

CODE FOR GOOD MANUFACTURING PRACTICES FOR  
FLEXIBLE AND FIBRE-BASED PACKAGING FOR FOOD

*A management tool for the  
prevention of migration, organoleptic changes and contamination  
and for compliance with the essential requirements for packaging and  
packaging waste*

A FLEXIBLE PACKAGING EUROPE initiative,  
realised in close co-operation with CITPA

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## 0. Introduction

Commission Regulation (EC) No 2023/2006 of 22 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 in those materials and articles. It has applied from 1 August 2008.

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 one such code for GMP and is intended to be adopted by manufacturers of flexible and fibre based packaging materials for food.

Regulation EC No 2023/2006 defines GMP as those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use. 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 No 1935/2004).

EC No 2023/2006 will furthermore bring about a change in the by then almost exclusive liabilities of converters concerning defects of the finished packaging material concerning compliance with (EC) 1935/2004. From August 1<sup>st</sup> 2008 onwards, upstream suppliers as well as customers can be held accordingly responsible for defects, if they missed on their disclosure duties.

Annexes to 2023/2006 have detailed rules on GMP for processes involving the application of printing inks to the non-food contact side of a material or article and on the recycling process for plastics.

The goals of this code are:

- to provide certifiable certainty that excessive migration of components from the packaging into the food is prevented as intended by Art. 3 of the EU Framework Regulation 1935/2004/EC,
- to assure that the packaging will neither endanger human health nor bring about unacceptable changes in the composition of food or cause organoleptic changes thereof,
- to ensure that the packaging will be in compliance with the essential requirements of the Packaging and Packaging Waste Directive 94/62/EC (as amended).

This code is a management tool; it provides the methods by which these goals can be attained. These methods can be adopted by the converter and their proper implementation can be audited. The code is not a stand alone document. It can only be implemented by converters who employ a good, independently audited, quality assurance system. It must be 'hooked on to' and 'embedded in' such a system as for example ISO 9001. Before adoption of this code, the converter's technical processes must be organized in such a way that they can be relied upon to produce only packaging materials that are in conformity with their specifications. The code also demands that a complete system for hygienic control be implemented.

With regard to the packaging products themselves, the code focuses on the design, development and specification stages in the manufacturing process. To 'design for compliance' is the short description of the chosen method. The choice of raw materials and production methods must be such that the products almost unavoidably answer to the goals of the code.

Traceability and certification of the raw materials are other important features. Certified compliance with legislation and conformity with the highest standards is demanded from the raw materials. The certification must be based upon an independently audited quality assurance system of the suppliers' manufacturing process.

The code, of necessity, fills the gaps that exist in European food contact legislation, mainly with regard to multi-material multi-layer packaging and non-plastic materials. It does so by indicating where national legislation, standards, recommendations or guidelines from authoritative bodies should be applied.

This GMP code was realised at the initiative of FLEXIBLE PACKAGING EUROPE, in close co-operation with CITPA. The original drafts were put to other trade associations of manufacturers of flexible and fibre based packaging, to supplier trade associations and to large customers and their trade associations and the Council of Europe. Much valuable advice and numerous worthwhile comments were received; all of which could be incorporated.

European trade federations of manufacturers of flexible and fibre based packaging materials are kindly invited to subscribe explicitly to this code and recommend the adoption to their members.

## **Industry support**

The following trade associations subscribe explicitly to this code and recommend the adoption to their members:

FPE: Flexible Packaging Europe

CITPA: International Confederation of Paper & Board Converters

### **Note to the reader**

*This is version 6.0 of this Code for Good Manufacturing Practices. Remarks and suggestions for improvement are welcome.*

*Please send them to the Flexible Packaging Europe Secretariat.*

*At this time, several Flexible Packaging Europe and CITPA member companies are introducing the code in production plants. In doing so, they will collect valuable practical experience and identify points that may need to be clarified. Together with comments and suggestions received from other sources, this will lead to improvements to this code.*

### **Disclaimer**

Flexible Packaging Europe and CITPA have done everything possible to assure the accuracy of the information contained in this document.

Flexible Packaging Europe and CITPA accept no liability whatsoever for the business decisions based on the contents of this document. These remain the sole responsibility of the users of the information.

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## **1. Scope**

This code applies to the manufacture of flexible and fibre-based packaging that is intended to come into contact with food. These packaging materials are made of paper, board, regenerated cellulose, plastic film or aluminium foil and laminates of these materials. They may be printed, varnished, glued, made into boxes or otherwise converted.

This code includes, for example, the preparation of inks, varnishes and adhesives, the extrusion of plastic film and metallising of paper and plastic film, in so far as these activities take place at the converter's premises.

## **2. Definitions**

ADI: Acceptable daily intake

BfR: Bundesinstitut für Risikobewertung – the German Federal Institute for Risk Assessment

CEPE: Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d' Art. (European federation of the paint and ink making industry)

CEPI: Confederation of European Paper Industries

CITPA: International Confederation of Paper & Board Converters

Contamination: All possible pollution of the finished packaging material, including microbiological contamination, contamination with insects, contamination with foreign substances such as lubricating oil, cleaning agents and waste water or contamination with foreign objects such as glass, knives and razorblades.

Converter: The producer of the packaging materials or cardboard boxes who has adopted this code.

EAA: European Aluminium Association

EFSA: European Food Safety Authority

EUPC: European Plastics Converters

EuPIA: European Printing Ink Association

FACET: Flavourings, Additives and Food Contact Materials Exposure Task

FPE: Flexible Packaging Europe

FDA: Federal Food and Drug Administration (USA)

Fibre-based packaging: Packaging materials made of paper, solid board, corrugated board, carton board and composite materials on the basis of these materials.

Flexible Packaging: Packaging which is supplied in reel or sheet form or as pre-made bags or pouches, which has no volumetric dimension of its own and will form around the product which is to be contained.

Food contact ink: An ink solely composed of substances listed as permitted for direct food contact, permitted as food or as an additive for the food that is to be packed in the packaging material that is to be printed with these inks.

Food product: The food product that is to be packed in the packaging material produced by the converter.

Functional barrier: Any integral layer of a packaging material which under normal and foreseeable conditions of use reduces the migration of non-authorized monomers and additives in plastic layers which are not the food contact layer to below 0.01 mg/kg i.e. 10 ppb. Such substances must neither be classified as proved or suspect "carcinogenic", "mutagenic" or "toxic to reproduction" (see Regulation (EC) No 1272/2008) nor be substances in the nano-form.

HACCP: Hazard Analysis Critical Control Points

ILSI: International Life Sciences Institute

Intended chemical reactions: Chemical reactions that take place in reactive raw materials such as two component inks, varnishes or adhesives when the supplier's instructions for use are followed correctly.

Laminate: A material of two or more layers bonded together by an adhesive or by any other means.

LOI: Level of interest

Multi-material multi-layer: Packaging material which consists of more than one layer of more than one material such as plastic, aluminium, paper or board.

Nano-form: The EU Commission is currently working on a harmonized definition.

NIAS: Non intentionally added substances (contaminants including degradation and reaction products)

NOAEL: No observed adverse effect level

OML: Overall Migration Limit generally expressed in mg/dm<sup>2</sup> of food or food simulant.

Packaging material: The packaging produced by the converter intended for the packing of food.

Principle of mutual recognition: The EU principle that a product that complies with the national legislation of one Member State must be permitted to circulate freely in any other Member State, even though it does not comply with the legislation of that Member State, unless it can be demonstrated that it represents a danger to public health. Detailed information on the principle can be obtained from the European Commission website (DG Enterprise and Industry).

QM: Maximum permitted quantity of residual substance permitted in a material or article. Expressed in mg/kg of finished packaging material.

QMA: Maximum permitted quantity of residual substance permitted in a material or article. Expressed in mg/ 6 dm<sup>2</sup> of finished packaging material.

Raw materials: All materials or intermediate products bought by the converter that are needed for the manufacture of the packaging material.

Repeat order: Customer order for a packaging material with a required performance and technical specifications that are identical to those of a previously produced packaging material for the same customer.

Required performance: The whole of all functional requirements that the packaging material must be able to meet.

Residual solvent: Small amount of solvent that remains in dried layers of ink, varnish or adhesive. Generally expressed in mg/m<sup>2</sup>.

SCF: Scientific Committee on Food. The role of this former EC committee has now been taken by EFSA panels – notably Food additives and nutrient sources added to food (ANS) and Food contact materials, enzymes, flavourings and processing aids (CEF)

SML: Specific Migration Limit generally expressed in mg/kg of food or food simulant.

TORC: Threshold of Regulatory Concern for human health, generally expressed µg/person/day.

Traceability: The possibility to retrieve reliable information with regard to composition, production methods, storage, shipment and other relevant features on packaging materials, their intermediate products and the raw materials that were used for their production. With this information the cause and extent of possible failures in the production and distribution chain and in the use of the packaging materials can be found whenever necessary.

TTC: Threshold of toxicological concern

Unintended chemical reactions: Chemical reactions that are not intended reactions or known expected side reactions, and reactions that take place where none was intended at all.

### 3. Objectives

#### 3.1 Food safety objectives

In line with Art. 3 of Regulation (EC) No 1935/2004 the objectives of this Code for Good Manufacturing Practice are to assure, under normal and foreseeable circumstances of use of the packaging material:

- the prevention of health hazards that may result from excessive migration of components of the packaging material into the packaged food product
- the prevention of unacceptable changes in the composition of food, for example by specifying the OML as a measure for the inertness of the plastic packaging material
- the prevention of unacceptable changes in the organoleptic characteristics of the food

Explanatory note: This environmental objective may be regarded as anomaly in this code, as it is not aimed at consumer protection. It is, however, included for practical reasons. Compliance with several of the essential requirements demands a strict control of the design process of the packaging material and the composition of the raw materials. This is also the case for the food safety objectives. Inclusion in this code prevents the need for an additional system of control.

#### 3.2 Environmental objective

The environmental objective of this Code for Good Manufacturing Practice is to assure the necessary contribution of the converter to the attainment of compliance with the essential requirements for packaging materials that result from the EU Packaging and Packaging Waste Directive (94/62/EC), as amended, as well as the harmonized European standards EN13427, EN13428, EN13429, EN13430, EN1343 1, EN13432.

## **4. Method**

### **4.1 Preliminary remarks**

The principal method by which the objectives of this Code for Good Manufacturing Practices are to be achieved is 'Designing the packaging material for compliance'.

'Designing' refers to all the decisions that need to be taken with regard to the final structure of the packaging material and the production techniques that are to be employed.

'Compliance' means compliance with legislation or official standards that cover the objectives of this GMP, and where these are incomplete or lacking, conformity with the best available guidelines and recommendations that fill the gaps.

'Designing the packaging material for compliance' means that the combination of:

- the choice of substrates
- the choice of other raw materials
- the composition of laminates
- the application of inks, adhesives, varnishes and other coatings
- the choice of the production techniques
- and the geometrical design (e.g. surface/volume ratio especially for infant foods)

will be such that protection against migration, organoleptic changes and contamination and compliance with the essential requirements are, as it were, 'built into' the finished product.

### **4.2 Design for compliance**

The converter will develop the products according to the principles of 'design for compliance'. All developed packaging materials will:

- be Fit-For-Use in accordance with its foreseeable applications and meet the required performance (see 4.3).
- meet the requirements for migration as described in chapter 5.
- meet the requirements on organoleptic properties as described in chapter 6.
- avoid contamination as described in chapter 7.
- meet the essential requirements regarding the Packaging and Packaging Waste Directive 94/62/EC and related standards as described in chapter 8.

### **4.3 Required performance**

To allow 'design for compliance', the required performance of the packaging material must be identified clearly during the development phase. In doing so, the following subjects shall at least be covered:

- the nature of the food product
- the surface/volume ratio
- the expected maximum shelf-life
- the filling, sealing and storage methods to be used
- the heating, cooling, sterilisation and pasteurisation processes to which the packaging material and contents may be exposed

The required performance shall, wherever possible, be translated into technical specifications such as permeability, mechanical strength, barrier properties and specific organoleptic tests to be performed.

#### 4.4 Adaptation to customer needs

When the original design of the developed packaging material is adapted to customer needs, the adapted design shall be rechecked in order to assure that the design for compliance remains intact.

To allow the 'design for compliance' to remain intact, the performance required by the customer must be identified clearly. This shall at least cover the subjects as mentioned under § 4.3 'Required performance'.

All customer changes and additions to the originally identified required performance are to be checked against possible interference with the packaging material's original design for compliance.

The required performance, as adapted to customers' needs, shall be translated into technical specifications such as permeability, mechanical strength, barrier properties and specific organoleptic tests to be performed. Both converter and customer are to convince themselves of the correctness of this translation.

Customers will be required to report any changes in the use or requirements of packaging materials that would otherwise be produced as a repeat order. In the case where these changes may affect the required performance, the design shall be rechecked in order to assure that the design for compliance remains intact.

Explanatory note: Many possible changes in the use of the packaging material may necessitate a change in the design. It is most important that the customer reports these changes and allows the converter to recheck the original design, even if, at first sight, the changes seem small and of limited relevance.

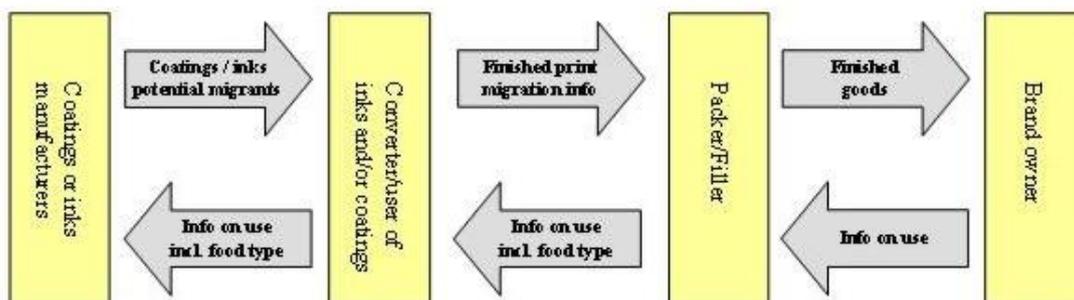
Translation of the required performance into technical specifications can be done by either the converter or the customer.

#### 4.5 Information flow along the supply chain

A suitable flow of information must be secured along the entire supply chain of raw material supplier, converter, packer/filler and food producer/brand owner so that the packaging can be designed for compliance.

At the example of coatings/printing inks a typical information flow process is described in the figure below.

#### Information flow along the supply chain



#### 4.6 Development constraints

When developing packaging materials, the following will also be taken into account:

- Only inks certified for direct food contact may be used on the food contact surface of the packaging material.

**Explanatory note:** Food contact inks are used very rarely. In some EU Member States, even the use of 'food contact ink' is not at all allowed in direct contact with the food.

- Transfer of substances from the printed surface to the food contact side shall not take place through the substrate or by set-off in the stack or reel in concentrations that lead to levels not in line with the requirements of Regulation 1935/2004/EC (Art. 3).
- The choice of substrates, inks, varnishes, lacquers, other coatings and adhesives should be based on the recommendations of the raw material suppliers and applied under the recommended conditions.
- The production process and specifically the preparation of all inks, varnishes and adhesives and the drying conditions on production machines, are to be specified in such a way that:
  - all materials are compatible and cannot undergo unintended chemical reactions
  - in the case of intended chemical reactions, these reactions cannot give rise to potentially hazardous by-products
  - in the case of intended chemical reactions, these reactions are completed so as to prevent residual reactants giving unacceptable set-off or migration
  - the level of residual solvents in inks, varnishes and adhesives will be such that it will not give rise to unacceptable organoleptic changes, unacceptable set-off or unacceptable migration
  - the extrusion of plastic film cannot give rise to unintended chemical changes to the plastic.
- In coordination with the European Federation of the Food and Drink Industries (CIAA), FPE developed a guideline for its members on the use of isocyanate based adhesive laminates to give members explanations as to why curing times are necessary and to provide guidance to ensure that the migration of primary aromatic amines meets the limit. This document can be downloaded from the FPE website [www.flexpack-europe.org](http://www.flexpack-europe.org)

**Explanatory note:** The converter will take all reasonably feasible measures to avoid unintended chemical reactions. These can include

- informing suppliers as to how materials are to be combined, e.g. adhesives/inks/solvents
- controlling the mixing of 2 component systems
- controlling processes to meet supplier recommendations to ensure intended reactions proceed to completion.

Known/expected side-reactions in two-component systems are not unintended chemical reactions in the context of this paragraph.

## 5. Migration

### 5.1 Achieving the objective

The objective of prevention of health hazards that may result from migration is achieved by:

- Continuous and full compliance of the packaging material with all relevant Food Contact Legislation or, where this is lacking or incomplete, with the best available guidelines and recommendations that fill the gaps, and
- Applying the above to each of the separate components of composite packaging materials, where legislation covering composite materials is lacking or where an efficient functional barrier cannot be demonstrated.

The converter shall thus ensure that the Overall Migration Limits, as well as the Specific Migration Limits and other limitations when applicable, are fully respected. This shall be attained by either:

- obtaining and verifying information received from supplier about the compliance with specific restrictions, or
- controlling or verifying the composition of the raw materials, or
- controlling or verifying the migration features of the raw materials, or
- the use of functional barriers, or
- testing directly the intermediate or finished products.

Explanatory note: Most flexible and fibre-based packaging materials are composed of more than only plastics and are therefore not fully regulated by a specific EU or national legislation.

As a result, there are, at present, many cases where there are no clear rules by which the converter can abide. In such cases, this code resolves the issue by demanding compliance with food contact legislation separately of each individual component of the composite material.

This code therefore goes beyond existing legislation. In doing so, it ensures that the converter is taking all measures possible to fully control the composition of food contact materials, and thus ensure the highest degree of consumer protection.

It is often impractical to carry out an assessment of compliance with migration limits (either overall or specific) for each and every finished product manufactured by the converter. The logistical consequences would otherwise be prohibitive, in view of the fact that the flexible packaging industry as a whole produces many tens of thousands of individual packaging materials. However, the decision not to test or otherwise assess the migration has to be justifiable in the context of protecting consumer health and safety. The two principal approaches which can be used, either separately or together, are:

- the "Family Approach", whereby all the products within a suitably defined product family, are considered to comply with the restrictions applicable to them, upon evidence that an appropriate selection of individual samples complies with those restrictions by a sufficiently wide margin; and
- the "Building Blocks Concept", whereby evidence of compliance with applicable restrictions for a number of products, or parts of them, leads to the conclusion that other products made by different combinations of identical or similar components or raw material grades, can be considered to comply with those restrictions too.

The considerations made by the converter in applying the above concepts, should become part of his documentation supporting the compliance status of his products.

Explanatory note: "Family Approach". For multi-layer materials there is no single "worst case" material that represents the ideal testing sample: a thin direct food contact layer is the worst case for the contribution to migration from the other layers, while a thick direct food contact layer is the worst case for the migration from that layer itself. There is a continuum of possible thickness combinations and it cannot easily be predicted which will give the highest migration.

Additionally, consideration needs to be given to the fact that countless numbers of multi-layers are put on the market so that it is not practical to test each and every one of them.

Therefore compliance work focuses on relevant samples, instead of testing every product or looking for a non-existent "worst case" sample.

To reduce the number of samples to be tested to a manageable number, the business operator manufacturing materials and articles will look for similarities in product formulation to justify naming one or more individual products out of a larger group (the "product family") as the relevant samples for that group. The precise details of these considerations are impossible to describe in full detail, as ultimately they will depend on the range of components used by the manufacturer, on his product portfolio, on the various processes used in manufacturing, on the types of end use applications, etc. These considerations, therefore, are part of the manufacturer's supporting documentation. Nevertheless the following guiding principles on defining product families can be specified:

For OML it is recognised that the overall migration is mainly driven by the direct food contact layer; therefore:

- 1) The primary consideration is the nature of the direct food contact layer. If that is a type of plastic having a wide range of possible formulations, such as for polyolefins, then it will be necessary to distinguish between the many sub-types e.g. LDPE, LLDPE, PE/acid-copolymer, OPP, cast pp homo polymer, cast pp copolymer, etc. If the direct food contact layer has a more defined composition, such as for PETP, CPET, PA6 etc., then it will be sufficient to consider those generic groups.
- 2) The layers behind the direct food contact layer are of secondary importance and it is sufficient to consider them on a generic level: PE, PP, PET, PA etc. except when the direct food contact layer is very thin (e.g. 5 microns or less).
- 3) Layers on the outside of a functional barrier can be ignored in sample selection.
- 4) Low migration inks and varnishes as defined by EuPIA are of no relevance to sample selection.
- 5) Chemically cured adhesives are of no relevance to sample selection.
- 6) Layer thickness of the direct food contact layer will be considered in proportion to the margin between the overall migration test result and the OML.
- 7) Layer thickness of an outer layer will only be considered if there is an order of magnitude difference or more, e.g. 15 $\mu$  OPA vs. 200 $\mu$  cast PA.

For SML:

- 8) The primary consideration is the nature of the layer or layer component in which the substance with SML is present. The nature of that layer or layer component has to be considered to the same degree of detail as for OML in point 1.
- 9) The nature of any layer(s) separating the layer or layer component containing the SML substance from the food, in which this SML substance is not present, can be considered on a more generic level.

- 10) Layer thickness, both for the layer containing the SML substance as for the intervening layer(s) if any, will be considered in proportion to the margin between the migration test result and the migration limit.
- 11) In case of functional barrier properties present within the multi-layer material or article, set-off and other ways of transfer to the food contact layer should be considered.

Explanatory note: "Building Blocks Concept". Having followed the principles of family approach, the business operator may establish compliance of several product families which are related in that they share certain components. The "building blocks concept" then states that the conclusion of compliance can be extended to certain other product families made from different combinations of those same components.

Example: tested product families are e.g. OPP/PE, PET/PE, OPP/PP and OPA/PP. Then according to the building blocks concept, structures such as PE/PP and OPA/PE would also comply.

It is understood that this applies to OML and that bringing a non-direct food contact layer - OPP, PET or OPA in the example above - to the direct contact position is excluded. The reverse, of course, is no problem; PP/PE could be included in the example above as a valid combination.

## 5.2 Legislation

Where food contact legislation for the packaging material or for separate components of composite packaging material exists, this is complied with in the following order of preference:

- EU legislation on food contact and national legislation resulting from the transposition of EU legislation.
- Where EU food contact legislation is found incomplete, national legislation of EU Member States. The national legislation that will be complied with is to be determined on a case by case basis, taking into account the following:
  - The Member State where the converter is established
  - The Member State where the product is packed
  - The Member States where the packed product is to be marketed
  - Appropriateness of the available legislation
  - The principle of mutual recognition

Explanatory note: Where the packaging material is produced in the same Member State as where the product is marketed, obviously the legislation in that Member State shall be complied with. However, where packaging materials are manufactured in one Member State and the product is marketed in one or more other Member States, the situation is not as simple; national legislations differ. Legally this should not pose a problem; any product legally marketed in one Member State can also be legally marketed in any other Member State. In practice this principle is not always easily recognised by national authorities. The converter's customers therefore prefer to avoid situations, where it is necessary to resort to legal arguments to obtain acceptance of a packaging material. This implies that, in some cases, the National Legislation that is to be complied with needs to be chosen with an eye for easy acceptance in the Member State where the product is to be marketed. Since, in many cases, converters do not have the information where the packed product is to be marketed, customers have to provide this information. In situations where EU food contact legislation is found incomplete, but no practical problems with mutual recognition need to be expected, preference is given to compliance with either with the national legislation of the EU Member States where the converter is established or with the national legislation from yet another Member State if this legislation is more appropriate.

### 5.3 Non-EU legislation and other guidelines or recommendations

Where EU and national legislation of Member States are found incomplete, reference can be made to the following for compliance purposes:

- Opinions of the EU Scientific Committee on Food (SCF) and EFSA
- National recommendations (e.g. BfR)
- Non-EU national legislation (e.g. FDA or Swiss Ordinance)
- Council of Europe Resolutions
- Relevant and, where possible, officially recognised industrial policies and standards established by European trade associations, such as the CEPE/EuPIA GMPs and exclusion lists, the EuPIA Guideline on Printing Inks Applied to the Non-Food Contact Surface of Food Packaging Materials and Articles and the EAA GMP for aluminium alloy semi products intended to come into contact with foodstuff.

Guidance for which specific materials might be affected by these sources is given in the template for a declaration of compliance issued by FPE.

### 5.4 Non regulated substances

In some cases, substances used in raw materials for flexible packaging may not be covered by any of the legislation, guidelines or recommendations mentioned in § 5.2 and § 5.3.

In those cases, confirmation shall be obtained from the supplier that he has identified and made a safety assessment of the non regulated substances, in order to avoid the exposure of consumers to migrating substances at levels that could potentially pose a risk to consumer health. However, the converter may implicitly assume the supplier has carried out any such safety assessment necessary, when he has declared his product complies with Regulation 1935/2004.

In the event that the converter is involved with the safety assessment for non-regulated substances carried out by his supplier, he has at his disposal a number of tools to establish the appropriate safety of the substances used in the applications envisaged, for example:

- details about the evaluation and/or authorization by a competent authority, or a scientific panel associated with it, of that substance in a field of application not strictly related to food contact (example: direct food additives)
- the functional barrier concept as laid down in Regulation (EU) 10/2011, but applied also to layers which are not plastics. The functional barrier need not be a specific layer, but can be considered an effect which reduces the migration of the substance to less than 10 ppb when tested with an appropriate technique

**Explanatory note:** This extended interpretation of the functional barrier concept overlaps with the Threshold of Regulatory Concern (see below) and with the "no-migration" principle as known under FDA.

- The substance is not transmitted to the food in excess of a Threshold of Regulatory Concern (TORC) that is recognised by either the EU or the Council of Europe
- the Threshold of Toxicological Concern (TTC) as recommended by ILSI Europe, in combination with a sufficiently conservative estimation of consumer intake of packaged food with the migrant under consideration

Explanatory note: The EU at present does not officially recognise a Threshold of Regulatory Concern, or at least not that terminology, however implicitly this is part of the functional barrier concept. In summary, it may be said that the TORC is a threshold on migration, while the TTC is a threshold on exposure. TTC therefore requires information about the exposure of the consumer on a more refined level than the standard EU "6 dm<sup>2</sup> cube" model. Information about the exposure of consumers to specific packaging materials is existing (Plastics Europe "Exposure Matrix" project) and will be refined to substance level in the "FACET" project under the EU's FP7 programme. It is important that in using exposure considerations, converters use recognised datasets and methodologies for handling them. At present the ILSI "TTC" is not a single value as it was in the past (1.5 µg/person/day). Rather they are proposing a tiered approach based on Cramer structural classes. See the 2005 ILSI Monograph on TTC for more details and a decision tree on how to apply these concepts.

- for substances with known toxicology, a refined exposure estimate demonstrating compliance with an established ADT (acceptable daily intake) or, with a suitable safety margin (factor 1000), a relevant NOAEL (no observed adverse effect level)
- calculations on quantitative structure activity relationship (QSAR) as can currently be carried out by scientific institutes
- targeted toxicological investigations, possibly in conjunction with exposure considerations as outlined above

The converter shall apply any of the above approaches to establish the safety of non-regulated substances he intentionally uses on his own initiative.

These methodologies may also be used to investigate the safety of not-intentionally added substances (NIAS) when these pose any safety concern. The converter is not expected to proactively look for NIAS substances in his products. However, when he becomes aware of the presence of potentially harmful substances, he has a "duty of care" to prevent harm to the consumer. Since NIAS substances are most often already present in the raw materials used (example: impurities) or are generated in the normal use of raw materials (example: breakdown and reaction products), a logical first step in their safety assessment would be to contact the supplier since he has the primary responsibility over the safety of these substances.

Explanatory note: When the NIAS substance has been clearly identified, the above methodologies may all be appropriate. In those cases where the NIAS substance cannot be identified to a sufficient level of certainty, reference can be made to the "level of interest" (LOI) concept as established in the Plastics Europe "Exposure matrix" project. The LOI is a threshold of no concern on migration, but based on the use of materials rather than the exposure of the individual substance.

At this moment it is not politically accepted, and it is therefore not recommended, to apply concepts of refined exposure estimates to assessing compliance for substances regulated as monomers and additives for plastics. This may however become relevant when, in the case of an established non-compliance, the question is raised whether or not there is a real threat to consumer health and safety.

## 5.5 Export outside the European Union

Where packaging materials are 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.

Where deviation is unavoidable, conformity is sought with the most appropriate of the following, in order of preference:

- National legislation of the importing country (to the extent that information in support can be obtained from suppliers)
- FDA regulations
- Any other regulations as specified by the customer.
- Industry standards as specified by the customer.

In the common case where a packaging material can be declared to comply both with EU and FDA regulations, the converter can have sufficient reassurance that his product does not harm the consumer, even if it is in conflict with national legislation of the importing country.

### **5.6 Imports into the European Union**

Importers into the European Union are obliged to follow the same legislative requirements concerning Good Manufacturing Practices and food contact compliance as any other European company doing business within the EU.

## 6. Organoleptic changes

### 6.1 Achieving the objective

The objective of prevention of unacceptable changes in the organoleptic characteristics of the food that may result from the release of components from the packaging material or the withdrawal of components from the food by the packaging is contributed to by the converter by either:

- using raw materials that are certified or known from previous experience by the converter to be organoleptically inert for the specified food and specified use of the packaging material, or
- by testing the finished or intermediate products appropriately for the specified food and specified use of the packaging material.

The objective of consumer protection against organoleptic changes has to be achieved jointly with the customer who is to assure that the combination of packaging material and food is suitable for the intended purpose and is only used as specified.

Explanatory note: The prevention of organoleptic changes cannot be obtained by the use of appropriate materials and production techniques alone. Deviations from the specified use for which the packaging material was satisfactorily designed or tested, may unexpectedly result in organoleptic changes.

This code assures that the converter produces packaging material which, under specified and controlled circumstances, will not give rise to organoleptic changes. The customer must, however, also contribute by preventing the use of the packaging material in circumstances other than those specified.

## **7. Contamination**

### **7.1 Achieving the objective**

The converter contributes to the prevention of health hazards and organoleptic changes that may result from contamination of the packaging material by:

- Maintaining strict hygienic standards for production personnel
- Maintaining strict hygienic circumstances in factories, warehouses and during transportation
- Identification and control of potential sources of contamination during the production processes, storage and transportation
- Identification of raw materials that are potential sources of contamination and control of the composition and use of these materials.

<p><u>Explanatory note:</u> Consumer protection against contamination cannot be obtained by the converter alone. This code however assures that the converter produces packaging material that in itself is not contaminated.</p>
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## 8. Essential requirements

### 8.1 Achieving the objective

The CEN standards related to the essential requirements are: EN13427, EN13428, EN13429, EN13430, EN13431, EN13432. The converter contributes to the objective of compliance with the essential requirements for packaging materials that result from the EU Packaging and Packaging Waste Directive 94/62/EC (as amended) by:

- Implementing customers' obligations concerning the realisation of designing the packaging material for minimum adequate weight and volume within the constraints imposed by the required performance and technical feasibility.
- Within the constraints imposed by the required performance and other customer demands; designing the packaging material such that its material can be recycled or, where this is not possible, designing the packaging material such that it exceeds the minimum caloric value necessary for efficient incineration with energy recovery, or that it can be recovered in the form of composting, or that it can be biodegraded.
- Avoiding the use of raw materials that contain toxic heavy metals as mentioned in the Directive over their maximum concentration levels.
- Avoiding the use of raw materials that contain substances that can give rise to noxious or hazardous emissions, ash or leakage when the waste of the product is incinerated or disposed of in landfill.

Complying with the limits on heavy metals and eco-toxic substances is adequately achieved by obtaining the appropriate certificate from the raw material suppliers.

Explanatory note: The above includes all the essential requirements mentioned in Directive 94/62/EC (as amended) that practically may apply to flexible and fibre-based packaging materials. This means that the essential requirements that are specific to reusable packaging have not been included.

Explanatory note: Compliance with the essential requirements cannot be attained by the converter alone. Minimum weight, minimum volume and recyclability can only be attained in so far as this is possible within the constraints imposed by the required performance and other customer demands. Also noxious or hazardous emissions during incineration can only be avoided with certainty if the incineration takes place under well controlled circumstances.

Explanatory note: This GMP is only aimed at flexible and fibre-based packaging materials that are intended to get into contact with food. These can presently only be recycled, composted or biodegraded in exceptional cases. The possibilities mentioned in this section of designing the packaging material such that its material can be recycled, recovered in the form of composting, or that it can biologically degraded are included mainly with an eye for the future.

Explanatory note: The responsibility for the essential requirements that are related to the converters' transport packaging needs to be considered.

### 8.2 Legislation, standards, guidelines, recommendations etc.

Legislation, standards or voluntary agreements concerning essential requirements are complied with in the following order of preference:

- Directive 94/62/EC (as amended)
- CEN standards related to the essential requirements
- National legislation or national voluntary agreements, where the legislation or agreement that is to be complied with is to be determined on a case by case basis, taking into account the following:
  - The Member State where the converter is established
  - The Member States where the food product is to be marketed

- The principle of mutual recognition and Art. 18 of Directive 94/62/EC (as amended)
- National standards

Explanatory note: Art. 18 of the Packaging and Packaging Waste Directive states: 'Freedom to place on the market: Member States shall not impede the placing on the market of their territory of packaging which satisfies the provisions of this directive'. Since in many cases converters do not have the information where the packed product is to be marketed, customers have to provide this information.

## 9. Raw materials

### 9.1 Purchasing and requirements

The purchasing of all raw materials shall be kept under strict control. All raw materials shall be purchased only from suppliers who employ quality assurance systems and GMP that meet the requirements of section 12.3. For materials purchased by the converter, the suppliers shall be required to:

- meet an agreed specification (as distinct from “typical” data sheet values)
- assure complete traceability of the composition and the production method of these materials and intermediate products as well as the origin of the components.

Explanatory note: Traceability in combination with quality assurance is an important feature in this GMP. It not only assures that the cause of possible mishaps can be found and remedied, but it also enables converters and their customers to rely on the previous steps in the production chain. Raw materials and their ingredients should be traceable up to the point where, for the first time in the production chain, the material is earmarked to be used for food packaging. At this point in the chain, it should be made certain that the material is indeed fit for this purpose by an appropriate method. The current FPE traceability guideline can be downloaded from the FPE website.

- certify compliance with applicable legislation, recommendations and standards.

Explanatory note: the converter should inform the supplier which legislation is relevant whenever this is not self-evident or the information received does not match the expectations.

- where a change in legislation, recommendations or guidelines, or alternatively a change in formulation, may influence the regulatory status of the raw material or packaging material made with that material, inform the converter of this change.
- identify all components that have been allocated an SML, QM or QMA.
- identify and quantify all components that are regulated as direct food additives or flavourings.
- certify that the material meets the compositional requirements of the Packaging Waste Directive with regard to heavy metals and substances dangerous to the environment.
- ensure that during production, handling, storage and transportation of the raw material it does not become contaminated and maintains its required quality.

The converter should aim to use raw materials for which the supplier provides information that is helpful in assessing the compliance with restrictions or specifications applicable to the raw material or the finished product.

### 9.2 Verification of migration requirements

In the compliance assessment for his finished product, the converter may use information provided by his suppliers about the compliance of raw materials with applicable restrictions. Care shall be taken that the conditions considered by the supplier match those that are relevant to the converter. These supplier assessments shall be performed by either:

- suitably designed tests in food simulants, or
- verification of the maximum permitted quantity of a substance in the material which correspond to the migration requirement, where the relation between quantity and migration has been established by adequate experimentation, or

- verification of the composition of a raw material which is known to comply with migration requirements and of which the relation between the composition and the compliance with migration requirements has been established by adequate experimentation, or
- the use of applicable and generally recognised diffusion models.
- worst case calculation assuming 100 % transfer of a substance from the food contact material.

Testing procedures must be in accordance with the relevant EU legislation and guidelines (most notably in matching test conditions to conditions of use). They will preferably follow the relevant CEN standards when available, such as for overall migration and a limited number of monomers in the case of specific migration (EN 1186 series and 13130 series). Alternative testing methods that are known to be reliable and to lead to the same results may also be used.

Explanatory note: The use of alternative testing methods is in line with Directive 97/48/EC as specified in Chapter IV. The use of 'extraction tests' may be particularly useful as results can be obtained much more quickly than with the conventional migration tests. They also may have particular relevance for materials that are not plastics. Such tests may be used if they are generally recognised, on the basis of scientific evidence, to produce results that are equal or higher than those obtained with the equivalent official test.

Where relevant CEN standards are not available for testing for Specific Migration, the testing shall be demonstrated to have taken place with an appropriate analytical technique.

Where purchased materials, such as 2-component adhesives, are intended to react chemically, the supplier's certification of migration requirements will apply to the resulting material after the intended reaction.

Explanatory note: Of course the supplier of chemically reacting components is not responsible for the actual use of the product by the converter. Certification of compliance is therefore only asked after the reaction as intended by the supplier. It is up to the converter to assure that the actual reaction indeed takes place as intended by the supplier.

In cases where materials need to be purchased from a supplier who cannot provide evidence of compliance with all relevant migration requirements, the supplier shall be required to provide the converter with all information necessary to enable verification of compliance with the migration requirements by or on behalf of the converter.

### **9.3 Recycled plastic**

Recycled plastics have to comply with Commission Regulation (EC) No 282/2008. However, this regulation does not apply to the following materials:

- i. recycled plastics used behind a functional barrier, as specified in Regulation (EU) 10/2011
- ii. Offcuts and scraps from the production of plastic food contact materials that have not yet been in contact with food and which are recycled within the manufacturing site or at another site where an audited quality assurance system is in place

## 10. Production

### 10.1 Manufacturing

Explanatory note: This code is meant to be hooked on to an existing quality assurance system. Such a system must be in place before this code can be applied. This means that it must be possible to rely on the technical processes in the converter's plant to produce packaging materials in conformity with their specifications. For the purpose of this code, it is therefore not necessary to describe in any detail how the production processes should be kept under control.

The manufacturing processes will be kept under strict control with the help of a quality assurance system. The control and quality assurance system will be such that it is assured and documented that the packaging material which is produced answers to the technical specifications that apply to it and that these technical specifications are in conformity with the design of the packaging material.

If necessary, the quality assurance system will be adapted in order to pay sufficient attention to subjects that are more important to the attainment of the objectives of this code than the attainment of the desired technical and aesthetic properties of the packaging material, such as:

- Traceability and therefore the use of the dedicated raw materials and proper record keeping during the production processes, and keeping track of intermediate and finished products till they reach the customers warehouse
- Correct setting of production parameters on production machines such as drying temperatures and reel tensions
- The control of migration or set-off by consulting suppliers for presence of migratable substances
- Chemical reactions to take place as intended.

Potential sources of contamination during manufacture shall be identified and analysed. Where necessary, appropriate measures will be taken to prevent contamination. These measures are to include:

- the control of pests, insects and rodents
- the systematic cleaning of production departments and the maintenance of strict hygienic circumstances in these departments
- the removal of materials from previous use from all equipment used for the preparation of inks, coating or adhesives and from all production machinery such as presses, laminators and varnishing machines before starting the next production run.

### 10.2 Personal hygiene

Explanatory note: This code does not prescribe any particular method of hygienic control or quality assurance. It is meant to fit within existing control systems. The ISO 9000 series and industry specific hygiene systems, such as CEN standard 'EN 15593 Packaging – Management of Hygiene in the Production of Packaging for Foodstuffs', the BRC/IoP 'Global Standard - Food Packaging and Other Packaging Materials' are examples of widely recognised systems to ensure hygiene within production facilities, or any other national or industry standard which as a minimum meets the CEN standards requirements.

Strict hygienic standards will apply to production personnel. These standards shall at least include:

- dress
- the behaviour in case of infectious diseases

- personal cleanliness
- procedures regarding the maintenance of sanitary facilities
- prohibitions on keeping or eating food and smoking in production areas

### **10.3 Warehousing and transportation**

Potential sources of contamination during warehousing and transportation shall be identified and analysed. Where necessary, appropriate measures shall be taken to prevent contamination. These measures are to include:

- the control of pests, insects and rodents
- the systematic cleaning of warehouses and means of transportation
- the maintenance of strict hygienic circumstances in the warehouses and during transportation
- the use of appropriate transportation packaging
- the training of drivers and fork lift truck operators in hygiene awareness
- the avoidance of mixed commodity loads on the same vehicle

Raw materials and packaging materials are identified, labelled and referred to in all documents in such a way that traceability is continuously assured. Food packaging material which cannot otherwise clearly be identified as such shall be labelled with appropriate text or with a special symbol (drinking glass and fork) according to Art. 15 of Regulation (EC) No 1935/2004. At the marketing stages the information shall be displayed on the accompanying documents or the labels or packaging or the materials and articles themselves. The information required shall be conspicuous, clearly legible and indelible.

Unless otherwise specified, raw materials are used on a first in first out basis and packaging materials are sent to the customer on a first in first out basis.

Certified and tested raw materials and packaging materials shall be clearly identified and be kept separate from other raw materials and products. Raw materials or packaging materials waiting for certification or testing shall be quarantined until approval or rejection.

Segregation shall be provided for the storage of rejected, recalled or returned raw materials or packaging materials.

Conditions during storage and transportation are such that deterioration of raw materials and packaging materials is prevented as much as possible.

## **11. Quality Assurance**

### **11.1 Converter quality assurance system**

The converter shall maintain a quality assurance system capable of assuring the attainment of the objectives of this code.

The converter's quality assurance system shall be audited and certified periodically by an independent body.

The converter's quality assurance system will be such that it can be verified by or on behalf of the customer, in order to check compliance with this Code for Good Manufacturing Practices.

### **11.2 Laboratory quality assurance system**

Laboratories which carry out migration tests and tests related to hygienic control or to essential requirements shall maintain an appropriate quality assurance system.

### **11.3 Supplier's quality assurance system**

The suppliers shall maintain a quality assurance system capable of assuring GMP and compliance with the requirements as listed in chapter 10 (Raw materials).

The supplier's quality assurance system shall be audited and certified periodically by an independent body.

Where this is not the case, the supplier's quality assurance system shall be verified by, or to the satisfaction of, the converter before first delivery and periodically.

### **11.4 Subcontractor's quality assurance system**

The converter shall only subcontract the manufacture of flexible and fibre-based packaging materials to converters that work in accordance with this or an equivalent Code for GMP and that have a quality assurance system in place capable of assuring this.

The subcontractor's quality assurance system shall be audited and certified periodically by an independent body. Where this is not the case, the subcontractor's quality assurance system shall be verified by, or to the satisfaction of, the converter before first delivery and periodically.

### **11.5 Continuous compliance**

Procedures will be in place to anticipate changes to legislation, guidelines and recommendations etc. with regard to food contact and essential requirements and to assure that these changes once in effect will find their way into all the relevant documents used for purchasing, manufacturing, etc.

These procedures will cover the legislation, guidelines and recommendations mentioned in:

- § 5.2, Migration: Legislation
- § 5.3, Migration: Guidelines and recommendations, and
- § 8.2, Essential requirements: Legislation, standards, guidelines, recommendations, etc.

Procedures will be in place to assure that:

- packaging development engineers will regularly consult the available documentation to keep themselves informed on the most recent legislation, guidelines, recommendations etc with regard to food contact and essential requirements.
- packaging development engineers will regularly consult the available documentation to keep themselves informed on the most recent insight with regard to organoleptic changes.
- in the case of changing legislation, guidelines and recommendations, existing packaging specifications and designs are checked for continued compliance.
- all changes find their way into all the relevant documents used for purchasing, manufacturing etc.
- all changes trigger an update of regulatory status of the products

### **11.6 Procedures in case of failures at any stage.**

Complete traceability of the flexible and fibre-based packaging materials produced must be assured.

Where flexible and fibre-based packaging materials have been produced, that may have undergone an unintended chemical reaction, produced excessive set off or are in some other way not up to standard, these materials will be clearly identified and segregated.

Where these materials cannot be reworked, they will be rejected and disposed off in a controlled way, and in accordance with the national regulations.

A procedure shall exist which enables the converter, in the event of a failure at any stage of the process or a complaint, to find the cause, rectify the problem, and if necessary make the appropriate improvements to the manuals or other controls to prevent a repetition

### **11.7 Declaration of compliance**

A written declaration of compliance shall be provided to the customers for all packaging materials upon delivery of the first batch that is produced after all test phases have been concluded. An authorized manager of the converter shall sign the declaration.

In the case of repeat orders, the declaration shall be provided upon the customers' request.

Explanatory note: Neither Regulation (EC) No 1935/2004 nor Regulation (EU) 10/2011 explicitly say in which cases a declaration of compliance has to be provided (for each and every delivery; repeat orders etc.). Therefore, the converter has to decide on his own whether he sends a certificate with each delivery, whether he makes the documentation available via a web link or in another appropriate way. The best procedure should be mutually agreed upon between supplier and customer.

The declaration of compliance shall be in accordance with Article 16 of Regulation (EC) No 1935/2004 and contain the information laid down in Annex IV of Regulation (EU) 10/2011.

The written declaration shall permit an easy identification of the materials, articles or substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.

The FPE template for a declaration of compliance can be used in order to identify the relevant legislation or standards for the different packaging components.

### **11.8 Supporting documentation**

Appropriate documentation to demonstrate that the materials and articles as well as the substances intended for the manufacturing of these materials and articles comply with the requirements of Regulation (EU) 10/2011 shall be made available by the business operator to the national competent authorities on request. That documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.

Explanatory note: It is not the intention that the converter has a finished document ready for each of his products. The supporting documentation can be compiled, on request for the authorities, from information related to various aspects of this activities.

## **12. Change control**

### **12.1 Changes to the packaging material**

Where in the case of repeat orders, raw materials or production methods will be used by the converter that are different from those in previous production batches, the design of the packaging material shall carefully be rechecked for compliance.

Where such a change in raw materials or production method may affect the compliance status of the packaging the customer shall be informed of the change.

### **12.2 Changes in legislation, recommendations and guidelines (migration)**

Where changes in legislation, recommendation or guidelines as referred to in chapter 5 'Migration' may affect the packaging material the design of the packaging material shall carefully be rechecked for compliance. Where such a change in legislation, recommendation, standards or guidelines may influence the regulatory status of the packaging the customer shall be informed of the change.

### **12.3 Changes in legislation, recommendations and guidelines (essential requirements)**

Where changes in legislation, standards, recommendation etc. as referred to in chapter 8 'Essential requirements' may affect the packaging material, the design of the packaging material shall carefully be rechecked for compliance.

Where such a change in legislation, standards, recommendation etc. may influence the regulatory status of the packaging the customer shall be informed of the change.

## **13. Personnel and training**

### **13.1 Commitment**

The entire workforce, involving all levels of management, shall make a strong commitment to the objectives of GMP and management shall assure that appropriate responsibility, authority and resources are given, understood and applied at each level in the organisation.

### **13.2 Information and training**

All personnel will be informed about the general concept of GMP, its objectives and the policy by which these are attained.

The converter shall establish and maintain procedures for identifying the training needs and provide training of all personnel performing activities which affect compliance with this code of GMP.

Personnel performing specific tasks shall be qualified on the basis of appropriate education, training or experience as required.

Appropriate records of training shall be maintained .