

BRC/FDF and Campden BRI  
Guidance on migration from packaging  
materials into food  
Consultation Draft Only

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# Contents

- Part One - Introduction*
- Part Two - About migration*
- Part Three - Legislative requirements*
- Part Four - Product development*
- Appendices*

**Part One:**

Introduction

Disclaimer

Document Scope

About the authors

## **Introduction**

Welcome to the first edition of the BRC, FDF and Campden BRI joint Migration guideline. This guideline has been developed to provide those with an active interest in the food supply chain with common understanding, terminology, and point of reference for good practice around migration.

This guideline is comprehensive in its approach, outlining what migration is and how it occurs, how it might impact on human health, how it can be avoided through new product or existing product development, and proffering a best practice approach to minimising the risk of migration of harmful substances to food products of all types.

Any and all organisations interested in the delivery of safe food to consumers should use this document, including retailers, brand owners, agents or brokers, food processors, packaging manufacturers and companies providing storage and distribution services.

## **Disclaimer**

This document is for guidance purposes only and in no way replaces any regulatory legislation or other legal guidance documentation. The BRC accepts no liability for the contents of this document, nor how an individual chooses to apply this document.

## **Document Scope**

The document is intended to apply to those activities in the food supply chain, including food processors, manufacturers, packaging manufacturers, converters, packaging specifiers (such as brands owners and retailers) and the intermediary services such as storage and distribution.

## **Excluded from Scope**

Processing, packaging and other handling equipment, e.g. conveyor belts and equipment.

Non-food chain activities (but principles are applicable – e.g. packaging of non-food products, consumer products).

Transient food contact ‘packaging’ materials, e.g. plastic cutlery, paper plates.

Edible and non-edible decorations in contact with food.

## **About the three organisations**

### **About the BRC**

- Paragraph detailing BRC as trade association, and owner of Global Standards.

### **About the FDF**

The Food and Drink Federation (FDF) represents the UK food and drink industry, the largest manufacturing sector in the country. The industry has a turnover of £81.8bn and Gross Value Added (GVA) of £21.5bn. The industry accounts for 15.7% of the total manufacturing sector by turnover and employs around 400,000 people.

### **About Campden BRI**

Campden BRI is a membership-based scientific, technical, legislative and information support to the food, drink and allied industries. Working closely with industry, Campden BRI offers a wide range of analysis and testing services and operational support underpinned by a vigorous programme of research and innovation and promoted through extensive knowledge management activities.

## Part Two:

What is Migration

Migration modelling and testing

What the BRC Standards say

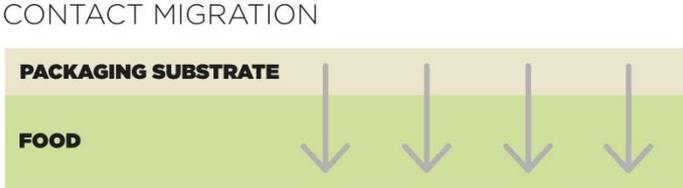
**What is migration?**

In the context of food contact materials (FCM) legislation, migration means the transfer of substances from packaging materials into food. Note that migrating substances can potentially come from packaging substrates, such as for example paper, board or plastics, as well as from packaging components like adhesives, printing inks or coatings used to make up the overall package. It is therefore important to consider the overall packaging material or article. The migration of substances into food will potentially result in non-compliance with FCM legislation (see later).

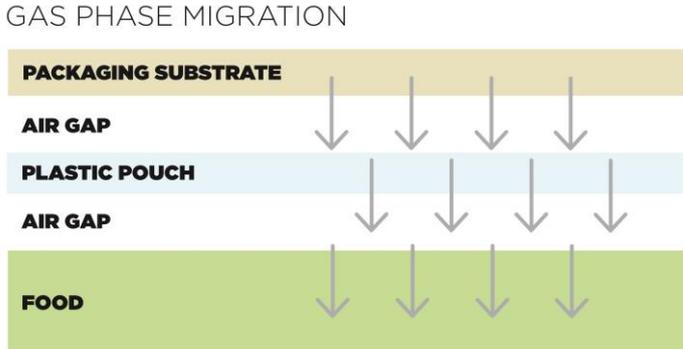
**Types of migration:**

Migration can occur in a number of different ways:

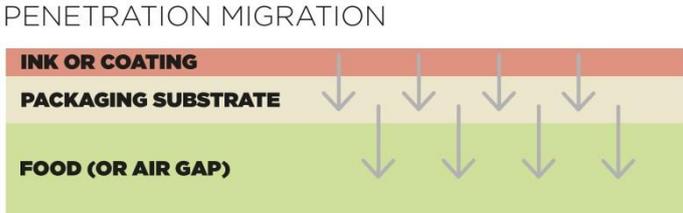
**Contact migration** – involves the direct transfer of substances from the food contact surface of the packaging into the food. Examples might include the transfer of substances from a cardboard pizza box to the underside of a pizza, or transfer of substances from a plastic tub, tray, pouch or wrapping into food.



**Gas phase migration** – involves the transfer of volatile substances through the airspace between food and packaging and into the food by the process of diffusion. A good example might be the diffusion of mineral oil from recycled paper-board, into solid dry foodstuffs. Note that in this case, mineral oil can potentially migrate from the cartons, through an airspace, through a plastic inner pouch (subject to its barrier properties) and through a second airspace into the food.

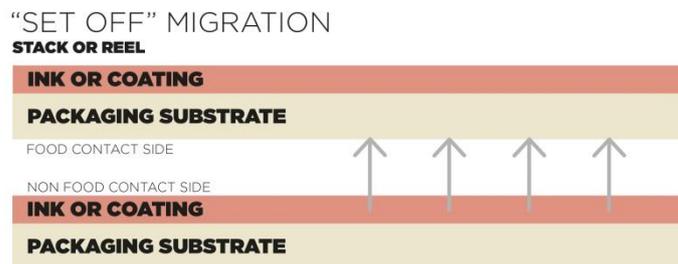


**Penetration migration** – involves the transfer of substances from the non food contact (often printed or coated) surface of the product’s packaging, through the substrate and onto the food contact side of the packaging. Once on the food contact surface, the migrating substances can be transferred to the food by either contact or gas phase migration.

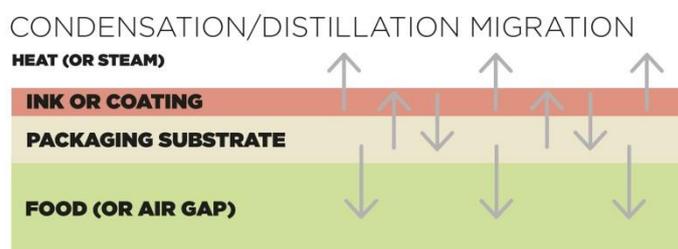


**Set-off migration** – involves the transfer of substances from printing inks, coatings or varnishes from the printed, non food contact side of the packaging to the food contact side, as a result of the stacking of printed items e.g. carton flats, or when winding a printed film into a reel. Note that set-off

migration may be either visible or invisible. Once on the food contact surface, substances arising through set-off can be transferred to the food by either contact or gas phase migration.



**Condensation / distillation migration** – involves the transfer of substances into food during heating processes such as sterilisation or boiling of e.g. pouched food, or oven / microwave cooking of food in cartons or trays. It involves the evaporation of volatile components from the packaging and by steam distillation in the case of moist / aqueous foods.



#### **Factors affecting migration:**

The rate of migration is affected by a large number of factors:

**Molecular size of the migrant** – generally speaking small molecules migrate faster than larger ones. As a rule of thumb, substances with a molecular weight of greater than 1000 Daltons are deemed too large to migrate to any significant degree. (e.g. Benzophenone is a much smaller molecule)

**Temperature** – since migration occurs through physico-chemical processes, it significantly increases with increasing temperature. Typically, little appreciable migration occurs under frozen conditions, other factors may still apply and affect migration activity, such as humidity. Note that both storage and processing, including cooking, temperatures need to be considered.

**Time** – migration is time dependent. A food package which is compliant at the beginning of its shelf life could be non-compliant by the end of its life. (e.g. long-life ambient product)

**Nature / composition of the food** – e.g. liquid or solid? aqueous or fatty? moisture / fat content? granular? particulate? surface area? Note that fatty foods will tend to attract non-polar migrants, while water-based foods will tend to attract polar migrants. Foods with a high surface area to volume ratio are typically more susceptible to migration. (e.g. high surface area – pasta)

**Nature / structure of the packaging** – different substrates differ in their permeability to potential migrants. Metal and glass are considered to be absolute barriers to migration. However, migration from metal containers into foods that may degrade the food contact surface should be considered as well as migration from coatings. The rate of migration through (e.g. plastic films and aluminium foils) will depend on thickness, density and chemical make-up. In technical terms the rate of migration will be determined by diffusion coefficients. Note that a given film may be a reasonable barrier to one potential migrant while presenting virtually no barrier to a chemically different migrant. (e.g. multi-layer materials used as barrier to multiple substances.) Please see later for a discussion / definition of “functional barriers”.

**Amount of migrateable substance in the packaging** – in the case of substances migrating from printing inks, coatings, varnishes or adhesives, this will relate to both the amount of migrant present in the ink / coating or adhesive and the weight of the ink, coating, varnish or adhesive applied. It is not inconceivable that the same potential migrant could be present in several of the components of the package, for example in a printing ink applied to a carton, in a plastic inner pouch and in an adhesive used to seal the carton (e.g. bag in box). Therefore all components of a particular package need to be considered.

**Ratio between packaging surface area and volume (weight) of packaged food** – the greater the packaging surface area in relation to the weight of food, the greater will be the impact of any potential migration. For example, the impact of migration into an individual portion of butter would be proportionately greater than into a catering pack packaged in the same materials due to the higher ratio of packaging per gram of product.

#### *Implications for direct and non-direct contact materials:*

Since migration can occur by penetration through a substrate, through set-off from the non contact side and by gas phase transfer through air gaps, it is not just an issue for surfaces in direct contact with food. Any or all components of the primary packaging could potential be involved, for example both a carton and an inner pouch or liner. Indeed, in the case of mineral oils, it has been shown that gas phase migration from secondary recycled board transit cases can occur through virgin board cartons and inner plastic liners into packaged dry foods.

## Migration modelling and testing

### *Risk assessment approach*

A risk assessment approach can in some instances determine that migration testing is not required. For example, where an assumption of ink composition and laydown is worst-case scenario, but is still within the permitted specific migration limit (SML). This type of modelling is acceptable where evidence is robust and consistent, taking into consideration any factors of variability over the course of a print run and the consistency of ink set-off or drying rates in differing environments.

### *What is migration testing looking for? (Migration limits and resource)*

The limits for migrating substances from food contact materials into foodstuffs are covered by regulation. There are two types of migration testing undertaken. The first is overall migration and the test results indicate the total of all extractables coming from the packaging material into the food or food simulant, while the other type of migration relates to specific chemicals as defined within the regulations. Migration testing may be undertaken to confirm compliance with legislative requirements.

### *Interpretation of results and certificates*

Example of a certificate and/or DOC.

What simulants mean

References to units and how to interpret.

### **Role of confidentiality with certificates and testing**

At times, it may be necessary to test material with regard to specific migration. In order to test for the ingredient/additive it is necessary to have full disclosure of all ingredients/additives present in the formulation. When reporting the results these additives may only be listed by a generic name such as “Polymer A” due to the need to maintain product confidentiality.

Due to the manufacturer requirements to keep the formulation confidential and the client requirement for an independent laboratory to test the material there is a need for a confidentiality agreement to be put into place.

For the compounds in question in the main formulation there may need to be additional agreements to obtain the minor ingredient formulations.

The confidentiality agreements are such that the independent laboratory cannot legally disclose any test data and/or formulations of other information to unauthorised companies. The only exception would be if so instructed by a court of law.

This practice is common, and acceptable where the output is a certificate (DOC) that declares compliance with any legal requirements.

### **Migration modelling (when/how)**

Migration modelling is usually used for risk assessment and Declaration of Compliance (DoC) Statements. There are a number of specialist programmes suitable for migration modelling and these are based on the laws of diffusion, molecular weight and partition coefficients. It should be noted that the techniques generally over-estimate migration.

Migration modelling is permitted under EU Regulation 10/2011 (Clause 32) which states:

“At each stage of [packaging] manufacture, supporting documentation, substantiating the declaration of compliance, should be kept available for the enforcement authorities. Such demonstration of compliance may be based on migration testing. As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculations, including modelling, other analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing. Test results should be regarded as valid as long as formulations and processing conditions remain constant as part of a quality assurance system.”

Further details can be found in Article 16 (Supporting Documents) of the regulation.

“Appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Regulation 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, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in Chapter V (of the Regulation).

### **Other tools for testing**

Chapter 2 of the regulation (10/2011) gives the following details on testing.

#### **Testing for specific migration of materials and articles not yet in contact with food**

## 2.2 Screening approaches

“To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered more severe than the verification method described [in the regulation].”

### 2.2.1. Replacing specific migration by overall migration

“To screen for specific migration of non-volatile substances, determination of overall migration under test conditions at least as severe as for specific migration can be applied.”

### 2.2.2. Residual content

“To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration.”

### 2.2.3. Migration modelling

“To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed such as to overestimate real migration.”

### 2.2.4. Food simulant substitutes

“To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants overestimate migration compared to the regulated food simulants.”

It should be noted that the results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches.

## *When and how to use migration testing – decision tree*

### **What the BRC Standards say**

While the most obvious Standards relating to migration are the Food Safety and Packaging Materials Standards, other BRC Global Standards will have a direct impact to the potential for migration throughout the supply chain. Within the scope of this document direct reference is made to the activities of agents, brokers, warehousing and distribution and their operations must also be considered to truly mitigate the risk of migration of harmful substances into food.

Below is a summary of how migration is referenced within each Standard, specific references as well as points where potential for migration should be a consideration.

#### **Food Safety, Issue 7:**

Technically, there is only one clause that specifically refers to aspects including migration:

##### 5.5.1 – Suitability of packaging

“When purchasing or specifying food contact packaging the supplier of packaging materials shall be made aware of any particular characteristics of the food (e.g. high fat content, pH or usage conditions such as microwaving)

which may affect packaging suitability. Certificates of conformity or other evidence shall be available for product packaging to confirm it complies with relevant food safety legislation and is suitable for its intended use.”

However, the Food Safety Standard (Issue 7) also refers to the potential for migration from contact with manufacturing equipment. This is out of scope of this document, but is mentioned here for completeness

#### 4.6.2 – Suitability of food contact equipment

“Equipment which is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.”

There are a number of additional requirements throughout the Standard where it is expected that a company will have thought about packaging and migration and therefore either include requirements or know why they have excluded them (e.g. risk assessment shows no issue). These are:

- Section 2 – HACCP (especially 2.3, and 2.7-2.12)
- 3.5.1.1 – Raw material risk assessment (raw materials include packaging in Issue 7)
- 3.5.2 – Goods Receipt (e.g. are there certificates or other checks required)
- 3.6.1 – Raw material specifications (again raw material includes packaging)
- 5.6.1 & 5.6.2 – Product Testing (packaging is not specifically mentioned but all relevant safety and quality parameters).

#### **Packaging, Issue 5:**

The Packaging Standard has specific mentions of migration which apply equally to both hygiene categories.

#### 2.2.5 – identification of all potential hazards in the hazard and risk analysis.

“The hazard and risk analysis team shall identify and record all potential hazards that are reasonably expected to occur at each step in relation to the product and process.”

(Followed by a list of factors.)

#### 5.1.1 – identification of critical use parameters or testing required as part of customer design requirements.

“Customer requirements relating to the design, development, specification, manufacture and distribution of the product shall be documented and agreed with the customer.

This shall take into consideration process requirements and end use, where possible.

Any critical-use parameters shall be identified and defined; for example, barrier requirements, max/min use temperature, machine running, use of recycled materials, and testing requirements (including migration, where relevant).

Special attention shall be made to any materials that are required or requested to be manufactured from recycled materials, to ensure that they are both appropriate and legal.”

Other clauses that may be of consideration where assessment of migration potential is taking place.

- 2.2.11 – review of the hazard and risk analysis (where product composition has changed and may include materials containing potentially harmful migrating substances).
- 3.4.1 – specifications must contain information to ensure the materials meet minimum legal requirements.
- 3.4.3 – declaration of compliance requires the nature of the material and any inclusion of post-consumer recycled materials.
- 3.6.4 – assessment of materials not drawn from approved suppliers.
- 3.7.2 – evaluation of any risks from subcontracting of manufacturing processes.
- 3.9.1 – traceability of all materials.
- 5.9.1 – appropriate protection of all materials, work in progress and product.
- 5.9.2 – control of storage to prevent contamination of the product.
- 5.9.4 – appropriate handling of hazardous chemicals.

### **Storage and Distribution, Issue 2:**

No specific mention as with the other Standards and obviously due to the fact that all products need to be pre-packaged does lessen the risk somewhat.

#### Section 2 (Hazard and Risk Analysis) – 2.7 -2.10

3.9.1 - Where products are held pending further investigation, this shall be carried out in such a way as to minimise any further deterioration of these products or contamination of other products.

4.3.2 - Adequate segregated storage facilities shall be available to enable incompatible products to be effectively segregated, where required, to minimise the risk of taint or cross-contamination.

4.3.4 - Battery charging areas shall be well ventilated and/or segregated from product storage areas.

4.3.5 - Appropriate storage facilities shall be provided for the control and storage of cleaning and maintenance chemicals, and sited so they shall not compromise the safety, legality and quality of the product.

6.1.3 - All diesel-powered handling equipment, where used, shall incorporate an appropriate exhaust filter system for the removal of particulates that can pose a contamination risk to product.

7.4.3 - Where allergenic materials are stored or transported, the potential risk of cross contamination shall be assessed and any necessary additional spillage controls incorporated. Where allergenic materials are packaged in a format at particular risk of damage (e.g. paper sacks) designated storage areas shall be used to reduce risk of damage and cross contamination of other products.

10.2.2 - The wholesaler shall, where appropriate, ensure that suppliers undertake factory trials and carry out thorough product conformity checks to verify that product formulation and manufacturing processes are capable of producing a safe and legal product.

10.2.4 - Wholesalers shall have processes in place to ensure that they are notified of changes in product formulation or process and that any such changes have been adequately assessed for safety and legality.

10.3.1 - Specifications shall be adequate and accurate, and shall ensure compliance with relevant safety and legislative requirements.

10.4.1 - Monitoring of incoming products for compliance to specification shall be based on risk assessment. Inspection method, frequency of inspection and procedures shall be specified and

documented. Suppliers of incoming materials, as appropriate, shall provide evidence of guarantees, certifications/declarations of analysis or certificates of conformity.

13.2 - Product and packaging materials shall be stored under conditions to prevent the risk of contamination and deterioration. Any part-used product or packaging materials shall be effectively protected before being returned to storage.

16.1 - The cleaning area shall be suitably segregated from product storage and handling areas to prevent any risk of contamination of products.

17.4 - The handling of materials received for waste/recycling shall be carried out in a manner which prevents the risk of contamination of products.

### **Agents and Brokers, Issue 1:**

The Agents and Brokers Standard has no specific mention of migration but it will still be a factor in some instances. If a company is a trader of food products and the food is already packaged appropriate testing and legality checks may be applicable. However, where the company is a trader of packaging then a number of clauses might imply a need to consider migration and either specifically include or exclude:

- Section 2 – HACCP/Hazard & Risk Analysis (especially 2.6 and 2.7-2.9)
- Section 4.4 – Product Testing and Inspection: appropriate tests should be completed and potential for specific migration may be a factor requiring testing.
- Clause 4.5.1 – Legality: the requirement includes reference to compositional requirements.
- Section 4.6 – Product Development (relevant where the trader is responsible for developing new products or amending formulation).

Each of the Standard also has requirements that the manufacturing company maintains compliance with legal requirements, not only in the country of manufacture but also use, where known. Additionally, each Standard requires the certificated company to have a mechanism in place to ensure they stay informed of legislation, codes of practice and scientific or industry developments.

## Part Three

Legislation and Codes of Practice

EU Food Contact Materials legislation

Dual-use additives

Food additives – definitions

Declaration of compliance (DoC)

EU Directive for Packaging and Packaging Waste

Customer specific policies or requirements

## Legislation and Codes of Practice

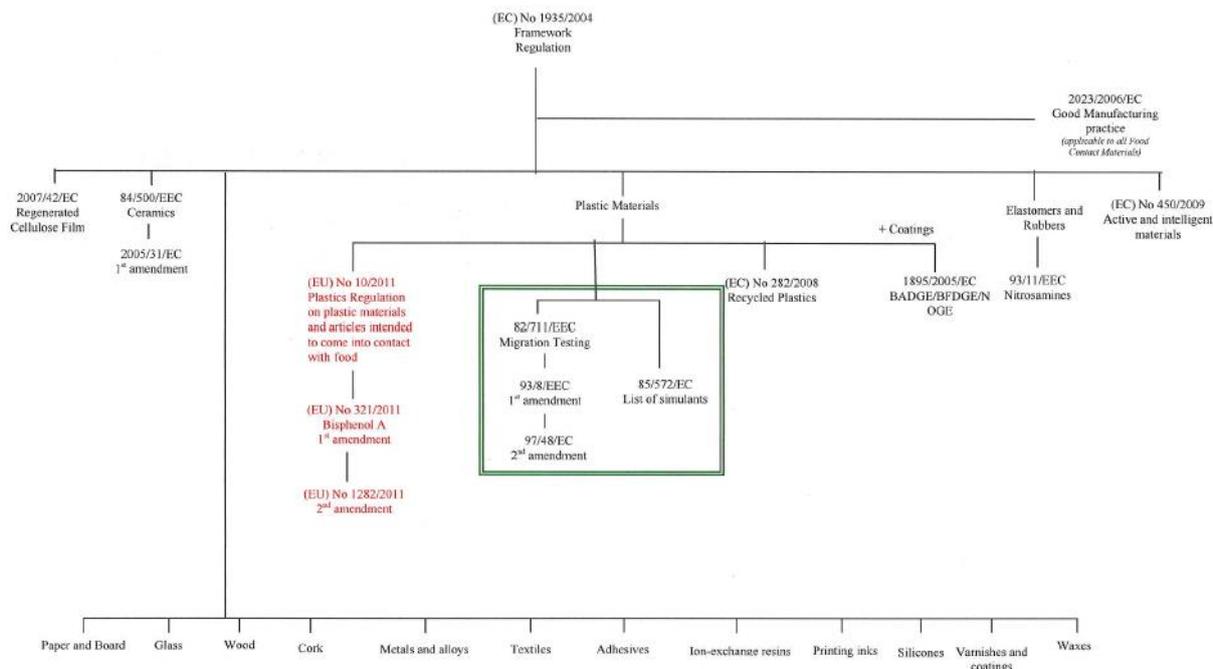
### EU Food contact materials legislation:

Insert diagram – EU overview of legislation (AC)

Overview of EU legislation (last update 08/02/2012)

(EU) No 10/2011 and its amendment as regards the restriction of use of Bisphenol A in plastic infant feeding bottles will be applicable as of 1 May 2011.

As of 1 January 2013 the rules provided by the legislations in the right green double frame will be replaced by the provisions on migration testing and simulants in (EU) No 10/2011



Article 3 of the [FCM Framework Regulation 1935/2004](#) requires that 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 into food in quantities which could:

- endanger human health
- bring about an unacceptable change in the composition of the food
- bring about a deterioration in the organoleptic characteristics of food

This is a key piece of legislation, as substances migrating from packaging into foods are likely to contravene at least one of the provisions in the bulleted list above.

[Regulation 2023/2006](#) on Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food provides further clarification on good manufacturing practice applicable to all sectors and stages of the packaging supply chain, up to but excluding the production of starting substances. The Regulation requires all the above parties to establish and implement quality assurance and quality control systems and to maintain related records and documentation to demonstrate compliance with good manufacturing practice (and hence with Article 3 of Regulation 1935/2004).

Annex 1 of Regulation 2023/2006 provides specific rules for printing inks applied to the non food contact side of materials and articles to prevent transfer to the food contact side:

- through the substrate or;
- by set-off in the stack or the reel

Article 5 of Regulation 1935/2004 enabled the future adoption of specific measures for the groups of materials and articles listed in Annex 1. To date, specific measures have been adopted only for:

- Ceramics: [Directive 84/500/EEC](#) (as amended by Directive 2005/31/EC) lays down limits for the migration of lead and cadmium from ceramic articles. Note that this legislation is currently under review.
- Regenerated cellulose film (cellophane): [Directive 2007/42/EC](#) lays down a list of approved substances which can be used in regenerated cellulose film and sets maximum limits for migration into food for certain substances (mono and di-ethylene glycol).
- Recycled Plastics: [Regulation 282/2008](#).
- Active and Intelligent Materials: [Regulation 450/2009](#).
- Plastics: [Regulation 10/2011](#) (as amended) – see detail later.

In addition there are also EU legislation relating to specific substances:

- Vinyl Chloride (Monomer): [Directive 78/143](#) sets a maximum limit of 1 mg / kg for vinyl chloride monomer in food.
- N-Nitrosamines / N-Nitrosatables from elastomer or rubber teats and soothers: [Directive 93/11](#) sets limits for the release of N-Nitrosamines / N-Nitrosatables under defined test methods.
- Epoxy derivatives (BADGE, BFDGE, NOGE): [Regulation 1895/2005](#) prohibits BFDGE and NOGE and sets specific migration limits for BADGE and derivatives.
- Bisphenol A (BPA) in polycarbonate baby bottles: [Regulation 321/2011](#) prohibits the use of BPA in manufacture of polycarbonate infant feeding bottles.

Although some of the above legislation sets limits on migration, by far the most relevant part of current EU legislation for migration is the Plastics [Regulation 10/2011](#), which replaced Directive 2002/72/EC:

- The scope of the Regulation covers:
  - FCM consisting exclusively of plastics
  - Plastic multi-layer materials held together by adhesives
  - Both of the above printed and / or covered by a coating
  - Plastic layers / coatings forming gaskets in caps and closures
  - Plastic layers in multi-material multi-layer materials
- Article 5 establishes a Union list of authorised substances consisting of:
  - monomers or other starting substances
  - additives excluding colorants
  - polymer production aids excluding solvents
  - macromolecules obtained from microbial fermentation
- The Plastics Regulation establishes Specific Migration Limits (SMLs) for a range of substances (Article 11 and Annex I) and Overall Migration Limits (OMLs – Article 12)
  - General OML = 10 mg / dm<sup>2</sup>
  - OML for plastics intended for use with foods for infants and young children = 60 mg / kg bw (of simulant)
- For Plastic multi-layer materials and Multi-material multi-layer materials, the Regulation lays down that layers not in contact with food and behind a “functional barrier” do not have to comply with the restrictions and specifications laid down in the Regulation and may be manufactured from substances not on the Union list, provided that these are not CMR substances (carcinogenic, mutagenic or reproductive toxins) or substances “in nanoform”.
- A “functional barrier” is defined by Article 3 as: “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”.

- Article 15 requires the operator putting the product onto market to issue a written DoC at all marketing stages other than at the retail stage. This applies to products from intermediate stages of manufacturing as well as the substances intended for the manufacturing of materials and articles.
  - Coatings, printing inks and adhesives are not covered by specific legislation and are therefore not subject to DoC requirements. Suppliers of printing inks and adhesives used in plastic articles are required to provide “adequate information” to enable the manufacturer of the final plastic article to ensure compliance with migration limits.
  - The Plastics regulation assigns food simulants (Annex IV) and migration testing conditions (Annex V) to be used for compliance testing. Note: the deadline for the exclusive use of the new migration test methods laid down by Regulation 10/2011 is 1 January 2016.
  - Article 3 defines “non-intentionally added substance” (NIAS) as “an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product”.
- Recital 20 requires that potential health risks arising from NIAS be assessed by the manufacturer “in accordance with internationally recognised scientific principles on risk assessment”.

The Plastics Regulation is by far the most well developed EU specific measure for FCMs. The Union list of substances and migration limits took many years to develop. Where substances on the list occur in other categories of FCM, where no harmonised legislation exists (such as for example printing inks or adhesives), both regulators and business operators use the SMLs laid down in the Plastics Regulation as a guide to compliance. Some Member States also apply the migration testing conditions laid down for plastics to other categories of FCMs.

The following is a list of materials not (yet) covered by specific harmonised EU Legislation:

- Paper and board
- Printing inks
- Varnishes and coatings
- Adhesives
- Metals and alloys
- Glass
- Wood
- Cork
- Ion exchange resins
- Waxes
- Silicones
- Textiles
- Rubber

All of these are covered by National Legislation or Standards in at least one Member State. The German BfR Recommendations are an example of standards which are guidance and do not have full legal status, but which provide useful guidance on compliance, in the absence of harmonised EU legislation. The EU Commission maintains a [summary of National Legislation](#). Further details are available from the various Member State authorities including:

- Germany - [BfR Recommendations](#).
- Netherlands – Updated [Waranwet](#).
- [France](#).

The [Council of Europe](#) (CoE) also provided a set of standards for FCMs in the form of Resolutions and Guidance. The CoE was active in developing FCM standards until 2008. Development of the COE

Resolutions has since been taken over by the European Directorate for the Quality of Medicines (EDQM) and there has been renewed interest recently from some Member States and trade organisations. With the exception of a Resolution and Technical Guide on Metals and Alloys published in 2013 (which lays down Specific Release Limits (SRLs) for metals such as iron and aluminium), most of the CoE Resolutions are somewhat out of date, however they remain a helpful technical reference for compliance in areas where harmonised EU legislation is not in place.

### *Dual-use additives*

[Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food This document has long list of dual use additives and other examples. Too long to insert.]

(link and/or appendix with list?)

Certain substances used in food contact plastics are, at the same time, authorised food additives or authorised flavourings respectively by Regulation (EC) No 1333/2008 or Regulation (EC) No1334/2008 or their implementing measures. These substances are called dual-use additives.

To avoid the unauthorised presence of food additives or flavourings in food, specific requirements are set out for the migration of these substances from food contact materials. The substances shall not be released into foods in quantities which have a technological function in the food.

If substances are added to the plastics to be released into food to have a technological function in the food, they are covered by the Regulation on active and intelligent materials and should comply with the relevant Union and national provisions applicable to food.

If the substances are added to the plastics with no intention to be released into food to have a technological function in the food, but they are authorised as a food additive or flavouring, the additional unintentional migration from food contact materials shall not lead to an exceeding of the authorised limit set out by the specific legislation on food additives or flavourings, even if this limit is lower than the SML set out in the Plastics Regulation.

If the substance is not authorised as a food additive or flavouring in a certain food, then the migration from food contact materials into this food should not achieve a technological function in the food, and neither impart odour or taste (flavouring), nor should the SML be exceeded. In cases where the substance does not exhibit a technological function in food, migration up to the SML should be allowed, even if the substance is not authorised as food additive or flavouring in that type of food.

To decide if a substance can be considered as a dual-use additive, it is sufficient that the chemical identity of the plastic additive matches that of an authorised food additive or flavouring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic.

USFDA (still needs added text)

It is the responsibility of the manufacturer of an FCS to ensure that food contact materials comply with the specifications and limitations in all applicable authorizations

Example required.

### *Food Additives - Definitions*

#### **US legislation**

(21 CFR 170.3)

A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container.

“Affecting the characteristics of food” does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss.

If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive.

Threshold of regulation for substances used in food-contact articles (21 CFR 171.8)

Substances used in food-contact articles (e.g., food packaging or food-processing equipment) that migrate or that may be expected to migrate into food at negligible levels may be reviewed under §170.39 of this chapter.

The Food and Drug Administration will exempt substances whose uses it determines meet the criteria in §170.39 of this chapter from regulation as food additives and, therefore, a food additive petition will not be required for the exempted use.

(a) A substance used in a food-contact article (e.g., food-packaging or food-processing equipment) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation if:

- not been shown to be a carcinogen
- presents no other health or safety concerns
- no technical effect in or on the food to which it migrates
- no significant adverse impact on the environment

## **21CFR174 – Indirect Food Additives – General**

This regulation prescribes the conditions under which food additive substances may be safely used. It also defines GMP for parts 174, 175, 176 & 177.

GMP includes the restriction that:

- a) the quantity of a food additive shall not exceed specified limits or when not specified reasonably expected to achieve the technological effect in the in the food contact article
- b) substances used in food contact must be pure enough for their intended use.

Additionally the regulation refers to GRAS with regard to food as well as packaging. It also allows for ‘prior sanctioned’ or approved.

For more detailed requirements for specific materials refer to the main parts of Chapter 21 relating to food contact materials are listed below

Part 170 – food additives

Part 171 – food additive petitions

Part 172 – food additives permitted for direct addition to food for human consumption

Part 173 – secondary direct food additives permitted in food for human consumption

Part 174 – indirect food additives; general

Part 175 – indirect food additives; adhesives and components of coatings

Part 176 – indirect food additives paper and paperboard components

Part 177 – indirect food additives; polymers

Part 178 - indirect food additives; adjuvant, production aids and sanitizers

Part 179 – irradiation in the production, processing and handling of food

Part 180 – food additives permitted in food or in contact with food on an interim basis pending additional study.

Part 181 – prior sanction food ingredients

### ***Declaration of Compliance***

[Example of DOC to go here (not earlier).]

The regulatory context in Europe allows the user of the packaging to receive more information from the supplier. EU Framework Directive 1935/2004 Art. 6 (5) states: "The specific directives shall require that such materials and articles be accompanied by a written declaration attesting that they comply with the rules applicable to them."

Declaration of compliance  
(Article 16 – Regulation 1935/2004)

"1. The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.

Appropriate documentation shall be available to demonstrate such compliance and that documentation shall be made available to the competent authorities on demand.

2. In the absence of specific measures, this Regulation shall not prevent Member States from retaining or adopting national provisions for declarations of compliance for materials and articles."

### **Role of the DoC for food contact materials and articles (M&A).**

The DoC is a document delivered by the supplier to his customer with the purpose of confirming compliance of the supplier's product with the Framework Regulation (EC) 1935/2004 and any material specific legislation (e.g. the Plastics Regulation (EU) 10/2011) . It is designed to providing the customer with adequate information to allow the customer, in turn, to establish or check the compliance of his own product

A DoC might not be a single document but should be sufficient documentation or evidence to ensure that starting materials, including chemicals, intermediates and final FCM are in line with existing EU regulation and the minimum requirements in it.

The DoC is mandatory within the EU for plastics (including recycled plastics), ceramics, regenerated cellulose, active and intelligent packaging

### ***Packaging and Packaging Waste***

COUNCIL DIRECTIVE 94/62/EC of 20 December 1994 on packaging and packaging waste

While the Directive covers recycling and disposal of packaging materials Article 11 relates to concentration levels of heavy metals present in packaging. This lays down the limits for heavy metals in packaging or their components

1. Member States shall ensure that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed the following:

- 600 ppm by weight two years after the date referred to in
- 250 ppm by weight three years after the date referred to in
- 100 ppm by weight five years after the date referred to in
  - Article 22 (i).

2. The concentration levels referred to in paragraph 1 shall not apply to packaging entirely made of lead crystal glass as defined in Directive

69/493/EEC (1).

### *North America legal requirements*

Diagram/overview of [US requirements](#)

General Regulations on FCM	
Food, Drug and Cosmetic Act (1958)	
Title 21, Code of Federal Regulation	
Authorization/Notification required*	Exempted from authorization
Direct Additive (21 C.F.R. Part 170.3)	Threshold of Regulation rule
Indirect Additive (21 C.F.R. Part 174-179)	GRAS <ul style="list-style-type: none"> <li>→ Common food ingredient before 1958</li> <li>→ Manufacturer self-determined GRAS</li> <li>→ FDA listed GRAS</li> <li>→ FDA approved GRAS</li> <li>→ FDA GRAS notification</li> </ul>
Food Contact Notification (FCN) program (only notification required)	Sanctioned before 1958

[Canada](#)

[Japan](#)

### *Keeping up to date with industry technical and scientific information.*

Membership of a recognised industry trade association will enable companies to track updates in legislation. Industry bodies are more likely to be involved at the draft/consultation stages of new legislation and as a member the company may be kept informed of planned changes before they occur. Other ways may be to register with government bodies responsible for regulations and obtain updates when they become available.

## Part Four

### Product Development Processes

New product Development and Change Control

Selection of materials

Design of 'low migration' inks and adhesives

Other factors complicating packaging material selection

Non-intentionally added substances (NIAS)

Good practice checklist

## Product Development Processes

Shared supply chain responsibility for prevention / minimisation of migration:

Suppliers of food packaging are responsible for ensuring that the materials supplied are fit for purpose and compliant, for example with the Plastics Regulation, suppliers of plastic materials and articles are required to provide a DoC. In the case of suppliers of materials covered by other harmonised EU specific measures (e.g. ceramics), a DoC is also required under Article 16 of Regulation 1935/2004. The Plastics Regulation requires suppliers of printing inks and adhesives to supply “adequate information” to enable the supplier of the plastic item to carry out the necessary compliance work. “Adequate information” could take the form of a statement of composition detailing potential migrating substances in the ink or adhesive.

The potential for and rate of migration is however highly dependent on the nature of the food being packed, the design of the overall package (taking all components into account), filling and storage temperatures, shelf life and usage instructions (e.g. temperature / time conditions), for example if the food is intended to be heated in the pack. The packaging supplier needs this information in order to select appropriate materials and processes and hence to ensure compliance of the packaging material supplied.

The ultimate responsibility for compliance of packaged food placed on the market rests with the food manufacturer / packer; however the manufacturer / packer cannot achieve this in isolation. The food manufacturer / packer needs to ensure that all necessary specification / design information relating to the potential for migration (see paragraph above) has been communicated to their packaging supplier and further up the supply chain, as required. Essentially therefore, the compliance of packaging and the prevention / minimisation of migration is a shared responsibility, with the necessary information flowing in both directions along the supply chain.

It is good practice for compliance work to be completed as early as possible in the chain to avoid duplication of effort; however there are circumstances in which migration testing or modelling may have to be conducted further down the supply chain. For example, a supplier of ink for a carton may not be aware of the weight of ink applied to the carton or the drying conditions. Similarly, an ink supply may not be aware of the nature of the plastic forming the inner bag of the overall pack, yet this may contain the same potential migrant as could be present in the ink.

### ***New Product Development and change control:***

It follows from the above that compliance (and prevention / minimisation of migration) needs to be “designed in” to the overall packaged product and this should be completed at the product development stage. Where a range of products is being developed, it may be possible to carry out compliance work (including possible migration testing or modelling) on the “worst case” of a family of products i.e. the product in the range most susceptible to migration.

Having designed compliance into the packaged food, it is important that change control procedures are put in place along the supply chain. Packaging (and component) suppliers should inform the food manufacturer / packer of any proposed changes in specification, raw materials or manufacturing processes, which might invalidate the completed compliance work. Migration testing or modelling may need to be repeated to validate the change in the packaging material.

Similarly, food manufacturers / packers should not use existing packaging for a food product with different migration potential, or use packaging designed for one purpose for a different purpose. For example a printed carton designed for ambient storage is unlikely to be suitable for an ovenable or microwaveable pack. A jar lid which is compliant for a jar filled with an aqueous food may not be suitable for an oil based food.

### *Selection of materials / design of “low migration” inks and adhesives:*

In the light of knowledge of the intended use of the pack, packaging suppliers / converters can specify appropriate materials / components to ensure compliance. For plastic packaging, an example could be the selection of an appropriate polymer to act as a barrier to potential migrating substances under the appropriate storage conditions. Polymers with low residual monomer content should also be selected.

Where a risk assessment identifies the potential for migration from recycled board into a given food product under given storage conditions, there are options to use a different grade of recycled board, or to use virgin board, or to employ a suitable “functional barrier” to prevent migration.

Ink and adhesive manufacturers also have the ability to design / select appropriate “low migration” inks or adhesives for specific applications. One possible option is the use of polyolefin based hotmelt adhesives, which have a narrower molecular weight distribution (lower proportion of molecules less than 100 Daltons) and hence a reduced migration risk compared to ethylene-vinyl acetate EVA based hotmelts.

Another option is the selection of plasticizer-free dispersion adhesives. Copolymer dispersions can be used instead of homopolymers with plasticisers. Plasticisers are typically low molecular weight substances, so eliminating them from the formulation reduces the risk of migration. Similarly, migratable substances can be minimised by limiting additives, preservatives and stabilisers etc. to the smallest amount necessary. In some cases, polymeric or polymer-bound additives can be used instead of low-molecular weight substances. These principles can be applied to both inks, coatings and adhesives.

In the case of UV curing inks, the photoinitiators used are potentially small, readily migrateable molecules. High molecular weight polymeric photoinitiators can however be selected, alongside increased acrylate functionality / cross linking density, to design a “low migration” UV ink. It is also important to ensure that UV inks are appropriately cured to minimise potential migration of unreacted monomers. UV lamps should therefore be correctly specified and in good working order.

Ink manufacturers have also developed “low migration” versions of other types of inks e.g. water based inks / coatings and conventional offset inks. However, there do not appear to be standardised definitions of the terms “low migration” or “reduced migration” and it is therefore important for all parties in the supply chain to clarify the exact meaning of any terminology used.

Ink and adhesive manufacturers have a great deal of knowledge in formulating components to prevent or minimise migration. Food manufacturers / packers and their packaging suppliers are therefore encouraged to take advantage of this supply chain expertise to determine the right solution for the specific packaging/product combination and its use.

### *Other factors complicating packaging material selection:*

Where printed inserts are included within a pack, their potential contribution to migration should be considered. Similarly the possibility of migration from printed adhesive labels should be considered; especially when these are applied either directly to food such as fruit, or to plastic films covering microwaveable products (ready meals etc.) which are not removed before microwaving.

Potential migration from inks used for ink jet coding of packaged foods should be considered. The possibility of migration from point of sale displays should be also be assessed. In both cases a risk assessment should be carried out and suppliers’ advice should be sought as to whether appropriate materials have been used for the application concerned.

The [Biocidal Products Regulation](#) (BPR) (Regulation 582/2012) requires all biocidal products to be authorised for use in specific “product types”. A programme for the submission and review / evaluation of biocidal product applications is underway. Biocides are used in the paper making

process and in water based inks, coatings, adhesives, sealants etc. Biocides are therefore potentially present in a wide range of food contact materials. Biocides are typically relatively small molecules and so could be potential migrants.

Anecdotal evidence suggests that some suppliers in the food contact packaging supply chain may be changing the biocides they use in order to ensure that the biocides are or will be authorised under the BPR. The effect on migration of any such changes should be considered along the supply chain.

The EU Commission are now understood to be taking a more pragmatic approach to what constitutes a “treated article” in terms of the BPR. Under this revised (but not yet finalised) approach, the addition of process biocides, for example in the paper making process, would not confer treated article status, unless there is biocidal activity in the finished material. Nevertheless the Commission has indicated that it also intends to set limits for residual process biocides in food contact materials; however the process and timescale for this is unknown.

Queries have been received over the potential transfer of allergens and / or genetically modified material into food from packaging materials (especially from bioplastics). Initial investigations have suggested that this is fairly unlikely, given the range of bioplastics currently used in food packaging, however this is a rapidly developing field and an appropriate risk assessment is important.

***Non-intentionally added substances (NIAS)***

NIAS are defined in Article 3 of the [Plastics Regulation](#), which lays down the responsibilities of the manufacturer in assessing any health risks (see above). There has been much recent discussion of NIAS in other, non-plastic, FCMs and there is an expectation that the packaging supply chain should also consider potential health risks from NIAS in non-plastic packaging. This is not straightforward in cases when the chemistry is either unknown or very complex. Nevertheless it would be good practice to consider potential migration from NIAS.

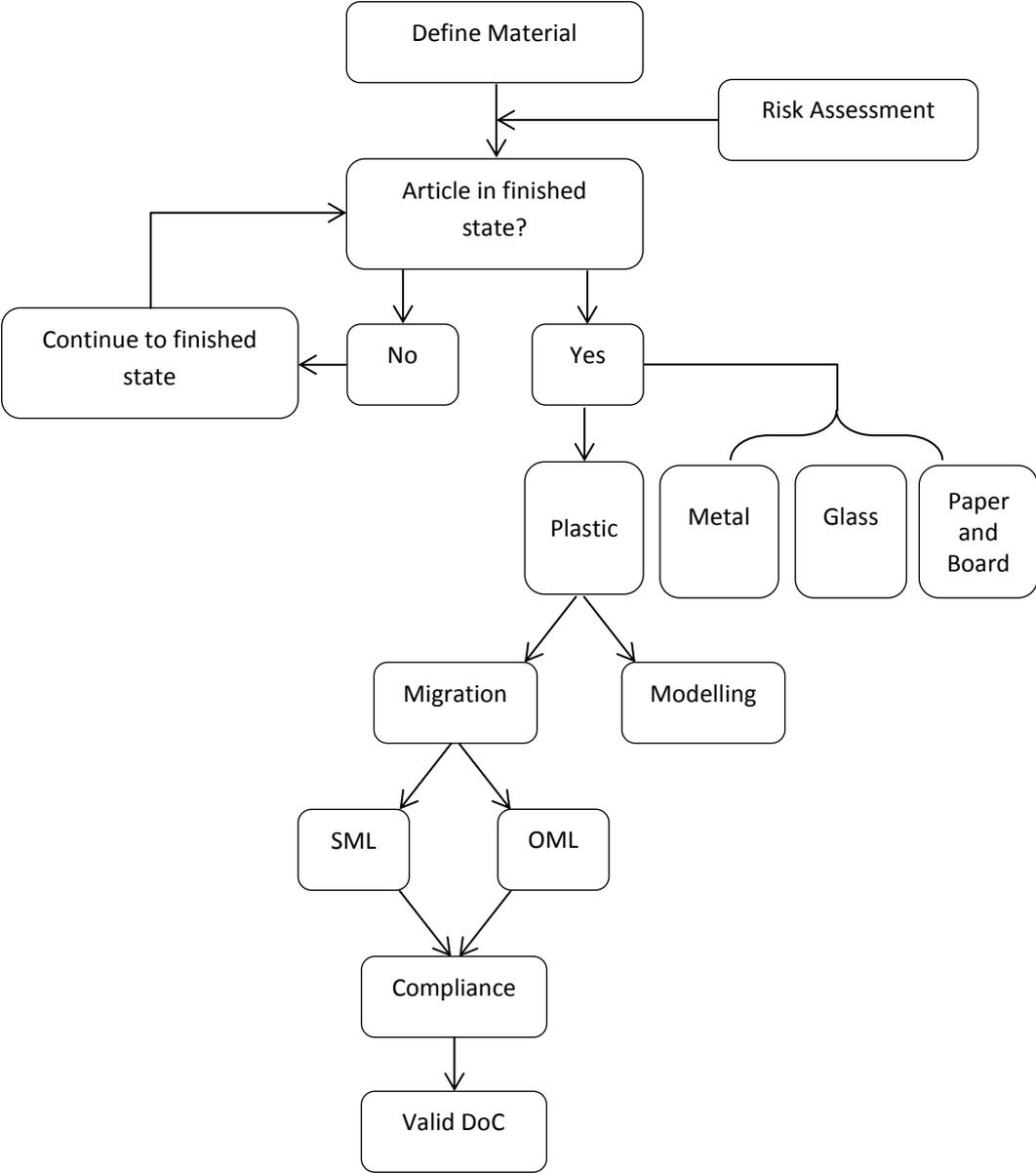
This is of particular importance in ovenable and especially microwaveable packs, where the temperatures achieved during cooking can cause some chemical breakdown, for example of the inks, adhesives and even potentially of substances in the substrates used. It is recommended that this possibility be discussed with packaging suppliers, taking into account views and information from the extended supply chain.

**Examples of usage instruction abuse (relocate to product development)**

Use of half a can then putting the can in the fridge (liner degradation)

Reuse of disposable packaging materials – oil stored in milk bottles.

# Migration testing decision tree



## Appendices

Appendix 1: References

Appendix 2: Glossary

- common glossary from BRC Participate
- additional words from newly published Packaging Standard
- any other words or phrases from this document