

# Information leaflet

## Printing Inks for Food Packaging

### 1. Introduction

Food packaging is printed to provide information to the final consumer in accordance with Directive 2000/13/EC relating to the labelling (concerning contents, food ingredients and nutrition facts) as well as the presentation and advertising of foodstuffs. 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 information paper mainly deals with printing inks applied on 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, offset, screen, non-impact printing or roller coating.

### 2. Legal requirements

Framework Regulation (EC) No 1935/2004<sup>1</sup> 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 has the responsibility for the compliance of the material and article with the legal requirements laid down in Article 3:

*Materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could:*

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

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<sup>1</sup> 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 2023/2006<sup>2</sup> 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 in 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.

There is not yet any specific EU legislation concerning printing inks for food packaging, with the exception of 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.

Switzerland amended their “Ordinance on Materials and Articles in Contact with Food”<sup>3</sup> with provisions on food packaging inks. This introduced a “list of permissible substances”. The amendment came into force on 1<sup>st</sup> April 2008 with a transitional period of two years; hence the requirement has been applicable since April 2010.

In May 2011, the Annex of this Swiss Ordinance was changed and some new evaluated substances were included.

The main specific measure pursuant to the Framework Regulation is Regulation (EU) No 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs. It lays down an overall migration limit (OML) of 60 mg/kg food or 10 mg/dm<sup>2</sup> of surface area. 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 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, for ink components which are listed, the relevant restrictions such as specific migration limits (SML) or maximum content (QM) have to be met.

### **3. Controls for Food Packaging**

Although raw materials for packaging inks applied on the non-food contact surface are selected whenever possible from the relevant listings (such as the Plastics Regulation (EU) No 10/2011 and its amendments, the Regenerated Cellulose Film Directive 2007/42/EC, or national legislation and recommendations, and US FDA Regulations), they are not formulated, manufactured or marketed for direct food contact and, as such, they are not exclusively made from raw materials intended for this purpose.

<sup>2</sup> 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

<sup>3</sup> 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> )

The following controls should be in place within the packaging chain at the ink manufacturing stage, as well as the application by the converters, in order to minimise the migration of substances into food (no-migration principle), and herewith to allow compliance of the final printed material and article with the existing legal provisions and to ensure the consumers' safety in terms of health.

### 3.1 Formulation and manufacture of packaging inks

Printing ink manufacturers that are members of EuPIA<sup>4</sup> commit that they will follow the EuPIA "Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles" (<http://www.eupia.org>), which sets out in full the responsibilities of the ink manufacturers within the packaging chain. Food packaging inks are formulated and manufactured taking into account many individual and varying parameters relating to the substrate, application and end-use. They are designed to minimise the potential for transfer of ink components into food by migration or set-off, whilst meeting the end use requirements.

An Inventory List comprising of raw materials of packaging inks applied to the non-food contact surface of food packaging has been published on the EuPIA website.

#### 3.1.1 Selection of raw materials

The raw materials<sup>5</sup> are selected in accordance with the "Selection scheme for packaging ink raw materials" of the EuPIA Guideline.

They do not belong to the following categories (exclusion criteria):

- a) classified as "carcinogenic", "mutagenic" or "toxic for reproduction" categories 1 and 2, according to the provisions of Directive 67/548/EEC on dangerous substances<sup>6</sup> (categories 1A and 1B according to CLP, Regulation (EC) No 1272/2008).

Category 3 substances (CLP Category 2) are only used after a migration study has confirmed that migration levels are either within published SML or TDI values, or are below an intake (threshold of toxicological concern) of 0.15 µg/person/day<sup>7</sup>. Category 3 reproductive toxicants (R62, R63; H361f, H361d)

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<sup>4</sup> EuPIA: European Printing Ink Association (a sector of CEPE aisbl)

<sup>5</sup> Raw materials may contain starting substances and/or components which are CMR or T, T+, but at levels which do not trigger a classification of the raw material itself as CMR Cat. 1 or 2 (CLP 1A or 1B) or T, T+. Any migration of these into foodstuffs must comply with any relevant limit.

<sup>6</sup> This Directive has been last amended by Directive 2009/2/EC (31. ATP) OJEU L11 26.1.2009; but Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (OJEU L 353 of 31. 12. 2008) in force since 20 January 2009 will repeal it on 1 June 2015.

<sup>7</sup> ILSI, Threshold of Toxicological Concern (TTC), Monograph, 2005, [www.ilsil.org/Europe/Publications](http://www.ilsil.org/Europe/Publications)

without a published limit may be used if the migration levels are confirmed to be not detectable (with a detection limit of 0.01 mg/kg food);

- b) classified as toxic (T) and very toxic (T+);
- c) colourants based on and compounds of antimony<sup>8</sup>, arsenic, cadmium, chromium (VI), lead, mercury, selenium;
- d) all substances identified in the REACH Regulation (EC) No 1907/2006, Title VIII and Annex XVII (restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles) and its amendments, if their use in a packaging ink would lead to an infringement of Article 3 of the Framework Regulation.

These criteria are under regular review and updated when necessary.

Packaging inks are formulated and manufactured in accordance with the EuPIA Good Manufacturing Practices available at <http://www.eupia.org>.

### 3.1.2 Purity requirements

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

### 3.1.3 Organoleptic properties (odour and taste)

The raw materials are carefully chosen to ensure that printing inks if correctly processed do not inadvertently affect foodstuffs in terms of odour and taste. It must be emphasised that various factors relating to the packaging may influence such effects on the foodstuffs. The packer or filler should carry out tests to confirm suitability.

### 3.1.4 Consideration of various parameters

Many different inks are needed for the wide variety of packaging that is printed. The following parameters are considered when formulating packaging inks:

- type of substrate and material combinations
- barrier properties of the layers
- type of foodstuffs to be packed

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<sup>8</sup> 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 labelled as T or T<sup>+</sup>

- printing process and printing equipment
- end-user specifications, e.g. product resistance and fastness properties

## **3.2 Design of packaging / Application of printing inks**

### **3.2.1 Responsibility**

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 in accordance with the requirements set out in paragraph 3.1.1. Due to the complexity of the process all members of the packaging chain must exchange the relevant information - under appropriate confidentiality agreements if necessary - in order to ensure that products can be formulated to be fit for purpose, and thus be compliant with all legal responsibilities. EuPIA members will supply a standard Statement of Composition for the use of these specific packaging inks.

The packaging ink suppliers are not able to issue certificates or declarations of compliance which cover the legal responsibility of others in packaging chain.

### **3.2.2 Design of packaging**

The correct design with regard to the final structure of the packaging material and the production techniques means that the combination of

- the choice of substrates
- the choice of other raw materials
- the composition of laminates
- printing and other processes
- the choice of the production technique

applying good manufacturing practices will result in a compliant packaging material.

This may be printed primary – or inner wrapping, or packaging containing a functional barrier which reduces the migration of components from any layer on the non-food side of the barrier into the food to ‘acceptable’ levels (specific migration limit SML or migration level of no concern).

### **3.2.3 Parameters in printing**

In the printing process a wide variety of parameters have to be considered for each individual food package. This is especially true for curing inks and coatings (e.g. two-component or UV systems) since it is the printer/converter who undertakes the determining process step (chemical reaction). Any visible set-off from the printed side to the food contact layer must be avoided by appropriate printing conditions. The following main subjects shall be covered by specific requirements in the recognised converters' good manufacturing practices:

- printing process and type of printing machine
- type of substrate, e.g. paper, board, regenerated cellulose, plastic film or aluminium 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 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 give rise to unacceptable organoleptic changes
- the time and pressure conditions in the stack or reel
- the storage conditions (time and temperature)
- the nature of the food product
- the expected maximum shelf life
- the filling, sealing and storage method
- the heating, cooling, sterilisation and pasteurisation processes to which the packaging material and contents may be exposed

### **4. Conformity of the 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 under the control of the converter.

Ink manufacturers can confirm 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, the printing ink manufacturer cannot provide any certification that the ink will meet all the legal requirements of the prints.

The obligation to issue a declaration of compliance does not apply to packaging inks. EuPIA members will provide relevant information in a Statement of Composition of the packaging inks.

The ultimate verification of compliance can therefore only be done on the finished printed and/or varnished 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.

Provided that the packaging inks are correctly processed and that the food packaging is designed in a way that there is no direct food contact with the print, they will allow compliance of the final product with the existing legal provisions.

## **5. 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 the absence of 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 recognised expert body.

## **6. Summary**

Printing inks for food packaging are not covered by any specific EU legislation. Therefore EuPIA members commit that they will follow the EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles” (<http://www.eupia.org>) which describes the responsibilities of printing ink manufacturers within the food packaging chain.

Raw materials are selected in accordance with the “Selection scheme for packaging ink raw materials” of the EuPIA Guideline and with specific purity requirements. The inks are formulated and manufactured taking into account many individual and varying parameters relating to the substrate, application and end-use in order to minimise the potential for migration of ink components into food and to allow the final package to comply with the legal requirements of Regulation (EC) No 1935/2004 and other existing regulations.

Packaging inks are formulated and manufactured in accordance with the EuPIA Good Manufacturing Practices available at <http://www.eupia.org>.

Nevertheless the converters have the responsibility for the compliance of the finished article; many important parameters are related to the application of the inks and are out of the control of the ink manufacturer.

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