INK, HEART & SOUL

KNOW HOW

Customer Guidance: Printing Inks for Food Packaging
Scope: European Regulations

SIEGWERK

Preface: Know How

Regularly recurrent reports on substance transfer (migration respectively set-off) from printing inks into packed food have partly spread across Europe via the so called "RASFF (=Rapid Alert System for Food and Feed)"- reporting system of the European Food Safety Authority (EFSA) and considerably irritated the packaging chain, end-users, authorities and also consumers.

Hence this caused intense discussions between all parties involved. At the core it revealed that in many cases responsibilities were not consequently perceived despite explicit legal regulations, that communication between all parties involved is dramatically lacking and needs substantial improvement and that parties involved are not aware of the consequences of changes in the "packaging system" and their respective impact on possible substance transfers into food (= lack of a "change management" awareness).

This Siegwerk Guidance shall assist in pointing out the shared responsibilities along the packaging chain within the existing legal framework. This will be done from the printing ink manufacturer's point of view. Critical issues along the chain, which require further discussion, are also highlighted.

However, this Guidance shall not give rise to questions of shifting responsibilities, on the contrary – we at Siegwerk explicitly recognize our responsibility and see ourselves as a partner in the packaging chain where ideal and safe solutions have to be found together.

Siegwerk is convinced that considering the recommendations in this Guidance and by consequently using our printing ink systems explicitly designed and optimized for their application, the converter is enabled to print food packaging which is fully compliant and safe for use.

We would appreciate, if you approached us in case of any remaining questions or open issues – we are happy to assist you at any time.

In our competence centers we have a vast pool of experts and expert knowledge as well as extensive research and development capacities which you may expect from a worldwide market leader in the segment of high-performance printing inks for food packaging.

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

The 6 steps and responsibilities for perfect food packaging

Ink manufacturers can certify the suitability of an ink series for food packaging applications, but they cannot certify the legal compliance of the final printed packaging. The reason for this being that many parameters have an influence on this compliance, such as the substrate used, the printing and converting process, and the storage conditions at all stages. In order to avoid any problems arising from an improper use of ink, it is important that all parties involved in the printing and packaging process collaborate (end-user, converter/printer, ink manufacturer). The first step is to clearly define the packaging specifications which normally would be within the responsibility of the food industry.

1. PACKAGING SPECIFICATIONS BY THE FOOD INDUSTRY
Clear specifications of the packaging need to be provided, taking into account all relevant parameters:
- Physical & chemical properties of the food to be packed
- Conditions of converting
- Storage
- Final use by the consumer.

2. PACKAGING CONCEPTION BY THE CONVERTER
Relevant issues are the choice of substrates and other adequate materials, graphics, printing and converting process with all parameters.

3. INK FORMULATION BY THE INK MANUFACTURER
After a final validation of the packaging specifications with the converter and a risk analysis (migration, physical & chemical resistances, organoleptic impacts), a recommendation on suitable inks and varnishes has to be made.

6
Final
Validation

5
Process
Validation

4
Advice
on Use

6. FINAL PACKAGING VALIDATION BY THE FOOD INDUSTRY
The food industry is responsible for checking the fulfillment of the packaging specifications and for controlling the limitations of packaging use. All necessary documents must be collected from the converter.

5. VALIDATION OF THE PRINTING PROCESS BY THE PRINTER
The combination of ink + materials and the process parameters have to be validated (odor, residual solvents, migration …).

4. INK MANUFACTURER'S ADVICE ON USE
In addition to the product recommendation, the converter needs to be advised on the conditions of use, which includes relevant documentation (technical data sheets, application guidelines …).

Content

1. The importance of migration

The first findings of isopropylthioxanthone (ITX) in baby milk and other liquid foodstuff (the "ITX case") were experienced in the year 2005. This alerted the packaging chain of the migration potential of substances from printing inks. The stakeholders within the packaging chain realized that transfer from printed and/or varnished layers, even if not intentionally brought into direct food contact, can happen nevertheless. The transfer phenomenon of ITX, a low molecular photoinitiator used in UV inks, into food could be described by a set-off in the reel (due to reel-to-reel printing). The set-off phenomenon is not restricted to UV curing inks, but can potentially occur with all types of inks in case of presence of low molecular substances.

As a consequence of the "ITX case" the European Commission was prompted to issue the so-called Regulation (EC) 2023/2006 on "Good Manufacturing Practice" which addresses processes involving the application of printing inks[1]. It is the first time that printing inks are explicitly regulated in the European Food Packaging Legislation.

In early 2009 new findings of 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, alerted the stakeholders to the fact that assessing migration risks on the packaging design is vital. This case clarified that the inner polyethylene pouch is not an efficient barrier which prevents the transfer of components from the print on the outer cardboard box. Thus only the use of specifically formulated "low migration" inks and varnishes would guarantee compliant packaging.

[1] See Appendix 1 "Legal requirements and responsibilities" for a complete overview of the applicable regulations.

2. Mechanisms of migration

Migrants are substances which are available for migration (which means transfer through a material layer) due to their chemical characteristics and molecular size and which do actually migrate if a "pathway" for migration is open to them in order to move from their original location, for example from a printed layer, into the packed food through a substrate.

Polymeric materials (polymeric ink binders, polymeric ink additives) generally are large molecules without migration potential, thus they are not usually regarded as migrants. In addition, if ever ingested, polymeric substances with molecular weight above 1000 Daltion are not absorbed by the gastro-intestinal 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 no migrants. Organic pigments commonly used as colorants in inks are generally[2] not regarded as being migrants, either.

However, migrants are substances consisting of small and mobile molecules which can easily penetrate into and diffuse across packaging material layers (**diffusion migration**). This can both happen while the printed material is not yet 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.
Migrants can "jump" from one layer to another, such as a surface printed layer to the non-printed back 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 a stack.

They can also "fly" from one layer to another. For example migrants can transfer from a cardboard layer into which migrants from a printed layer have penetrated (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 also happen with migrants such as mineral oils or some UV photoinitiators that might not be generally known as being volatile such as organic solvents.

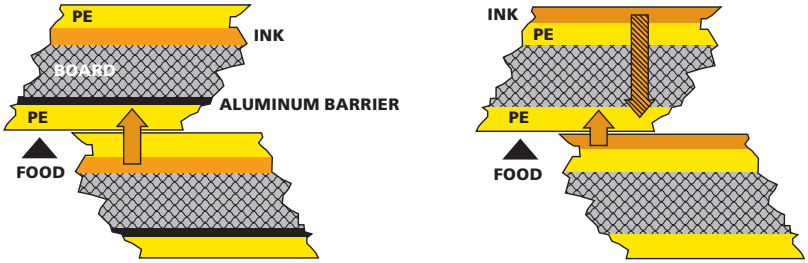
As a general rule it can be stated that potential migrants from inks/printed layers mostly belong to the class of ink additives.

The quantity and weight of food contained in a package is usually much higher than the quantity and weight of packaging material involved, not to mention the even smaller ink grammages.

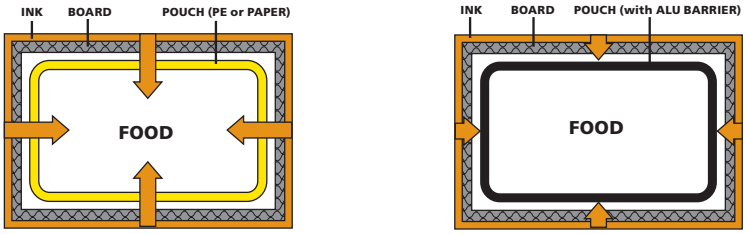
[2] However, see chapter 5.2 for information on the bleeding properties of certain organic pigments.

Migrants based on physical-chemical rules usually disperse proportionately to the given quantities of the adjacent media (ink layer, packaging substrate layer, foodstuff). This means that, if the contact materials allow transfer of substances and if the contact time is long enough, migrants from thin ink layers might disperse completely and will for the most part end up in the packed foodstuff.

The following *left* hand 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 figure on the *right* hand below illustrates a situation where both penetration (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".



Migration via diffusion and via gas phase (air) is shown in the figures below. The ink is printed on an outer wrap which represents a cardboard box. On the *left* hand it is shown that despite of an inner wrap, which separates the cardboard box from the food, this PE or paper pouch **is not a functional barrier** to migration. The situation shown displays the "4-MBP" migration scenarios of 2009. On the *right* hand, the inner pouch is made of aluminum, as aluminum of sufficient thickness serves as an absolute barrier preventing migration, and represents an ideal scenario.



3. Migration thresholds

3.1. Evaluated substances

In the past decades, the European regulations on direct food contact materials, in particular on plastics, required the industry to obtain approval of the substances which are used and thus are present in packaging (=positive list principle). At any time this approval process is also required when there is an intention for use of any new substances not yet listed on the positive list. In order to be approved, comprehensive toxicological data has to be compiled for each new substance.

The toxicological evaluation of substances is performed by the toxicologists of the authorities. In case of EU legislation this is done by the experts from the European Food Safety Authority (EFSA) according to a very demanding and comprehensive set of data on toxicity which focuses on the chronic effects from life-long exposure to the substances in question. Depending on the quality of the toxicological data they determine acceptable exposure levels to which the consumer can be exposed, by using high safety margins and by deciding on the tolerable substance concentrations in the food. 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 a SML, it should be understood that for those substances without a SML the food packaging regulations specify an upper limit for the substance transfer which is defined as the sum limit of all substances that have migrated into food **(Overall Migration Limit, OML)**.

While, in the EU, printing inks as well as printed layers on food packaging are currently not regulated via positive lists[3], it is by coincidence that many evaluated substances are in current use for printing inks.

If substances with SMLs are contained in a printing ink, the entire packaging, including the printed layer, must comply with these limits. In addition, the OML (normally 60 mg/kg = 60 ppm) will also be applied to the entire packaging, including the printed layers. Both provisions require attention from the ink manufacturer and the converter.

[3] However, in Switzerland a positive list entered into force April 1, 2010 (see Appendix 1).

3.2. Non-evaluated substances

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

It is common sense amongst legislators that substances without or with only a small amount of toxicological data made available by the industry, are not considered as safe, by default. Consequently for these substances there is no formal approval by authority toxicologists available.

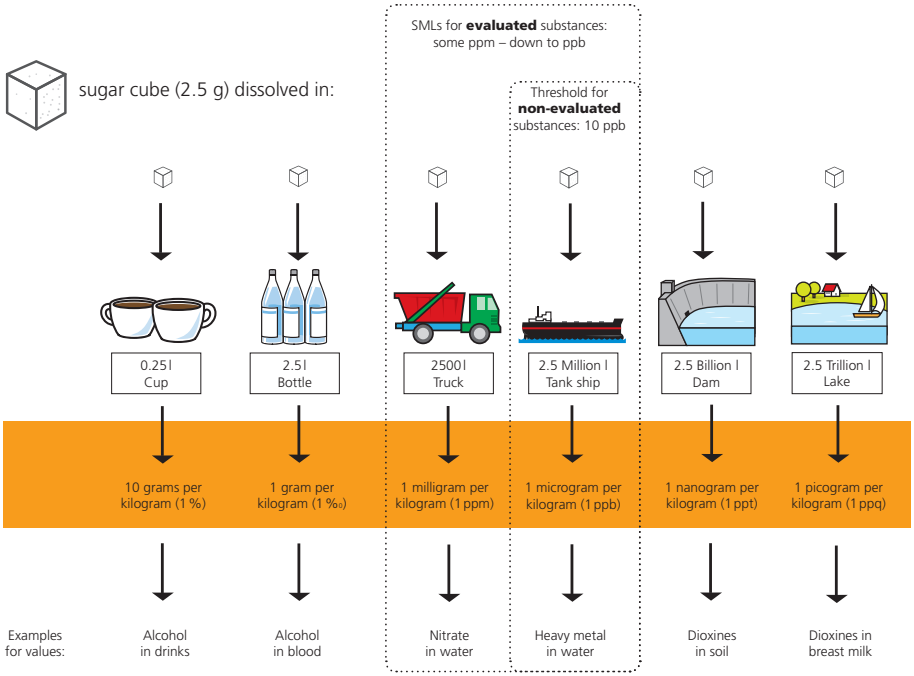
Relevant regulations determine that non-evaluated substances should not be detectable in food.

There is a general understanding that "detectability" means that a default threshold of 10 µg/kg=10 ppb for all of these substances is applicable.

As outlined above, this threshold can only be ignored if favorable toxicological data is supporting a higher safety margin. The resulting new threshold must be determined by recognized toxicologists and according to the criteria established by EFSA.

3.3. Acceptable migration is very low

The printer should be aware of the minute amounts of substances which can, in case of migration, lead to non-compliance:



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 via diffusion through the other packaging material layers and/or where possible via gas-phase transfer as well as via set-off. These calculations are based on "100 % migration" also known as "worst-case" migration.

Of course it is important to state that migration in conventionally packed food units is not likely to happen to this extent, as the majority of practically observed migration cases does 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 foodstuff. However regulations provide that this assumption must be verified on the packaging in its finished state.

Content of migrant in dried ink layers, applied at 100 % area coverage	Typical example of migrant	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
		With 3 g/m² dry ink	With 5 g/m² dry ink	With 3 g/m² dry ink	With 5 g/m² dry ink	
Evaluated substances						
25 %	ATBC (plasticizer, solvent- based inks)	45 mg/kg	75 mg/kg	187 mg/kg	312 mg/kg	60 mg/kg[4]
10 %	DEHA (plasticizer, solvent- based inks)	18 mg/kg	30 mg/kg	75 mg/kg	125 mg/kg	18 mg/kg
2 %	Erucamide (slip agent, solvent- based inks)	3.6 mg/kg	6 mg/kg	15 mg/kg	25 mg/kg	60 mg/kg[4]
2 %	Dimethylamino-etha-nol (neutralizing agent, waterbased inks)	3.6 mg/kg	6 mg/kg	15 mg/kg	25 mg/kg	18 mg/kg
0.02 %	Benzo-isothiazolinone (biocide, water-based inks)	0.036 mg/kg	0.06 mg/kg	0.15 mg/kg	0.25 mg/kg	0.5 mg/kg
5 %	Benzophenone (photo-initiator in UV inks not intended for food packaging)	9 mg/kg	15 mg/kg	37 mg/kg	62 mg/kg	0.6 mg/kg

[4] Overall Migration Limit (OML).

Content of migrant in dried ink layers, applied at 100 % area coverage	Typical example of migrant	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
		With 3 g/m² dry ink	With 5 g/m² dry ink	With 3 g/m² dry ink	With 5 g/m² dry ink	
Non-evaluated substances						
25 %	Mineral oil (oleoresinous offset inks not intended for food packaging)	45 mg/kg	75 mg/kg	187 mg/kg	312 mg/kg	0.01 mg/kg (10 ppb)
5 %	Low molecular photoinitiators (UV curing ink not intended for food packaging)	9 mg/kg	15 mg/kg	37 mg/kg	62 mg/kg	10 ppb
0.5 %	Acetylacetone (from adhesion promotor of solvent based ink not intended for food packaging)	0.9 mg/kg	1.5 mg/kg	3.7 mg/kg	6.2 mg/kg	Not detectable

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.

Regulations explicitly allow the verification of compliance via this method. If the results of the worst-case calculation for the actual packed food unit are lower than the applicable thresholds, then no further measures, such as a practical migration testing, are required. However it must be taken note of the fact that the permissible migration is not stipulated for the average packed food in the average packaging, but, as a matter of fact, the enforcement by authority control labs is ultimately performed on the actual packed food wrapped into the actual packaging unit. Therefore, all potential factors of influence, such as the ratio of the surface to the volume of the food and the other parameters as provided by Appendix 2 have to be carefully considered. In case of any doubt, the real migration should be assessed by the printer and the food packer involving official analytical methods provided by the regulations.

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					
6 dm²/kg food ("EU cube 10×10×10 cm, 1 kg food"), with 3 g/m² dry ink, 100 % area coverage					
Content of migrant in dried ink layers	Migration risk of the packaging structure = **Migration rate**				
	Worst case = 100 %	50 %	10 %	5 %	1 %
0.005 % = 50 ppm	10 ppb	5 ppb	1 ppb	0,5 ppb	0,1 ppb
0.05 %	100 ppb	50 ppb	10 ppb	5 ppb	1 ppb
0.5 %	1000 ppb	500 ppb	100 ppb	50 ppb	10 ppb

Considering the minute amounts which can lead to non-compliance, examination of the individual material combinations and their migration risk is indicated.

4. The responsibilities assumed by SIEGWERK

SIEGWERK's subsidiaries in Europe, Russia and Turkey, in line with all members of the European Printing Ink Association (EuPIA), are committed to full compliance with the **EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles** (see most recent version on www.eupia.org) which extensively describes the responsibilities of ink manufacturers within the packaging chain. Food packaging inks are formulated and manufactured taking into consideration many individual and varying parameters relating to the substrate, application and end-use. They are designed to minimize the potential for transfer of ink components of concern into food by migration or set-off, whilst meeting the end-use requirements.

All substances used by SIEGWERK in the formulations of printing inks intended for food packaging are part of the **EuPIA Inventory List** published on the EuPIA website and of the positive list of Swiss Ordinance 817.023.21 (Annex 6; see Appendix 1).

4.1. Selection of raw materials

The raw materials[5] are selected in accordance with the **"Selection scheme for packaging ink raw materials"** which is included in the above mentioned EuPIA Guideline. Consequently, raw materials do not belong to the following categories (exclusion criteria):

a) classified as "carcinogenic", "mutagenic" or "toxic to reproduction" categories 1 and 2, according to the provisions of Directive 67/548/EEC[6] and Regulation (EC) No 1272/2008 on dangerous substances. Note: Category 3 substances are only used after a migration study has confirmed that the migration levels are within published SML or TDI values or below 10 ppb;
b) classified as toxic (T) and very toxic (T^+);
c) colourants which are based on and compounds of antimony[7], arsenic, cadmium, chromium (VI), lead, mercury, selenium.
d) substances listed in the REACH Regulation (EC) No 1907/2006, Title VIII (formerly regulated by the Directive 76/769/EEC, relating to restrictions on marketing and use of certain dangerous substances and preparations) and its amendments, if their use in packaging ink would lead to an infringement of Article 3 of the Framework Regulation (EC) No 1935/2004.

Furthermore, SIEGWERK packaging inks are formulated in exclusion of raw materials covered by the Japanese **Negative List (NL) Regulation of JPIMA**[8].

[5] 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. If they migrate into foodstuffs, they must comply with any relevant limit.
[6] This Directive was last amended by Directive 2009/2/EC (31. ATP) OJEU L11 26.1.2009; but Regulation (EC) No 1272/2008 on Classification, Labeling and Packaging of Substances and Mixtures (OJEU L 353 of 31.12.2008) in force since 20 January 2008 will repeal it on 1 June 2015.
[7] With the exception of non-bio-available pigments in which antimony is a constituent of the crystal lattice and of organic derivatives not classified nor labeled as T or T^+.
[8] Voluntary Regulations Concerning Printing Inks (Negative List ("NL") Regulations), current Edition May 1, 2006 (available on request). Definitions and terms of this document from the Japanese Printing Ink Manufacturers Association do apply.

The colorants used meet the purity requirements of the Council of Europe (CoE) Resolution **AP(89)1** *on the use of colorants in plastic materials coming into contact with food*[9].

How SIEGWERK ensures the control of its raw materials:

SIEGWERK has implemented a comprehensive raw material introduction process based on a centrally coordinated approval via Corporate HSE which is operated on a worldwide basis:

With this process, which is also applied backwards to currently used raw materials, SIEGWERK strives to even further achieve the 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 grounded 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).

SIEGWERK packaging inks are formulated and manufactured in accordance with the EuPIA Good Manufacturing Practices available at www.eupia.org.

4.2. 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.

[9] www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/

4.3. Formulating towards low migration

SIEGWERK inks and varnishes clearly identified for food packaging use are formulated in such a way to both minimize potential migration of concern through the substrate or the set-off from the printed outer side to the food contact surface in the stack or the reel.

As a rule[10], SIEGWERK performs:

- Either **worst-case calculations** for each relevant migrant which enable the converter to identify potential violations of SMLs; for this purpose, by default, SIEGWERK assumes an upper standard dry ink film weight of **3 g/m²** and a standard volume/weight ratio of **6 dm²/kg**[11] (the "SIEGWERK reference limits").
- Or, if the result of the worst-case calculation indicates an exceedance of a SML, **exemplary migration testing** in accordance with the current state of knowledge on packaging, which is representative for the purpose the specific ink product has been designed for; the results obtained for each relevant migrant must demonstrate that under normal conditions, and when applied as unique component on the packaging, the final food packaging can be compliant.

This means, the formula is designed in a way that the final packaging as produced under the control of the printer/food packer has to meet the following relevant thresholds:

- for evaluated substances the applicable SML applies
- for non-evaluated substances the following limit values apply:
    - ≤ 10 ppb, in case of substances with insufficient toxicological data,
    - ≤ 50 ppb, for substances where three negative mutagenicity tests requested by the EFSA[12] Guidelines are available,
    - > 50 ppb, if substances are supported by favorable toxicological data and/or a toxicological evaluation in accordance with the EFSA Guidelines is available.

For non-evaluated substances, whose migration behaviour in industrial practice is likely to provide insufficient margins of safety versus applicable thresholds, SIEGWERK is committed to work with the suppliers, aiming to make available or generate toxicological data for higher thresholds. Ultimately, in such cases, SIEGWERK strives for appropriate authority evaluations.

[10] For the specific SIEGWERK product, the dedicated information included in the respective SIEGWERK "Statement of Composition" is applicable.
[11] Further assumptions made by SIEGWERK are: 100 % of surface is covered with the ink, 100 % transfer of migrant into the foodstuff.
[12] European Food Safety Authority

5. The printer's selection of ink

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		Conditions of Use
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 informs about resistance and fastness properties of each individual ink. They have to be checked for applications which involve non-intended but foreseeable short-time and /or low-area direct contact with food, as per chapter 5.2.

5.1. Categories of food packaging and their migration risk

5.1.1. Categories WITH potential migration risk

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

Only inks and varnishes intended for food packaging as indicated in the Technical Data Sheet and related communication must be used.

The printer should additionally use the "Appendix 2 – Checklist: Processes and Parameters which potentially trigger non-compliance (migration, organoleptic effect)" for their verifications.

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

Application	Flexible Packaging	**Sandwich print in laminates or surface print on monofilm**		**Thermally Treated Packed Food. Sandwich print in laminates or surface print on monofilm**	**Surface print monofilm and liddings**
		WITHOUT the inner layer(s) being a barrier to migration		**WITHOUT the inner layer(s) being a barrier to migration**	**WITH the inner layer(s) being a barrier to migration**
Examples		Cheese, meat products, tea bags, confectionery, bakery products, butter wrappers		Ready meals, bakery, pasteurized, sterilized dry or in autoclave, boil-in-the-bag, microwaveable	Dairy products (aluminum lids)
Potential migration risk of the packaging structure		Yes, migration both via diffusion across the layers and via set-off.		Yes, migration both via diffusion across the layers and via set-off. Migration can be enhanced by temperature, pressure and water/steam distillation.	Yes, migration via set-off to high absorbance layer (heat-seal varnish, PE …).
About inks for this application		Solvent and water-based	UV curing	Solvent and water-based	Solvent and water-based / UV curing
		Only products intended for food packaging.	Only products intended for food packaging ("Low Migration") No UV curing products for small packaging for food for infants and small children.	Only products intended for food packaging.	Only products intended for food packaging. / Only products intended for food packaging ("Low Migration") No UV curing products for small packaging for food for infants and small children.
Measures recommended to the printer		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.	Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab.	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. Observe Appendix 2.	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. / Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab.

Sandwich print in laminates	Paper & Board Packaging	Rigid Packaging, Tags, Trays			Rigid Packaging		
WITH the inner layer(s) being a barrier to migration		**WITHOUT the inner layer(s) being a barrier to migration**			**WITHOUT the inner wrap being a barrier to migration**		
Meat products, ready meals, soup, spices, coffee, tea, preserved food, packed in laminates with aluminum foil		Folding Carton (with or without PE- or varnish coating) for fast food, frozen food, confectionery, bakery, dry pasta, rice,sugar, cereals, vegetables, fruits, Tea tags.	*Some use for ready meals for microwave and baking oven.*	Corrugated Board Boxes for pizza, fast food, bakery	Folding Carton with dry food (cereals) in PE, PP or paper bag inside the box, with air room between the two packages		
Yes, migration via outer layer(s) and set-off.		Yes, migration both via diffusion across the layers, via set-off and gas phase. *Migration can be enhanced by temperature and water/steam distillation.*			Yes, migration via diffusion & gas phase, or via set-off, diffusion & gas phase		
Solvent and water-based		UV curing	Oleoresinous offset	Water-based	UV curing	Oleoresinous offset	
Only products intended for food packaging.		Only products intended for food packaging (“Low Migration”) No UV curing products for thermally treated food (microwave, baking oven) and for small packaging for food for infants and small children.	Only products intended for food packaging (“Low Migration”)	Only products intended for food packaging	Only products intended for food packaging (“Low Migration”) No UV curing products for small packaging for food for infants and small children.	Only products intended for food packaging (“Low Migration”)	
Calculate migration of actual combination of products on specific packaging using SIEGWERK Statements of Composition.		Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab.	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. *For microwave and baking oven, observe Appendix 2.*	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. *For microwave and baking oven, observe Appendix 2.*	Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab.	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	

		Paper Packaging		PE-coated Board Packaging		In-Mould Labels (IML) for cups, tubs, trays
		WITHOUT the inner layer(s) being a barrier to migration		**WITH or WITHOUT the inner layer(s) being a barrier to migration**		
		Paper Bags for bakery, confectionery, sugar, flour, fruits, vegetables, wrappers (with or without PE- or varnish coating) for fast food cheese, meat. *Some use for microwave.*		Milk and fruit juice cartons, sauces, soups		Dairy products, sauces
		Yes, migration via diffusion & gas phase, or via set-off, diffusion & gas phase. *Migration can be enhanced by temperature and exposure to water/ steam*		Yes, migration via diffusion and/or set-off to high absorbance PE layer		Yes, migration via diffusion and set off. Label will be melted on the container and become a primary food packaging which is stacked before filling
	Water-based	Water-based		Water-based, Solvent Based, UV Curing, Electron Beam Curing		UV curing, Oleoresinous offset, water-based Overcoatings
	Only products intended for food packaging	Only products intended for food packaging		Only products intended for food packaging (UV: "Low Migration") No UV curing products for small packaging for food for infants and small children.		Only products intended for food packaging ("Low Migration")
	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	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. *For microwave and baking oven, observe Appendix 2, point 1.7.*		Calculate migration of actual combination of products on specific packaging using SIEGWERK Statements of Composition. Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab.		Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab.

Rigid Liquid Food Packaging

Self-Adhesive Labels, Cups, Tags, Sleeves, Tubes

Sleeves or Glued or Pressure-sensitive Adhesive (PSA) Labels, laminated or not laminated, for cups, tubs, trays	**Glued or PSA-Labels for Primary Packaging and Lidding**		**Shrink sleeves on PET bottles**	**Shrink sleeves on PE/PP/OPS bottles**	**Tubes, cups**
Dairy products, sauces	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
Yes, migration via diffusion and set off. Sleeve or label will be applied onto the container, become a primary food packaging which is stacked before filling	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
UV curing	UV curing	Water-based, Solvent Based	UV curing (Cationic UV Flexo, radical UV Offset and Flexo)	UV curing	UV curing
Only products intended for food packaging ("Low Migration")	Products intended for food packaging ("Low Migration") highly recommended. In any case, odor optimized products ("Low Odor") recommended.	Products intended for food packaging recommended.	Products intended for food packaging ("Low Migration") highly recommended. In any case, odor optimized products ("Low Odor") necessary.	Only products intended for food packaging ("Low Migration")	Only products intended for food packaging ("Low Migration")
Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab.	Individual case to be assessed. In any case, consider formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab. Sensorial issues to be considered.	Individual case to be assessed. Consider calculating migration of actual combination of products on specific packaging using SIEGWERK Statements of Composition.	Individual case to be assessed. In any case, consider formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab Sensorial issues to be considered.	Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab.	Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab.

5.1.2. Categories WITHOUT migration risk

In case the converter could avoid set-off taking place and would have proof for the existence of an efficient functional barrier towards migration and organoleptic taint, also inks and varnishes not intended for food packaging could be used. The following table provides an exemplary listing.

Application	Example	Potential migration risk of the packaging structure	About inks for this application	Measures recommended to the printer
Paper & Board Packaging				
Rigid Packaging WITH the inner wrap being a barrier to migration	Cereal in a laminate OPP/**Aluminum foil**/PE bag inside the box.	No. Food is completely tight-sealed against migrants coming through the air room between the two packages.	UV Curing, Oleoresinous offset, water-based In any case, odor optimized products ("Low Odor") necessary.	If the layer eligible for being a functional barrier is not aluminum foil (ie. vacuum deposited aluminum on PET is not necessarily a barrier): formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab. Sensorial issues to be considered.
Self-Adhesive Labels, Sleeves				
PSA-Labels for Primary Packaging and Lidding WITH the inner wrap or the lidding being a barrier to migration	Labels applied on filling line to preformed and filled packaging/lidding with aluminum foil layer, i.e. labeled ready meal packs or aluminum tubs.	No. Aluminum foil prevents diffusion migration, and set-off is not possible[13].	UV Curing, Oleoresinous offset, water-based In any case, odor optimized products ("Low Odor") necessary.	Sensorial issues to be considered.
Shrink sleeves on glass bottles	Soda, Mineral water, alcoholic beverages.	No. Glass is by default a recognized functional barrier.	UV curing (Cationic UV Flexo, radical UV Offset and Flexo) In any case, odor optimized products ("Low Odor") necessary.	Sensorial issues to be considered.

[13] Impossibility of migration may also apply to 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.

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

There are cases where unintentional but foreseeable short-term and/or "low-area" contact of the printed and dried or cured ink and/or varnish layer to the food is possible. Examples for these cases are

- Lamination print job where few single packages may expose the printed layer to food at the cutting edges, or
- on a packaging line where wrappers of few food packages (i.e. butter wrappers) are partly folded such as a small area of the printed surface is turned inside, or
- food could be spilled onto a surface print upon opening of the package by the consumer (who may lick it off) – this might happen with boxes, trays or cups for fast food, or
- paper or plastic wrappers used at the point of sale (i.e. for meat, fish and pastry, where temporary direct food contact could occur as a consequence of careless wrapping), or
- kitchen towels and napkins made from tissue paper (which the consumer might use for wrapping food with the printed surface towards the food).

Regulations do not explicitly provide rules to protect consumer's safety for these situations. However, in accordance with good manufacturing practice principles, SIEGWERK recommends precautionary measures to the converter to minimize the risk of migration. 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 colour 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 a potential migration of the relevant migrants via a worst case calculation.

6. Ink application by the printer and verification of packaging compliance

6.1. Converter's Good Manufacturing Practice

SIEGWERK confirms that a packaging ink is fit for the intended purpose. However, since most of the process areas are outside the control of the ink manufacturer, it is not possible to provide any certification that the printed ink film as applied on the substrate will automatically lead to a fully compliant food packaging.
The ultimate verification of compliance can therefore only be accomplished for the finished food package. The manufacturer of the final article has the legal responsibility to ensure that it is fit for the intended purpose as food packaging.
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 (e.g. printing speed, temperatures, …) which are controlled by the converter.
The following main subjects shall be covered by specific requirements in the recognized **converter's good manufacturing practices**[14]:

- 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.

[14] **Appendix 2** provides a comprehensive and concrete list of critical processes and parameters

6.2. Practical measures recommended to the printer

6.2.1. Visible set-off

Any **visible set-off** from the printed side to the food contact layer must be avoided by appropriate printing conditions.

6.2.2. Evaluation of risk

Appendix 2 "Processes and Parameters which potentially promote non-compliance (migration, organoleptic effect)" provides guidance for the printer's assessment of the potential level of risk in terms of a checklist.

In any case, the printer should check if the application weight and the volume/surface ratio exceeds the "SIEGWERK reference limits" of 3 g/m^2 respectively 6 dm^2/kg (see Appendix 2 for guidance on practical application weights of various types of inks and varnishes). In this case verifications indicated below are highly recommended.

6.2.3. Verifications

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 category[15].

SIEGWERK recommends the measures for verification listed per application category (packaging type) in the tables of chapters 5.1.1 respectively 5.1.2 to the converter.

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.

[15] Frequently 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.

6.2.4. Information provided by SIEGWERK

On request, SIEGWERK will provide information on evaluated and non-evaluated migrant substances in a "Statement of Composition" for packaging inks. Additionally, these documents provide results of worst case calculations for relevant migrants. In some cases, to safeguard proprietary information, signature of a confidentiality agreement and/or involvement of an independent third party might be requested.

In any case, SIEGWERK is committed to disclose, without any reservation, every information necessary for the identification and quantification of evaluated and non-evaluated migrants. The related documentation will be provided, after signature of a confidentiality agreement, to those parties specifically involved in the compliance control and possessing appropriate capabilities for practical migration testing and evaluation of the results.

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[16].

[16] See the Customer Information "Analytical Institutes recommended for migration testing of food packaging printed with SIEGWERK inks and varnishes", available on request.

Appendix 1 – Legal requirements and responsibilities

1. Introduction

based on EuPIA Information

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 the Directive 2000/13/EC 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 Appendix 1 mainly deals with printing inks applied to the non-food contact surface of food packaging (packaging inks).

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, off-set, screen, non-impact printing or roller coating.

2. Legal requirements

based on EuPIA Information

2.1. Europe[17]

European Union

Framework Regulation (EC) No 1935/2004[18] 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:

Materials and articles [...] shall be manufactured in compliance with the 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.

[17] In some European countries there may be some specific requirements on printing inks for food packaging available. These are not subject to this Appendix.
[18] REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJEU L338 of 13.11.2004.

The GMP Regulation (EC) No 2023/2006[19] 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 contact side of a material or article[20]:

1. Printing inks applied to the non food-contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side:
(a) through the substrate or;
(b) by set-off in the stack or the reel,
in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

2. Printed materials and articles shall be handled and stored in their finished and semi-finished states in such a manner that substances from the printed surface are not transferred to the food-contact side:
(a) through the substrate or;
(b) by set-off in the stack or reel,
in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

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

[19] 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
[20] 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.eupia.org

There is not yet any **specific** EU legislation concerning printing inks for food packaging, with the exception of the Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film, which states that the printed surface of regenerated cellulose film must not come into contact with food.
The main specific regulation pursuant to the Framework Regulation is the **Regulation (EU) No 10/2011** 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 (SML) or maximum contents 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, printed plastic packaging is covered if there are ink components which are listed (thus are so-called **evaluated** substances), therefore the relevant restrictions such as specific migration limits (SML) or maximum content (QM) have to be met.

Switzerland

Switzerland amended their "Ordinance on Materials and Articles in Contact with Food"[21] with provisions on food packaging inks. This introduced a positive list ("list of permissible substances"). It came into force on 1st April 2008 with a transitional period of two years, hence the requirements became applicable as from April 2010.

SIEGWERK has ensured and continues to ensure that all raw materials which are used in printing inks and varnishes intended for food packaging are included in this positive list.

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 is due to process notifications by requestors from industry for toxicological evaluation and determination of a SML. Notifications must include appropriate data provided in the form of 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".

Where required, SIEGWERK is committed to work with the suppliers to achieve such evaluations.

[21] Ordinance on Materials and Articles in Contact with Food, "Verordnung des EDI über Bedarfsgegenstände", 7. März 2008 SR 817.023.21 (http:www.admin.ch/ch/d/sr/8/817.023.21.de.pdf)

2.2. Non-European Countries

The following information is given as a guidance for printed packaging to be exported.

USA based on napim Information

General requirements and definitions

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 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, that is, become a component of the food. Printing inks or coatings that are converted in or on food packaging materials may be potential indirect food additives. They are regulated by 21CFR Parts 170-190.

The FDA regulates food additives, not food contact. There is no procedure for the approval of formulations (there are no "FDA approved inks"); the FDA can approve individual ingredients.

Packaging inks applied on the non-food contact surface

Printing inks or coatings applied on the non-food contact surface of food packaging (that is outside or sandwich printing) are not regulated. The FDA does not have any specific guidelines for this scenario. "*This type of contact does not in and of itself require compliance with the indirect food additive guidelines. […] The contact must be reasonably expected to result in the ink or coating becoming a part of the food. Migration of properly converted and dried ink or coating films generally will usually not take place by this mere inconsequential contact. If it does occur, then the indirect food additive guidelines at 21CFR Parts 170-190 must be complied with. Generally speaking in situations where exterior printing results in significant migration to a food product there is a quality control problem and most likely the result of an inappropriate ink/coating product, package design or structure for the specific application" (NAPIM leaflet "Printing Ink and Food Packaging Regulations*"[22]).

[22] Printing Ink and Food Packaging Regulations, issued September 1, 1999, and adapted March 2000, NAPIM.

Canada

The Canadian Food Inspection Agency (CFIA) and the Health Products and Food Branch 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 in contact with food. (It is important to note that a Letter of No Objection does not absolve the packager 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 package 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.

Japan

Under the Food Sanitation Law, the inertness of food packaging must be ensured. The Japanese Printing Ink Manufacturers Association (JPIMA) has issued the Voluntary Regulations Concerning Printing Inks (Negative List ("NL"))[23] Regulations for backup.

[23] Current Edition May 1, 2006 (available on request).

3. Responsibility

based on EuPIA Information

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 the relevant information as laid down in the chapter "The 6 steps and responsibilities for perfect food packaging" of this Guidance.

Under the 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 the 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.

4. Direct food contact applications

There are some instances with intended direct food contact of printing inks, protective coatings heat-seal coatings, anti-fog coatings or slip coatings. In comparison with non-food contact prints there is an increased risk of migration into the food.

In **Europe**, in the absence of a 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[24].

Under **FDA** provisions, **direct food contact** refers to a printing ink or coating (e.g. protective, sealing, antifog, slip lacquers) that is intended by design to be the surface 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 21CFR Parts 170-190[25].

[24] See also: "Printing Inks and Varnishes intended to come into Direct Contact with Foodstuffs", EuPIA, www.eupia.org.
[25] Printing Ink and Food Packaging Regulations, issued September 1, 1999, and adapted March 2000, NAPIM.


SIEGWERK


od.
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Nr.
P.R.

Appendix 2 – Checklist:

Processes and parameters potentially promoting non-compliance (migration, organoleptic effects)

Long term experience indicates that the following non-exhaustive list of 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.

1. Design of the food packaging

1.1. Barrier properties of the material layers lying between ink and food
Migrants from printed ink layers **diffuse** more and quicker the worse the barrier properties of the substrate or materials wrapping the food are:

Poor barrier properties: coated paper, uncoated paper, coated board, uncoated board, regenerated cellulose, polyethylene, polypropylene, ionomer, adhesive layers, printing varnish or lacquer coating layers.

Limited barrier properties: polyamide, polyethyleneterephthalate, polyvinylidene chloride, metallization layers.

Better barrier properties: appropriate SiO_x and AlO_x layers on polyethyleneterephthalate, sufficiently thick layers of polypropylene.

Recognized as functional barrier: aluminum foil, tinplate, glass; sufficiently thick layers consisting of polyethyleneterephthalate or polyvinylidenechloride.

Note that diffusion can happen both via the substrate and/or via the vapor phase enclosed inside the packaging between material and food.

1.2. Nature of the surface which is in contact with the ink/varnish layers
After printing, within the reel or stack, **invisible** set-off can happen because the surface in contact with the printed layer may absorb migrants:

Very high probability of set-off: coating on paper, board, aluminum, plastics; regenerated cellulose; thin extruded layers of polyethylene or polypropylene;

High set-off: films or cups/tubs made of polyethylene, polypropylene, polystyrene.

Medium set-off: uncoated paper, uncoated board, polyamide, polyethylene terephthalate.

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

1.3. 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, i.e. via a worst-case calculation.

The printer is responsible for complex combinations of primers, inks and overprint varnishes, often from different suppliers. If they might result in higher application weights, they require special attention. The following table, which indicates the typical application weights, should be considered by the printer:

Solvent or water-based flexographic ink (white) in laminate or surface printed onto plastic film or paper/board or aluminum	1.5 g/m²
Solvent or water-based flexographic ink (colour) in laminate or surface printed onto plastic film or paper/board or aluminum	1.0 g/m²
Solvent or water-based flexographic overprint varnish, surface printed onto plastic film or paper/board or aluminum	1.5 g/m²
Solvent or water-based gravure ink (white) in laminate or surface printed onto plastic film or paper/board or aluminum	2.0 g/m²
Solvent or water-based gravure ink (colour) in laminate or surface printed onto plastic film or paper/board or aluminum	1.0 g/m²
Gravure overprint varnish, surface printed onto plastic film or paper/board or aluminum	2.0 g/m²
Oleoresinous or UV curing offset ink printed onto paper or plastic film	2.0 g/m²
Dispersion varnish over offset ink	3.0 g/m²
UV varnish	4.0 g/m²

The printer has to verify the actual application weight in comparison with the above values before printing each individual job.

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

1.5. Type and nature of the packed food
Food types whose nature can enhance diffusion of migrants through the substrate/packaging material and/or mobilization of migrants present because of previous set-off:

High uptake of migrants:
- Aqueous, acid, alcoholic and/or fatty liquid food
- Fatty solid or liquid food in aqueous liquid food (i.e. mozzarella cheese)
- Fatty and powdery foods
- Fatty and 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 (i.e. choco biscuit bar)

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

1.6. Long shelf life of the packed food
While the reservoir of migrants available in the printed layer for diffusion through the packaging material or absorbed via set-off can theoretically migrate completely within minutes already, the normal migration is slower. Thus the longer the food is stored, the more migrants might end up in the packed food.

1.7. Processes to which the printed food packaging is exposed
Migration increases with temperature and time. Thus, any thermal exposure as well as retort conditions (water/steam under pressure) can enhance substance transfers:

- Heating by oven, sterilization in autoclave and pasteurization before delivery to retail[26, 27],
- Heating by microwave or boiling in the bag by the consumer[27,28].

[26] The EuPIA (ex CEPE) / ETAD information note "Primary Aromatic Amines in Food Packaging Inks, Compliance with Directive 90/128/EEC" (predecessor of Regulation (EU) No 10/2011), available on request, gives information on potential risks in relation to colored inks containing azo pigments.
[27] Formal qualification via migration testing order upon previous SIEGWERK disclosure to intended lab should be considered.
[28] The EuPIA Information "Use of Diarylide Pigments in Printing Inks and Prints at Temperatures higher than 200°C", www.eupia.org, should be observed.

2. Printing

Generally, the following parameters may increase the amount of migrants in the ink layer and/or the diffusion of migrants:

2.1. Drying processes

Drying by heat (insufficient drying may lead to increased residual solvents that might migrate)

- High printing speed – insufficient drying energy (oven temperature, drying air flow)
- High amount of ink/varnish printed on the substrate – insufficient drying energy (oven temperature, drying air flow)
- Too high amounts of retarder in ink – insufficient drying energy (oven temperature, drying air flow).

UV curing (insufficient curing may lead to unreacted monomers and increased photoinitiator amounts)

- High printing speed – insufficient UV drying energy
- Loss of power of aged lamps (decrease of the UV radiation dose at print surface)
- High amount of ink/varnish printed on the surface – insufficient drying energy (UV radiation dose at print surface)
- Addition of photoinitiator and/or acrylate monomer – insufficient drying energy (UV radiation dose at print surface).

2.2. Print shop activities

Adding printing additives to make press-ready inks which are not recommended by SIEGWERK and validated as fit for the purpose by the printer.

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 for carry-over if the printer also uses the same equipment for inks that are not intended for food packaging.

Inappropriate control 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.

Using the wrong dosage of hardener which therefore is out of the recommended range (case of 2-component systems).

2.3. Winding to reel or stacking – invisible set-off is enhanced by:

Surface printing:

- Long time in the reel or stack
- High pressure in the reel or stack
- Storage above ambient temperature in the reel or stack.

Off-line lamination, winding before lamination:

- Long time in the reel
- High pressure in the reel
- Storage above ambient temperature in the reel.

3. Packing

Migration increases at a higher temperature:

- Hot filling by the packer/filler.

Disclaimer

The information contained herein is based upon data believed to be up-to-date and correct at the time of writing. It is provided to our customers to enable them to comply with all applicable health and safety laws, regulations and orders. In particular, customers are under an obligation to carry out a risk assessment under relevant Good Manufacturing Practices (GMP) in-line with EU food contact legislation and as a result take adequate risk management measures to protect food consumers.
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