

BPiF labels

Good Manufacturing Practice Guide

For the printing of labels and related packaging for the food, drinks and sensitive product sectors



Good Manufacturing Practice Guide

- For the printing of labels and related packaging for the food, drinks and sensitive product sectors.
- A management tool for the minimisation of migration, organoleptic changes and contamination.

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This good manufacturing guide was developed at the initiative of BPIF labels.

BPIF labels would like to give special thanks to ECMA and BPIF cartons for allowing them to use their GMP as a template for the GMP for the label industry.

The content covered in the present publication is within the industry recognised as the core public European GMP reference for labels and related packaging.

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Note to the reader

This is the first version of the BPIF labels –GMP
Remarks and suggestions for improvement to future publications are most welcome.

Disclaimer

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1 Introduction and Objectives

1.1 Scope and introduction

- 1.1.1 This guide is developed for companies which manufacture labels and related packaging products, intended to come into contact with food, or that could be brought into contact with food, or that could be the source of chemical migration into food.
- 1.1.2 This GMP is an information and management tool with methods that can be adopted by converters and audited through proper implementation. It focuses on the design, development and specification stages in the manufacturing process of packaging products.
- 1.1.3 It should be implemented by converters who employ an effective, independently audited, quality management (QM) system. It must be “embedded” in a system such as ISO 9001. It is not to be used as a standalone document.
- 1.1.4 Before adoption, your technical processes must be organized to reliably produce only labels and related packaging that conform to specifications. You will also need a complete system for hygienic control, EN 15593/ ISO 22000 (or equivalent such as BRC/IOP).
- 1.1.5 GMP “design for compliance” is the short-term description of the best approach. The choice of raw materials and production methods must be such that the products match entirely with the goals of this GMP.
- 1.1.6 Traceability and certification of raw materials are also important. Certified compliance with legislation and conformity with the highest standards is recommended for the raw materials. This certification must be based on an independently audited QM system of the supplier’s manufacturing process.
- 1.1.7 This code gives guidance and information that will enable the converter to ensure that, under specified and controlled circumstances, packaging will not give rise to non-compliant migration, organoleptic changes or contamination. This can however not be achieved through appropriate materials and production techniques alone. The customer must contribute to compliance by giving appropriate information and by only using the packaging for the purpose originally designed and intended.
- 1.1.8 This GMP supports the information provided in the European Food Contact Legislation. Any National legislation, standards, recommendations or guidelines from local authoritative bodies should also be followed as part of successful implementation of the GMP.

1.2 Objectives

- 1.2.1 In line with Article 3 of Regulation (EC) No 1831/2003, the primary objective of this GMP guidance document is to provide practical advice and information to enable printers and converters to assure the prevention of:

- 1.2.2 health hazards that may result from migration of components of the packaging material into the packaged food product.
- 1.2.3 unacceptable changes in the composition of a food
- 1.2.4 unacceptable changes in organoleptic characteristics of a food product that may result from the release of components.

1.3 Legislation

- 1.3.1 The Framework Regulation (EC) No 1935/2004 is the first food contact regulation often referred to, and especially Article 3 of this regulation requiring that :
“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 : (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic properties thereof.” Regulation (EC) No 2023/2006 of 22nd December 2006 lays down rules on Good Manufacturing Practice (GMP) for the groups of materials and articles intended to come into contact with food listed in Annex 1 to Regulation (EC) No 1935/2004 and combinations of those materials and articles used together. It has applied since from 1st August 2008 and is embraced within EU law. It states that manufacturing of these materials and articles should be in compliance with general and detailed rules on GMP. It refers to some sectors of industry having established GMP guidelines. This is BPIF label’s GMP guide for the label and related packaging sector and is intended to be adopted by converters of labels and related based packaging for food, drinks and other sensitive products. The purpose of this guide is to ensure compliance with both key regulations. Guides such as this are acknowledged and encouraged by the various Food Standards Agencies around Europe.
- 1.3.2 Article 3 of the Regulation (EC) No 1935/2004 is an all-encompassing requirement. The difficulty is how to interpret what levels of transfer could endanger human health. The rationale behind the Framework Regulation is to set requirements for all food contact materials, which are then elaborated in a series of material-specific Directives. This is a slow process. To date mainly plastics and recycled plastics have been covered. (Entire list of specific measures listed in 2.2.6)
- 1.3.3 The principal concern regarding chemical contamination of food is the effect on human health of low doses over long periods of time (chronic exposure) and, in particular, if there is any evidence of carcinogenicity, mutagenicity or toxic effects to human reproduction. Input materials used shall not contain substances classified as CMR (carcinogenic, mutagenic or repro-toxic) or pigment colorants based on antimony, arsenic, cadmium, chromium (vi), lead, mercury or selenium, and contain toxic or very toxic substances according to the Dangerous Substances and CLP Directives.
- 1.3.4 Regulation (EC) No 2023/2006 defines GMP as those aspects of QA that ensure materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and quality standards appropriate to their

intended use. In particular, GMP shall ensure that materials and articles do not endanger human health or cause an unacceptable change in the composition of the food or cause a deterioration in the organoleptic properties thereof (Article 3 of Framework Regulation (EC) No 1935/2004).

- 1.3.5 Compliance with Regulation (EC) No 1935/2004 and Regulation (EC) No 2023/2006 has shared responsibility for the whole supply chain.
- 1.3.6 Annex 1 to Regulation (EC) No 2023/2006 has rules on GMP for processes involving the application of printing inks to the non-food contact side of a material or article.

2 Regulations, recommendations and guidance documents

2.1 Introduction

The legislation concerning materials and articles intended to be in contact with food is complex. Paper and board, and also printing inks are not specifically covered by EU legislation.

This chapter gives an overview of the most relevant horizontal as well as material specific legislation and guidance.

2.2 Horizontal legislation in the EU

2.2.1 Horizontal legislation is applicable to all materials and articles.

2.2.2 Regulations are directly applicable in the 27 Member States, which means that national authorities do not need any legislative measures to implement the requirements present in regulations, by contrast to Directives. The requirements within regulations also supersede any contradicting national provisions. In other words, the EU requirements in regulations must be complied with on the application date set therein.

2.2.3 Two legally binding regulations at EU level create the general legal “food contact” frame which label converters have to observe, the so-called “Food Contact Framework Regulation” and the “Good Manufacturing Practices Regulation”

2.2.4 The Food Contact Framework Regulation (EC) N° 1935/2004 (27 October 2004) stipulates general requirements for all food contact materials and mentions how specific measures for certain listed materials may be developed.

2.2.5 Often reference is made to Article 3 of this Framework Regulation
“Materials and articles ... shall be manufactured in compliance with good manufacturing practice so that, under normal foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health or, bring about an unacceptable change in the composition of the food or, bring about a deterioration in the organoleptic characteristics thereof.”

2.2.6 From the 17 product groups listed in Annex 1 of the framework regulation, specific measures were developed for food contact plastics, regenerated cellulose, ceramics, nitrosamines, lead from metal coatings, plasticisers in gaskets, recycling plastics, and active and intelligent materials, not for paper and board, adhesives, coatings and printing inks.

2.2.7 The Good Manufacturing Regulation (EC) 2023/2006 applicable since August 2008, determines the minimum requirements for good manufacturing practices, the need for a quality assurance system, appropriate documentation and the establishment of quality control procedures.

2.2.8 Annex 1 specifies how the printing inks applied to the non food contact side of materials and articles shall not transfer substances to the food in concentrations

which are not in line with the previously mentioned article 3 of the FCFR (through the substrate or by set off).

- 2.2.9 For food products (including packaged foods), Regulation (EC) No 178/2002 is the basic legal reference laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety. Article 14 stipulates the food safety requirements. Food shall not be placed on the market if it is unsafe. Food shall be deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption.
- 2.2.10 The Defective product liability Directive (85/374/EEC), also applicable to food products stipulates the broad liability of all involved in the supply chain for physical or material damage caused.

2.3 Horizontal guidance documents.

2.3.1 Quality management standards

- ISO 9001 standard describes requirements on an effective, process-oriented quality management system.
- ISO 9004 deals with efficiency and effectiveness of the quality management System.

2.3.2 Hygiene management standards

Hygiene constitutes a legal field of its own in the production of food packaging. Hygiene management standards lay down rules for hygienic conditions in the production of food contact materials and articles. They are however not offering a guarantee for compliance with the GMP or the Food contact framework regulation.

- EN 15593 Packaging, deals specifically with the hygiene management in the production, storage and transport of food packaging. The manufacturer needs to be aware of and control the hygiene risks at every stage of the manufacturing process, through an appropriate hazard analysis and risk evaluation.
- BRC/IoP Global Packaging Standard was developed by the British Retail Consortium together with the Institute of Packaging and has similar objectives as EN 15593. Specific is the classification of products in risk categories, depending on the type of food and the type of contact between food and pack.
- ISO 22000 Food safety management systems - requirements for any organisation in the food chain. The purpose of this standard is to specify requirements on companies that are involved in food manufacturing either directly or indirectly. The standard specifies the role of the HACCP concept and requires the suitability and success of all measures to be checked and documented before, during and after implementation. Proof of preventive measures and prerequisite programmes (PRP) has to be provided.
- Companies should be aware of PAS223 and EN15593 which are currently being incorporated into a new standard TS22002-4.
- The International Food Standard (IFS) applies to food manufacturers that supply store brands. Specific requirements on packaging are included in chapter 4.

2.4 Material specific legislation and guidance documents e.g.

2.4.1 Paper (and general food contact legislation and guidance at member state level)

2.4.1.1 EU legislation

For paper and board no specific EU legislation has been adopted so far. In areas not harmonised, Member States can maintain or introduce national regulations.

2.4.1.2 Member state legislation and recommendations

France

The Decree 2007-766 defines the required content of chemical substances authorisation files and reaffirms the obligation to issue conformity documents for food contact materials and objects. Fiche on paper annexed to the information note DGCCRF N° 2004-64 issued the 6th May 2004. It presents the recommendations of the French public authorities applicable to paper in food contact applications.

Germany

Widespread in the sector also outside Germany are the BfR (Federal Institute for Risk Assessment) recommendations. Although not legally binding, the BfR Recommendations are broadly recognized by industry BfR Recommendation XXXVI on paper, stipulates which raw materials, production aids and refining agents can be used for making food contact paper.

Italy

The Italian Ministerial Decree 21 March 1973, as amended, covers in Annex II paper (Section IV)

Netherlands

In the Netherlands, the Warenwet of 28 December 1935, as amended¹, is the framework legislation setting out the general provisions for food contact materials, food, cosmetics and a number of other areas. A specific decree or “besluit” known as the “Warenwetbesluit Verpakkingen en Gebruiksartikelen” (Packaging and Utensils Decree) adopted pursuant to the Warenwet defines the scope of the food contact legislation and outlines the general requirements that food contact materials must meet² Specific regulations entitled “Regeling Verpakking en Gebruiksartikelen”, as amended (Packaging and Utensils regulations)³ implement the Decree. Appendix A of these regulations is essentially a compilation of “positive lists” for different types of substances, including paper (Chapter II) that are permitted in the Netherlands for use in manufacturing food packaging materials.

United Kingdom

The UK Government added The Materials and Articles in Contact with Food (England) Regulations 2010 – 2010 No. 2225 which added the European legislation to The Food Safety Act on the UK Statutes, applied from 20th October 2010.

2.4.1.3 Council of Europe

The resolutions of the Council of Europe are often used guidance references. Those resolutions are not binding and were until now, nowhere implemented in national laws. Resolution ResAP (2002) 1 covers paper and board materials intended to come in contact with food.

1 Wet van 28 december 1935, houdende voorschriften betreffende de hoedanigheid en aanduiding van waren

2 The Warenwetbesluit Verpakkingen en Gebruiksartikelen was most recently updated on 30 May 2005

3 Regeling verpakking en gebruiksartikelen (Dutch Packaging and Utensils Regulations) of 20 November, 1979, as most recently amended on 21 February 2011

2.4.1.4 Industry documents

CEPI (Confederation of the European Paper Industries) and CITPA (International Confederation of paper and board converters in Europe) issued an Industry Guideline for the compliance of paper & board materials and articles for food contact, and additionally a Good Manufacturing Practice document for the manufacture of paper and board for food contact.

<http://www.cepi.org/topics/foodcontact/publications/industryguidelineissue2>

2.4.2 Printing inks

2.4.2.1 EU legislation

No harmonised EU legislation is applicable for printing inks.

It is however generally interpreted that any migration limits set in the Plastics Regulation (EU) No 10/2011, for substances which are also components of printing inks should be respected.

The advantage of using limits specified in the Plastics Regulation (EU) No 10/2011, which have been set by the EU's expert Scientific Committee for Food (SCF) or the European Food Safety Authority's expert Panel on food contact materials, enzymes, flavourings and processing aids (CEF), is that such limits can be regarded as being without undue risk (i.e. acceptable). Unfortunately, the majority of substances used in the manufacture of printing inks are not covered and have not been assessed by the SCF or CEF.

2.4.2.2 Member State legislation & Recommendations

France

- Advice from the Supreme Council on public hygiene CSHPF 7/11/1995 on inks and varnishes intended to come into contact with foodstuffs. Determines restrictions for colouring materials, solvents, technological additives, and gives guidance on purity specifications and the required genotoxic safety.
- DGCCRF Fiche on printing inks (June 2010 update)

Germany

National regulations on printing inks are expected in 2014.

2.4.2.3 Council of Europe

Resolution ResAP (2005) 2 on food packaging inks applied to the non food contact surface of food packaging and articles.

2.4.2.4 Third Country legislation.

Switzerland

Although not an EU member state, Switzerland is a member of the European Economic Area and has issued an Ordinance on Materials and Articles in Contact with Food SR 817.023.21 (as amended) that has and will have a major impact in European packaging markets as regards printing inks. A chapter on printing inks was added to the Swiss ordinance on 1st April 2010 and is periodically revised. This Ordinance, as revised, establishes positive lists of all authorised substances, with restrictions, including specific migration limits, where applicable. Listed substances without toxicological information available have to comply with a 10 ppb migration limit.

In the absence of an EU harmonized measure on printing inks, the Swiss legislation is referred to as best practice by industry to establish compliance with Article 3.1 a) of the Framework Regulation.

2.4.2.5 Industry documents.

- The European Printing Ink Association EuPIA published several guidelines for the printing of food packaging, exclusion lists and inventory lists of used and suitable substances and photo initiators, and a GMP for the production of packaging inks for use on the non food contact side of food packaging and articles. Refer to <http://www.eupia.org/index.php?id=3> and <http://www.eupia.org/index.php?id=29>
- In the absence of specific restrictions concerning migration of most printing ink components, ink manufacturers are recommended that it is prudent to follow the approach and guidelines used by the SCF and CEF to set limits for substances used. These limits are set according to the toxicological properties of the substance:
 - Substances found to migrate at levels above 10ppb should show favourable results from three mutagenicity tests.
 - Substances that migrate at levels above 50ppb should have additional toxicity data in support of these higher levels and should not be known CMRs.
 - Substance migration levels significantly in excess of these thresholds, without appropriate supporting toxicity data, shall be avoided. In such instances, it cannot be stated that the risk to a consumer is negligible.
- The packaging Ink Joint Industry Task Force (PIJITF) in which the food industry, packaging material sectors and ink manufacturers are represented, published a “Guidance for the use of printing inks for paper and board packaging used for contact with food” and also an “Explanatory note for assessing the migration potential from food packaging inks.”
- BPIF labels, in April 2011 published, prior to this GMP a brochure highlighting the problems associated with ink migration.
http://www.bpiflabels.org.uk/filemanager_net/files/BPIFL_Food_and_drinks_Layout_1.pdf

2.4.3 Varnishes and coatings

2.4.3.1 EU legislation

No harmonised EU legislation is applicable for varnishes and coatings.

2.4.3.2 Member State legislation & Recommendations

Germany

BfR Recommendation XIV on plastic dispersions containing guidance on the composition of lacquers, varnishes and coatings. BfR Recommendation XLI, covers only Linear Polyurethanes for Paper Coatings.

Italy

The Italian Ministerial Decree 21 March 1973, as amended, covers in Annex II lacquers & varnishes (Section III Parts A,B, C&D), & coatings (section I parts A & B).

Netherlands

In the Netherlands, specific regulations entitled “Regeling Verpakking en Gebruiksartikelen”, as amended (Packaging and Utensils regulations) implement the

Decree “Warenwetbesluit Verpakkingen en Gebruiksartikelen” (Packaging and Utensils Decree).

Appendix A of these regulations is essentially a compilation of “positive lists” for different types of substances, including coatings (Chapter X), waxes (covered by Chapters II and X), that are permitted in the Netherlands for use in manufacturing food packaging materials.

Spain

The Spanish resolution from the 4th November 1982 covers in Annex 1 lacquers & varnishes and coatings. This Resolution is currently being revised and the forthcoming legislation will maintain varnishes and coatings under regulation.

2.4.3.3 Council of Europe

Resolution ResAP(96) 5 on surface coatings intended to come into contact with food.

2.4.4 Adhesives

2.4.4.1 EU legislation

No harmonised EU legislation is applicable for adhesives.

2.4.4.2 Member State legislation & Recommendations

Germany

BfR Recommendation XXVIII on cross linked polyurethanes as adhesive layers for food packaging materials.

Italy

The Italian Ministerial Decree 21 March 1973, covers in Annex 2 adhesives (Section 3 Part D).

Spain

The Spanish resolution from the 4th November 1982 covers in Annex 1 adhesives. This Resolution is currently being revised and the forthcoming legislation will maintain adhesives under regulation.

2.4.4.3 Council of Europe

No document on adhesives was published by the Council of Europe.

2.4.4.4 Third Country legislation

Reference is commonly made to a US FDA approval.

2.4.4.5 Industry documents

FEICA, the Association of European Adhesives & Sealants Manufacturers issued a food safety guidance note and a template to describe the legal food contact status of adhesives, which is currently under review.

http://www.feica.com/images/stories/library/papers/110322_feica_food_contact_status_paper_version_3_final.pdf

2.4.5 Plastic layers

2.4.5.1 EU legislation

Plastics Regulation (EU) No 10/2011

When packaging concepts including plastic components are developed, label converters need to take into consideration the requirements included in the Plastics

Regulation (EU) No 10/2011, consolidating 12 existing sets of European rules for plastics in one regulation.

The Plastics Regulation covers multi-materials multi-layers and requires that plastic layers used in multi-materials multi-layers must comply with the compositional requirements of that Regulation.

The paper/board part of the plastic/paper/board multilayer is not covered by the Plastics Regulation (EU) No 10/2011.

In any event, the safety requirement set in the Framework Regulation must always be complied with.

2.4.5.2 Member State legislation & Recommendations

Germany

A variety of BfR Recommendations have been issued as regards plastics:

- I. High Polymers Containing Plasticizers
- II. Plasticizer-free polyvinyl chloride, plasticizer-free copolymers of vinyl chloride and mixtures of these polymers with other copolymers and chlorinated polyolefins containing mainly vinyl chloride in the total mixture
- III. Polyethylene
- V. Polystyrene Produced exclusively from the Polymerisation of Styrene
- VI. Styrene Copolymers and Graft Polymers, and Mixtures of Polystyrene with other Polymers
- VII. Polypropylene
- IX. Colorants for Plastics and other Polymers Used in Commodities
- X. Polyamides
- XI. Polycarbonates and Mixtures of Polycarbonates with other Polymers or Copolymers
- XII. Unsaturated Polyester Resins
- XVI. Polyvinyl Ethers
- XVII. Poly(terephthalic acid diol esters)
- XX. Polyisobutylene, Isobutylene Copolymers and Mixtures of Polyisobutylene with other Polymers
- XXII. Polymers Based on Esters of Acrylic and Methacrylic Acids, their Copolymers, and Mixtures of these with other Polymers
- XXXIII. Acetal resins
- XXXIV. Vinylidene Chloride Copolymers with a Predominant Content of Polyvinylidene Chloride
- XXXV. Copolymers of Ethylene, Propylene, Butylene, Vinyl Esters and Unsaturated Aliphatic Acids, and their Salts and Esters
- XXXVII. Polybutene-(1)
- XXXIX. Commodities Based on Polyurethanes
- XLII. Plasticizer-Free Chlorinated Polyvinyl Chloride, Plasticizer-Free Chlorinated Copolymers of Vinyl Chloride and Mixtures of these Polymers with other Copolymers
- XLIII. Poly(4-methylpentene-1)
- XLVI. Cross-linked Polyethylene
- L. Copolymers and Graft Polymers of Acrylonitrile
- LII. Fillers for Commodities Made of Plastic

Netherlands

In the Netherlands, specific regulations entitled “Regeling Verpakking en Gebruiksartikelen”, as amended (Packaging and Utensils regulations) implement the Decree “Warenwetbesluit Verpakkingen en Gebruiksartikelen” (Packaging and Utensils Decree).

Appendix A of these regulations is essentially a compilation of “positive lists” for different types of substances, including for use in plastics (Chapter I), that are not regulated at EU level and that are permitted in the Netherlands for use in manufacturing food packaging materials.

2.4.5.3 Council of Europe

Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food.

2.4.6 WAXES

2.4.6.1 Member State legislation & Recommendations

Germany

BfR Recommendation XXV on hard paraffins, microcrystalline waxes and mixtures of these with waxes, resins and plastics.

Netherlands

In the Netherlands, specific regulations entitled “Regeling Verpakking en Gebruiksartikelen”, as amended (Packaging and Utensils regulations) implement the Decree “Warenwetbesluit Verpakkingen en Gebruiksartikelen” (Packaging and Utensils Decree).

The waxes used on paper and board must meet one of the two parts of the Dutch legislation on food contact materials:

- Requirements described in appendix A, chapter II, paragraph 1.2.2.i waxes for the use on paper and board only
- Requirements as described in appendix A, chapter X, paragraph 4 or 8, which describing waxes for generic purposes.

2.5 Mutual recognition of national laws

2.5.1 Mutual recognition applies for materials and articles intended for food contact and which are not subject to specific legislation, besides the EU horizontal provisions (i.e., the Framework Regulation and the GMP Regulation). This principle has been developed by the European jurisprudence and more specifically following the Cassis de Dijon case. Thanks to the mutual recognition principle, imported products lawfully manufactured and marketed in a given Member State may freely circulate and be marketed in the other Member States, even though not fully compliant with the national laws of those Member States. It is only where a Member State can demonstrate, on the basis of a comprehensive risk assessment, that a product presents a health risk that he can restrict or prohibit the marketing of a given product.

2.5.2 However when a Member State intends to restrict the marketing of an imported product, it must in principle comply with the procedural requirements. Regulation (EC) No 764/2008 of the 9 July 2008 lays down procedures relating to the application

of certain national technical rules for products lawfully marketed in another Member State.

2.6 Exports Outside the European Union

- 2.6.1 Where packaging is exported to a country outside the European Union it may be necessary to deviate from the previous sections. Preference is however given to minimising these deviations as much as possible.
- 2.6.2 Where deviation is unavoidable, conformity is sought with the most appropriate of the following, in order of preference
 - a. national legislation of importing country with customer support
 - b. FDA regulations
 - c. other regulations specified by the customer
 - d. industrial standards specified by the customer

2.7 Import from countries not being a member of the EU



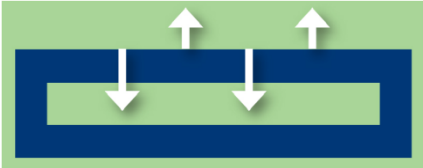

- 2.7.1 The importer from third country products is responsible for ensuring compliance and should thus ask his third country based supplier for as much information as possible.

3 Migration

3.1 Types of Migration

3.1.1 Migration of a constituent is the transfer of the constituent into food through the packaging material. Specific regulations determine the migration limits for certain substances. Migration above compliance limits can occur from different layers of packaging, unless there is a functional barrier in place.

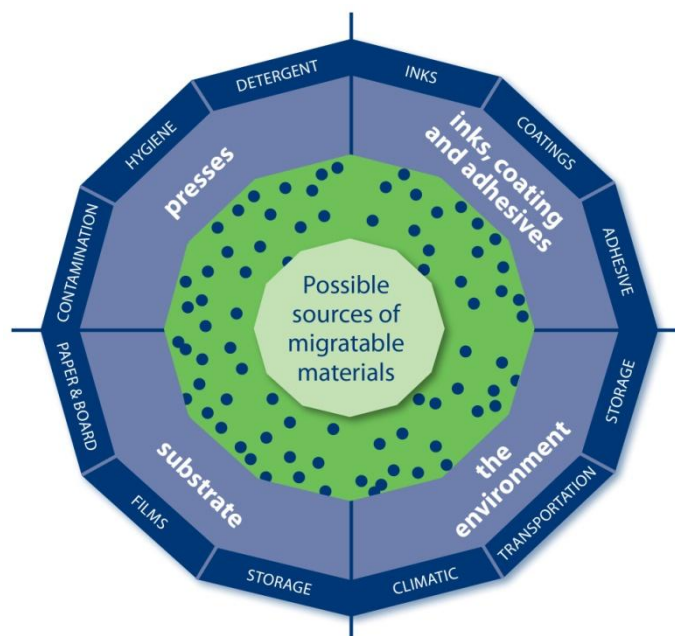
3.1.2 There are four key ways in which migration occurs:

<p>1.</p>	<p>Penetration Through the substrate to the reverse side of the printed surface and through to the packaged product.</p>		<p>Ink Substrate and/or Adhesive Packaged Product and/or Adhesive</p>
<p>2.</p>	<p>Contact Impression transfer to the reverse side of stacked sheets or in the reel due to set-off. This could then give risk to penetration. See 1. above.</p>		<p>Ink Substrate and/or Adhesive</p>
<p>3.</p>	<p>Gas phase migration Transfer of volatile substances in the airspace between food and packaging or between different layers.</p>		<p>Printed/ Coated Surface Substrate</p>
<p>4.</p>	<p>Condensation extraction of critical components during any heating process.</p>		<p>Printed/ Coated Surface Substrate</p>

3.1.3 Visible set-off is caused by mechanical rub or by “blocking” of a partially dried ink film and is generally regarded as a quality problem. Set-off of substances that are prone to migrate are usually invisible. Both types of set-off can lead to non compliant packaging from a food safety perspective.

3.2 Sources of contamination

Possible sources of contamination during manufacture of packaging, through four primary aspects (substrate, printing and conversion, ink and varnish composition, environment) are identified in the diagram below:



3.3 Migration influencing parameters

3.3.1 Subsequent transfer of substances originating from the printed layer to the food contact side of packaging and subsequently to the food is dependent on many different parameters. Composition and design of the packaging and its components (substrates, inks, varnishes, and adhesives), the molecular weight of the substance, the type of food, the surface/volume ratio, storage time and temperature, other storage conditions of the filled packaging, are only a shortlist of the most important parameters influencing possible transfer of substances into food. For types of food refer to references on page 42 – Plastics Regulations.

3.4 Food contamination

3.4.1 Dual use substances require extra attention in risk assessments. Such substances are authorised as food additives and can also be part of the ink or varnish formulation. It is important to take account of all sources when checking compliance.

3.4.2 Certain substances may also be already in the food by nature, or the food may be contaminated with unintentionally added substances from other sources.

4 Recommendations for GMP Compliance

4.1 Key Actions for the Converter

- 4.1.1 To achieve the objectives of this GMP, the converter should ensure that the product is produced with a consistent quality so as to meet the requirements mentioned in the Framework Regulation, as well as other generic and material specific measures (for details see Chapter 2) by using materials that are compliant for the specified use of packaging or known from previous experience to be compliant for the specified use of the product.
- 4.1.2 A risk assessment must be carried out by all parties in the supply chain. It is essential that these parties communicate with each other so that information cascades through the supply chain. Should any factors change then this should result in a new risk assessment.
- 4.1.3 These actions should be supported by obtaining, controlling and/or verifying:
- information from suppliers about compliance with specific restrictions, and/or
 - migration features of the raw materials, and/or
 - composition of the raw materials, and/or
 - use of a functional barrier, and/or
 - tests of the intermediate or finished products directly
- 4.1.4 Assessment of compliance with specific migration limits for each finished product manufactured is often difficult, given the range of packaging scenarios and food contact approved materials.
- A full documented risk assessment should be undertaken to include:
- supplier-supplied certification confirming suitability of the materials (including all component parts) for their intended or foreseeable uses, as well as dialogue with the customer who is often best placed to carry out any migration testing specific to any end use of the packaging;
 - a “family approach”, whereby all products within a suitable defined product family are considered to comply;
 - a “building block” concept where evidence of compliance with applicable restrictions for a number of products, using similar materials or combinations of materials, are considered to apply.

This building block concept is seen as the core safety approach for label converters.

4.2 Commitment and Responsibilities

- 4.2.1 The Board level management team are essential to the success of implementing an appropriate QA system to satisfy the requirements of the GMP and should all be fully engaged and conversant with the EU regulations relevant to migration in food packaging. They should appoint a senior board-level sponsor and key responsibility holders as the core enabling team to own the responsibility for ensuring the GMP objectives are met. They should consult with the relevant national federations and

European industry bodies such as BPIF labels. That team should have the authority and resources needed and the entire workforce and department managers must make a total commitment to the GMP objectives.

4.3 Purchasing

- 4.3.1 Clear specifications for the raw materials should be provided, taking account of:
- a. physical and chemical properties of the food types that will be packed
 - b. conditions of converting
 - c. storage
 - d. final use
- 4.3.2 Raw materials should be purchased from suppliers with QA systems compatible with the converter's QA system and also ensure the manufacture and supply of raw materials will be in compliance with all relevant legislation.
- 4.3.3 In any assessment the converter can use information provided by suppliers about the compliance of raw materials (substrate, ink, coatings, adhesives, etc) but must ensure the suppliers have relevant matching conditions to their own. Converters should seek confirmation on materials from all suppliers for:
- a. traceability of composition and production method and components origin
 - b. certificate of compliance with applicable legislation
 - c. inform at earliest opportunity of any raw material change
 - d. measures on non-intentionally added substances
 - e. assurance of no contamination during delivery or storage
 - f. risk consideration of non-compliant articles created through combinations of individually compliant raw materials and confirm any necessary actions
- 4.3.4 Supplier assessments must use testing procedures in accordance with EU directives (though proven alternative reliable analytical tests may be used) and should include the following:
- a. verification of raw material composition (this may be in the form of a statement of composition).
 - b. worst case calculation of 100% transfer from food contact material.
 - c. verification of maximum permitted substance quantities.
 - d. use of suitably designed test in food stimulants.

4.4 Design Specification

- 4.4.1 Designing packaging material for compliance is the principal method by which the objectives of the GMP may be achieved. In this GMP designing refers to all decisions that need to be taken regarding the final structure of the packaging.
- 4.4.2 Design of the packaging for compliance is a shared responsibility between the customer of the packaging and the converter. Ultimately the customer is responsible for approving the appropriate selection of:
- substrates
 - other starting materials

- application techniques for inks
- production techniques
- structural and graphical design

4.4.3 Printing inks, adhesives and overprint varnishes developed for applying to the non-food contact surface of food packaging are not intended to come into direct contact with foodstuffs. Where a risk assessment finds that the food will contact a printed or varnished or adhesive surface, then a suitable functional barrier must be included in the pack design.

4.4.4 There are certain functional coatings which are specifically intended to come into contact with foodstuffs; these include grease-resistant dispersion coatings, silicone release layers and heatseal coatings, but they are usually applied by a convertor upstream from the printer, and specific regulations apply to them. They are outside the scope of this GMP guide. Besides the non-food contact surface inks and varnishes for food packaging, a specific range of inks, adhesives and varnishes fulfilling additional requirements is available for printing on the side in direct contact with foodstuffs.

http://www.eupia.org/index.php?id=32&tx_edm_pi1%5BshowUid%5D=25&cHash=8cfc422918a317124a308b44bd48a922

4.4.5 Depending on the nature of the product and its intended use, the following parameters should be taken into consideration in the product specifications.

- **General**
 - existing customer specifications
 - customer's requirements about the production process
 - printing on the reverse
 - surface/volume ratio between the food and the packaging
- **Legal background**
 - legal regulations and limits
 - export from the EU and legal regulations associated with this
- **Characteristics of the product packaged**
 - consistency: solid, grated, liquid, paste
 - surface area/volume including a consideration of the internal surface area, for example a sponge or wafer
 - physical properties: dry, moist, fatty
 - if necessary: determination of chemical properties (e.g. reaction with volatile substances in environment, acid content, temperature dependence, etc).
- **Intended use by the customer and consumer**
 - expected contact with edible fats or food regarded as fatty foods⁴ in migration testing
 - preparation of the food together with the material or article both by the food filler (sterilization, pasteurisation) as well as prescribed and expected handlings performed by the consumer (defrosting, heating temperature/duration, cooking/baking)

⁴ Foods regarded as fatty foods are defined in Regulation (EU) No 10/2011

- storage period (maximum shelf life)
- storage conditions (in chillers, deep freeze ...)
- **Suitable materials**
 - customer's requirements about materials to be used.(precondition: suitability for food packaging, content recovered fibres)
 - inks and varnishes (UV, conventional, sensory/migration-optimised)
 - adhesives (dispersion, hotmelt, sensory/migration-optimised)
 - proven suitability of the materials for food contact
 - criteria for filling of the packaging
- **Migration risk and barrier**
 - information about the use of an absolute and/or functional barrier
 - description of the contact between the packaging and the product (physical direct contact, airspace contact ...)
 - migration testing
- **Extras and function (e.g.: toys)**
 - information about product extras, and the conformity of those extras
 - further use and legal regulations of the packaging after it is emptied
- **Sensory test**
 - limits in sensory tests if requested: specific customer requirements about implementation of sensory tests (info about procedure that differs from DIN EN 1230)

4.5 Product Development and Performance

4.5.1 **Product Development:** A number of factors must be taken account of in terms of what the developed packaging must or must not be capable of.

4.5.2 The technical configuration of the products and the approval of suitable material combinations are based on the specifications agreed between the manufacturer and buyer of the food contact material and article in question. Branded goods manufacturers sometimes specify the materials that have to be used. If agreement cannot be reached on migration-optimised systems, an alternative technical configuration should be designed in such a way that product marketability is guaranteed.

4.5.3 The key factors to consider for development are:

- customer specification, the answers given in 4.4.5 and any/all changes – must be validated
- fit for purpose – foreseeable applications and required performance
- substances in materials – fully compliant with migration figures, barrier properties,
- relevant legislation or compliance testing
- raw materials - known to be organoleptically inert or tested for changes and cleared by the customer
- no transfer – within Regulation (EC) No 1935/2004 (Art. 3) requirements

- unintended chemical reactions or breakdowns – none in substrates, inks, varnishes, coatings or adhesives
- all materials – must be compatible
- residue solvents in inks – must not give rise to unacceptable organoleptic changes, unacceptable set-off or unacceptable migration
- reverse side printing presents a special challenge. In the case of printing on the adhesive this could cause even further problems.
- all changes – must be checked for compliance and customer approved
- all legislation changes – design checked for compliance; customer informed

4.5.4 Once the necessary product specifications and production operations have been discussed and agreed with the customer, the approval process in accordance with the GMP has been completed.

4.5.5 **Production Performance:** The performance of any product must be designed at the development stage.

4.6 Relevant Control Points

4.6.1 Each constituent part of the packaging materials should be checked and validated to ensure complete and satisfactory control is achieved for the GMP. Statistical analysis may be appropriate in addition to standard tests. Recording of printing conditions including speed, curing conditions and printing sequence is recommended. Relevant control points at converters include the following:

- ambient conditions: avoiding contact between raw materials / products and dirt, exhaust gases and vapours
- personnel hygiene and response to hygiene incidents
- excellent condition of all machines used
- contact points between machine and product (including lubricants)
- choice and grouping of product specifications
- selection of suitable inks and varnishes, adhesives, auxiliary materials, cleaning agents and other chemicals
- obtaining clearance certificates for materials and articles used
- storage of raw materials, work in progress and finished goods
- cleaning and resetting operations, particularly on printing machines
- maximum acceptable application volumes for ink, varnish and adhesive layers according to the risk analysis
- adaptations of the material flow (e.g. ventilation of printed piles before the next process operation)
- covering of printed stock during intermediate storage
- monitoring of the drying/curing of printed layers
- traceability of products and materials manufactured

4.7 Goods In and Out and Storage

- 4.7.1 The QA System is essential for warehousing and transportation controls. Reels or stacks of sheets should be stored immediately on receipt prior to printing in such a way that the safety characteristics are not affected.
- 4.7.2 Appropriate covering should be used before transport to any print finishing or subsequent processing. Loading areas must be kept swept and free from strong odours, wooden pallets checked, etc. All packaging for despatch should carry relevant batch numbers/codes and necessary documentation.
- 4.7.3 Storage requires a plan for the avoidance of contamination, being either physical, chemical or (micro)biologic of nature. Controls will include the likes of pest control system, glass protection, the use of electric internal transport equipment etc. For reference the BRC logistic standard or equivalent will be accepted.
- 4.7.4 Transport of finished goods also requires loading and identification controls together with hygiene and cleanliness rules applied. The following points should be noted:
- loading areas and lorries well swept and free from strong odours, sharp objects and with protection against moisture
 - protection against contamination from other goods or volatile substances during transportation
 - staff responsible for checking loading areas before each loading begins

4.8 Traceability

- 4.8.1 According to Article 17 of the Regulation (EC) No 1935/2004, the traceability of materials and articles intended to come into contact with food must be ensured at all stages of production. The legal rules require identification of suppliers of starting materials (upstream traceability) as well as of buyers of finished products (downstream traceability). It is advisable for all stages of the packaging production chain to mark their products so that individual production batches can be identified. If a recall is made, the loss can be restricted to one or just a few batches as a result.
- 4.8.2 Packaging manufacturers should have tracking systems that permit clear identification. Information about internal material flow that requires documentation is as follows:
- identification of the company's own production location
 - order numbers
 - identification of the suppliers
 - identification of the batch of all materials used
 - code of the ink mixing formulations
 - identification of the shipping units (corrugated board boxes, pallets etc)
 - despatch date of the finished goods
 - delivery address
- 4.8.3 The converter should include references to test and work instructions and names of people responsible for each process operation. Inclusion of further technical data

(varnishing rollers, cutting/creasing and embossing dies) is advisable, but not necessary to prove the products are marketable.

- 4.8.4 Since traceability must be guaranteed within the company as well, information should be available at every stage of production. This should be different from the traceability rules defined for food in Regulation (EC) No178/2002. Paper traceability needs to comply with Regulation (EC) No 1935/2004.

The Regulation does not specify technical rules for documentation (electronic or in paper form) and for identification systems so there are no rules about how long the documented data have to be kept for the converter or the distributor. In this context it is advised that the converter reaches agreement with the customer on the time production samples are kept (eg: same as maximum shelf life).

4.9 Quality Checks

- 4.9.1 The converter should maintain a quality management (QM) system to assure attainment of the GMP objectives. The QA system should be independently audited and certified periodically and be capable of being verified by or on behalf of customers to check compliance with the GMP.

- 4.9.2 Suppliers should maintain a QA system capable of assuring GMP and compliance with the requirements as listed in Section 4 of the GMP.

- 4.9.3 Converters should only subcontract manufacture of direct contact food packaging to converters who are conducting their activities in compliance with this GMP.

4.10 Training

- 4.10.1 All personnel must be informed about the general concept of the GMP, its objectives and the actions needed to achieve them. The converter should establish training is provided to personnel performing activities affecting compliance. Personnel performing specific tasks shall be deemed qualified on the basis of relevant education, training or experience as required. Records of training should be maintained as part of the QA system.

4.11 Hygiene

- 4.11.1 Workplace Hygiene: Workplace hygiene is particularly important in the industrial production of food contact materials and articles. Its purpose is to prevent product contamination by people and machines during manufacturing so it comprises both personnel and production hygiene.

- 4.11.2 Production hygiene regulations outline the procedure for maintaining factory cleanliness. Scheduled cleaning, rules for private belongings in production areas, eating meals, open containers and food handling, smoking zones, insect controls, etc must all be included within the hygiene procedures.

- 4.11.3 Personnel hygiene includes rules about personal care, wearing of jewellery, working clothes and procedures in the case of illness. Visitors and/or staff who are only in

storage or production rooms for a short time are required to observe these regulations too. The same is true of external partners (contract suppliers). Hygiene zones must be identified by appropriate signs.

- 4.11.4 Cleaning operations have to be documented, including the name, the date and the signature of the person who has done the work. Such precautions are mandatory for certification of compliance with hygiene standards.
- 4.11.5 This GMP should be used in conjunction with an existing QA system which must be in place before the GMP can be applied. It must be possible to rely on the converter's technical processes to produce packaging in conformity with their specifications. Consumer protection cannot be provided by the converter alone, but this GMP assures that the converter should be able to produce packaging that in itself is not contaminated.
- 4.11.6 Machine Hygiene: As converter you are responsible for preventing the risk of health hazards and organoleptic changes that may result from contamination of packaging. You should identify and control all potential sources of contamination through all processes from purity and storage of raw materials, through production to delivery. You should ensure you identify, control and maintain strict hygiene controls and standards for production personnel and in all factory, warehouse and transportation areas.
- 4.11.7 Press cleaning is a key aspect of hygiene. To prevent contamination always use absolutely clean equipment and tools. Anilox rollers, machine rollers and ink ducts must be cleaned thoroughly. This should be done using a dedicated cleaning agent. Standard press wash-ups can also be a significant source of unwanted migration. They are by nature both liquid and prone to migration.
- 4.11.8 When a risk assessment indicates the need for a low-migration press wash the ink supplier can recommend suitable press washes and provide guidance for its use that 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.
- 4.11.9 Appropriate quarantine areas should be designated for the control of production waste and rejects. From printed reject reels through to rewind and/or sheeting waste, left-over inks and varnishes, adhesive waste and hazardous substances that must be disposed of in accordance with instructions provided by the manufacturers.
- 4.11.10 A good starting point for all of the above is PAS223.

4.12 Hazard Analysis

- 4.12.1 Manufacturers of food contact materials and articles must be confident that the production operations they carry out comply with the legal regulations that apply to them. Possible impairments of product quality need to be identified and avoided in advance. This is done via a suitable form of hazard analysis and risk evaluation, on the basis of which dangers can be identified at an early stage, while their causes can

be contained and countermeasures can be taken and/or checked. Rooms, operations, material combinations and ambient conditions of temperature, humidity, etc must all be included within the hazard planning and control.

4.12.2 When carrying out a risk assessment, consider the following:

- different transfer mechanisms (set-off, permeation, vapour-phase transfer)
- type of barrier material (eg: aluminium or glass may represent an absolute migration barrier); PET, a specific barrier; other materials (e.g.: paper and/ PE/PP, film or extrusion layer) are insufficient barriers to migration of most substances liable to migrate from ink and varnish layers
- suitable functional barriers may prevent permeation but not exclude set-off

4.13 Testing

4.13.1 Laboratories where migration tests and tests related to hygienic control are carried out should maintain appropriate QM systems.

4.13.2 Raw material suppliers need to make available all relevant information for 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.

4.13.3 Migration test methods with all types of simulants are available. The most commonly used simulant for paper packaging is modified polyphenylenoxide (MPPO) simulating a range of dry non fatty foods including sugar, flour and cereals, and sometimes also used as simulant for hot fat food. Simulants can also be introduced at Member State level.

4.13.4 The following points are important to be aware of:

- other simulants less appropriate for paper are specified in the Plastics Regulation (EU) No 10/2011
- transfer by migration is a time dependant phenomenon. If potential migrants exist in the packaging, 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.
- migration testing is crucial to getting correct results on which to base important decisions. Proper sampling procedures must be strictly followed to ensure correct and reproducible results. Key parameters are: number, type and size of samples, supply of unprinted reference samples, and wrapping conditions to avoid contamination during transport.

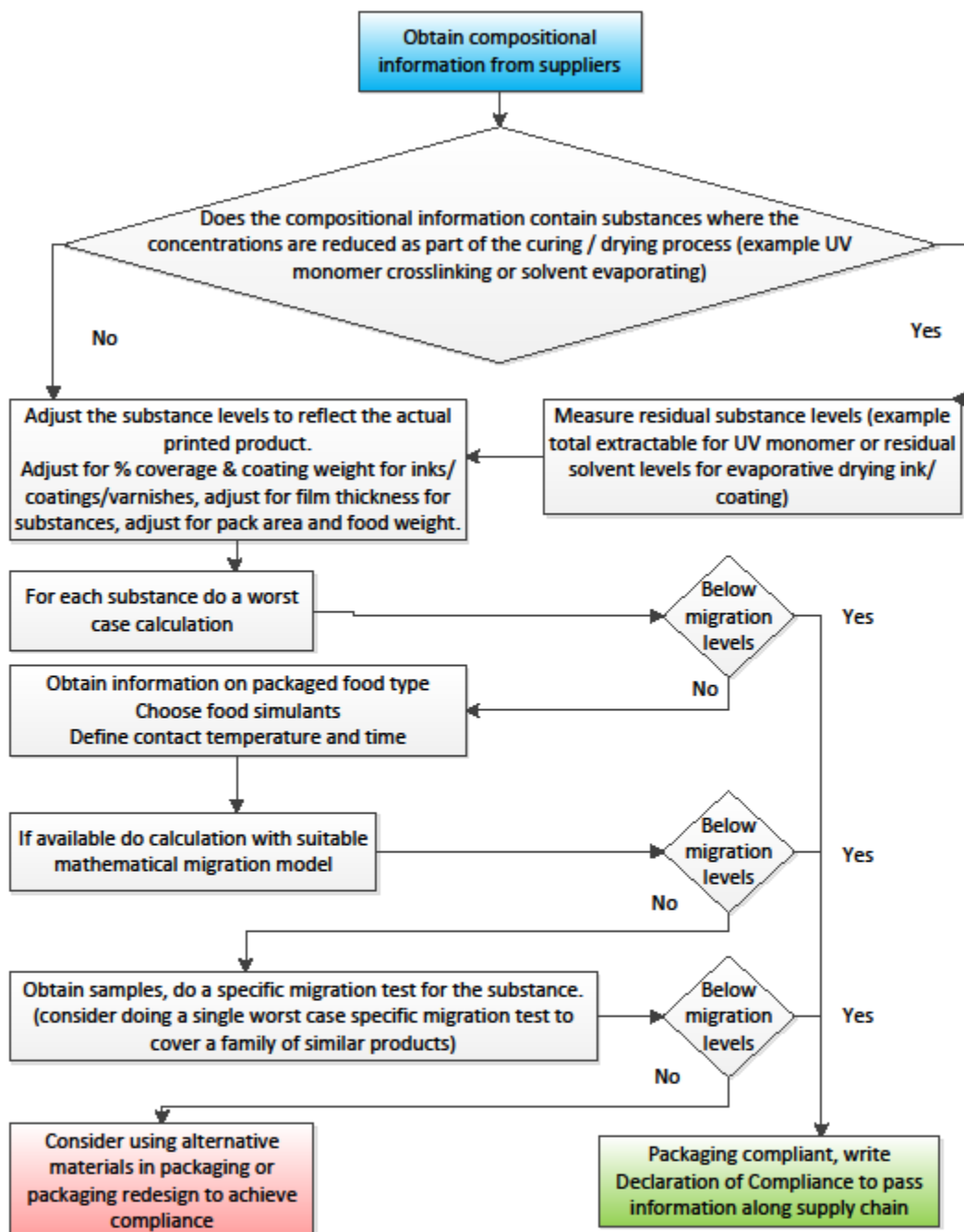
4.13.5 Flow chart migration testing (as an example)

Migration testing can only be done on the final product. In case where a producer is not the manufacturer of the final product, testing obligations can be shifted to the next party in the chain.

However, an operator may choose to perform specific migration testing, overall migration testing or residual content testing for marketing reasons (in order to demonstrate that his part of the packaging can meet the requirements of the

applicable legislation) or because he does not want to reveal the substances for which he can guarantee that the restrictions are met. However, as explained below, demonstrating compliance with the relevant restrictions can be achieved by other means such as using worst-case migration calculation or mathematic modelling or using available data on worst-case sample or test results obtained in more severe migration test conditions.

Selection of relevant migration testing



Determination of compliance with residual content limit

Worst case calculation

Provided that the amount of the substance in the starting materials is known, it is possible to assume that 100% of the substance remains in the product (residual content) or that 100% of the substance migrates to the food (in case of the specific migration).

Mathematic modelling

For some materials, it is possible to perform modelling using the recognized diffusion models. More information can be found in the guidance document “applicability of generally recognized diffusion models for the estimation of specific migration in support of EU Directive 2002/72/EC” as prepared by the JRC.

Testing covered by worst-case sample/testing

In some cases, testing can be avoided by using existing testing results obtained for other samples or the same sample but under more severe testing conditions. Examples are testing of a sample with a larger thickness or where more ink is applied, or testing which has been performed for samples at a higher temperature or a longer contact time.

Analytical testing

In some cases analytical testing cannot be avoided. In respect to the overall migration, testing should be performed according to existing CEN standards where available.

It might be necessary however to alter the CEN method, as the CEN methods are prepared for plastics. Regarding the specific migration testing, the migration could be done according to CEN 13130-1 (Materials and articles in contact with foodstuffs - Plastics substances subject to limitation); the analytical determination of the substances in the food stimulant may be done with any suitable analytical method.

EN 14338 Migration into Tenax is available for paper and board.

Companies new to analytical testing may wish to refer to the BCF/EuPIA web sites for a suitable list of laboratories.

Representative samples

Testing should be done on representative samples. The following aspects should be taken into consideration:

- The samples must be representative for the whole batch, (scrap produced when changing from one batch to another batch should not be used)
- The samples must have undergone the maximum set-off or the set-off must be mimicked in such a way that the set-off effects are included in the evaluation.
- The samples taken must stored and transported in such a way that contamination of the samples or loss of substances is avoided.
- Appropriate documentation must be kept as to the condition under which the samples were selected (i.e. who selected them, when they were selected, from which batch etc).

4.13.6 Sensoric testing

Regulation (EC) No 1935/2004 requires that food contact materials should not bring about any organoleptic deterioration of the characteristics of the food.

It has to be well understood that due to the large variety of foods being packed and the variations in substrates and contact situations, it is practically impossible for a converter to assess the sensoric neutrality of all its products to a standardized reference.

Therefore it is of prime importance to have sensoric requirements for a specific application included in the design stage of packaging (see 4.4.4). The sensoric suitability of a label/packaging film for its purpose needs to be assessed and confirmed by the end user from the specification or first trial production. In general the converter's control on sensoric properties, or taint and odour contamination will be limited to a generic observation of off odour and taint on raw material deliveries, quality control operations, transport vehicle inspections and the likes as these are described in the pre-requisite programs of hygiene standards such as BRC-IoP or equivalent.

Product specific sensoric testing can be performed by a converter. Taint and odour testing methods are described in -EN 1230-1 (2009) and -EN 1230-2 (2009), but the methodology and criteria of approval or reject are subject to agreement between the individual parties involved. The reject criteria need to be validated by the end user, and in any case where the converter agrees to perform sensoric evaluation of its packaging, it should not release the end user from his/her responsibility to perform sensoric evaluation on its food product.

4.14 Evidence supplied by Material Suppliers

4.14.1 Manufacturers of food contact materials and articles demonstrate the suitability of the materials they use for food applications by submitting written statements from their suppliers. These documents relate to individual products (e.g. ink), product groups (e.g. ink series) or product combinations (e.g. ink and varnish) and confirm that the relevant legal regulations have been observed:

- Materials subject to individual legal measures require a Declaration of Compliance (DOC) determined by that measure. If absent, another statement (statement of composition etc.) can be obtained in accordance with supplier agreements.
- Contents of such statements are not specified legally, but compiled in liaison between converter and supplier. Requirements in Regulation (EC) No 1935/2004 and Regulation (EC) No 2023/2006 act as the basis.
- Note : Although no specific harmonised EU regulation in place, some countries require formal Declarations of Compliance for all food contact materials. This is for example the case in Belgium, France, Italy and Romania, without however clear rules on how to issue DOCs.
- Compliance certificates confirm materials used are in line with food contact law. They are issued by accredited specialised laboratories or test institutes.
- Supporting documents (e.g. test results) that are enclosed with a declaration and/or confirmation of compliance are other types of proof. The packaging

manufacturer is only legally obliged to disclose these supporting documents to the authorities responsible.

Depending on the material involved, care should be taken to make sure in particular the following information is provided due to various specific requirements:

- **Self adhesive face papers:** satisfaction of the requirements included in CEPI/CITPA Industry Guideline / BfR 36 about paper and board intended to come into contact with food.
- **Inks and varnishes:** prevention of the migration of contents to the food (in quantities that are not approved) when processed properly. The guidelines issued by the European Printing Ink Association (EuPIA) are observed too. If there are specific migration limits (SML) for certain substances, compliance with them is demonstrated, indicating the relevant legal document (e.g. Regulation (EU) No 10/2011/EC) and the CAS identification numbers. Dual-use substances that are contained are also disclosed indicating the CAS number.
- **Plastics:** the production of plastics is governed by the Plastics Regulation (EU) No 10/2011/EC. Appropriate declarations of compliance therefore have to be obtained for plastic materials that are bought (e.g. films).
- **Adhesives:** satisfaction of the requirements about plastic dispersions, including Annex II “Monomers and other starting materials” and Annex III “Additives” of the Plastics Regulation (EU) No 10/2011/EC. Often reference is also made to the German BfR Recommendation XXVIII on cross linked polyurethanes as adhesive layers for food packaging materials.

A more detailed list of legal references is given in Chapter 2 of the GMP Guideline.

4.14.2 Ink manufacturers will make available all relevant information for 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. Your ink supplier should be able to supply a document with specific guidance on the clauses required in ink supply contracts.

4.15 Statement of composition

4.15.1 A statement of composition can be provided to the customer (where contractually agreed). This way converters fulfil their obligation to share information in the supply chain.

4.15.2 Documentation to show materials, articles and substances intended for manufacturing of food contact packaging comply with the requirements of Regulation (EC) No 1935/2004 and all other regulations, directives, standards and/or guidelines, with conditions and results of any compliance testing carried out must be maintained by the converter and available to national competent authorities on request.

4.15.3 On request by the authorities, supporting documentation related to various aspects of the company’s activity should be available from the information system.

5 Guidance on Inks and Varnishes

5.1 Introduction

Inks and varnishes have been subject to a number of investigations related to concerns over food safety, For this reason a specific chapter in this GMP Guideline is dedicated to inks and varnishes.

The content of chapter 5 is extensively, but not exclusively, influenced by the guideline approved in the Packaging Ink Joint Industry Task Force “Guidance for the use of printing inks for paper and board packaging used for contact with food”.

5.2 Ultra-Violet Cured (UV) Inks and Varnishes

5.2.1 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. However, after curing of standard UV inks and varnishes, 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 ink film or are absorbed into the substrate
- incomplete reaction of ink components due to inadequate curing

5.2.2 Substrate

- Ensure that the label/package substrate is suitable for food packaging applications.
- Some label substrates, including certain grades of paper, are themselves sensitive to the radiation which is used to cure UV inks and varnishes, and can later taint the packed food.
- Paper substrates can be very receptive to airborne migration of volatile materials and are very absorbent to vapours and liquids such as those from press washes or conventional additives and chemicals in press room atmospheres.

5.2.3 The majority of raw materials in standard UV ink and varnishes have not been evaluated for food contact. The low molecular-weight components of these inks and varnishes can migrate, so their use requires a full risk assessment. Specially formulated low migration UV inks are recommended, designed to give low-migration ink layers after sufficient curing. Ink manufacturers need to make available all information for monitoring of transfer of substances by migration and invisible set-off. Confidentiality agreements can be signed with third parties specifically involved in the compliance process.

5.2.4 Migration test methods with simulants are available. The most commonly used simulant for non laminated paper labels which will be in contact with dry food is modified polyphenylenoxide (Tenax), simulating a range of dry foods including sugar, flour and cereals. Migration testing with laminated paper can be done with the simulants as described for food contact plastics.

5.2.5 Flexography with UV-curing inks and varnishes is of special concern, because the application viscosity of these materials needs to be much lower than the equivalent offset inks and coatings. This means that there is a greater concentration of low molecular weight components to begin with, and therefore a high risk of migration.

5.3 Conventional inks and water-based inks and overprint varnishes

5.3.1 Standard offset oxidative printing inks and water-based inks and varnishes may contain substances that are liable to migrate. For the printing of food packaging specially formulated low-migration inks and water-based inks and varnishes are available and should be used.

5.4 Digital inks and toners

Inks used for digital technologies are in a different category and discussions should take place with your preferred supplier, should these processes be used for packaging produced in accordance with this GMP.

5.5 Printing additives and fountain solutions.

- Use only printing additives approved for the specific low-migration ink system when using low-migration inks or coatings.
- For offset printing special low-migration fountain concentrates have been developed, as standard fountain solution concentrates may contain potential migrants such as wetting agents or alcohol substitutes.

5.6 Ink Mixing and Colour Matching

5.6.1 Many inks needed in packaging printing are mixes, spot colours or brand colour matching. 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.

- Use the inks from their original containers
- Avoid contamination (and ensure traceability) 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

5.7 Cleaning

5.7.1 To prevent contamination always use clean equipment and tools.

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

- For digital printing ensure you comply with your suppliers guidelines

5.7.2 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 and 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.

5.8 Ink Drying

5.8.1 Oxidation drying:

Drying: When low-migration inks are used, the addition of driers or drying accelerators on the press is not allowed. When conventional offset inks are used, ink films must be completely dried after application. Pallets with printed sheets should not be stacked before an appropriate drying time.

5.8.2 Radiation 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 necessary power is readily available
- ensure correct number of lamps of correct power and intensity are used and also relate to press speed
- ensure regular maintenance of lamps and reflectors

5.8.3 Evaporation drying:

A variety of factors influence the degree of drying these include:

- web temperature
- ambient temperature
- velocity and volume
- efficiency of extraction systems

It is important that printers monitor the residual volatile substance levels.

5.9 Ink Film Weight

5.9.1 The higher the film weight, the more difficult it is to achieve sufficient drying. Excessive film weight must be avoided, in particular UV dark shades and UV opaque white. Controlled by the use of densitometry (either hand-held or using the press-manufacturers built-in software/hardware) is recommended. Observe optimum densities for 4-colour and avoid highbuild 4-colour solids)

5.10 Control

5.10.1 The following summary are highly recommended control point reminders:

- use inks from their original containers

- record printing conditions including speed, curing conditions and printing sequence
- reels or stacks of sheets should be stored before and after printing in such a way that the organoleptic characteristics are not affected: Appropriate covering should be used before transport to any print finishing or subsequent processing
- statistical migration/sensorial analysis may be appropriate in addition to standard tests

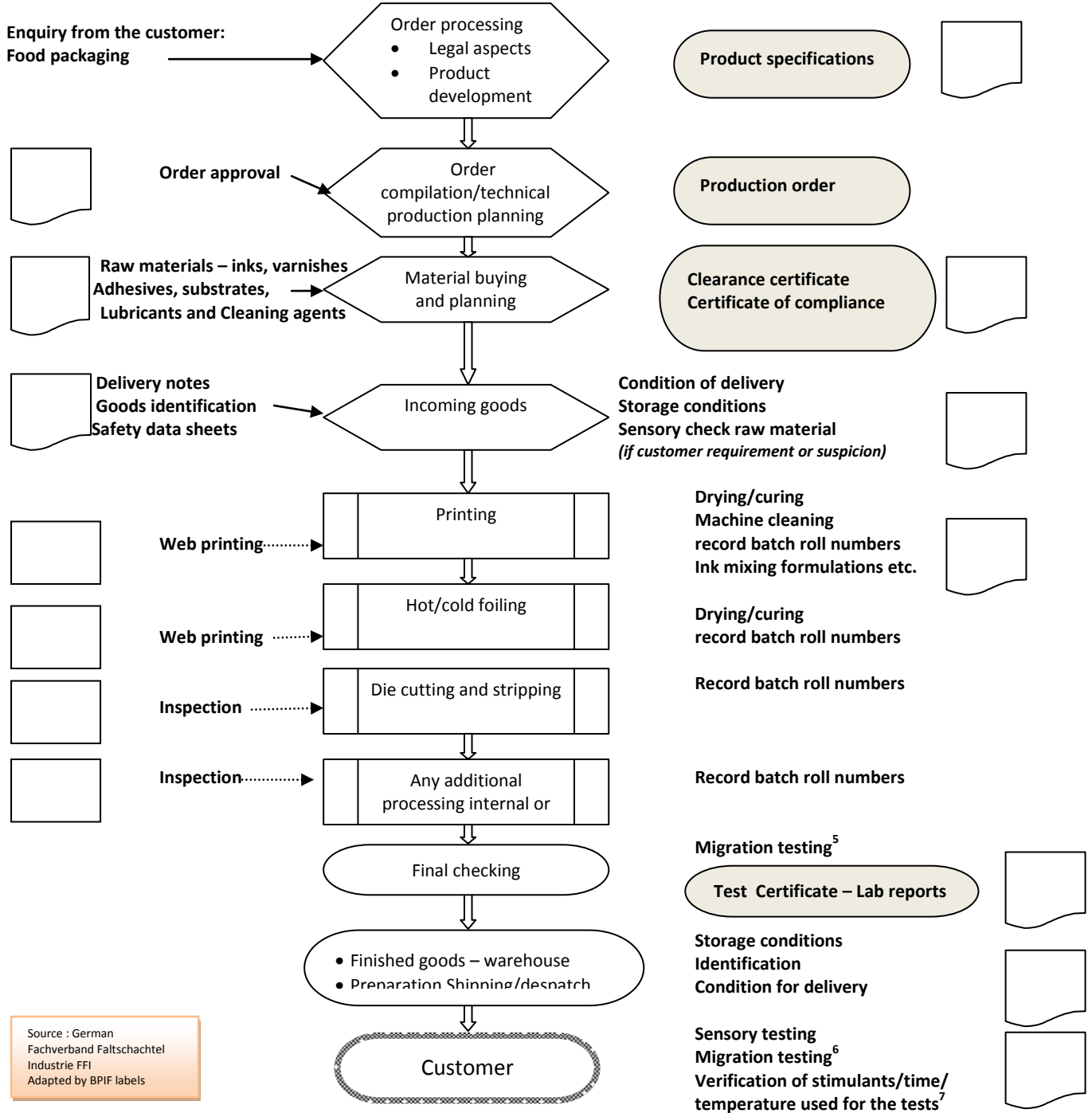
5.11 Changing from Normal to Low-Migration Printing

5.11.1 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 (nonexhaustive) list provides the basis for a code of practice for the changeover:

- use inks from original containers
- empty all ink and coating, ducts and pipes
- for the flexographic ink process, clean anilox and plate cylinders, clean any tanks and small pipe work. Pay particular attention to chambered systems and any awkward corners. Very small amounts cause contamination.
- for the offset process, change fount to the one recommended by the supplier. Clean all mixing and storage tanks, filters and pipes as part of the procedure.
- clean all rollers and blankets
- certain substances liable to migrate may remain in the system – a risk assessment should be used to determine an appropriate time period to ensure any non-low migration traces are removed completely from rubber blankets or rollers
- for 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
- if ink is supplied to the press from a drum ensure 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
- storage next to unsuitable ink can also lead to migration

6 Process Flow (A typical flow chart)

- General GMP requirements**
- Appropriate factory hygiene
 - Clear allocation of responsibilities
 - Maintenance and cleaning plans
 - Internal identification system
 - Use of suitable consumables and auxiliary materials
 - Awareness about the production of food contact materials & articles (training)
 - Hazard analysis and risk evaluation of production
 - Protection of the product against contamination throughout the process chain



Source : German Fachverband Faltschachtel Industrie FFI Adapted by BPIF labels

5 Testing can only be done on the finished food contact material. In case the customer adds another layer or material for example (inner bag), migration testing must be done on the combination of the inner layer AND the printed label/packaging. In principle, the printer needs to perform testing only on the printed material/article for which he is responsible. Note that migration testing can be avoided when other ways can be used to demonstrate compliance (modelling, worst case calculations, using results of other samples/more severe conditions)

6 Should the customer undertake an additional process to the packaging a suitable risk assessment is to be carried out which may result in further migration testing.

7 The customer needs to verify that the migration testing performed by the producer of the printed label/packaging is sufficient and adequate for the food he is intending to place in the packaging. Tables with simulants that need to be selected and that are for example included in the Regulation on Plastics can be used as a guidance. However, it is the responsibility of the customer to verify whether this guidance is appropriate for his food.

7 References used

The following list includes key document references with direct links to online documents. This list is not exhaustive but is essential reading for any manufacturing specialist within the graphic arts and packaging industry involved in printing and converting products intended for use with food.

The documents are listed in order of direct importance to label producers.

October 2004 – Framework Regulation (EC) No 1935/2004 – (Article 3)

Regulation on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC – states that such 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.

<http://www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:en:PDF>

December 2006 – Commission Regulation (EC) No 2023/2006

On good manufacturing practice for materials and articles intended to come into contact with food listed in Annex 1 to Regulation (EC) No 1935/2004 – Applied since August 2008.

<http://www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:384:0075:0078:EN:PDF>

January 2002 – Regulation (EC) No 178/2002

Laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

<http://www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>

July 1985 – Council Directive 85/374/EEC

On the approximation of the laws, regulations and administrative provisions of the Members States concerning liability for defective products

<http://www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31985L0374:EN:HTML>

June 2009 – UK FSA (Food Standards Agency)

Guideline on legal compliance and good practice for business documentation for materials and articles in contact with food.

<http://www.food.gov.uk/multimedia/pdfs/publication/legalcompliancefoodpackaging.pdf>

September 2012 – CEPI / CEFIC / CITPA / FPE

Industry guideline for compliance of paper & board materials and articles for food contact.

www.cepi.org/Objects/1/files/Industry%20guideline-final.pdf

Swiss Ordinance SR 817.023.21

Switzerland has issued an Ordinance on materials and articles in contact with food. In a revised version applicable since April 2010, a new chapter on printing inks was added.

<http://www.bag.admin.ch/themen/lebensmittel/04867/10015/index.html?lang=en>

November 2012 – EuPIA Guide to Inks for Food Packaging *(updated from September 2009)*
Guideline on Printing Inks applied to the non-food Contact Surface of Food Packaging
Materials and Articles (updated from April 2008). <http://www.eupia.org/index.php?id=29>

Plastics Regulation (EU) No 10/2011 and its amendment

The Plastics Regulation consolidates 12 existing sets of European rules for plastics in one regulation and also sets out food types and food stimulants. The third amendment was published as Commission Regulation (EU) No 1183/2012 of 30 November 2012

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2011R0010:20111230:EN:PDF>

PAS223

A food safety standard issued by BSI for the manufacture of packaging for food.

www.bsigroup.com

8 Abbreviations, Definitions and Glossary

BPIF labels: Is the trade association for the self adhesive and label industry

BCF: Is the British Coatings Federation

CEPI: Confederation of European Paper Industries – www.cepi.org

CITPA: International Confederation of Paper and Board Converters in Europe - www.citpaeurope.org

CLP: Classification of Labelling and Packaging Directive

Coatings: There are different types of coatings, each of which has different properties and Advantages. Self adhesive laminate may have coatings which are designed to improve the ink adhesion and appearance and brilliance of the printed product. They can also be used to offer a degree of grease resistance. *See also lamination.*

Composite packaging material: Packaging material that consists of more than one layer of material such as adhesive, paper, plastic, aluminium.

Contaminant: Any biological, microbiological, chemical agent, foreign matter or any substance unintentionally added which can compromise safety or adequacy.

Converter: The producer of the packaging who has adopted this code

ECMA : European Carton Makers Association - www.ecma.org

EFSA: European Food Safety Authority – www.efsa.europa.eu

EuPIA: European Printing Ink Association member of CEPE (European Council of producers and importers of paints, printing inks and artists" colours) - www.eupia.org

FCM: Definition of FCM from 1935/2004. Materials and articles which, in their finished state, are intended to be brought into contact with food, or, are already in contact with food and were intended for that purpose, or, can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

FDA : US Food and Drug administration - www.fda.gov

FSA: UK Food Standards Agency

Formulations: Formulations are the composition of constituents of semi-finished or finished products. The constituents are used in the phases of the manufacturing process. In the formulation, as well as the constituents, technological coadjuvants can also be considered if within the system and objectives of the GMP.

Functional barrier: A “Functional Barrier” means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this regulation.

GMP (Good Manufacturing Practice): Those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof (from Regulation 2023/2006/EC, art. 3).

Grammage : The weight of the material expressed in grams per square metre (g/m²).

HACCP: Hazard analysis and critical control point.

ISO: International Organisation for Standardisation.

Label : A label is used to identify the packaged product. It can either be self adhesive or plain paper.

Lamination: The printed product is covered with a thin protective layer in plastic layer, normally a PE or PET film. Laminates can be shiny, matt and can be applied in or off line. A laminate offers excellent protection against dirt, damp and wear. The same can also be for offering an aesthetic finish.

Low migration ink: A “low migration ink” designed for use on food packaging is – according to the definition given by EuPIA - 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 Practice, in accordance with guidance given by the ink supplier for the intended application.

Manufacturing or production processes: This includes all phases of converting of raw materials, starting substances and semi-finished articles for obtaining semi-finished articles and finished products. In the manufacturing process, within the context of Regulation 2023/2006/EC, the phases of storage and handling of raw materials, starting substance and semi-finished articles are considered along with the final phases of packaging and palletisation of semi-finished articles and finished products, as well as the storage and transport phases.

Materials and articles in Contact with Foodstuffs (FCMs): Materials and articles, in the state of finished products that are for contact with food products; or that are already in contact with food products and are for that purpose; or that it be reasonably presumed that they may be placed in contact with food products or that transfer their own components to food products in normal or foreseeable conditions of use (from Regulation (EC) No 1935/2004 art. 2).

OML: Overall migration limit.

Packaging material: Is material that is usually printed on PP or PE material and is used to identify the packaging product.

PAS223:

A food safety standard issued by BSI for the manufacture of packaging for food.

www.bsigroup.com

PE: Poly-ethylene – plastic film used either as a self adhesive label substrate or packaging for unsupported film.

PIJITF: Packaging Inks Joint Industry Task Force

PET: Polyethylene-terephthalate commonly known as polyester

Polyester: Polyethylene terephthalate

PP: Poly-propylene - plastic film used either as a self adhesive label substrate or packaging for unsupported film.

Photoinitiator: Highly absorbent photochemical initiator in the UV domain. The energy from UV rays forms free radicals which initiate the process of the polymerisation of the ink.

Printing ink: Coloured pigment that is transferred to the print area with the aid of a transporting vehicle and hence fixed to the surface of a substrate by fixing agents such as resins.

Quality Assurance System (QAS): Any and all organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use (from Regulation 2023/2006/EC, Article 3).

Quality Control System (QCS): The systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the Quality Assurance System (from Regulation 2023/2006/EC, Article 3).

Quality Management System (QMS) : A *quality management system* is a set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved.

RCP: Relevant control point

Residual content: The residual content of a migrant is for food contact materials expressed in mg/m² or mg/kg of food. For certain substances legislation has set residual content restrictions.

Screening: Also called “screen frequency” or “resolution”; it indicates the number of lines of screen per unit of length, measured in lines per inch (lpi). The greater this is, the more detailed the picture. The type of printing process and label substrate determine the screening that can be used during the print process.

Set-off: Transfer from the printed surface which is not properly dry, to the non-printed surface which can come into contact with food during storage in reels or stacks. When it is visible, it is commonly called maculation.

SML: Specific migration limit.

Specifications: As understood under Regulation 2023/2006/EC, Article 3, these are specifications concerning the “requisites” defined for the raw materials and semi-finished articles. Specifications for the requisites for raw materials and semi-finished articles fall under conformity requirements with the legislation on materials and articles for food contact.

Tenax: Poly (2,6 – diphenylphenylene oxide). Sometimes commonly known as MPPO (modified diphenylphenylene oxide).

Traceability: The ability to retrieve reliable information with regard to composition, production methods, storage, shipment and other relevant features on packaging materials. Traceability is a requirement within Regulation (EC)No 1935/2004 (Article 17)

UV coatings: Ultra-violet coatings that are spread directly during printing, as well as during a subsequent lacquering phase. It gives the surface a gloss or matt finish.

9 Questions & Answers

Q1 What does GMP mean?

It is short for Good Manufacturing Practice.

Q2 How are GMPs for food packaging defined?

GMPs are defined as “those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof”.

Q3 What is Regulation (EC) No 2023/2006 ?

This is a legislative tool adopted by the EU to defend consumers in application as under Article 3 of the Regulation (EC) No 1935/2004 covering materials and objects for contact with food products.

Q4 What does Article 3.1 of Regulation (EC) 1935/2004 establish?

This Article lays down that the materials and articles, comprising active and intelligent materials and articles, have to be produced conforming to GMPs so that, under normal foreseeable conditions of use, they do not transfer to the food product components in quantities that they might: a) endanger human health; b) bring about an unacceptable change in the composition of the food; or c) bring about a deterioration of the organoleptic characteristics thereof.

Q5 What is the field of application of Regulation (EC) No 2023/2006?

The present Regulation applies to all sectors and all the phases of production, processing and distribution of materials and objects for contact with foodstuffs up to and excluding the production of starting materials.

Q6 What are the production chains of the different materials?

The production chains are the total sum of industrial processes that from the production of the raw materials lead to the obtaining of the finished article and its distribution.

Q7 Who has to ensure the application of GMPs?

All parties in the chain for the production of materials and articles for food contact are required to observe what is laid down by an appropriate GMP with respect to their individual function within the supply chain. However, starting materials suppliers are not subject to the GMP requirements of Regulation (EC) No 2023/2006.

Q8 Can one demand the application of Regulation (EC) No 2023/2006 applied to the production of semi-processed articles or finished products from countries outside the EU?

Yes. Inter EU trade only occurs via the circulation of goods compliant with EU laws, hence a producer from outside the EU has to follow Regulation (EC) No 2023/2006.

Q9 What are quality management systems?

Quality Assurance Systems define the relevant activities and processes with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applied to them and the quality standards necessary for their intended use.

Q10 Do businesses have to be certified under the GMP regulation?

No. Regulation (EC) No 2023/2006 does not lay down any obligation of system or product certification, however, downstream users are likely to request a compliance document including reference to GMP2023/2006.

Q11 Are GMPs necessary if my company is already ISO 9000 and BRC certified?

Yes. Whilst quality management systems ensure production is carried out following specific documented procedures to obtain a preset quality level, a GMP system is focused on measures to fulfil the specific legislative requirements on materials and objects in contact with foodstuffs.

Q12 Can you graft a GMP system into a certified quality scheme such as ISO22000 or PAS223?

Yes. A certified Quality System (i.e. EN.ISO 9000, BRC) stands as an excellent basis for implementing a GMP, but should not be confused with the Quality System in itself. QA systems can include the GMP but cannot in themselves be considered a sufficient condition.

Q13 If the business is small, are the obligations as laid down in Regulation (EC) No 2023/2006 still the same ?

The obligations laid down in Regulation (EC) No 2023/2006 do not consider the size of the business but, in the foreword (preliminary Comments 6) it is stated that “The rules on GMPs should be applied proportionately to avoid undue burdens for small businesses”. As well as that, in Article 5 (Systems of quality assurance) it is laid down in section 5.1 (b) that “the system has to [...] be applied considering the size of the business, so as not to constitute an excessive burden for the business”.

Q14 What is FCM traceability?

Traceability as defined in Article 2.1 a) and regulated by Article 17 of Regulation (EC) No 1935/2004 is the possibility to reconstruct and follow the route that materials and articles follow through the processing, converting and distribution phases. The Traceability of the FCMs has the aim of food safety, facilitating the handling of emergencies, enabling the recall of defective products from the market, tracing the causes of non conformity and attribution of responsibility.

Q15 How can I ensure an adequate hygiene level?

Companies should ensure that they have a certified hygiene system in place. This will probably mean that suppliers also need to be audited

Q16 How can I prevent contamination?

Contamination can be prevented through knowledge of and the current application of a GMP, in particular the controlling of critical phases of the entire process and the application of all measures suited to the prevention of potential contamination. A good starting point is to adopt HACCCP principles.

Q17 Are the requisites the same along the entire production chain?

No. GMPs should be applied relative to the position of each player in the supply chain.

Q18 Does one have to involve all company personnel?

Yes, All personnel must be aware of the fact that a product is intended for food contact.

Q19 What should one ensure when training staff to observe within GMPs?

For the correct application of GMPs, staff must receive adequate training and precise instructions on the correct methods of working.

Q20 Who is responsible for implementation and enactment of a GMP?

The business owner is ultimately responsible for management of resources and activities necessary to guarantee that Regulation (EC) No 2023/2006 is understood and applied at all levels within their company or organization.

Q21 Does Regulation (EC) No 2023/2006 require the creation of a specific person responsible for the QAS and/or GMPs?

No. The Regulation demands that the business owner guarantees that Regulation (EC) No 2023/2006 is understood and applied at all levels of the company or organisation in order to obtain FCMs conforming to the applicable legislation. Every company can organize its activities best befitting its size and activity subject to the condition that the system is effective, implemented, maintained and documented and that products conforming to the applicable legislation are obtained.

Q22 What do I need to do for the documentation?

Documentation and its correct management and updating is a key aspect of what is required for the maintenance of an effective GMP system. As well as suppliers' documentation, documentation enabling the tracing of all production phases should be recorded and maintained.

Q23 If a business has not drawn up a manual but limits itself to registering its own management system via the relevant documentation, is this enough to demonstrate conformity to Regulation (EC) No 2023/2006 ?

Yes. In Regulation (EC) No 2023/2006 there is no reference to the obligation to draw up a manual but there should be appropriate documentation (in Article 7 mention is made of "adequate documentation on paper or in electronic format").

Q24 What should one do to manage GMPs of raw materials?

Supplier documentation must be obtained that enables full tracing of each lot of raw material to a specific batch of finished product to ensure full traceability within a certain sector of the segment. This should consider the technological feasibility, so as to enable control of all companies that supplied the materials and articles and, if appropriate, the substances and products used in the processing.

Q25 How does one manage the change?

Any variation in a given process that has influence on the conformity and requisites on FCMs (i.e. the use of a new raw material, a new formulation, or a new machine) should be evaluated before implementation. The GMP system should be re-evaluated at each change to check any need for review of the system. Documentary traces of any changes should be kept.

Q26 How does one correctly manage handling, transport and storage?

Handling, transport and storage conditions should always avoid adulterations and contaminations both of raw materials, as well as semi-processed and finished articles.

Q27 How do I manage activities carried out by third parties?

Each job contracted to third parties must have a written contract and be carried out in accordance with the appropriate GMPs and must be comparable to that applied for the processes placed at the same level in the production chain on the contractor's premises.

Q28 How can I check the effectiveness of the GMP?

The Quality Control System must be organized to include verification activities for implementation and total compliance with the GMP. Effectiveness must also be checked through controls on finished products.

Q29 Who checks the application of the GMPs?

The implementation of controls in the application of GMPs (in Regulation (EC) No 2023/2006) is entrusted to the Quality Control System of each individual business within the supply chain. Verification by Competent Authorities are carried out as under the Discipline of the Official Control of Food Products (Regulation (EC) No 882/2004 of the European Parliament and the Council 29th April 2004/EC).

Q30 Where does one find clarification on the responsibility of the producers of materials and object intended for food contact and for the food industry?

Each European country will have its own respective food standards agency to whom it should refer.

Q31 Where can I find clarification on the application of the traceability in the sector of Production of Materials and Objects Intended for Food Contact (Article 17 Regulation (EC) No 1935/2004)?

You should refer to Article. 17 of Regulation (EC) No 1935/2004 specifically for each food packaging sector "Industrial Guidelines on traceability of materials and articles for food contact" is available on the website *Joint Research Centre – Community Reference*

Q32 Which information needs to be available for customers?

When contractually agreed, a description of composition can be provided to customers. This way label and packaging converters fulfil their obligation to share information in the supply chain.

Q33 Does one have the obligation to issue a declaration of compliance ?

No, only the materials subject to individual legal measures require a Declaration of Compliance. The obligation to issue a declaration of compliance for all food contact materials is however a legal obligation in national law of certain Member States.

This is for example the case in Belgium, France, Italy and Romania, without however clear rules on how to issue DOC's.

10 Compliance statement with BPIF labels GMP Guide

Companies fulfilling certain preliminary standards explained in 1.1.3 and 1.1.4 of this GMP guide can confirm their self declared compliance with the BPIF labels Good Manufacturing Practices Guide.

Such a self declared and voluntary compliance statement for the manufacturing of labels and related packaging for the food, drinks and sensitive product sectors, can only be issued at plant level.

Companies having issued such a self-declared compliance statement towards BPIF labels are listed on the public part of the BPIF labels website www.bpiflabels.org.uk and are allowed to use the BPIF labels developed GMP self declared compliance seal, which is as follows :



The standard compliance letter is also available on the public part of the BPIF labels website.

Disclaimer: As this BPIF labels developed GMP compliance seal is self declared and voluntary, it may not be construed by any means as an approval or endorsement by BPIF labels or any of the contributors of compliance with the GMP guide or with any applicable requirements, including the safety requirement, of labels and related packaging manufactured by companies using the seal.

The publication by BPIF labels of the list of self-declared compliant companies using the seal is not either to be construed as an approval or endorsement by BPIF labels or any of the contributors. The use of the seal is made by each individual company under its sole responsibility, having due regard to the GMP guide and the applicable legislation.

11 Document Evidence

11.1 Statement of Composition

Statements of composition can be obtained from your supplier. These are required in order to provide a good recording of substances used in the production of labels and packaging used for the packaging of food and related products.

11.2 EuPIA Guideline on Printing inks applied to the non-food contact surface of food packaging materials and articles

These guidelines were produced in November 2011 and can be downloaded from the EuPIA web site: www.eupia.org

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