

Legally compliant varnishing

Fulfilment of applicable food packaging regulations

Taking responsibility seriously

The safety of foodstuffs in packaging printing has become increasingly important. There are many regulations, guidelines and norms to be considered in this context. All used food contact materials have to comply with applicable food packaging regulations; substances originating from the packaging must not present any risk to health and not negatively change the packed foodstuff's composition or properties. Finally, it is the responsibility of those who bring a packaging into circulation to analyze if the overall packaging is suitable for the designated filling good. Consequences for packaging printers are clear: More than ever they need to be on the safe side.

Legal requirements:

Packaging in the direct or indirect food contact must not transfer any constituents to food in quantities, which could a) endanger human health, b) unacceptably change the food composition or c) bring about deterioration in the organoleptic characteristics thereof. This also includes the appropriate choice of raw materials, as these have to correspond to established specifications and applicable law. The **Regulation EC No. 1935/2004** lays down such materials and substances, which come, or may come, into contact with foodstuffs. Authorized raw materials must be of high technical quality and fulfil defined purity criteria. You have to comply with specific and overall migration limits – the sum of all substances that can be transferred to the food at the maximum. In addition, it is important to guarantee the traceability of materials used at all levels of the supply chain. These principles are also anchored in German legislation by means of the **Foodstuffs and Consumer Goods Law**.

The **Plastic Directive EC No. 10/2011 (PIM)** represents a specific measure in the sense of Regulation EC No. 1935/2004. Although it does not contain any direct requirements for the assessment of coatings in contact to foodstuffs, it lays down the applicable principles for plastic materials in direct food contact. This includes migration testing, the concept of a functional barrier as well as requirements made on conformity declarations. Moreover, the directive defines a global migration limit of 60 mg/kg (EU cube model); substance-specific migration limits (SML) and a compliance with the so-called Union positive list in its applicable form.

For the production of food packaging, the **Good Manufacturing Practice Regulation (EC) No. 2023/2006** claims compliance with a good manufacturing practice (GMP). It describes requirements made on product manufacturing as well as quality management. Requirements especially refer to two areas: production and product safety. Here, it is particularly important to build up a good risk management system. Substances must be evaluated that are added to the product intentionally (intentionally added substances), but also non-intentionally (non-intentionally added substances). The Good Manufacturing Practice is legally defined for all materials in contact to foodstuffs according to EC No. 1935/2004/EG.

The **Swiss Ordinance** (SR 817.023.21) is valid for all food packaging produced in Switzerland, but also for those food packaging imported from outside the country. In this ordinance, there is a two-part positive list with substances that can be used for the printing of food packaging. By nominating the **Nestlé Guidance Note on Packaging Inks** as a basic requirement, the Swiss Ordinance also shows relevance over national borders.

Direct versus indirect food contact

Direct food contact refers to materials that physically contact foodstuffs. Migration potential here is high, as an immediate transfer is possible.

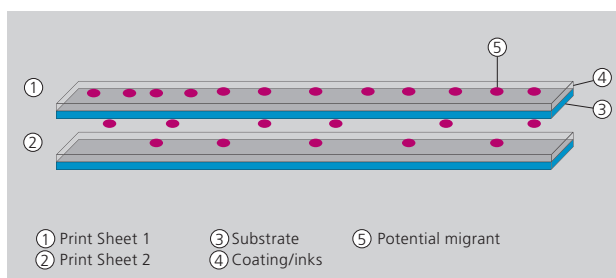
Indirect food contact refers to those substances that might come into food contact, such as on the outside of folded boxes for foodstuffs.

Types of migration

Migration represents the transfer of substances to the packed filling good, for example from the substrate, the printing inks or the coating. We distinguish between two main types of migration:

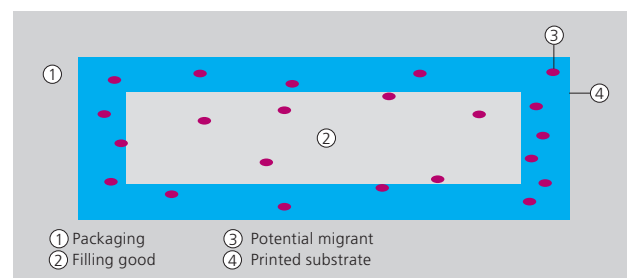
1. Set-off

Set-off migration is caused by the contact of a print sheet's printed side with the unprinted side of another print sheet. For example, this may happen in the sheet pile or while rolling up.



2. Penetration

In this case, substances from the substrate, the printing inks or the coating may be transferred to the filling good through the overall composition. Potentially used barrier materials possibly play an important role.



Apart from set-off and penetration, there are also other types of mass transfer:

3. Direct contact

Substances in the physical, respectively direct contact to the filling good are transferred to the foodstuff.

4. Gaseous phase transition

Especially at higher temperatures, volatiles from the packaging layers evaporate and pass over to the foodstuff, for example during heating up in the microwave.

Referring to the types mentioned above, migration mainly depends on three aspects:

- the barrier properties of the packaging composition (functional versus absolute barrier),
- the materials used: substrate, printing inks or coatings as well as
- the corresponding processing conditions (prevention of set-off, complete curing/drying of inks or coatings, and others).

Functional versus absolute barriers

A **functional barrier** makes the ready food packaging compliant to legal requirements. These are packaging structures in order to prevent migration of some of the potentially migrating substances into the filling good.

Impermeable materials, such as metal (e.g. aluminum) or glass, represent the **absolute barrier** towards mass transfer.

Consequences at a glance

For the production of legally compliant food packaging, there are many requirements and consequences to consider in various categories.

For raw materials

This contains:

- Compliance with purity criteria and ban lists
- Compliance with specifications and applicable law
- (Solely) use of authorized substances

This is how you implement those requirements:

- Careful choice of all raw and auxiliary materials to be applied
- Appropriate definition of all materials in accordance with end product and usage
- Consideration of the filling good type
 - direct/indirect food contact
- Analysis of the main raw materials by accredited laboratories

For production

This contains:

- Securing a Good Manufacturing Practice on all levels
- Introduction of defined and controlled process operations
- Establishment of quality safety and quality control systems
- Documentation of process parameters, production and quality control

This is how you implement those requirements:

- Concrete agreements on the processing practice with suppliers and system partners
- Standardized and documented process operations and product controls (GMP compulsory)
- Appropriate processing of all materials under controlled process conditions
- Securing the Good Manufacturing Practice by means of a (certified) management system

For products

This contains:

- Guarantee of inertness – only uncritical transfer of substances to foodstuffs
- Compliance with migration limits (global and specific)
- Traceability on all levels
- Conformity declarations (plastic materials) or appropriate information based on reliable evidence with regard to the compliance with applicable regulations
- (Solely) use of authorized substances

This is how you implement those requirements:

- Minimization of set-off
- Use of a functional barrier having:
 - Sensitive filling goods
 - Doubts about the compliance with migration limits
- Conformity evaluation on ready products, possibly with external testing laboratories

Excursus

A. Measures at ACTEGA Terra for legally compliant varnishing of food packaging

Raw materials

- Use of highly purified raw materials
- Extensive quality controls of raw material batches
- Regular analysis of raw materials by accredited testing laboratories
- Regular analysis by internal analytics

Production

- Storage and production in high-quality steel tanks
- Automated production with additional filtration system
- Independently certified hygiene management according to HACCP
- Certified management and environmental management system according to ISO 9001 and 14001

Coatings

- Extensive quality controls of coating batches
- Regular analysis of coatings by accredited testing laboratories
- Certifications by accredited testing laboratories
- Reference samples of each batch

Security & consultation

- Highly qualified department for product safety
- Extensive know how with regard to food law, packaging law and chemical law

B. FoodSafe

Not only low migration, but the fulfilment of applicable food packaging regulations. For a definite classification, water-based coatings for food packaging are marked with the addition FoodSafe. FoodSafe coatings fulfil three quality attributes at the same time.

- FoodSafe coatings are characterised by low migration. They fall below the global migration limit of 60mg/kg (EU cube model).
- FoodSafe coatings have been tested by accredited testing laboratories and are certified for the direct contact to dry and fatty foodstuffs.
- FoodSafe coatings correspond to the Swiss Ordinance. They only contain those raw materials that are specified in the positive list (SR 817.023.21).

Moreover, FoodSafe coatings do without unrequested constitutional components such as mineral oils (MOSH, MOAH), heavy metals and phthalates. They are characterized by low odour. All FoodSafe coatings are water-based. UV coatings currently do not fulfil the strict requirements made on FoodSafe (e.g. direct food contact).



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