5.2.2 Direct food contact applications

In the vast majority of food packaging structures, the printing ink is applied to that side of the packaging which is not in direct contact with the packed food. But there are some instances with intended direct food contact of printing inks (or protective coatings, heat-seal coatings, anti-fog coatings or slip coatings). It is obvious that in comparison with non-food prints there is a massively increased risk of migration into the food.

In Europe, today, in the absence of specific legislation concerning printing ink products intended for direct food contact, only raw materials are used that are included in positive lists and/or have been evaluated by a recognized expert body. However, the situation is about to change: the German Ordinance on Printing inks will provide a positive list of substances that are allowed to be used for direct food applications as long as the given migration limits are met.

Under FDA provisions, direct food contact refers to a printing ink or coating (e.g. protective, sealing, anti-fog, slip lacquers) that is intended by design to be in direct contact with a food product. By virtue of this intimate contact, components of the printing ink or coating have the potential to migrate to food and, therefore, must be in compliance with the indirect food additive guidelines at 21 CFR Parts 173-178. Indian Standard IS 15495 addresses also printing inks and varnishes for direct food contact. It is stipulated that, “if for some specific requirements it is necessary for the printed surface to be in contact with food, the printing inks shall be formulated with materials which are acceptable as food additives” and “produce a non-toxic printed surface that complies with the appropriate regulations”.

In any case, for such critical DFC applications, the printer is advised to use only designated inks for intended direct food contact and to safeguard with great care that no unacceptable migration takes place under the foreseeable conditions of use.
Ink manufacturers can certify the suitability of an ink series for food packaging applications, but they cannot warrant the legal compliance of the final printed packaging. Many other parameters have an influence on compliance, such as for example the substrate used, the printing and converting process, the type of food packed and the storage conditions at all stages. In order to avoid problems arising from an improper use of ink, it is very important that all parties involved in the printing and packaging process collaborate (end user <-> converter/printer <-> ink manufacturer). The first step, to clearly define the packaging specifications, is usually within the responsibility of the food industry.

The manufacturer of the packaging and the filler are responsible for the properties of the food packaging and its compliance with legal requirements. The packaging ink suppliers are responsible for the composition of the preparations. Due to the complex nature of the packaging chain, all members have to exchange relevant information (also see the picture on the packaging chain on the inner side of the cover of this brochure).

Under GMP Regulation (EC) No 2023/2006 and its Annex, which only refers to the application of printing inks to the non-food contact side of a material or article and to the storage of printed articles, the ink manufacturer does not have an independent responsibility in this regard, however, the converter who actually applies the ink or coating is responsible for compliance with this regulation.

As an example, the Indian Standard IS 15495 is similarly clear about the responsibility of the printer. It states: “The responsibility of the printer and the converter is to ensure that the food packages are manufactured and stored in such a manner by which any preventable transfer of material from the ink or coating to the food contents is avoided, even if such transfer is unobjectionable on the grounds of health, odour and flavour.”
The following main subjects, which also include essential properties to become included into specifications agreed between the food packer and the converter, shall be covered by specific requirements in the recognized converter’s Good Manufacturing Practices:

- printing process and type of printing machine
- type of substrate, e.g. paper, board, regenerated cellulose, plastic film or aluminum foil or laminates of these materials
- the functional barrier effect of the substrate and/or the layer(s) separating the ink layer from the food
- the amount of ink per surface unit
- the ratio of the surface in contact with food to the volume of the packed food
- the printing speed
- the drying or curing energy (e.g. oven temperature, lamp power)
- the nature of the surface in contact with the ink layer in the stack or reel with regard to the potential for invisible set-off
- the level of residual solvents should not lead to unacceptable organoleptic changes
- the nature of any printing ink additives added or used by the printer, such as cleaning agents and fountain solutions
- the time and pressure conditions in the stack or reel
- the storage conditions (time and temperature)
- the nature and usage of the food product (e.g. for infants and small children)
- the expected maximum shelf life
- the filling, sealing and storage method
- the heating, cooling, sterilization and pasteurization processes to which the packaging material and contents may be exposed

The BLL guide is clear in its message that concrete, targeted specifications are the basis for the verifications which have to be performed by the manufacturer of the final packaging article. It provides detailed workflows and communication processes, as well as concrete checklists assessing barrier properties and migration risks. It is also applicable for the suppliers of the converter, including the ink manufacturer. All these guidelines and standards make it evident therefore that the potential for migration and deterioration of organoleptic characteristics depends not only on the individual composition of the packaging ink, but also on the printing conditions which are controlled by the converter.
6.2 Practical measures

6.2.1 Checklist on processes and parameters potentially causing noncompliance

Long-term experience indicates that the following items should generally be checked by the printer and the packer/filler prior to any print or packaging job. However, the following information can only be indicative and implies no warranty whatsoever.

Design of the food packaging

Barrier properties of packaging material

Migrants from printed ink layers diffuse more – and more quickly – the worse the barrier properties of the materials wrapping the food are.

Limited: Polyamide, polypropylene, polyethylene terephthalate, polyvinylidene chloride, metallization layers;

Better: Appropriate SiOx and AlOx layers on polyethylene terephthalate, sufficiently thick layers of polypropylene, polyvinylidene chloride lacquered PP or cellophane, Poly-methyl methacrylate (PMMA) lacquered PP;

Best (absolute barrier): Aluminum foil (>6 μm), tinplate, glass; sufficiently thick layers consisting of polyethylene terephthalate or polyvinylidene chloride (>12 μm).

Set-off depending on the surface

After printing, invisible set-off can occur within the reel or stack because the surface in contact with the printed layer may absorb migrants. The likelihood of set-off depends on the nature of the surface.

Very high: Coating on paper, board, aluminum, plastics; regenerated cellulose; thin extruded layers of polyethylene or polystyrene;

High: Films or cups/tubs made of polyethylene, polypropylene, polyethylene terephthalate;

Medium: Uncoated paper, uncoated board, polyamide, polyethylene terephthalate.

Set-off can be reduced if the surface is not completely even, but rough.

Design of the print

A high amount of ink and primer or overprint varnishes printed per surface unit (many superposed ink layers) can increase the amount of migrants and thus enhance migration. By default, Siegwerk assumes an upper standard dry ink film weight of 3 g/m² when formulating packaging inks and assessing the potential migration of concern, e.g. via a worst-case calculation.

The printer is responsible for the combinations of primers, inks and overprint varnishes, which are often from different suppliers. If they result in higher application weights, special attention is required. The following table indicates the typical application weights:

<table>
<thead>
<tr>
<th>Inks and Varnishes</th>
<th>Application Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solvent-based or water-based flexographic ink (white)</td>
<td>1.5 g/m²</td>
</tr>
<tr>
<td>Solvent-based or water-based flexographic ink (color)</td>
<td>1.0 g/m²</td>
</tr>
<tr>
<td>Solvent-based or water-based flexographic overprint varnish, surface printed onto plastic film or paper/board or aluminum</td>
<td>1.5 g/m²</td>
</tr>
<tr>
<td>Solvent-based or water-based gravure ink (white) in laminate or surface printed onto plastic film or paper/board or aluminum</td>
<td>2.0 g/m²</td>
</tr>
<tr>
<td>Solvent-based or water-based gravure ink (color) in laminate or surface printed onto plastic film or paper/board or aluminum</td>
<td>1.0 g/m²</td>
</tr>
<tr>
<td>Gravure overprint varnish, surface printed onto plastic film or paper/board or aluminum</td>
<td>2.0 g/m²</td>
</tr>
<tr>
<td>Oleoresinous or UV-curing offset ink printed onto paper or plastic film</td>
<td>2.0 g/m²</td>
</tr>
<tr>
<td>Dispersion varnish over offset ink</td>
<td>3.0 g/m²</td>
</tr>
<tr>
<td>UV varnish</td>
<td>4.0 g/m²</td>
</tr>
</tbody>
</table>
The printer has to verify the actual application weight before printing each individual job.

Surface/volume ratio of packaging
The larger the contact surface and the lower the volume or weight of the packed food, the more migrants may end up in the food (see chapter 3.4).

Nature of the packed food
The type and nature of the food have an influence on the transfer of migrants. These migrants could either be present on the food-contact side of the packaging material due to previous set-off or migrate via diffusion through the packaging material.

High uptake of migrants:
- Aqueous, acidic, alcoholic and/or fatty liquid food
- Fatty solid food in aqueous liquid food (e.g. mozzarella cheese)
- Fatty, powdery foods
- Fatty, pasty foods

Medium uptake of migrants:
- Aqueous pasty foods with no or minimal fat content
- Acidic pasty foods with no or minimal fat content
- Fatty and solid foods with a shape preventing full contact with the packaging (e.g. chocolate biscuit bar)

Low uptake of migrants:
- Solid and dry foods with no fat content

Shelf life of the packed food
Migration increases with time. The migrants in the printed layer could theoretically migrate completely within minutes, however, the normal migration is much slower. Thus, the longer the food is stored, the more migrants might end up in the packed food.

Processes to which the printed food packaging is exposed.
Migration increases with temperature. Any thermal exposure can enhance substance transfers:
- Hot filling by the packer/filler
- Heating by oven, sterilization in an autoclave and pasteurization by the food manufacturer
- High printing speed – insufficient UV drying energy
- High amount of ink/varnish printed on the surface – insufficient drying energy
- Too high amounts of retarder in ink

UV curing (insufficient curing may lead to unreacted monomers and increased photoinitiator amounts)
- High printing speed – insufficient UV drying energy

Print shop activities
Activities that may increase the risk of migration or lead to non-evaluated substances in the print:
- Adding printing additives to ink which are not recommended by Siegwerk and not validated as fit for the purpose by the printer or not observing the maximum amount specified
- Using the wrong dosage of hardener which therefore is out of the recommended range (case of 2-component systems)

6.2.2 Printing parameters
Generally, the following parameters may increase the amount of migrants:

Drying process
Drying by heat (insufficient drying may lead to increased residual solvents that might migrate)
- High printing speed leading to insufficient drying energy
- High amount of ink printed on the substrate
- Too high amounts of retarder in ink

Print shop activities
Activities that may increase the risk of migration or lead to non-evaluated substances in the print:
- Adding printing additives to ink which are not recommended by Siegwerk and not validated as fit for the purpose by the printer or not observing the maximum amount specified
- Inappropriate printing machine cleaning agents – substances may carry over to and contaminate the non-printed ink and thus the print
- Inappropriate cleaning of equipment in contact with inks, such as rollers and rubber blankets for offset – risk of carry-over if the printer also uses the same equipment for inks that are not intended for food packaging
- Inappropriate use of fountain solutions – risk of carry-over if offset printer also uses them on the same machine for inks that are not intended for primary food packaging

17 Formal qualification via migration testing order upon previous Siegwerk disclosure to intended lab should be considered.
18 The EuPIA Information “Use of Diarylide Pigments in Printing Inks and Prints at Temperatures higher than 200°C”, www.eupia.org, should be observed.
Winding to reel or stacking
Invisible set-off is enhanced by the following conditions in surface printing, off-line lamination or winding before lamination:
- Long time in the reel or stack
- High pressure in the reel or stack
- Storage above ambient temperature in the reel or stack

6.2.3 Verification
Depending on the potential level of risk linked to migration across the layer(s) between the print and the food and to invisible set-off, the printer should conduct representative practical investigations, such as organoleptic testing, migration assessment via worst-case calculation or – preferably – via practical analytical migration testing to cover each relevant application category19.

Siegwerk recommends to every food contact material converter the measures for verification listed per application category (packaging type) in the tables of chapters 5.1.1 and 5.1.2.

Verification data on migration should be obtained via appropriate representative worst-case samples which cover every individual printed packaging material and article in its finished state, taking into account normal and foreseeable conditions of use.

Food packaging intended for particularly sensitive consumer groups (such as infants and small children) requires formal qualification in any case, as a rule via practical analytical migration testing. This is applicable as well for packaging without functional barrier to migration which is intended for high temperature exposure.

All of these complex parameters need careful consideration by the partners in the packaging chain.

Appropriate actions, applied correctly, will finally lead to the safest packaging for food!

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19Frequently asked questions on the legal status of printing inks, coatings and varnishes for the non-food contact surface of food packaging (packaging inks), EuPIA, www.eupia.org
The printing of this product was carbon-neutral. The greenhouse gas emissions caused by its production have been compensated by investments in a Gold Standard climate project.

The paper used originated from responsibly managed forests and other controlled sources.