	Checklist for ECMA GMP Guide
1 Introduction and Objectives	
1.1 Scope and introduction	
1.1.1 This guide is developed for companies that manufacture cartons, 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. Windowed and laminated cartons are also in the scope. Cartons used in dry, fatty and frozen food categories are in, while cartons for liquids are out, of the scope of this GMP.	Is there an overview of all customers, including all of the produced articles? Does the business operator have a clear overview of which products are being produced? Is there a manufacturer cadastre of the products to be produced? Does the business operator have an implemented procedure for doing systematic risk assessments (e.g. on the basis of the ECMA/FFI sales checklist)?
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.	This ECMA GMP Guide is to support the business operator in compliance with the legal requirements established in the Regulation (EC) No 2023/2006. Therefore the business operator can check: How is the ECMA GMP Guide business-internally being integrated into the existing systems?
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, not used as a standalone document.	How is the ECMA GMP Guide being integrated into the overall management system? Are there references to already existing procedures?
1.1.4 Before adoption, your technical processes must be organized to reliably produce only cartons that conform to specifications. You will also need a complete system for hygienic control, EN 15593/ ISO 22000 (or equivalent).	Has the business operator implemented a hygiene management system (e.g. CEN 15593, ISO 22000, BRC IoP, IFS)?
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.	Are suitable suppliers approved and is there an appropriate approval procedure, which ensures that only suitable raw materials get used in compliance with the GMP? Are food contact articles being produced in compliance with proper production methods?
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. Does the business operator have an appropriate procedure implemented for monitoring the upstream and downstream traceability? 2. Does the management periodically check the suitability of this procedure? 3. Is the traceability to the suppliers demonstrably checked? 4. Has the business operator verified that the raw material suppliers for their part ensure the traceability of their products? 5. Has the business operator checked that the raw material suppliers have an independently audited QM system of their manufacturing processes?

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1.1.7 This code assures the converter of producing packaging that, under specified and controlled circumstances, 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.	Are procedures which ensure that communication with the customers is safeguarded implemented? Are procedures which ensure that the outcome from the communication gets documented implemented? Are appropriate tools (e.g. ECMA/FFI sales checklist) being used as needed?
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.	Does the business operator by use of appropriate procedures ensure: That all relevant laws and guidelines for the markets in which cartons are being marketed are present and known? That there are always current editions at hand? That the requirements in terms of content are known by the persons with authority?

1.2 Objectives

1.2.1 In line with Article 3 of Regulation (EC) No 1935/2004, 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: o health hazards that may result from migration of components of the packaging material into the packaged food product o unacceptable changes in the composition of a food o unacceptable changes in organoleptic characteristics of a food product that may result from the release of components.	Are procedures implemented by the business operator, which guarantee that risks and hazard potentials for the planning, manufacturing and distribution of food contact articles are detected?
1.3 Legislation	

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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 ECMA's GMP guide for the carton sector and is intended to be adopted by manufacturers of carton-board based packaging for food. 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.	Has the business operator implemented an appropriate procedure to ensure that the general requirements concerning food contact articles as set in the Framework Regulation (EC) No 1935/2004 are being achieved by the product?
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)	Are procedures implemented by the business operator to ensure compliance with the general requirements concerning the product according to Framework Regulation (EC) No 1935/2004, even though for individual materials and articles in contact with food (see attachment 1 to the Framework Regulation (EC) No 1935/2004) no material-specific regulations existed until now?
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 Directive in only negligible amounts.	Has the business operator implemented an appropriate procedure to ensure compliance with the legal requirements concerning products?

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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).	The requirements concerning a GMP according to Regulation (EC) No 2023/2006 and according to ECMA GMP Guide, for example due to the existence of a QA according to standard series ISO 9000ff, are insufficiently complied with. Does the business operator thereafter ensure with appropriate measures that a GMP according to Regulation (EC) No 2023/2006 is implemented?
1.3.5 Non-compliance with Regulation (EC) No 1935/2004 and Regulation (EC) No 2023/2006 has shared responsibility for the whole supply chain.	Do the applied production methods and communication processes with all partners of the supply chain guarantee that the whole supply chain of the packaging production complies with the state-of-the-art in the legal requirements of food laws.

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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.	Article 3 Framework Regulation (EC) No 1935/2004 contains general requirements, which concern all food contact articles. The Regulation (EC) No 2023/2006 limits its scope in Annex 1 to applying printing inks only on the side of the materials or objects, which do not come in contact with the food. The EU legislation means with this the outside of the packaging. Inks and varnish systems developed for applying to the non food contact side of food packaging may not be used in contact with the food. Has the business operator implemented procedures, which safeguard this basic requirement? With the Regulation (EC) No 2023/2006 the inside printing with printing inks or rather a varnish layer of cartons, is thus not regulated. To be used in this case is only the Framework Regulation (EC) No 1935/2004 with the general requirements within Article 3. Part of a risk assessment, inside printing is only allowed if the applied inks and varnishes do not transfer their constituents to food in qualtities which could (a) endanger human health; (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic properties thereof. It is known that printing inks and varnish subject to conditions of printing on the inside and outside, can possess different migration potentials. It is therefore to be safeguarded against by appropriate methods by the business operator: Is the possibly higher migration potential of printing on the inside adequately taken into account?
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.	[see 1.1.8]
2.2 Horizontal legislation in the EU	
2.2.1 Horizontal legislation is applicable to all materials and articles.	[see 1.1.8]

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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.	[see 1.1.8]
2.2.3 Two legally binding regulations at EU level create the general legal "food contact" frame which carton makers have to observe, the so-called "Food Contact Framework Regulation" and the "Good Manufacturing Practices Regulation"	[see 1.1.8]
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.	[see 1.1.8]
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."**	[see 1.1.8]
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.	[see 1.1.8]
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.	The requirements concerning a GMP according to Regulation (EC) No 2023/2006 and according to ECMA GMP Guide, for example due to the existence of a QA according to standard series ISO 9000ff, are insufficiently complied with. Does the business operator thereafter ensure with appropriate measures that a GMP according to Regulation (EC) No 2023/2006 is implemented?
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).	[see 1.1.8 and 1.3.6]

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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.	[see 1.1.8]
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.	[see 1.1.8]
2.3 Horizontal guidance documents.	
2.3.1 Quality management standards o ISO 9001 standard describes requirements on an effective, process-oriented quality management system o ISO 9004 deals with efficiency and effectiveness of the quality management system	The requirements concerning a GMP according to Regulation (EC) No 2023/2006 and according to ECMA GMP Guide, for example due to the existence of a QA according to standard series ISO 9000ff, are insufficiently complied with. Does the business operator thereafter ensure with appropriate measures that a GMP according to Regulation (EC) No 2023/2006 is implemented?
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. o 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. o BRC/IoP Global Packaging Standard was developed by the British Retail Consortium together with the Institute of Packaging 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. o 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. o The International Food Standard (IFS) applies to food manufacturers that supply store brands. Specific requirements on packaging are included in chapter 4.	Are Hygiene management standards known by the business operator? On the basis of which evaluation, which standard was selected as appropriate and implemented? In case no Hygiene-management certificate exists, which standard is intended to be implemented? When does the implementation occur?
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)	[see 1.1.8]

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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.	[see 1.1.8]
2.4.1.2 Member state legislation and recommendations	[see 1.1.8]
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 and board annexed to the information note DGCCRF N° 2004-64 issued the 6th May 2004. Presents the recommendations of the French public authorities applicable to paper and board 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 and board, stipulates which raw materials, production aids and refining agents can be used for making food contact paper and board.	
Italy The Italian Ministerial Decree 21 March 1973, as amended, covers in Annex II paper and board (Section IV)	
Netherlands In the Netherlands, the Warenwet of 28 December 1935, as amended, 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 meet. Specific regulations entitled "Regeling Verpakking en Gebruiksartikelen", as amended (Packaging and Utensils regulations) 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.	

	Checklist for ECMA GMP Guide
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.	[see 1.1.8]
2.4.1.4 Third country legislation	[see 1.1.8]
2.4.1.5 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.	[see 1.1.8]
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.	Is it known by the business operator that the Plastics Regulation (EC) No 10/2011 can be used as orientation by the risk management in evaluation of printing inks, but not as rules?
2.4.2.2 Member State legislation & Recommendations	[see 1.1.8]

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France o 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. o DGCCRF Fiche on printing inks (June 2010 update)	
Germany National regulations on printing inks are expected in 2012.	
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.	Is it known by the business operator that the Resolution ResAP (2005) 2 on food packaging inks can be used as orientation by the risk management in evaluation of printing inks, but not as rules?
2.4.2.4 Third Country legislation. Switzerland Although not an EU member state, Switzerland 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. Indeed, in a revised version applicable since 1 April 2010, a new chapter on printing inks was added. 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 in practice by industry to establish compliance with Article 3.1 a) of the Framework Regulation.	[see 1.1.8]

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2.4.2.5 Industry documents. o 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. o 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: a. Substances found to migrate at levels above 10ppb should show favourable results from three mutagenicity tests. b. Substances that migrate at levels above 50ppb should have additional toxicity data in support of these higher levels and should not be known CMRs. c. 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. o 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." o ECMA released prior to this GMP two public recommendations on food safety, one on UV printing in April 2009, and a second on the recommended use of low migration inks for food packaging and the safety of recycled cardboard in combination with systematic risk assessment procedures on packaging concepts in September 2010.	Does the business have implemented procedures, which guarantee that the raw materials being used are being supplied and converted in compliance with the branch standards of the Suppliers Association?

2.4.3 Varnishes and coatings

	Checklist for ECMA GMP Guide
2.4.3.1 EU legislation No harmonised EU legislation is applicable for varnishes and coatings.	Is it known by the business operator that the Plastics Regulation (EC) No 10/2011 can be used as orientation by the risk management in evaluation of varnish and coatings but not as rules?
2.4.3.2 Member State legislation & Recommendations	[see 1.1.8]
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 and varnishes (Section III Parts A,B, C&D), and 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.	Is it known by the business operator that the Resolution ResAP (95) 5 on surface coatings can be used as orientation by the risk management in evaluation of varnish and coatings, but not as rules?
2.4.3.4 Third Country legislation	[see 1.1.8]
2.4.3.5 Industry documents	Has the business operator implemented procedures which guarantee that the raw materials being used are being supplied and converted in compliance with the branch standards of the Suppliers Association?
2.4.4 Adhesives	

	Checklist for ECMA GMP Guide
2.4.4.1 EU legislation No harmonised EU legislation is applicable for adhesives.	Is it known by the business operator that the Plastics Regulation (EC) No 10/2011 can be used as orientation by the risk management in the evaluation of adhesives, but not as rules?
2.4.4.2 Member State legislation & Recommendations	[see 1.1.8]
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.	[see 1.1.8]
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.	Has the business operator implemented procedures which guarantee that the raw materials being used are being supplied and converted in compliance with the branch standards of the Suppliers Association?
2.4.5 Plastic layers	

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2.4.5.1 EU legislation Plastics Regulation (EU) No 10/2011 When packaging concepts including plastic components are developed, carton makers 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 and provides that national rules apply as regards OML and SMLs. 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.	Has the business operator implemented procedures that ensure that in the case of multi-materials multi-layers (exclusively) for the plastic share/laminate (incl. windowed cartons) a risk assessment according to Plastics Regulation (EC) No 10/2011 is done? (Attention: Does not apply to the whole of the multi-materials multi-layers) Has the business operator implemented procedures that guarantee that for delivered plastic raw material there exists a Declaration of Compliance according to Plastics Regulation (EC) No 10/2011?
2.4.5.2 Member State legislation & Recommendations	[see 1.1.8]

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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.	

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2.4.5.3 Council of Europe Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food.	
2.4.5.4 Third Country legislation	
2.4.5.5 Industry documents	Has the business operator implemented procedures to guarantee that the raw materials used are being supplied and converted in compliance with the branch standards of the Suppliers Association?
2.4.6 Waxes	
2.4.6.1 Member State legislation & Recommendations	[see 1.1.8]
Germany BfR Recommendation XXV on hard paraffins, microcrystalline waxes and mixtures of these with waxes, resins and plastics.	
The 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	[see 1.1.8]

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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.	[see 1.1.8]
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.	[see 1.1.8]
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.	[see 1.1.8]
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.	[see 1.1.8]
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.	Does the business operator have procedures implemented to ensure that raw materials delivered by third countries match the prescribed specifications?
3 Migration	
3.1 Types of Migration	

	Checklist for ECMA GMP Guide
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.	Has the business operator implemented procedures to ensure that basic knowledge and competences on the migration of substances exists with the personnel involved in the organization and the process of carton production? Are the responsibilities on questions concerning the migration subject sorted out? Are procedures implemented to ensure that professional knowledge about raw materials to be used, their use in accordance with regulations and their migration-potential is documented?
3.1.2 There are four key ways in which migration occurs:	[see 3.1.1]
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 not compliant packaging from a food safety perspective.	[see 3.1.1]
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:	[see 3.1.1]
3.3 Migration influencing parameters	[see 3.1.1]
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 size 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.	[see 3.1.1]
3.4 Food contamination	[see 3.1.1]
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 check overall compliance should take account of all sources	[see 3.1.1]

	Checklist for ECMA GMP Guide
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.	[see 3.1.1]
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: a. using raw materials certified as known from previous experience to be compliant for the specified use of the packaging, and/or b. carrying out a documented risk assessment, and/or c. testing the finished or intermediate products appropriately for the specified food and specified use of the packaging.	1. Does a QM-System exist, in which the GMP is integrated? 2. Are the deployed raw materials approved? Has the business operator designated a procedure, based on which appropriate decisions are being made based on tests (by the supplier or first-hand) or safety declarations? 3. Has the business operator designated a procedure to ensure that shared agreed upon (customer/converter) product specifications exist, that specify the contact that exists between the food contact article and the food? 4. Has the business operator designated a procedure, based on which material combinations have been approved after a risk assessment and sensibly been selected for an intended purpose? 5. Do process controls for periodical tests of migration and sensors exist?

	Checklist for ECMA GMP Guide
4.1.2 These actions should be supported by obtaining, controlling and/or verifying: a. information from suppliers about compliance with specific restrictions, and/or b. migration features of the raw materials, and/or c. composition of the raw materials, and/or d. use of a functional barrier, and/or e. tests of the intermediate or finished products directly.	Has the business operator designated a procedure to ensure that a documented communication (to Nos 4.1.2 a-e) with customers and suppliers exist, at the end of which appears a product specification as well as a description of composition? Are the deployed raw materials approved? Has the business operator designated a procedure, based on which appropriate decisions are taken on the basis of tests (by the supplier or first-hand) or safety declarations? Has the business operator designated a procedure, based on which material combinations have been approved after a risk assessment and sensibly selected for an intended purpose?
4.1.3 Assessment of compliance with migration limits (overall or specific 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: a. 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 b. a 'family approach', whereby all products within a suitable defined product family are considered to comply c. a 'building blocks' 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 blocks concept is seen as the core safety approach carton makers have to implement. Starting from minimum corporate standards as defined in sections 1.1.3 and 1.1.4 and compliance with this GMP, carton makers need to develop positive lists of packaging systems. Once a combination of a board, ink and glue type has been thoroughly tested as compliant for a certain type of application, this combination (packaging system) can be used safely for many customers. In order to guarantee the safety over time, regular compliance testing of the packaging systems needs to be in place.	
4.2 Commitment and Responsibilities	

	Checklist for ECMA GMP Guide
4.2.1 The Board level management team are essential to the success of implementing an appropriate QA 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. Consult with relevant national federations and European industry bodies such as ECMA. 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.	Is the GMP incorporated in the business policy? Is a GMP person with authority at board level (board of directors, management, associate, owner, etc.) designated? Is a core team to ensure the GMP objectives designated? Are the needed resources available?
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.	Has the business operator designated a procedure to ensure that raw materials are procured based on a coordinated specification? Basis: - Risk assessment - compliance work - supplier selection and approval - contractual regulation
4.3.2 Raw materials should be purchased from suppliers with QA systems compatible with the converters' QA system that also ensure the manufacture and supply of raw materials will be in compliance with all relevant legislation.	Does an approval procedure for suppliers exist? Does the procedure take into account approval criteria according to ISO 9001, hygiene standards, GMP statements and/or branch GMPs of suppliers (according to Annex 7 ECMA GMP guideline)?
4.3.3 In any assessment the converter can use information provided by suppliers about the compliance of raw materials (board, 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 unintentionally 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.	Has the business operator designated a procedure to ensure that declarations from suppliers exist, which certify the suitability of the raw materials? Do contractual agreements exist, based on which changes of raw materials with relevance to the migration behaviour and the organoleptic characteristics of the food contact article must be disclosed immediately?

	Checklist for ECMA GMP Guide
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. use of suitably designed tests in food stimulants b. verification of maximum permitted substance quantities c. verification of raw material composition d. worst case calculation of 100% transfer from food contact material.	Are the test methods that were approved by the supplier, or rather the institute commissioned, being used?
4.3.5 Where a supplier cannot provide evidence of migration levels, then they should be required to provide all the necessary information to enable, to carry out verification.	[Risk assessment occurs in individual cases]
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. Designing refers to all the in this GMP covered decisions that need to be taken regarding the final structure of the packaging.	Has the business operator designated a procedure to ensure that all relevant information (specification / checklist) is available for the business already in the design stage so that the GMP requirements are appropriately taken into account?
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: o substrates o other starting materials o application techniques for inks o production techniques o structural and graphical design.	Has the business operator designated a procedure to ensure that mutually approved specifications for food contact articles exist (e. g. based on ECMA/FFI sales checklist)? Are agreed specifications signed by customers as part of the contractual agreement ?
4.4.3 Printing inks 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 surface, then a suitable functional barrier must be included in the pack design.	How is made sure that food has no direct contact with the non food contact colour/varnish layer ?

	Checklist for ECMA GMP Guide
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 packaging 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 and varnishes fulfilling additional requirements is available for printing on the side in direct contact with foodstuffs.	
4.4.5 Depending on the nature of the packaging and its intended use, the following parameters should be taken into consideration in the product specifications (for additional guidance see ECMA checklist to use with customers, available from the member section of the ECMA website): **o General** o existing customer specifications o customers' requirements about the production process o printing on the inside o surface/volume ratio between the food and the packaging.	Do systems exist in the business, which ensure that the relevant requirements for food contact articles are collected and documented by the risk assessment (basis e.g. ECMA/FFI sales checklist)?
o Legal background o legal regulations and limits o export from the EU and legal regulations associated with this.	
o Characteristics of the product packaged o consistency: solid, grated, liquid, pasty o surface area/volume including a consideration of the internal surface area, for example a sponge or wafer o physical properties: dry, moist, fatty o if necessary: determination of chemical properties (e.g. reaction with volatile substances in environment, acid content, temperature dependence, etc).	
o Intended use by the customer and consumer o expected contact with edible fats or food regarded as fatty foods1 in migration testing o 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) o storage period (maximum shelf life) o storage conditions (in chillers, deepfreeze ...).	

	Checklist for ECMA GMP Guide
o Suitable materials o customer's requirements about o board grade (precondition: suitability for food packaging, content recovered fibres) o inks and varnishes (UV, conventional, sensory/migration-optimised) o adhesives (dispersion, hotmelt, sensory/migration-optimised) o proven suitability of the materials for food contact o criteria for filling of the packaging.	
o Migration risk and barrier o information about the use of an absolute and/or functional barrier (e.g. Bag in box) o description of the contact between the packaging and the product (physical direct contact, airspace contact ...) o migration testing.	
o Extras and function (eg: toy, cutlery) o information about product extras, and the conformity of those extras o further use and legal regulations of the packaging after it is emptied.	
o Sensory test o 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.	Has the business operator designated a procedure to ensure that proper and professional specifications exist, mutually agreed upon by the parties concerned?

	Checklist for ECMA GMP Guide
4.5.3 The key factors to consider for production development are: o customer specification, the answers given in 4.4.4 and any/all changes – must be validated o fit for purpose – foreseeable applications and required performance o raw materials – fully compliant with migration figures, barrier properties, relevant legislation or compliance testing o raw materials - known to be organoleptically inert or tested for changes and cleared by the customer o no transfer – within Regulation (EC) No 1935/2004 (Art. 3) requirements o unintended chemical reactions or breakdowns – none in substrates, inks, varnishes, coatings or adhesives o all materials – must be compatible o residue solvents in inks – must not give rise to unacceptable organoleptic changes, unacceptable set-off or unacceptable migration o reverse side printing presents a special challenge, because the reverse side of many boards and papers is provided with little or no clay- or carbonate coating. This coating is often effective in limiting the absorbency of the substrate towards ink and varnish, and hence limiting migration. o all changes – must be checked for compliance and customer approved o all legislation changes – design checked for compliance; customer informed.	Do systems exist in the business to ensure that the relevant requirements for food contact articles are collected and documented by the risk assessment (basis e.g. ECMA/FFI sales checklist)?
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.	Has the business operator designated a procedure to ensure that the necessary product specifications and production procedures are agreed upon with the customer?
4.5.5 **Production Performance:** The performance of any product must be designed at the development stage.	Has the business operator designated a procedure to ensure that all relevant information (specification / checklist) is available for the business already in the designing stage so that the the GMP requirements are appropriately taken into account?
4.6 Relevant Control Points	

	Checklist for ECMA GMP Guide
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: o ambient conditions: avoiding contact between raw materials / products and dirt, exhaust gases and vapours o personnel hygiene and response to hygiene incidents o excellent condition of all machines used o contact points between machine and product (including lubricants) o choice and grouping of product specifications o selection of suitable inks and varnishes, adhesives, plastic films for windows, auxiliary materials, cleaning agents and other chemicals o obtaining clearance certificates for materials and articles used o storage of raw materials, work in progress and finished goods o cleaning and resetting operations, particularly on printing machines o maximum acceptable application volumes for ink, varnish and adhesive layers according to the risk analysis o adaptations of the material flow (e.g. ventilation of printed piles before the next process operation) o covering piles during intermediate storage o monitoring of the drying/curing of printed layers o traceability of products and materials manufactured.	Are procedures implemented to guarantee checking, conformity and documentation of the described requirements?
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.	Within the framework of the risk assessment, does the business take into account processes in the area of logistics and storage? Have specifications for accepted quality been set internal and responsible persons been named ? Are there guidelines handed out to suppliers and the own logistics staff ? Are suppliers trained in the print factories hygiene and safety standards ? Are the responsible persons for storage and logistics defined ? Does everybody know just these persons take the decisions ? How is made sure that by storage the characteristics of the raw materials are preserved? How are contamination risks controlled?

	Checklist for ECMA GMP Guide
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.	How are the materials in the process protected against contamination? To what extent does the cleaning management take the GMP requirements into account? Wooden pallets checked for dirt, humidity, cracks and overhanging parts ?
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.	Has the business operator implemented measures which prevent the contamination of raw materials and finished goods during storage and transport (internally and externally)?
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: o loading areas and lorries well swept and free from strong odours, sharp objects and protected against moisture o protection against contamination from other goods or volatile substances during transportation o staff responsible for checking loading areas before each loading begins.	Does the business perform controls in the area of storage and delivery of semi-finished goods or finished goods to guarantee the precise identity as well as flawlessness of the means of transportation?
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.	Does the business have a system for the identification of product batches and for the localization and tracking of all raw materials from the conversion to the distribution of the finished products to the customer? Does documentation exist?

	Checklist for ECMA GMP Guide
4.8.2 Packaging manufacturers should have tracking systems that permit clear identification. Information about internal material flow that requires documentation is as follows: o identification of the company's own production location o order numbers o identification of the suppliers o identification of the batch of all materials used o code of the ink mixing formulations o identification of the shipping units (corrugated board boxes, pallets etc) o despatch date of the finished goods o delivery address.	as 4.8.1
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.	Do the process documentations make sure that proper reference is made to the employed technical facilities and tools?
4.8.4 Since traceability must be guaranteed within the company as well, information should be available at every stage of packaging production (e.g. printing machine, cutting/creasing machine, gluing machine). Different from the traceability rules defined for food in Regulation (EC) No 178/2002, paper and board 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 minimum shelf life).	How is traceability assured in the internal operation? Which requirements exist regarding the required archiving of data and retained samples?
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.	Does the business maintain a certified quality management system, which periodically gets audited externally? Is the current certificate still valid? Does the business do internal audits in scheduled intervals with the purpose to test the effectiveness of the quality management system, and at the same time, test if the converting of products meets GMP standards?

	Checklist for ECMA GMP Guide
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.	Can the business operator provide evidence that the production of relevant suppliers meets GMP standards, or rather do the suppliers get audited according to the GMP Guidelines of the ECMA? Do the auditors have adequate training and are they independent from the audited area/supplier?
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.	Do sub-suppliers by use of a risk assessment get qualified with the same GMP rules (incl. traceability)? Does a procedure exist for commissioning sub-suppliers?
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 and 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.	Did the personnel (from every shift) get acquainted with the GMP rules? Are records kept about the training? Are repeat courses planned? Is part-time employed personnel (part-time, temporary work) included in the training program?
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.	Are hygiene guidelines of the business, or a certified standard on the hygiene, documented and being lived by all personnel including visitors of the production facilities?
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.	(Questions come from the text) Does verifiable, written documentation exist?
4.11.3 Personnel hygiene includes rules about personal care, wearing of jewellery, working clothes and procedures in the case of illness. Visitors 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.	(Questions come from the text) Does verifiable, written documentation exist?

	Checklist for ECMA GMP Guide
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.	(Questions come from the text) Does verifiable, written documentation exist?
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.	(Questions come from the text) Does verifiable, written documentation exist?
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.	Has the business operator done a risk assessment concerning the hazards by part of deployed production machines and at the same time considered all the machine components, maintenance and repairs as well as the deployed operating supplies?
4.11.7 Press cleaning is a key aspect of hygiene. To prevent contamination always use absolutely clean equipment and tools. Rollers and blankets 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.	Do cleaning and maintenance plans exist in the business, which outline the work to be done? Are cleaning, maintenance, and repair documented efficiently ? Are appropriate approved components (printing inks, print accessories, cleaning agents, oils, greases etc.) being used? Can one prove using only certified/verified print-and cleaning agents ? Are these exclusive materials known by all responsible persons as standards ?
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.	Has the business operator implemented operation instructions for cleaning blankets, impression cylinders, etc. of printing machines in the production sequence, which regulate the approved cleaning agents and requirements before new production?

	Checklist for ECMA GMP Guide
4.11.9 Rules must also be clearly marked out for the control of production waste, from printed reject sheets through to cutting and creasing waste, left-over inks and varnishes, adhesive waste and hazardous substances that must be disposed of in accordance with instructions provided by the manufacturers.	Are there procedures that regulate handling of production wastes and prevent mixing them with goods in the manufacturing process? Are places/rooms for waste defined and labelled ?
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.	Does a formal risk management system exist, which ensures that all hazards to production safety and integrity are spotted and that implements safeguards regarding solids, chemical and microbial risks, mislabelling and mix-up?
4.12.2 When carrying out a risk assessment, consider the following: o different transfer mechanisms (set-off, permeation, vapour-phase transfer) o type of barrier material (eg: aluminium or glass) may represent an absolute migration barrier; PET, a specific barrier; other materials (eg: paper and board or a PE, film or extrusion layer) are insufficient barriers to migration of most substances liable to migrate from ink and varnish layers o suitable functional barriers may prevent permeation but not exclude set-off.	Does the business have a risk assessment in the framework of product development (e.g. through ECMA/FFI sales checklist)?
4.13 Testing	
4.13.1 Laboratories where migration tests and tests related to hygienic control are carried out should maintain appropriate QM systems. Within the ECMA Technical Committee a list of appropriate specialised external laboratories has been elaborated. This list is available on the ECMA website www.ecma.org ->public affairs -> product safety.	Is there a collaboration with specialised laboratories for the testing of conformity of products?
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.	Has the business operator designated a procedure to ensure that within the compliance work suppliers are asked to provide information concerning migration-capable substances?

	Checklist for ECMA GMP Guide
4.13.3 Migration test methods with all types of simulants are available. The most commonly used simulant for paper and board 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.	For information. Selection done by specialised laboratories at their own responsibility.
4.13.4 The following points are important to be aware of: o other simulants less appropriate for paper and board are specified in the Plastics Regulation (EU) No 10/2011 o 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 o 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.	For information.
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.	Does the business have a procedure for sampling, storing and handling of tests?

	Checklist for ECMA GMP Guide
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. 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. 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 simulant may be done with any suitable analytical method. EN 14338 Migration into Tenax is available for paper and board. Representative samples Testing should be done on representative samples. The following aspects should be taken into consideration: o The samples must be representative for the whole batch, (scrap produced when changing from one batch to another batch should not be used) o 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. o The samples taken must stored and transported in such a way that contamination of the samples or loss of substances is avoided o 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).	Are results from migration analysis transferred to other production systems? Is there a rule for it?

	Checklist for ECMA GMP Guide
4.13.16 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. For example the requirements for a carton in direct contact with chocolates would be very different to those for the carton holding aluminium bags with dried potato flakes. 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 carton for its purpose needs to be assessed and confirmed by the end user from the specification or first trial production. In general the converters' 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.	Do procedure controls, for periodical tests of the sensors exist?
4.14 Evidence supplied by Material Suppliers	

	Checklist for ECMA GMP Guide
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: o Materials subject to individual legal measures require a Declaration of Compliance (DOC) determined by that measure. If absent, another statement (description of composition etc.) can be obtained in accordance with private law. 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 DOC's. o Compliance certificates confirm materials used are in line with food contact law. They are issued by accredited specialised laboratories or test institutes. o 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.	see 4.3.2

	Checklist for ECMA GMP Guide
Depending on the material involved, care should be taken to make sure in particular the following information is provided due to various specific requirements: o Folding carton board: satisfaction of the requirements included in CEPI/CITPA Industry Guideline / BfR 36 about paper and board intended to come into contact with food. o 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. o 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). o 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.	
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. A document with specific guidance on the clauses to have in inks supply contracts is available from the member section of the ECMA website.	Are procedures implemented in the business, which guarantee that the printing ink manufacturers (and all other suppliers of food contact materials) continually provide current information on consistency, the existence of migration-capable substances and on the sensoric characteristics of the delivered printing inks and varnishes (e.g. according to EuPIA Statement of Composition)?
4.15 Description of composition	
4.15.1 A Description of composition can be provided to the customer (where contractually agreed). This way carton makers fulfil their obligation to share information in the supply chain. Examples of such documents are available from the member section of the ECMA website.	Are procedures implemented in the business, which guarantee that the customer is given a declaration of compliance where this is legally required (e.g. on the basis of EU Plastics REG 10/2011 or national regulations as in France, Italy, Belgium. Switzerland) or rather given a product description at the request of the customer, where there are no individual measures for materials and articles according to Attachment 1 of the Frame-REG No 1935/2004/EU or no national regulations?

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4.15.2 Documentation to show materials, articles and substances intended for manufacturing of food contact carton board-based 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.	Has the business operator implemented a system that is able to timely show the required risk assessments and evaluations, the traceability as well as the product and processing documentation, during an official inspection? Is made sure that the defined documentation is fully taken up and appropriately archived?
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.	see 4.15.2

5. Guidance on Inks and varnishes

5.1 Introduction Inks and varnishes have been a prime source of food safety incidents. For this reason a specific chapter in this GMP Guideline is dedicated to inks and varnishes. The content of chapter 5 is based on 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. After curing of standard UV inks and varnishes, however, certain residual components may be present which have the potential to migrate due to: o decomposition products of photoinitiators and non-reacted photoinitiators o residual monomers that remain in ink film or are absorbed into the substrate o incomplete reaction of ink components due to inadequate curing	Has the business operator implemented procedures, which ensure that appropriate risk assessments are made concerning conversion of UV inks and varnishes regarding migration potentials (e.g. incl. process description, printing machines; control UV lamps)? Is the appropriate production process adequately defined? Has the business operator implemented an appropriate test procedure (state-of-the-art test criteria and test frequency) to ensure that the UV inks and varnishes are cured?

	Checklist for ECMA GMP Guide
5.2.2 Substrate o Ensure the paper/board substrate is suitable for food packaging applications o Some substrates, certain grades of paper and board are themselves sensitive to the radiation which is used to cure UV inks and varnishes, and can develop an odour which can later taint the packed food. o Paper and board are very receptive to airborne migration of volatile materials and are very absorbent to vapours and liquids such as those from press washes or conventional ink in press room atmospheres	[see 5.2.1] Be sure the combination of UV inks and board type has been checked for not causing taint/odour.
5.2.3 The majority of raw materials in standard UV ink and varnishes have not been evaluated for food contact. 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 control.	Has the business operator implemented procedures, which ensure that risk assessments are done for food contact articles that were produced with UV inks and varnishes? Has the business operator implemented procedures to ensure that for food packaging only UV inks and varnishes are used that are suitable for the intended purpose? Has the business operator implemented procedures, which through the use of tests of the finished products ensure that the migration limits are adhered to? Has the business operator implemented procedures to ensure that appropriate incoming inspections (label check) are done for UV inks and varnishes?
5.2.4 Migration test methods with simulants are available. The most commonly used simulant for not laminated paper and board packaging which will be in contact with dry foods is modified polyphenylenoxide (MPPO), 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.	Have procedures been implemented by the business operator, which ensure that by self-performed migration assessments the appropriate methods and appropriate food simulants are chosen. Have procedures been implemented by the business operator, which ensure that for external migration assessments, and for the migration method to be applied, appropriate specialised institutes have been chosen?

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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.	Have procedures been implemented by the business operator, which ensure that adequate risk assessments get done for the use of Flexography inks with UV-curing inks and varnishes? Is the production process adequately described? Has the business operator implemented an appropriate test procedure (state-of-the-art test criteria and test frequency), which ensures that the Flexography inks with UV-curing inks and varnishes are cured?
5.3 Conventional inks and water-based overprint varnishes Standard offset oxidative printing inks and water-based varnishes may contain substances that are liable to migrate. For the printing of food packaging specially formulated low-migration inks and water-based varnishes are available and should be used. Low migration inks are formulated using selected components ensuring that migration from the resultant printing ink film is intrinsically within all legal migration limits for the intended application.	For the printing of cardboard packaging for foodstuffs low migration inks and varnishes are recommended. In case this recommendation is not followed, have procedures been implemented by the business operator, which with agreement of the customer ensure that in using conventional printing inks and varnishes, the legal requirements are complied with? How is in such a case compliance demonstrated ? According to prevailing opinion, the legal requirements, without a functional barrier, indeed can only be achieved by means of so called low migration printing inks and varnishes.
5.4 Printing additives and fount solutions o Use only printing additives approved for the specific low-migration ink system when using low-migration inks or coating. o For offset printing special low-migration fount concentrates have been developed, as standard fountain solution concentrates may contain potential migrants such as wetting agents or alcohol substitutes.	Have procedures been implemented by the business owner, which ensure that only appropriate additives and fount solutions are being used?
5.5 Ink Mixing and Colour Matching	

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5.5.1 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. o Use the inks from their original containers o Avoid contamination (and ensure traceability) during ink mixing o Containers and tools must be clean o Cleaning agent residues must be avoided o Inks blended at the converter's plant should be re-used only after being checked for suitability for re-use.	Have procedures been implemented by the business operator, which ensure that only appropriate ink systems are used? Have procedures been implemented by the business operator, which ensure that traceability for mixed inks is transparent?
5.6 Cleaning	
5.6.1 To prevent contamination always use clean equipment and tools. o Rollers and blankets must not be contaminated. o Thorough cleaning with a dedicated cleaning agent.	Has the business operator established cleaning schedules for machines, building and tools and processes, which guarantee their efficiency? Are procedures implemented, which document the efficient control?
5.6.2 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.	Has the business operator done appropriate risk assessments regarding the suitability of cleaning agents according to migration aspects? Has the business operator implemented procedures, which guarantee appropriate cleaning of rollers and blankets ? Has the business operator implemented procedures to ensure that an adequate number of unused run-up sheets are gathered?
5.7 Ink Drying	
5.7.1 Conventional Ink 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.	Does the business operator through the use of appropriate procedures ensure that deployed drying technology in connection with the deployed printing components is appropriate for the drying of printing inks and varnishes?

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5.7.2 UV 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: o Check necessary power is readily available o Ensure correct number of lamps of right power and intensity are used o Ensure regular maintenance of lamps and reflectors.	Have procedures and operation instructions been defined by the business operator, which ensure that UV ink layers and varnish layers are cured? Check power and also the suitable positioning of the UV interdecks to ensure efficient curing. Is the UV equipment checked and maintained regularly ? Is ensured that the UV equipment is not mixed up (e.g. different run hours or age) ? Are maintained UV lamps labelled in a way everyone understands the lamps are OK for use ?
5.7.3 A variety of factors influence the degree of curing – the type and energy of UV lamp output including condition of reflectors, the press speed, the time interval between printing and curing, and the substrate (particularly when printing on non- coated board surface in relation to the absorbency). This means it is essential to continuously monitor and document the curing quality and output. Verify that current printing speed corresponds to pre-validated conditions and run tests to check there is sufficient curing of ink film. Note that the addition of non-approved curing accelerators on the press is not allowed.	Have procedures and operation instructions been defined by the business operator, which ensure that UV ink layers and varnish layers are cured? Have procedures been defined by the business operator, which establish appropriate test methods for the evaluation of degree of curing? Have procedures been defined by the business operator, which ensure that the results from risk assessments are documented? Is it made sure by appropriate procedures that no additives (photo-initiators) are added on the press ? The amount of curing agents (photoinitiators) should be defined by the ink suppliers and printer by testing. Hereby curing power has to be preferred rather than using more photoinitiators.
5.8 Ink Film Weight	
5.8.1 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. The colour density for black should not be above 2.5. This must be controlled by the use of densitometry (either hand-held or using the press-manufacturers built-in software/hardware. Observe optimum densities for 4-colour and avoid high-build 4-colour solids).	Have procedures been defined by the business operator, which in the framework of print data processing help establish the optimal area coverage of the printing motif ?
5.9 Control	

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5.9.1 The following summary are highly recommended control point reminders: o use inks from their original containers o statistical migration/sensorial analysis may be appropriate in addition to standard tests o record printing conditions including speed, curing conditions and printing sequence o 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.	Have procedures been defined by the business operator, which ensure that relevant control points are observed and adhered to? With regard to this, is the personnel being appropriately trained and informed?
5.10 Changing from Normal to Low-Migration Printing	
5.10.1 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 (non-exhaustive) list provides the basis for a code of practice for the changeover: o use inks from original containers o empty all ink and coating, ducts and pipes o for offset process, change fount to the one recommended by supplier, cleaning mixing and storage tanks, filters and pipes as part of procedure o clean all rollers and blankets o 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 o 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 o 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 o ensure all subsequent processes are free of the risk of migration from solvents, plasticisers, oils, greases and other potential migrants o storage next to unsuitable ink can also lead to migration.	Has the business operator conducted a basic risk assessment to see whether, due to the combined operation, additional migration risks exist? Within the framework of risk assessment, were measures to reduce migration hazards determined? Has the business defined a procedure, which as a binding guideline ought to make sure how the cleaning is to be done when changing to a higher standard ink and/or varnish system (among other things number of unused run-up sheets)? How are blankets and rollers cleaned ? Is the application of suitable guidelines assured and checked ?

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6. Process Flow [a] 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 carton. In principle, the printer needs to perform testing only on the printed material/article for which he is responsible. However, if an inner bag is used for example, it is for the customer of the printer to evaluate the combined printed carton with the inner bag. 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).	
[b] Migration testing needs to be done by the customer in case the customer places an additional layer or material between the printed material and the food (an inner bag as the first example or a bottle that is placed between the printed carton/paper and the food).	
[c] The customer needs to verify that the migration testing performed by the producer of the printed carton/paper 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 carton makers.	
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://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:en:PDF	

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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. 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://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://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	
March 2010 – CEPI / CEFIC / CITPA / FPE Industry guideline for compliance of paper and 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	
September 2009 – EuPIA Guide to Inks for Food Packaging Guideline on Printing Inks applied to the non-food Contact Surface of Food Packaging Materials and Articles (updated from April 2008). www.eupia.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=10008E&eas:dat_im=05048E	
Plastics Regulation (EU) No 10/2011 and its amendment The Plastics Regulation consolidates 12 existing sets of European rules for plastics in one regulation. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF	
8. Abbreviations, Definitions and Glossary	
Carton : A carton is the end product used to package goods. Cartons are made of cartonboard.	

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Cartonboard: Cartonboard or cardboard is made using a multi ply construction and the differences in what is used to make each layer creates the differences between the basic grades. Virgin fibres : Solid bleached board, Solid unbleached board, Folding boxboard Recycled fibres : White lined chipboard	
CEPI: Confederation of European Paper Industries – www.cepi.org	
CITPA: International Confederation of Paper and Board Converters in Europe - www.citpa-europe.org	
Coatings: There are different types of coatings, each of which has different properties and advantages. Cartonboard has usually a mineral coating on the printing surface in order to improve its printability. Coatings can also be used to make the carton grease resistant or to emphasize the brilliancy of the design or of a given detail. See also lamination.	
Composite packaging material: Packaging material that consists of more than one layer of material such as paper or board, 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 Standard Agency – www.efsa.europe.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	
FDA: US Food and Drug Administration – www.fda.gov	
FFI: Fachverband Faltschachtel-Industrie e.V. – www.ffi.de	
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).	

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Grammage : The weight of the cardboard expressed in grams per square metre (g/m2). The paper with a grammage weight above 160 g/m2 is normally called cardboard, because this is the threshold after which a fibrous material has the sturdiness and stiffness that makes it suitable for constructing packaging. Most cardboard packaging has a basis weight of from 160 to 600 g/m2 .	
HACCP: Hazard analysis and critical control point.	
ISO: International Organisation for Standardisation	
JRC: Joint Research Centre – The European Union's scientific and technical research laboratory – http://ec.europa.eu/dgs/jrc/index.cfm	
Lamination: The printed sheet is covered with a thin protective layer in plastic-metallic material, the laminate. Laminates can be shiny, matt and can be applied using a special laminating machine. 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.	
PE: Poly-ethylene – plastic film often used as board liner.	
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 the cardboard by fixing agents such as resins.	

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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/6dm². 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 cardboard and the choice of print method determine the screening that can be used during the print	
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 piles or on bobbins. 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	
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.	

	Checklist for ECMA GMP Guide
10 Compliance statement with ECMA 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 ECMA Good Manufacturing Practices Guide. Such a self declared and voluntary compliance statement for the manufacturing of food cartons, can only be issued at plant level. Companies having issued such a self-declared compliance statement towards ECMA are listed on the public part of the ECMA website www.ecma.org and are allowed to use the ECMA developed GMP self declared compliance seal, which is as follows: The standard compliance letter is also available on the public part of the ECMA website. Disclaimer : As this ECMA developed GMP compliance seal is self declared and voluntary, it may not be construed by any means as an approval or endorsement by ECMA of compliance with the GMP guide or with any applicable requirements, including the safety requirement, of cartons manufactured by companies using the seal. The publication by ECMA of the list of self-declared compliant companies using the seal is not either to be construed as an approval or endorsement by ECMA. 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.	