

## Explanatory Note on the assessment of migration potential from food packaging inks and its dependency on the packaging structure

### **What type of food packaging should be included in the assessment of migration potential and subsequent choice of preferred ink system?**

When assessing potential migration transfer from printed packaging, it is important to consider the complete package, any barrier properties, the conversion process and the type of food.

The basis of such an assessment will normally focus on primary packaging of food. Primary packaging being defined in the Packaging and Packaging Waste Directive (94/62/EC as amended) as packaging that constitutes a sales unit to the final user or consumer at the point of purchase.

Primary food packaging may consist of one or two<sup>1</sup> easily separable wraps, frequently of different materials. The inner wrap is in direct contact with the foodstuff. Laminated or labelled material consisting of two or more not easily separable layers is considered here to be one single wrap.

### **How might a suitable ink system be chosen for particular food packaging structures?**

When selecting a suitable ink system, the barrier properties of the inner and outer wrap of a packaging structure should be considered, as well as the potential transfer of ink components to the food contact side by set-off or by vapour phase transfer during the conversion process.

It should be noted that any printed surface in *direct* contact with the food should be risk assessed separately, such scenarios are rare, and require a quite different risk management approach.

In conventional packaging designs, seven different structural/risk combinations have been identified (see table). For four of these combinations, there is a high potential migration risk. Note that in most cases, where the inner (food contact) wrap is not a barrier to ink ingredients under the conditions of use, the potential migration risk is relatively high. In such scenarios the use of inks which are designed to predictably deliver low migration potential would be recommended, to ensure that migration levels are within accepted limits<sup>2</sup>.

This explanatory note provides a range of examples, which themselves can vary depending on the processes involved. The examples given in the table should not be considered exhaustive, and are simply meant to be illustrative and use of the table would not remove the need for the packaging manufacturers to perform their own risk assessment.

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<sup>1</sup> In case of primary packaging with more than two wraps, and the inner wrap is not a barrier, the additional outer wraps as well as the secondary or tertiary packaging (as defined in the Packaging and Packaging Waste Directive) must also be considered in the assessment whether the primary packaging meets the requirements of Article 3 of Regulation (EC) No. 1935/2004.

<sup>2</sup> A level of migration for the particular substance that does not result in the Tolerable Daily Intake (TDI) or Acceptable Daily Intake (ADI) being exceeded, or does not breach limits or requirements according to food additive legislation, or does not exceed the Specific Migration Limit (SML) under standard conditions, or does not exceed limits or restrictions specified in national legislation or established in accordance with internationally recognised scientific principles on risk assessment.

**Table of Packaging Scenarios**

case	Is the inner wrap a barrier to ink ingredients?	Wrap to be printed	Is the outer wrap a barrier to ink ingredients?	Possibility of set-off <sup>5</sup> or vapour phase transfer	Potential migration risk	Examples <sup>3</sup>
1	no	inner	<i>(not relevant)</i> <sup>4</sup>	<i>(not relevant)</i> <sup>4</sup>	High	single wrap packaging, e.g. - printed paper bag or cardboard box, also PE coated ones, or - printed flexible pouch or rigid container made of non-barrier material (e.g. PP or PE), or - plastic bottle with printed label (which counts as one wrap, as it is not easily separable)
2	no	outer	no	<i>(not relevant)</i> <sup>4</sup>	High	- food products in PP pouch in a printed cardboard box
3	no	outer	yes	yes	High	- printed box made of aluminium laminated board, containing food products wrapped in paper or PP
4	no	outer	yes	no	Low	- printed tinplate box without internal lacquer, containing food products which are packed separately in unprinted PP pouches
5	yes	inner	<i>(not relevant)</i> <sup>4</sup>	yes	High	- aluminium lidding, or - printed pouch made of barrier laminate material, or - packaging made of laminate material with aluminium as inner layer
6	yes	inner	<i>(not relevant)</i> <sup>4</sup>	no	Low	- glass bottle or can with printed label, or - coated/printed cans where set-off can be excluded, e.g. without internal lacquer, or printed/coated after forming
7	yes	outer	<i>(not relevant)</i> <sup>4</sup>	<i>(not relevant)</i> <sup>4</sup>	Low	- glass bottle in printed outer container

Please note: For every specific packaging, an individual risk assessment must be performed.

On those packaging types with a high potential migration risk, the use of low migration<sup>5</sup> inks is recommended.

<sup>3</sup> Multi-layer structures, where both inner and outer wrap are printed, can be assessed analogously.

<sup>4</sup> Not relevant, as migration is possible irrespective of the outer wrap (cases 1, 2, 5), or can be excluded because of the presence of a functional barrier (cases 6, 7).

<sup>5</sup> Definition is given in the Glossary of Terms

## Glossary of terms

### Low migration ink

A low migration ink is an ink designed for use on food packaging that is formulated using selected components which should ensure that migration from the resultant printing ink film will be within accepted migration limits, provided that the packaging structure is suitable, and the packaging ink is applied under Good Manufacturing Practices in accordance with guidance given by the ink supplier for the intended application.

The use of such inks should be supported by indicative analytical testing and/or relevant worst case calculations. As a result – assuming correct application and appropriate packaging type – any migration from the printed packaging should be within currently accepted limits.

Please note: The terminology 'Low Migration Ink' has been adopted within trade names of certain types of ink technology, more specifically UV and Sheetfed packaging inks. This nomenclature has in general not been used to date in other ink technologies.

Sheetfed inks (conventional and UV) are used in the manufacture of food as well as non-food packaging, and also in publication printing. Therefore ink suppliers do clearly indicate whether a particular sheetfed ink is a "low migration" ink. This designation reflects the capability of these products to be used to deliver acceptable, legal migration levels within structures where no functional barriers are present.

Although the 'Low Migration' terminology is in general not used in other ink technologies, this does not mean that they are not capable of matching the requirements of a "Low migration ink" outlined above. For example, the majority of liquid inks for the manufacture of food packaging are inherently "low migration inks", even if not explicitly termed as such. This is because many liquid inks used on plastic films have been designed with additives that would not migrate above legal limits set out in the Annexes of the Plastics Regulation (EU) No 10/2011 even if 100% of the additive was to migrate into the foodstuff or food stimulant.

### Barriers and Set-Off

The barrier properties of the inner wrap are decisive in determining whether or not through migration is a tangible risk, independently of which ever wrap is printed. Transfer of migrants is possible whenever the inner wrap is not a barrier.

It should be noted that paper, board and most films are not absolute barriers. Only glass and metal, (in the case of aluminium with a thickness of  $>8\mu$ ) can be considered absolute barriers.

In the absence of an absolute barrier, assessment of migration risk must be made at the final packaging stage

Even when barrier materials are used, transfer of substances from the ink film is possible through set-off mechanisms, for instance where:

- there are multilayer films (surface printed or laminated), in a reel
- or, printed aluminium laminated cardboard, in a stack
- or, metal sheets, in a stack
- or, labelled thermoform containers, in nested form

Again, the potential for set-off migration must be assessed for risk at the final packaging stage

## Endorsement

The creation of this Explanatory Note has been sponsored and issued by the Member Associations of the Packaging Ink Joint Industry Task Force (PIJITF).

This document is under frequent review of the PIJITF and may be amended, as appropriate, in the light of new information.

### PIJITF Member Associations:

- **ACE:** The Alliance for Beverage Cartons and the Environment. [www.ace.be](http://www.ace.be)
- **CEPE:** European Council of Paint, Printing Ink and Artists' colours Industry. [www.cepe.org](http://www.cepe.org)
- **FoodDrinkEurope:** Confederation of the food and drink industries of the EU. [www.fooddrinkeurope.eu](http://www.fooddrinkeurope.eu)
- **CITPA:** International Confederation of Paper and Board Converters. [www.citpa-europe.org](http://www.citpa-europe.org)
- **ECMA:** European Carton Makers Association. [www.ecma.org](http://www.ecma.org)
- **EMPAC:** European Metal Packaging Association [www.empac.eu](http://www.empac.eu)
- **EuPC:** European Plastics Converters Confederation. [www.plasticsconverters.eu](http://www.plasticsconverters.eu)
- **EuPIA:** European Printing Ink Association. [www.eupia.org](http://www.eupia.org)
- **FEFCO:** European Federation of Corrugated Board Manufacturers [www.fefco.org](http://www.fefco.org)
- **FPE:** Flexible Packaging Europe. [www.flexpack-europe.org](http://www.flexpack-europe.org)

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