

Guidance for the use of printing inks for paper and board packaging used for contact with food

1-Regulations

The Framework Regulation (EC) No 1935/2004 states that materials and articles shall be manufactured in compliance with good manufacturing practice (GMP) so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities, which could:

- Endanger human health,
- Bring about an unacceptable change in the composition of food,
- Bring about a deterioration in the organoleptic characteristics of the food.

The new Regulation (EC) No 2023/2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food applies to all stages of manufacture, processing and distribution. An Annex concerning the application of printing inks to the non-food contact side of a material or article requires that printing inks shall be formulated and/or applied so that substances from the printed surface are not transferred to the food contact side 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.

The Guidance in this document describes the good practice in the use of printing inks for paper and board packaging as a basis of achieving conformity with the Annex 1 of the Regulation (EC) No 2023/2006.

2-Transfer Mechanisms

Transfer of substances from the printed non-food contact side of food packaging to the food contact side can occur by:

- set-off in the stack or the reel, which is the transfer of substances from the printed image to the unprinted reverse side above it (the food contact side). Visible set-off is caused by mechanical rub or by “blocking” of a partially dried ink film but is not necessarily an indicator that set-off migration is occurring. Set-off of substances which are prone to migrate is usually invisible.
- transfer of substances by migration from the printed image through the substrate to the unprinted reverse side (permeation),
- the transfer of volatile substances in the enclosed air space of the finished and packed stack or reel (vapour phase migration).

The possibility of subsequent transfer of substances originating from the printed layer, to the food contact side of the packaging and subsequently to the food is dependent on many different parameters. Composition and design of the packaging and the packaging components (substrates, inks, varnishes, adhesives), type of food, storage time and storage conditions of the filled

packaging are only the most important parameters influencing possible transfer of substances into food.

3-Guidance for design of food packaging

3.1-Packaging specifications

Clear specifications for the packaging need to be provided, taking into account all relevant aspects, including:

- Physical & chemical properties of the food that will be packed
- Conditions of converting
- Storage
- Final use

3.2-Packaging design by the converter

Design of the packaging for compliance is a shared responsibility between the purchaser of the packaging and the converter. Ultimately the purchaser is responsible for approving the appropriate selection of:

- substrates,
- other starting materials,
- application techniques for inks, varnishes, adhesives, and other coatings,
- production techniques,
- structural design,
- graphical design.

Printing inks, coatings and adhesive layers are not intended to come into direct contact with the packaged foodstuff. Where there is an assessed risk of transfer of substances to the food contact side of the packaging, a suitable functional barrier must be included in the package design.

When carrying out a risk assessment, the following must be considered:

- the different possible transfer mechanisms (set-off, permeation, and vapour-phase transfer),
- the type of barrier material. Some materials, such as aluminium or glass may represent an absolute barrier to migration, others, such as PET, a specific barrier to migration. Other materials such as paper and board, the plastics PE or PP are insufficient barriers to migration of most substances liable to migrate from ink and varnish layers.
- A suitable functional barrier may prevent permeation, but not exclude set-off.

3.3-Ink formulation – Ink manufacturing

Following the creation of the packaging specification, including any necessary risk assessment, the ink manufacturer will be requested to provide recommended ink formulations. The following considerations apply to printing inks for food packaging:

Ultra- Violet cured (UV) inks / varnishes:

UV inks dry by means of a chemical reaction that takes place in the UV curing unit on the printing press. During this reaction the UV-reactive, low-molecular photoinitiator and vehicle molecules are cross-linked to build a polymeric, solid film. After curing of standard UV inks and varnishes, however, certain

residual components may be present which have the potential to migrate due to:

- decomposition products of photoinitiators and non-reacted photoinitiators
- residual monomers that remain in the ink film or are absorbed into the substrate
- incomplete reaction of ink components due to inadequate curing.

The majority of raw materials used in standard UV inks and varnishes have not been evaluated for food contact. Because of the potential of the low molecular weight components to migrate, standard UV inks are unlikely to be suitable for printing in most applications of primary food packaging.

For the printing of packaging for food contact, specially formulated UV inks are recommended that are designed to give low-migration ink layers after sufficient curing.

Conventional inks and water-based overprint varnishes:

Standard offset printing inks and water-based varnishes are not suitable for the manufacture of primary food packaging since they may contain substances which are liable to migrate and which have not been evaluated for food contact.

For the printing of primary food packaging, specially formulated low-migration inks and water-based varnishes are available and should be used when indicated by the risk assessment.

4- Guidance for printing of food packaging

4.1- Paper and Board

- Ensure that the substrate is suitable for food packaging applications
- Specifically in relation to UV printing inks:
- UV radiation can cause some substrates to give off strong odour or develop a strong taint.
 - Paper and board are very receptive to airborne migration of volatile materials and are very absorbent both to vapours and liquids such as those from press washes or conventional ink in the press room atmosphere.

4.2- Inks, varnishes & fount solutions

- Use only low-migration products that are recommended for primary food packaging, unless a risk assessment for the packaging in question shows that a risk of transfer of ink ingredients to the food by set-off, permeation or vapour-phase migration can be excluded.
- Use the inks from their original containers
- Avoid over-emulsification in the case of conventional sheet-fed inks
- Use only printing additives approved for the specific low-migration ink system
- For offset litho printing special low-migration fount concentrates have been developed, as standard fountain solution concentrates may contain potential migrants such as wetting agents or alcohol substitutes.

Ink mixing and colour matching

Many inks needed in packaging printing are mixes, spot colours or brand colour matchings. For low migration inks care must be taken to use all components of the blend from the same series of ink type. Even a small amount of a component of a 'non-low-migration' or standard ink can have an effect both on low odour performance and in migration testing.

- Avoid contamination during ink mixing
- Containers and tools must be clean
- Cleaning agent residues must be avoided.
- Inks blended at the converter's plant should be re-used only after being checked for suitability for re-use.

4.3 Cleaning

To prevent from contamination always use clean equipment and tools.

- Rollers and blankets must not be contaminated
- Thorough cleaning with a dedicated cleaning agent

Normal press washes can also be a potentially significant source of unwanted migration. They are by nature both liquid and prone to migration.

When a risk assessment indicates the need for a low migration press wash the ink supplier can recommend a suitable press wash and provide guidance for its use which should be followed. A low migration press wash is unlikely to be as economic or efficient as a normal wash and great care must be taken to change procedures to take account of this. It is best practice to wipe the rollers and blankets dry of solvent wash after cleaning to reduce the risk of migration.

4.4 Drying of conventional inks

When low-migration inks are used, addition of driers or drying accelerators on the press is not allowed.

When conventional offset inks are used (e.g. in the case of packaging which is not in contact with the food and with, when appropriate, a suitable functional barrier) ink films must be completely dried after application, 48 hours being the recommended period.

4.5. UV curing

Incomplete curing of UV ink layers greatly increases the risk of migration and also the possibility of organoleptic effects giving rise to odour.

The following is the recommended good practice to obtain satisfactory curing:

- Check that the necessary power is really available and,
 - specifically the correct number of lamps of the right power and age
- Regular maintenance of lamps and reflectors

A variety of factors influence the degree of curing:

- the type and energy output of the UV lamps
- the press speed
- the time interval between printing and curing
- the substrate and specifically its absorbency.

This means it is essential to continuously monitor the quality of curing and the output of the UV lamps.

- Verify that current printing speed corresponds to pre-validated conditions
- Check the sufficient curing of the ink film using appropriate tests

Addition of non-approved curing accelerators on the press is not allowed.

4.6 Ink film weight

- The higher the film weight, the more difficult it is to achieve sufficient curing
- Excessive film weight must be avoided, in particular UV dark shades and UV opaque white

4.7. Control

- Statistical migration/sensorial analysis may be appropriate in addition to standard tests.
- Recording of printing conditions including speed, curing conditions and printing sequence is recommended.
- Reels or stacks of sheets should be stored before and after printing in such a way that the organoleptic characteristics are not affected: If considered necessary, appropriate covering should be used before transport to any print finishing or subsequent processing.

4.8 Changing from normal printing to low migration printing

Ideally the same ink type should be run continually on a press to avoid the need for costly clean-downs and to avoid potential contamination. However in circumstances when such changeovers cannot be avoided the following (non-exhaustive) list provides the basis for a code of practice for the changeover:

- Empty all ink and coating ducts and pipes
- For the offset process, change the fount to the one recommended by the supplier, cleaning the mixing and storage tanks, filters and pipes as part of the procedure.
- Clean all rollers and blankets
- For the first print run an adequate quantity of run-up sheets should be printed as a way of removing any last traces of 'non-low migration' materials. Allow an appropriate time period for substances liable to migrate which might be retained from previous standard inks to be extracted completely from rubber blankets and rollers.
- If ink is supplied to the press from a drum ensure that there is no contamination from normal inks by using a clean pump and pipes and if a 'bag' is used in lining the drum ensure that there is no contamination from plasticisers.
- Ensure all subsequent processes are free of the risk of migration from solvents, plasticisers, oils, greases and other potential migrants

5-Testing for Transfer

Inks manufacturers will make available all necessary information for the monitoring of transfer of substances by migration and invisible set-off. Confidentiality agreements can be signed with third parties specifically involved in the compliance control.

Migration test methods with all types of simulants are available. The most commonly used simulant for paper and board packaging is Tenax®, simulating a range of dry foods including sugar, flour and cereals.

Note: Transfer by migration is a time dependant phenomenon. If potential migrants exist in the packaging then the risk of unwanted transfer to the packaged food will increase with time.

This can be a two-way process with volatile substance being lost from the packaging through evaporation.

Note on sampling for migration testing: The sampling process is crucial to getting the correct results on which to base important decisions. Proper sampling procedures must be strictly followed to ensure correct and reproducible results and key parameters are: number, type and size of samples, supply of the unprinted reference samples, and wrapping conditions to avoid contamination during transport

6-Risk assessment:

The application of these guidelines requires a special attention to the risk of migration in the case where: the foodstuff is directly in contact with the packaging, which is printed on the non-food-contact side.

The case where the packaging is not in contact with the food is more complex and two situations can occur:

- The packaging in contact with the food is not a sufficient barrier: some components of the external printed side of the outer packaging can migrate to the foodstuffs (through the substrate or by vapour phase).
- The packaging in contact with the food represents a real barrier (with no possible exchange, e.g. glass jars, metal cans).

There is no regulation today regarding the outer packaging in these circumstances. If there is any doubt concerning the permeability of the packaging in contact with the food (e.g. certain PE or PP pouches), the application of the regulations for food contact for the outer packaging and the use of low-migration inks is recommended. If there is an adequate barrier, and a migration risk has been assessed to be very unlikely or analyses have shown that there is no migration, no change of printing process is required.

If printed packaging materials are intended to be used at high temperature or for sensitive food products (chocolate, ice cream, fatty food), the suitability of the packaging must be thoroughly evaluated.

References to:

- EuPIA Guideline
- EuPIA GMP
- FEFCO/ESBO: "International Good Manufacturing Practice Standard for Corrugated and Solid Board".
- FPE/CITPA "Code for GMP for flexible and fibre-based packaging for food"

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