

Conformity of Food Packages

Migration and Invisible Set-off

More than 90 % of all foodstuffs sold on the Western European market are packaged. The various forms of packaging available all perform the same functions, which range from protecting the foods they contain against contamination and going bad to carrying advertising messages and consumer information.

The packaging protects the food, but must not contaminate it with any of its own constituent components.

The pertinent directives, laws, regulations, ordinances and standards serve to protect the consumer against health hazards arising from contaminated food and also to ensure the purity of the food.

Consequently, it is imperative that manufacturers of food packaging and the components required to make packaging - such as printing inks and substrates - are fully aware of the relevant statutory requirements.

Ever since the European Union - in all its previous forms - was founded, efforts have been made to harmonise national legislations.

The following describes the possible interactions between food and packaging as well as the most important legislation.

Interaction between food and printed packaging

The following forms of interaction between food and packaging can arise: permeation, migration, invisible set-off and substance transfer via the gas phase of the packaging.

Permeation

is the transport of a substance through the packaging. Substances can pass from the environment to the package contents and vice versa in this way.

Migration

refers to the transfer of a substance from the packaging to the foodstuff inside and vice versa. The concentration of migrants is stated in mg/dm² of packaging or mg/kg of foodstuff (package contents).

Invisible set-off

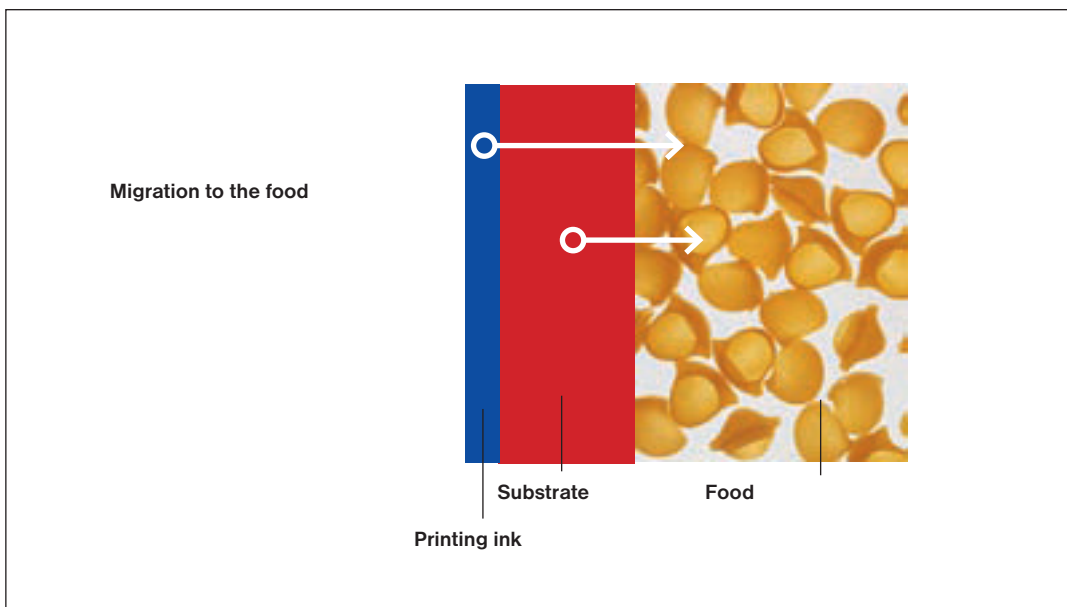
can occur in the stack or on the reel subsequent to printing. Invisible to the human eye, there is a danger of low-molecular substances being able to transfer to the side of the packaging that will come into contact with the package contents.

Substance transfer via the gas phase

Volatile substances can transfer via the gas phase inside the packaging and to the food.

From a physical point of view, permeation and migration are founded on the same subprocesses of distribution (solubility) and diffusion of transportable substances in the area of contact between packaging and foodstuffs.

With respect to interaction between printing inks, packaging materials and foodstuffs, only migration, invisible set-off and transfer via the gas phase are of significance. The rest of this Technical information sheet will deal with these forms of interaction solely with regard to those types of packaging in which there is no contact between the food and the printed surface.



The concentration of migrants in the packaged food depends on

- the initial concentration of the migrant in the printed packaging
- the speed with which the migrant migrates (diffusion speed)
- the equilibrium of distribution of the migrant, i.e. its solubility in the printed packaging and the foodstuff
- the temperature
- the storage time.

The maximum concentration of a migrant is to be found in the medium in which it best dissolves.

In order to protect the consumer, we must make absolutely certain that neither the quality of the edible products is impaired nor that the consumer suffers from any detrimental effects on their health caused by the migration of constituents from the packaging to the foodstuff.

In the event of specific migrant concentrations being exceeded in a packaging/foodstuff combination or toxicologically unevaluated migrants being transferred,

- other combinations of materials must be used,
- functional barrier layers that prevent migration must be used.

Paper and folding-carton board do not act as a barrier to migrants. In contrast to an all-purpose barrier, such as one made of coated aluminium, functional barriers are impermeable only for specific classes of material.

Example 1

In the case of LDPE-coated board, the film acts as a barrier to water not to fats.

Example 2

If folding-carton board used to make primary packaging for foodstuffs is printed with classical sheet-fed offset inks, solvents (mineral oils, fatty acid mono alkyl esters) may transfer to the foodstuff by means of migration.

In this case, there are two possible approaches to preventing this migration:

- using a functional barrier*
- using **MGA**[®] printing inks and coatings from the **hubergroup**:

Migration test

The basis is EU Regulation (EC) No. 10/2011 (before that Council Directive 82/711/EEC) that lays down the basic rules necessary for testing the migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

This Regulation lays down rules for determining the global migration (GM) and the specific migration of individual substances using food simulants and under defined test conditions.

Since it is not always feasible to use real foods when testing materials that come into contact with foodstuffs, food simulants are used. By convention, these are classified in one or more foodstuff categories according to their character.

Here is a list of food simulants as stipulated in EU Regulation 10/2011:

| Foodstuff categories and food simulants | | |
|----------------------------------------------------------|---------------------------|------------------|
| Foodstuff category | Food simulant | Abbreviation |
| Aqueous foodstuffs (pH >4.5) | 10 % vol. ethanol | Food simulant A |
| Acidic foodstuffs (Aqueous foodstuffs with a pH <4.5) | 5 % acetic acid by weight | Food simulant B |
| Alcoholic foodstuffs Up to 20 % alcohol content | 20 % vol. ethanol | Food simulant C |
| Dairy products > 20 % vol. alcoholic foodstuffs | 50 % vol. ethanol | Food simulant D1 |
| Fatty foodstuffs | Vegetable oil | Food simulant D2 |
| Dry foodstuffs/high temperatures | Tenax [®] | Food simulant E |

Carrying out migration tests

After being set up in a migration cell, the unprinted side of the packaging is coated with the particular food simulant in question. After a specified exposure time at a defined temperature, the concentration of migrants in the simulant is measured.

* A functional barrier is defined as „that layer of a composite material that, when used in the manner intended, reduces the migration into foodstuffs of constituents from further layers located behind said layer to a level that is below the analytical detection limit and is organoleptically insignificant“.

National and European legislation on food packaging

Although some national and European regulations differ with respect to their form and expression, they share many common principles that apply to food packaging:

- There must be no use or migration of carcinogenic, mutagenic or reprotoxic substances (CMR substances)
- The level of migration of even physiologically non-objectionable (non hazardous) substances must remain below defined concentration limits
- There must be no change in the colour of the foodstuff
- There must be no change in the odour or taste of the foodstuff
- There must be no adulteration of the foodstuff.

What forms of legislation regulate food packaging?

EU legislation

EU Regulation (EC) 1935/2004

Within the European Union, food packages are regulated by 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 und 89/109/EEC.

According to Article 1 (2) this Regulation applies to materials and articles, ...which in their finished state

- a) are intended to come into contact with foodstuffs or
- b) are already in contact with foodstuffs and are intended to or
- c) can reasonable be expected to be brought into contact with food or to transfer their constituents to food under normal and foreseeable conditions of use.

The requirements laid down for food packages are regulated by Article 3 of this Regulation:

Article 3

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could

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

The requirements laid down in the laws relating to foodstuffs relate to the final product „packaging“ and not to its constituent components such as printing inks and coatings.

For this reason, it is the manufacturers and marketers of consumer goods and not the supplier of substrates and printing inks who bear responsibility for ensuring their products comply with the legal requirements.

* Organoleptics is the testing of foodstuffs in accordance with a specific rating system in relation to the quality-influencing properties, taste, odour, colour, appearance, shape retention and consistency, without the use of aids but purely by means of the human senses.

EU-Regulation (EC) 2023/2006

Regulation (EC) No. 2023/2006 lays down „good manufacturing practices“. It covers the same field of application as EU Regulations (EC) No. 1935/2004 (aka the „Framework Regulation“) and is therefore applicable to all materials that come into contact with food and not just plastics. This Regulation also covers printing inks used to print food packaging.

The key provisions of this Regulations are as follows:

- The company must operate an effective and documented quality assurance system.
- The raw materials chosen must comply with predefined specifications.
- The various procedures must be carried out in compliance with predefined instructions and processes.

Annex 1 specifically goes into the composition and application of printing inks and coatings:

- Printing inks must be formulated/applied in such a way that substances from the printed surface are not allowed to transfer to the food-contact side of materials and articles „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 printed surfaces are not permitted to come into direct contact with foodstuffs.

This Regulation came into force on 1 August 2008

EU Regulation (EC) No. 10/2011

Plastic packaging for foodstuffs is further regulated by EU Regulation (EC) No. 10/2011, which covers plastics, plastics composites and plastic layers in multilayer sandwich materials used in packaging materials that come into contact with food.

It regulates which monomers and other base materials are approved for the manufacture of such plastic materials and articles intended to come into contact with food.

For packaging made of paper and board, there is presently no separate European legislation that goes further than Regulation (EC) No. 1935/2004.

National statutory regulations

Germany

German Foods, Consumer Goods and Feedstuffs Code

According to German law, food packages are consumer goods within the meaning of § 2 (6) of the Foods, Consumer Goods and Feedstuffs Code (LFGB) dated 27 April 2006.

Among other things, this includes

- articles that are intended to be brought into contact with food
- packages, containers or other forms of wrapping that are intended to be brought into contact with cosmetics.

Of importance to this particular area are §§ 30 and 31 of the LFGB with the following wording:

§ 30, Sec. 1 LFGB

Prohibitions for the purposes of health protection

It is forbidden to manufacture or handle consumer goods in a manner that, when they are used as intended or in a way that can be foreseen, means the goods are likely to be detrimental to human health due to their material composition, in particular due to toxicologically active substances or contamination.

§ 31, Sec. 1 LFGB

Transfer of substances to foodstuffs

It is forbidden to use or market materials or articles within the meaning of § 2, Sec. 6, Clause 1, No. 1 that do not comply with the requirements laid down in Article 3, Sec. 1 of Regulation (EC) No. 1935/2004 with respect to their manufacture.

The Consumer Goods Ordinance of the Federal German Ministry of Health dated 14 June 2000 applies exclusively to plastic packages.

This consumer good ordinance is the current German implementation of EU Directive 2002/72/EC and will be superseded by EU Regulation (EC) No. 10/2011.

Germany is presently drawing up a regulation that will specifically relate to printing inks, will be based on the Swiss Ordinance and will anticipate an EU-wide regulation.

Recommendations of the Federal Institute for Risk Assessment (BfR)

Recommendations made by the BfR are not legally binding statutory regulations. They do, however, represent the current state of the art for a range of materials.

- 9th Recommendation on „Colorants for plastics used in commodities“
- 14th Recommendation on „Plastic dispersions“
- 15th Recommendation on „Silicones“
- 36th Recommendation on „Paper and board for food contact“.

This is currently the only basis on which to select and evaluate papers and boards intended to come into contact with food.

Switzerland

Switzerland's Federal Department of Home Affairs (EDI) has issued the Swiss Ordinance on Materials and Articles in Contact with Food (Bedarfsgegenständeverordnung, SR 817.023.21). An amendment adopted on 1 April 2008 introduced rules that apply specifically to printing inks („packaging printing inks“). Since 1 April 2010, only packaging that has been printed with inks that comply with this Ordinance is allowed to be brought into circulation.

The key paragraphs of this Regulation are as follows:

- Printing inks may comprise only substances that are listed in Annexes 1 and 6
 - Note: the lists in Annex 6 were compiled by the European Printing Ink Association (EuPIA) and adapted by Switzerland's Federal Ministry of Health (Bundesamt für Gesundheit, BAG).
- The lists in Annex 6 are in two sections:
 - Section A: Substances that have undergone officially recognised, scientific testing. Any migration limits specified in this list must be complied with.
 - Section B: Substances that have not undergone officially recognised, scientific testing. Migration of such substances must not be detectable or must not exceed a concentration of 0.01 mg/kg.
- Inks must be manufactured and put to use in accordance with Good Manufacturing Practice (GMP).

Other regulations/provisions

• Resolutions of the Council of Europe

- ResAP (96)5 „On surface coatings intended to come into contact with foodstuffs.“
- ResAP (2005)2 „Resolution on food packaging inks applied to the non-food contact surface of food packaging and articles intended to come into contact with foodstuff.“
- ResAP (89)1 „On the use of colorants in plastic materials coming into contact with food.“
- ResAP (2002)1 „On paper and board materials and articles intended to come in contact with foodstuffs.“

Resolutions adopted by the Council of Europe are merely recommendations with no legally binding character.

• EuPIA Guideline

In October 2005, the European Printing Ink Association (EuPIA) passed a Guideline relating to printing inks for food packaging: *Printing inks applied to the non-food contact surface of food packaging materials and articles*.

This guideline defines rules for the selection of raw materials and the production of printing inks for food packaging. Also part of the EuPIA Guideline are rules on Good Manufacturing Practice (GMP) applicable to printing inks intended for use in the production of food packaging.

Fundamental requirements

The lack of specific statutory regulations on printing inks intended for food packaging, printed packages made of paper and board and paper and board composites does not mean this area is totally unregulated by statute.

Both fundamental national and European regulations have legal force.

EU Regulation (EC) No. 10/2011 lays down limits with respect to the concentration of certain substances in packaging or of migrants in foodstuffs or corresponding food simulants.

These regulations are based on the toxicological data of substances. Only those substances whose physiologically non-objectionable (non-hazardous) character has been evaluated by the European Scientific Committee on Food (SCF), its successor organisation the European Food Safety Authority (EFSA) or other authorised institutions may migrate to foodstuffs in such concentrations.

To be able to evaluate data pertaining to the migration characteristics of consumer goods, these data must be referred to the unit area of the goods. Still in use for this purpose is the „EU cube model“, which represents the packaging for 1 kg of food. The EU cube has an edge length of 1 dm and consequently, with a volume of 1 litre, has a surface area of 60 dm². Apart from that, it is assumed that an EU citizen weighs 60 kg and has a maximum daily intake of 1 kg of a foodstuff.

EU Regulation (EC) No. 10/2011 stipulates that a maximum of 10 mg/dm² or 60 mg/kg of physiologically non-hazardous substances may transfer from the packaging to the foodstuff (Overall Migration Limit). Substances whose toxicological evaluation has led to the stipulation of restrictions may

- migrate to the foodstuff or
- be present in packaging

either not at all or only up to defined maximum concentrations (specific migration limits).

These limits can be found in the ‚positive lists‘ mentioned above.

Overall Migration Limit (OML = global migration)

The maximum quantity of non-volatile substances allowed to transfer from a material or article to a food simulant, expressed in mg/dm².

Specific Migration Limit (SML)

The maximum quantity of a specific substance allowed to transfer from a material or article to a foodstuff or food simulant (SML = ADI x 60).

ADI

Acceptable Daily Intake, expressed in mg/kg; i.e. the quantity of a toxicologically evaluated substance that may be consumed with foodstuffs on a daily basis without risk to health (toxicological concentration limit x safety factor of 100).

The migration of substances for which no toxicological data is available must be below 10 µg/kg (ppb), as laid down in the Note of Guidance issued by the EFSA (European Food Safety Authority).

QM

The maximum concentration of a toxicologically evaluated substance in the packaging material, expressed in mg/kg.

Substances with a molecular mass > 1,000 g/mol (Dalton) pose as good as no risk from a toxicological point of view or possess only a very slight if not zero migration potential.

Consequently, substances > 1,000 D are of no significance as regards EU and national laws and recommendations.

The problem faced by manufacturers of food packaging is that it is only after the finished packaging has been tested with respect to every single component (migrant) with an SML or QM limit value that they (the manufacturers) can determine whether the concentration of these components in the food (or food simulant) is tolerable.

The only context in which testing can be waived is if, on the basis of the packaging to contents-mass ratio and assuming total transfer of the migrant, a violation of the set limits can be precluded (worst case).

If this precondition is met, all that has to be adhered to is the relatively high limit for global migration (10 mg/dm² or 60 mg/kg of foodstuff). The limit for global migration has no toxicological foundation, but serves solely to maintain the purity of the food (to prevent adulteration).

Instead of practical migration tests, Regulation (EC) No. 10/2011 also allows the migration potential to be calculated using generally accepted diffusion models based on scientific evidence („migration modelling“).

The suitability of colorants

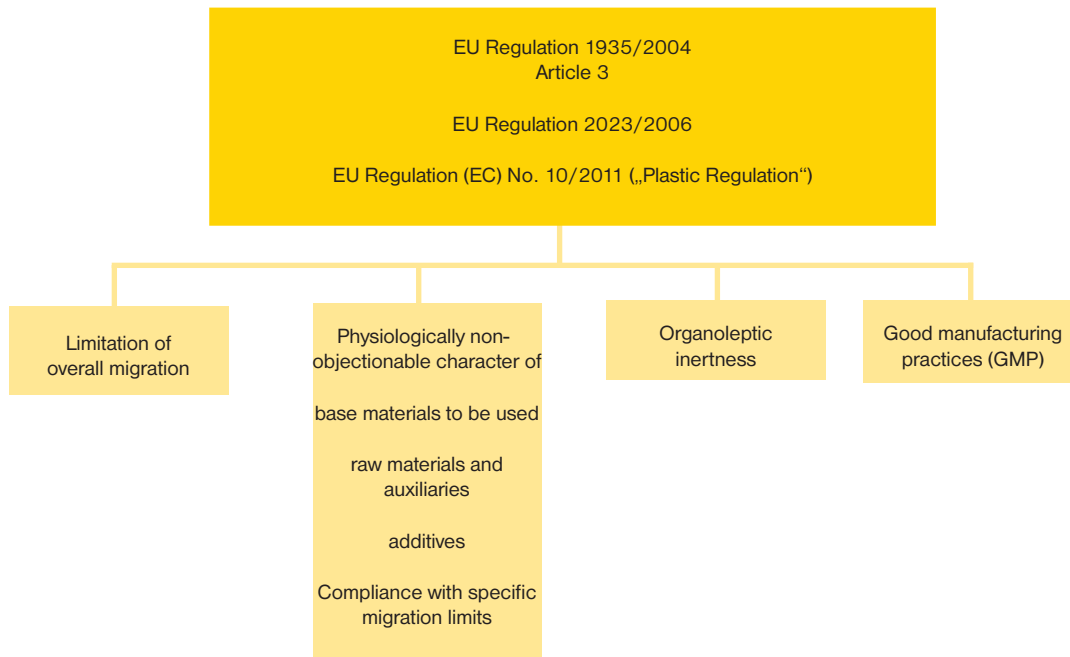
There are no reservations with regard to the use of colorants to dye plastics for consumer goods within the meaning of 1935/2004/EC as long as the colorants are fit for purpose and no traces of these agents are transferred to the foodstuffs when the consumer goods are used in the manner for which they were intended.

The requirements laid down for colorants are regulated in Council of Europe (CoE) Resolution AP (89)1 “On the use of colorants in plastic materials coming into contact with food” and in Germany in the 9th Recommendation of the BfR entitled “Farbmittel zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände” (Colorants for dyeing plastics and other polymers for consumer goods) dated 1 June 1994.

These regulations apply to plastics, not to printing inks. The printing inks produced by the **huber**group specifically for food packages, however, contain only types of pigment that meet the requirements laid down in CoE Resolution AP (89)1, in accordance with the EuPIA Guideline.

Summary

Below is a table of the statutory requirements laid down for food packaging (European)



Conformity of food packages

There is no all-purpose combination of ink and substrate for manufacturing food packages. It is only possible to satisfy all consumer protection regulations and desires with regard to the design of packages by employing a wide range of materials.

Consequently, when choosing the raw materials to be used to manufacture packaging and the inks and coatings that match them, it is essential that you know

- what type of food is to be packaged,
- under what conditions the packaged food is to be stored or further processed (sterilisation, baking oven, microwave oven)
- where the packaging is to be marketed.

Responsibility for the packaging rests with the manufacturer and packer. However, satisfactory solutions can only be found for new packaging developments if all the suppliers, the manufacturer and the packer co-operate fully with one another. This is the only way you can ensure that all the necessary information is available and the actions to be drawn from this information can be put into effect. The challenge is just as much that of the substrate supplier as it is that of the ink manufacturer. But if they don't know the specific purposes or goals a particular type of packaging is intended to fulfil, neither of them is in a position to make practicable recommendations. Whatever the case, the ink manufacturer takes from the outset all measures possible to provide the greatest degree of consumer protection feasible.

Due to the wide range of demands made on printing inks and coatings with respect to the various printing processes and substrates, it is not possible to formulate an all-purpose ink that satisfies all the goals of packaging. This is why it is essential to make appropriate enquiries with the ink and coating manufacturer when actually defining the specific procedures rather than leave it until problems arise when using standard printing inks on packages.

As already mentioned, the statutory framework actually makes it easier to design packaging of all kinds. When this framework is complied with, the packaging can be used by the consumer without any risk. If in doubt or if the necessary data about packaging materials is not available, it is always possible to submit a particular type of packaging to a recognised institute for individual testing to verify its harmlessness.

As long as the necessary data are available, it is also permissible to calculate the migration potential of a given composition of packaging material when those components of an ink that are capable of migration are known (migration modelling). This migration modelling makes it far easier to check whether or not a particular packaging/foodstuff combination actually conforms to the relevant statutes.

More information on the subject of food packaging can be found in the information sheets **published by the European Printing ink association (EuPIA).**

- Information leaflet: Printing Inks for Food Packaging
- EuPIA Guideline on Printing Inks applied to the non-food Contact Surface of Food Packaging Materials and Articles
- Inventory List Comprising Packaging Ink Raw Materials Applied to the Non-Food Contact Surface of Food Packaging
- Good Manufacturing Practices for the Production of Packaging Inks Formulated for Use on the Non-Food Contact Surfaces of Food Packaging and Articles intended to Come Into Contact with Food
- Customer Information Note regarding the use of sheet-fed offset inks and varnishes for the manufacture of food packaging
- EuPIA Information leaflet on Printing Inks and Varnishes intended to come into Direct Contact with Foodstuffs
- Exclusion List for Printing inks and Related Products - 7th edition

The information sheets listed above are up to date and are valuable supplement to this Technical information sheet.

They can be found on the EuPIA's website at www.eupia.org

Contact addresses for advice and further information can be found under www.hubergroup.de

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