

# ESG Guideline for Paper Sacks in Contact with Food

## Issue 2

Based on compliance with the  
EU legal status as per  
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**CEPI EUROKRAFT**  
European Kraft Paper Producers for the flexible packaging industry



## FOREWORD

The objectives of the European Paper Sack Research Group (hereinafter referred to as the ESG) are to:

- Establish a scientific knowledge base and to present facts to support lobbying business in Eurosac and CEPI Eurokraft.
- Provide models and tools that support individual member companies in their development of the paper sack system.
- Help and support members to comply with new directives and laws in the paper sack area.

The main purpose of the ESG Food Contact Guideline is to propose a structured way as a support to the paper sack manufacturer to handle food contact legislation. It should be emphasised though that food contact legislation is very complex and should be handled by a knowledgeable person in the company.

The ESG Food Contact Guideline has as the objective to make the sack producer understand his responsibilities towards different regulations. The guideline should show how and when these different regulations are needed to be met depending on type of food product, composition of the paper sack, lead times, temperatures, storage conditions, input material, etc. It should also clarify who is responsible for what and when in the “life time” of a paper sack from production of input materials to emptying of the food product filled in the paper sack.

The guideline should also transfer some learnings about existing regulations and directives and show where these can be found in their full extent.

The revised CEPI/CITPA/CEFIC/FPE Industry Guideline were published on September 21, 2012. In some cases this guideline and ESG Guideline are overlapping but should be seen as complimentary documents. The Industry Guideline are focused on paper and board for food contact and not in detail on packaging converting as ready for use by food industry. For a paper supplier following the Industry Guideline will make him act fully in accordance with the actual legislation.



The “ESG Food Contact Guideline” has been prepared on the initiative of Eurosac and CEPI Eurokraft within the frame of the ESG – European Paper Sack Research Group.

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## Table of Contents

FOREWORD .....	2
Introduction to the Guideline .....	6
Introduction to some important regulations, recommendations and guidelines on food contact .....	8
EU regulations.....	8
Regulation (EC) No 1935/2004.....	8
Regulation (EC) No 10/2011 on plastic food contact materials (previously called PIM, Plastic Implementation Measure).....	9
Regulation (EC) No 2023/2006 on GMP – Good Manufacturing Practices.....	9
National recommendations on paper and board.....	10
German BfR (Bundesinstitut für Risikobewertung) Recommendation XXXVI (plus parts I, 2 & 3).....	10
National recommendations on printing inks .....	11
Switzerland.....	11
Nordic Countries (Denmark, Sweden, Norway, Finland, Island) have published checklists for compliance.....	11
Germany ( <i>not in force yet</i> ) .....	11
Further guides.....	12
CEPI/CITPA Industry Guideline- Issue 2.....	12
EuPIA – European Printing Inks Association - documents related to the manufacture and supply of food packaging inks, Annex II .....	12
Mutual recognition .....	12
ESG/Key Eight Steps to food contact compliance.....	14
E - Establish background prerequisites .....	14
S – Specify sack construction and applicable legislation.....	14
G – Generate compliance with legislation .....	14
E- Establish background prerequisites .....	15
STEP 1. Classify the type of food which will be packed in the paper sack.....	15
STEP 2. Document the temperature of the food at filling.....	15
STEP 3. The time and temperature for storage of printed paper, empty paper sack and filled paper sack .....	15
S – Specify sack construction and applicable legislation.....	17
STEP 4. Describe the paper sack material composition and select the similar reference paper sack construction TYPE I, II, III, IV, V .....	17
STEP 5. Applicable regulations & recommendations for the sack material composition.....	18
G – Generate compliance with legislation .....	19
STEP 6. Collect the documentation for each layer of materials and other components in the specific paper sack material composition.....	19
*) If the organic coating is based on chemicals present in the plastic legislation DoC should be used and if the coating is based on chemicals in the BfR not present in European legislation, Adequate Information is sufficient.....	20
Most.....	20
STEP 7. Find out about the testing needed for the specific paper sack material composition .....	23



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STEP 8. Document which show compliance of the specific paper sack construction with the regulations and recommendations .....	25
Labeling.....	26
Annex I - Description of foodstuffs according to Regulation (EC) No 10/2011 and resulting type of simulant in testing .....	27
Annex II - List of regulations and recommendations.....	32
European level.....	32
National level .....	32
Others .....	33
CEPI Good Manufacturing Practice for papermaking published in 2010 .....	33
Annex III - Definitions.....	34
Plastics.....	34
Definitions of materials construction in line with Regulation (EC) No 10/2011.....	35
Additional definitions.....	36
Examples of materials composition .....	36
Annex IV - Recycled paper.....	38

## Introduction to the Guideline

The main component in a paper sack is paper, to a large extent based on virgin fibres, together with plastics, metals, inks, adhesives, glue, etc. Along with that chemicals, for the process or the packaging performance, are needed to provide today's paper sacks with properties that meet the various demands. When the food comes into contact with packaging, a mass transfer process of these chemicals into the food might start and lead to varying concentrations of these chemicals in the packed food. This process is called chemical migration of substances. Community legislation on food contact materials covers the following products: materials that are already in contact with food such as the packaging of prepacked food; materials that are intended to come into contact with food, such as cups, dishes, cutlery, and food packaging not yet in use; materials that can be reasonably expected to be brought into contact with food as table surfaces and food preparation areas or the inner walls and shelves of refrigerators; and materials that can be reasonably expected to transfer their constituents to food as a cardboard box around a plastic bag. These substances involved shall hereafter be called food contact substances.

Type of food has a main influence on migration and the need for/kind of testing. Food products can be fat on the surface, contain fat in itself e.g. cheese, and be dry e.g. rice or be moist e.g. cooled food products. As all the packaging materials and inks or glues contain chemicals, some of them might by diffusion move into the moisture or fat environment in the food. This phenomenon is called migration and is dependent on e.g. kind of food, type of moving chemicals as well as on time and temperature, during the life time of the material. Diffusion of the chemicals is investigated through migration testing with simulants. A "food simulant" means a test medium imitating food; in its behavior the food simulant mimics migration from food contact materials. The amount of substances in the packaging material which might migrate is controlled by extraction testing.

The Regulation (EC) No 1935/2004 is the community regulation that covers all materials and articles intended to come into contact with food. In addition there are the Regulation (EC) No 10/2011 on plastic food contact materials, the Regulation (EC) No 2023/2006 on Good Manufacturing Practices as well as national recommendations / legislations for materials without a specific European regulation e.g. paper and board or inks.

A paper sack intended for food products can be constructed in many different ways, with different materials. It can be constituted of only paper (one or more layers), plastic added on a paper layer with extrusion or lamination or as a free standing layer or have other layer materials e.g. aluminium. The plastic or aluminium layer is intended as a barrier towards moisture, oxygen or fat. A sack containing a barrier material e.g. aluminium could be seen as having a functional barrier.

The paper sack could be printed on the outside layer and the outside layer could have a surface treatment e.g. plastic and it could be coated on top of the printing. In addition to the material layers and inks also glue could be used in the manufacturing process.

The “life time” of a printed sack covers steps as storage of the pre-printed paper reels, manufacturing of paper sacks, filled paper sacks with food products until date of expiry for the food in the filled bag. This “life-time” can be very different from rather short to quite long lead time and many different conditions in storage and handling are involved.

As many input materials are present in the paper sack and at the same time different foods can be packed in the paper sack, there is a need for information from suppliers of all used materials for the construction as well as type of food that will be packed in the sack. There is also a need of clarifying who is responsible for fulfilling food contact demands linked to materials, paper sacks and food, during the “life time” of the sack.

The *food producer* has to fulfil the Regulation (EC) No 178/2002 on food which ensures the quality of foodstuffs intended for human consumption and animal feed. It guarantees the free circulation of safe and secure food and feed in the internal market.

The food producer needs the information and the food contact compliance of the paper sack manufacturer to fulfil his obligations to Regulation (EC) No 178/2002.

To facilitate this for the paper sack manufacturer we have established the “ESG/Key Eight Steps Guideline” which should help to unlock the road to compliance with the legislation. It is strongly recommended though to have a good dialogue with the supplier and the customer, the paper sack filler, in these matters.

*For some materials, e.g. paper and board, no specific measure exists within EU for the time being. National legislation then applies with the mutual recognition principle as described in Regulation (EU) 764/2008. Regulation (EC) No 1935/2004 must always be fulfilled.*

The Guidelines begins with a general introduction to food contact regulations where we have picked the most important ones for paper sack manufacturers.

## Introduction to some important regulations, recommendations and guidelines on food contact

To ensure that a paper sack producer complies with regulations on different markets, an understanding of the fundamental elements of food contact regulations and their crucial similarities and differences is necessary.

All materials and products are subordinated to the Regulation (EC) No 1935/2004 which is "horizontal" and applies to all materials and articles sold on the European market. Demands on specific materials is depending on the finished product construction (the finished packaging) where they are included, the kind of material and how they are related to different directives.

### EU regulations

#### Regulation (EC) No 1935/2004

The Regulation (EC) No 1935/2004 concerns all parties from producers of raw materials, chemicals, inks, adhesives, packaging materials or packaging or brand owners to food packers or processors and retailers.

The Regulation (EC) No 1935/2004 applies to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:

- (a) are intended to be brought into contact with food; or
- (b) are already in contact with food and were intended for that purpose; or
- (c) can reasonably be expected to be brought into contact with food or to transfer their constituent to food

The principle underlying the Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

General requirements are:

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- (a) endanger human health; or
- (b) bring about an unacceptable change in the composition of the food; or

- (c) bring about deterioration in the organoleptic characteristics thereof.
2. The labeling, advertising and presentation of a material or article shall not mislead the consumers.
  3. The traceability of materials and articles intended to come into contact with food should be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

*This European Framework Regulation must always be met and a company shall always be prepared to show compliance with it.*

**Regulation (EC) No 10/2011 on plastic food contact materials (previously called PIM, Plastic Implementation Measure)**

This Regulation shall establish the specific rules for plastic materials and articles to be applied for their safe use and repeals Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs.

This Regulation shall apply to materials and articles which are placed on the EU market and fall under the following categories:

- (a) materials and articles and parts thereof consisting exclusively of plastics;
- (b) plastic multi-layer materials and articles held together by adhesives or by other means;
- (c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating;
- (d) plastic layers or plastic coatings, forming gaskets in caps and closures that together with those caps and closures compose a set of two or more layers of different types of materials;
- (e) plastic layers in multi-material multi-layer materials and articles.

Depending of the sack construction, the plastic layer of paper sacks intended for food can belong to category C when the plastic layer construction is not laminated or coated to paper. If the construction of the sack cover plastics and paper laminated or coated together, the plastic layer is covered by E.

**Regulation (EC) No 2023/2006 on GMP – Good Manufacturing Practices**

The Regulation (EC) No 2023/2006 lays down the rules on good manufacturing practices (GMP) for materials and articles intended to come into contact with food. The Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances. See reference also to CEPI GMP (Annex II).

An Annex in the GMP regulation covers migrations of chemicals from printing inks. Even if the specific European regulation on printing inks is not in place in the European system the GMP regulations state that; "the printing inks should not contaminate foods". Processes

involving the application of printing inks to the non-food contact side of a material or article have to acknowledge the following detailed rules of good manufacture practice, Regulation (EC) No 2023/2006.

1. Printing inks applied to the non-food-contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side:
  - (a) through the substrate or;
  - (b) by set-off in the stack or the reel, in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.
  
2. Printed materials and articles shall be handled and stored in their finished and semi-finished states in such a manner that substances from the printed surface are not transferred to the food-contact side:
  - (a) through the substrate or;
  - (b) by set-off in the stack or reel, in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

## National recommendations on paper and board

### **German BfR (Bundesinstitut für Risikobewertung) Recommendation XXXVI (plus parts I, 2 & 3)**

BfR – covers different types of materials. The BfR system and § XXXVI are for paper and board. Since 1958 the Federal Institute for Risk Assessment (BfR) or its predecessor institutions have published the "Recommendations on the health assessment of plastics and other high polymers" (Plastics Recommendations) like for instance paper and rubber. The acceptance of new substances into the recommendations and the adaptation of current legal regulations require regular amendments, which are published in the "Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz" as notifications. The substances permitted for use in paper and board conforming to this Guideline is given in BfR Recommendation XXXVI. The limits prescribed for the use of permitted substances in these Recommendations shall be applied. (See Annex II)

## National recommendations on printing inks

Packaging inks are preparations from printing inks and varnishes intended for printing on the non-food contact surface of materials and articles. They are manufactured in particular from binders (monomers), colorants, pigments, plasticizers, solvents, driers and other additives and are applied to the materials and articles by a suitable printing or varnishing process. In their finished state, packaging ink layers are thin films of dried or hardened printing ink or varnish on the surface of the materials and articles.

### Switzerland

Ordinance of the FDHA, Federal Department of Home Affairs, on articles and materials (RS 817.023.21) of 23 November 2005, Section 8b on Packaging inks. The provisions of this Section apply to packaging inks as specific constituent elements of materials and articles. The provisions of this Section do not apply if:

- a. the packaging ink layer is in direct contact with foodstuffs;
- b. a migration of any substance from the packaging inks to the foodstuffs is impossible due to the condition of the materials and articles;
- c. the set-off of substances or their transfer via a gas phase can be excluded

Packaging inks may only be manufactured from the substances set out in annex 1 (Lists I and II of plastics) and in annex 6 (lists I - V of packaging inks), subject to the requirements set out therein. The following substances are listed in annex 6:

- |     |   |
|-----|---|
| I   | List of binders (monomers)  |
| II  | List of colorants and pigments  |
| III | List of solvents (including the energy curing monomers)                       |
| IV  | List of additives (without the additives used in the preparation of pigments) |
| V   | List of photoinitiators   |

The ordinance is valid for Switzerland and since Switzerland is not a member of EU, Mutual Recognition does not apply.

### **Nordic Countries (Denmark, Sweden, Norway, Finland, Island) have published checklists for compliance.**

The checklists for the control of compliance for printing inks set a specific frame with minimum requirements to all relevant links in the chain from producers or importers of chemicals and raw materials like additives to the users of the final FCM to users in the food industry and to trade, including intra-community trade in the EU and import from third countries.

### **Germany (*not in force yet*)**

Since late 2010, Germany has been developing an amendment to the German Ordinance on Materials and Articles, introducing printing ink-specific provisions. Publication in Legal bulletin end of 2013/Q1 2014 and with a current transition period of 1 year is expected.

## Further guides

### **CEPI/CITPA Industry Guideline- Issue 2**

The Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact was first published by CEPI and CITPA in March 2010 and this is the second issue, published in September 2012. It is a reference for the paper and board food packaging value chain. See link in Annex II.

### **EuPIA – European Printing Inks Association - documents related to the manufacture and supply of food packaging inks, Annex II**

The annex contains

- Frequently Asked Questions on the legal status of Printing Inks, Coatings and Varnishes for the non-food Contact Surface of Food Packaging (food packaging inks)
- EuPIA Guideline on Printing Inks applied to the non-food Contact Surface of Food Packaging Materials and Articles
- Customer Information Note regarding the use of sheet fed offset inks and varnishes for the manufacture of food packaging
- Customer Guidance Note for Using Ink Statements of Composition when Considering Compliance of Food Packaging

EUPIA takes a position on threshold limits of substances migrating from the dried printing ink layer. Where they exist, specific migration limits (SML) must be met. With regard to non-evaluated substances, migration limits of no concern - based on toxicological assessments – have to be established.

### **Mutual recognition**

Besides the Regulation (EC) No 1935/2004 which is in force on global EU market, the countries have national rules, where there is no material specific European Regulation. The rule of mutual recognition applies to avoid barriers of trade. Mutual recognition is defined as “In intra-EU trade in goods, mutual recognition is the principle that a product lawfully marketed in one Member State and not subject to Union harmonization should be allowed to be marketed in any other Member State, even when the product does not fully comply with the technical rules of the Member State of destination”.

There is one exception to this principle: the Member State of destination may refuse the marketing of a product in its current form only where it can show that this is strictly necessary for the protection of, for example, public safety, health or environment. In that case, the Member State of destination must also demonstrate that its measure is the least trade-restrictive measure.

See further the following link <http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/mutual-recognition/>

This is supported by the European Crème de Cassis de Dijon case.



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*“Court of Justice Important EU Court case inventing mutual recognition of standards. EC Court verdict from 1979 stating that, as a general rule, products in one EU country are also legal in other EU countries (case 120/78). The verdict forced the member states to agree on common standards to which they would otherwise not have agreed. The verdict paved the way for decisions by qualified majority under the so-called Internal Market, introduced by the Single European Act in 1987.”*

This is an extremely important decision, because its scope is potentially very wide since many national measures are capable of having an effect on the free trade of goods.

## ESG/Key Eight Steps to food contact compliance

The *ESG/Key Eight Steps* describe the procedure of information collection, evaluation, documentation and compliance for the specific paper sack material composition. By following the *ESG/Key Eight Steps* the paper sack producer can build up the information and data collection which is needed for the evaluation of the specific paper sack material composition in line with the regulations and recommendations applicable for that paper sack.

All paper sack material compositions are subordinated the Regulation (EC) No 1935/2004. To fulfill this regulations the paper sack manufacturer applies the specific rules and recommendations applicable for the specific materials in different types of paper sack material composition as a group. It should though be in combination with the food for which the paper sack is intended. *In general there is only a necessity to show compliance for each sack type as described under STEP 4 for each specific food product the paper sack is intended for.*

There are three parts of the *ESG/Key Eight Steps*:

### **E - Establish background prerequisites**

1. Classify the type of food which will be packed in the paper sack
2. Document the temperature of the food at filling
3. Document the time and temperature for storage of printed paper, empty paper sack and filled paper sack

### **S – Specify sack construction and applicable legislation**

4. Describe the paper sack construction and select the similar reference paper sack material composition in list TYPE I, II, III, IV, V
5. Find applicable Regulations & Recommendations for reference paper sack material composition

### **G – Generate compliance with legislation**

6. Collect the documentation for each layer of materials and other components in the specific paper sack material composition
7. Find out the testing needed for the specific reference paper sack
8. Document and show compliance of the specific paper sack material composition with the regulations and recommendations

## E- Establish background prerequisites

The main objective of the first part of the *ESG/Key Eight Steps* is to classify the food and filling and storing conditions as a basis for testing that might be needed.

### STEP 1. Classify the type of food which will be packed in the paper sack

The food has been classified by Regulation (EC) No 10/2011 in eight main food groups as well as divided into subgroups (see Annex 1). The producer of the paper sack should know what kind of food the paper sack can and will be used for.

#### *Action*

To choose the right “simulant” for migration testing find the product your paper sack is intended for and its classification in Annex I. If testing is needed or not is later decided under STEP 8

### STEP 2. Document the temperature of the food at filling

The speed of migration is dependent on the temperature of the type of packed food in itself and in combination with the properties of the packaging material and time. If the food product is frozen the migration is slower than if the food product has room temperature. The information to bring further in Step 2 is a documentation of the temperature of the food at filling as a basis for selecting parameters for migration testing.

#### *Action*

Document food temperature at filling..

- Ambient: > +5°C
- Cold: 0°C < Temp < + 5°C
- Frozen: < 0 °C

### STEP 3. The time and temperature for storage of printed paper, empty paper sack and filled paper sack

The speed of migration is also dependent on the temperature of the packaging material which is influenced by the storage time and temperatures. The storage time of printed sacks has an influence on permeation through the material as well as on set-off during storage. Set-off means that printing inks are transferred to the other side of the printed layer in the reel or stack.

Table 1 gives an indication from a paper sack manufacturer of maximum storage times/temperatures in different parts of the value chain that might appear.

Table 1 – Estimated maximum storage time and temperatures

Steps in the value chain	Time months maximum	Temperatures °C
Pre-printed paper reels at the manufacture	1	10 to 30
Empty bags at the manufacturer	12	10 to 30
Empty bags at the customers	12	5 to 25
From filling the food to the delivery of the filled sack	6	0 to 25
Customer- date of expiry for the food in the filled sacks (from date of filling )	24	

The producer of the paper sack should estimate the maximum storage times in (weeks or months) and the storage temperatures (°C) in the following parts in the chain:

- From printed reel to sack production (if pre-printing of reels)
- From produced sack to filling
- From filling of food to emptying of sack

This is to ensure that the paper sack manufacturer creates an understanding of the conditions that will appear in the value chain and risk associated with this and that knowledge about this is transferred to the packer/filler through the Declaration of Compliance.

If the sack producer don't know anything about the time from production of sack to filling and from filling to emptying of the filled sack the worst case testing approximations can be used.

*Action*

- Document temperature and storage time for steps:
- From printed reel to sack production (if preprinting of reels)
  - From produced sack to filling
  - From filling of food to emptying of sack

## S – Specify sack construction and applicable legislation

The objective of this second part of the *ESG/Key Eight Steps* is to link the paper sack material composition to the appropriate legislation.

### STEP 4. Describe the paper sack material composition and select the similar reference paper sack construction TYPE I, II, III, IV, V

Make a description of your specific paper sack material composition. The main issues of interest here is if the paper sack contains plastic layers, if it is printed, paper sheets composition and presence of functional barrier. Compare your specific paper sack material composition and select the closest of the reference types in the table below.

Table 2- Shows the different material compositions of the paper sack, Type I to V.

Basic sack type	Description
TYPE I	The paper sack contains only paper and/or inorganic coated paper
TYPE II	The paper sack contains paper and organic coated paper
TYPE III	The paper sack contains paper and paper laminated by a plastic film
TYPE IV	The paper sack contains paper and a free plastic film as a free standing plastic layer
TYPE V	The paper sack contains paper and a plastic tube in contact with food

Inorganic means here coating based on pigment inorganic mineral and organic means plastics dispersions.

Additional information needed:

#### *Is the paper sack printed or not?*

This is important since printing inks might cause problems in food contact. The relative size of the printed area has in relation to regulations no relevance but the area of the paper sack that is printed is important since larger printed area means increased possible migration risk and set-off.

#### *Is the lamination made with adhesive?*

Important since if the lamination is made with adhesive this is seen as a separate layer in the material composition and more information needs to be collected from supplier.

#### *Does the paper sack contain a high performance barrier?*

Important since these types of high performance barriers acts as “functional barriers” and further testing might be reduced a lot or not be necessary at all since these layers prevents migration of substances. Definition of a functional barrier: “functional barrier means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of EC Regulation No 1935/2004 and with the provisions of EC Regulation L10/2011”. Examples of materials than can “work” as “functional barrier” are aluminium or PET.

*Which material is in direct contact with food?*

The packed food shall be protected by the total material composition of the sack, which should be sufficiently inert in relation to the food. The highest requirements regarding migration protection from the total composition is on the material in direct contact with food. Therefore the material in direct contact with food demands the most complete information from supplier and the demand on information from supplier is increasing from TYPE I to TYPE V.

As soon as the composition contains organic coating of plastic or plastic layers one must collect information regarding specific migration for substances with limitations within the plastic layer, see Table 2.

*Action*

Classify your sack construction according to:

- Type I – V
- Printed or not and relative estimated printed area
- Adhesive in lamination
- Contains functional barrier
- Material in direct contact with food

**STEP 5. Applicable regulations & recommendations for the sack material composition**

In the table below you will find an overview of regulations and/or recommendations that are applicable for the different paper sack constructions. Links to different legislative documents can be found in Annex II.

*Table 3 - The Sack Type (I to V) and the main applicable regulations/recommendations*

Layer	Type I	Type II	Type III	Type IV	TYPE V
<b>European regulations</b>					
L1935/2004	X	X	X	X	X
L 2023/2006 (GMP)	X	X	X	X	X
L 10/2011, 1282/2011 (Regarding Type II)*		X	X	X	X
L 10/2011, 1282/2011 (Regarding Type II)**			X	X	X
<b>National recommendation on paper</b>					
BfR § XXXVI paper	X	X	X	X	X
BfR § XIV, § XLI, organic coating		X			
<b>National recommendations on ink</b>					
L 817.023.21(Swiss ordinance on inks) (ONLY APLICABLE IN sWITZERLAND)	X	X	X	X	X
Germany ordinance on inks	NOT	IN	FORCE	YET	

**\*) If plastic dispersion \*\*\*) If non plastic dispersion**

Since late 2010, Germany has been developing an amendment to the German Ordinance on Materials and Articles, introducing printing ink-specific provisions expected to be in force end 2013 / Q1 2014.

The following materials can be used in the construction of the sack: paper and board, plastics, other barrier materials, adhesives, glues, coatings, varnish, printing inks. At the present, besides the European specific regulations on materials, there are national standards or recommendations or regulations. Besides the table above where some important regulations/recommendations are listed there are also other national legislations, standards, recommendations and guidelines that might be applicable. These can be found under the EU link, [http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum\\_nat\\_legis\\_en.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum_nat_legis_en.pdf). It is important that you consult this link in every case.

*Action*

Depending on collected information in STEP 4 and 5 list the regulations/recommendations that will be applicable to your paper sack, including national ones.

## **G – Generate compliance with legislation**

The objective of this last part is to collect relevant information about the paper sack material components, decide if relevant testing is needed and finally make the Declaration of Compliance or similar.

### **STEP 6. Collect the documentation for each layer of materials and other components in the specific paper sack material composition**

The documentation in relation to the specific regulation or recommendation of the material and article can only be ensured if, along the supply chain relevant **information exchange** takes place between the supplier and the customer and vice versa. Collection of information for each layer and other components in the paper sack material composition should follow the description of the type of documentation as shown here. The documentation should be delivered by the supplier to his customer. It has two main aims:

- It confirms to the paper sack manufacturer the compliance of the material with the relevant requirements of the Regulation (EC) No 1935/2004, the Regulation (EC) No 10/2011, the Regulation (EC) 2023/2006 and/or national material regulations if the specific European regulation is missing.
- It provides the paper sack manufacturer with relevant information necessary for him to establish the compliance of his paper sack.

The specific documentation has different status depending on if it has been written by the supplier in relation to the existing EC regulation or in relation to the specific national recommendations or regulations.

The Declaration of Compliance – DoC – is a document delivered by the supplier of plastics to customers. Regulation (EC) No 10/2011 defines demands on the information. For the *plastic*

*layer components* it confirms to the customer the compliance of the product with the relevant requirements of the Regulation (EC) No 10/2011 and the Regulation (EC) No 1935/2004. In order to allow the exchange of relevant information the requirements on the DoC are set out in a standard format in the Plastics Regulation. (Annex II and Table 5). This document provides guidance which information should be provided at the different stages to fulfil these requirements.

For the *non-plastic layer components* (see page 33 for definition) the Framework Regulation does not set out an obligation to issue a Declaration of Compliance. However, as the Plastics Regulation requires that migration of authorized substances and certain other substances should not exceed the established migration limits it is necessary that *Adequate Information (AI)* is provided by the suppliers of *adhesives, printing inks, glues and inorganic coatings*, that allows the manufacturer of the final plastic containing article to establish compliance with the Plastics Regulation for these substances. **This does not apply to paper layers.**

Paper and board Adequate Information (AI) should be in line with the BfR (Germany) § XXXVI) or other applicable national regulation specific for paper and board, which are in force in countries like Italy, France or Netherlands.

The table below shows a summary of information that should be requested by the paper sack manufacturer from his supplier: The AI can be linked to national legislation only or also to L10/2011. The AI information can then differ.

Table 4- Type of requested documentation depends on the construction of the paper sack

Layers	TYPE I	TYPE II	TYPE III	TYPE IV	TYPE V
Plastic layer(-s), (L10/2011)	-	-	DoC	DoC	DoC
Paper layer(-s), (BfR §XXXVI)	AI	AI	AI	AI	AI
Organic Coating (non plastic), BfR § XIV	-	AI	-	-	-
Plastic dispersion, (L10/2011)	-	DoC*			
Adhesive(-s) (for lamination)		AI	AI	AI	AI
Glue (for construction)	AI	AI	AI	AI	AI
Ink(-s), national recommendations if any	AI	AI	AI	AI	AI

\*) If the organic coating is based on chemicals present in the plastic legislation DoC should be used and if the coating is based on chemicals in the BfR not present in European legislation, Adequate Information is sufficient.

Most of the regulations are valid for all sack types I – V but depending on TYPE there are different requirements on information content from supplier. This is requested information depending on Type.

*TYPE I - The paper sack contains only paper and/or inorganic coated paper*

- Adequate Information (AI) for paper based on national recommendations for paper as stated in CEPI/CITPA Industry Guideline.
- General requirements for Adequate Information on glue, inks.

*Note that the Industrial Guidelines states that the paper supplier should issue a Declaration of Compliance. In these Guidelines we have used the wording AI (Adequate Information).*

*TYPE II - The paper sack contains paper and organic coated paper*

- Adequate Information (AI) for paper based on national recommendations for paper as stated in CEPI/CITPA Industry Guideline.
- Declaration of Compliance showing chemicals with limitations in organic coated layer in plastics regulation.
- General requirements for Adequate Information on glue, inks.

*TYPE III – The paper sack contains paper and plastic laminated paper*

- Adequate Information (AI) for paper based on national recommendations for paper as stated in CEPI/CITPA Industry Guideline.
- Declaration of Compliance (DoC) showing chemicals with limitations in the regulation for plastic layer of the plastic laminated paper.
- Migration test mandatory by supplier of plastics layer in the plastic laminated paper.
- Overall and specific Migration tests mandatory from supplier of plastic layer in laminate material depending on plastic chemistry.
- Adhesive in laminate gives need for Adequate Information (AI) on adhesive layer.
- General requirements for Adequate Information on glue, inks.

Requirements above are valid whether the plastic laminated paper is in direct contact with food or not.

*TYPE IV - The paper sack contains paper and a free plastic film*

- Adequate Information (AI) for paper based on national recommendations for paper as stated in CEPI/CITPA Industry Guideline.
- Declaration of Compliance for free plastic material showing chemicals with limitations in the regulation for plastic layer.
- Overall and specific Migration tests mandatory from supplier for free plastic material depending on plastic chemistry.
- General requirements for Adequate Information on glue, inks.

Requirements above are valid whether the plastic laminated paper is in direct contact with food or not.

*TYPE V - The paper sack contains paper and a plastic tube in contact with food*

- Adequate Information (AI) for paper based on national recommendations for paper as stated in CEPI/CITPA Industry Guideline.
- Declaration of Compliance for tube plastic material showing chemicals with limitations in the regulation for plastic layer.
- Overall and specific migration tests mandatory from supplier for free plastic material depending on plastic chemistry.
- General requirements for Adequate Information on glue, inks.

Declaration of Compliance, DoC for plastic must be in line with Regulation (EC) No 10/2011, referred to in Article 15, and it shall contain the following information for plastics layer:

- (1) The identity and address of the business operator issuing the declaration of compliance;
- (2) The identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;
- (3) The identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials/articles;
- (4) The date of the declaration;
- (5) Confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation L No 1935/2004;
- (6) Adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II in L 10/2011 Regulation to allow the downstream business operators to ensure compliance with those restrictions;
- (7) Adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;
- (8) Specifications on the use of the material or article, such as:
  - (i) Type or types of food with which it is intended to be put in contact;
  - (ii) Time and temperature of treatment and storage in contact with the food;
  - (iii) Ratio of food contact surface area to volume used to establish the compliance of the material or article;
- (9) When a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

Paper producers can follow CEPI/CITPA Industry Guideline requirements.

Adequate Information (AI) is for non-plastic layers as glue, adhesives, inorganic coatings or printing inks so that requirements set under Plastics Regulations are met in the plastics-multilayers materials. The following information should be present in AI:

- (1) The identity and address of the business operator issuing the AI;
- (2) *Information not mandatory;*
- (3) The identity of the substance, CAS number, with the limits as well information on dual use additives (E number – food additives);
- (4) The date of the documents;
- (5) Confirmation that substances is authorised under L 10/2011;
- (6) Relevant restrictions as SML, SML (T), QM or limits of specific use;
- (7) *Information not mandatory;*
- (8) Specifications on the use of the material or article, such as:(i) type or types of food with which it is intended to be put in contact;(ii) time and temperature of treatment and storage in contact with the food;
- (9) *Information not mandatory.*

*Action*

Collect the DoC and/or AI from suppliers according to demands shown under STEP 6

**STEP 7. Find out about the testing needed for the specific paper sack material composition**

The sack manufacturer has different possibilities to test the whole sack construction to ensure the sack inertness and safety for the food. The need for the paper sack manufacturer to do testing of the specific paper sack construction has to be based on the background information that has been collected during STEP 1-7.

The paper is tested by the paper producer following Industrial Guidelines but the actual printed final construction is the responsibility of the paper sack manufacturer. Inorganic coating is part of the paper and testing is handled by the paper producer but also here the final printed paper sack construction is the responsibility of the paper sack manufacturer.

If the paper sack contains organic coated paper where the organic coating contains substances with limitations regarding Specific Migration the responsibility for testing and verifying compliance could initiate a discussion between the ones making the coating and the paper sack manufacturer as responsible for the final printed paper sack material composition. Same situation when it comes to laminated paper.

In principle, the one producing the different components of a paper sack should take responsibility for any specific migration limits in these components but it is the paper sack manufacturer who has responsibility for the final paper sack material composition. Good quality and completeness of collected information simplifies the task for the paper sack manufacturer to show compliance for his paper sack.

The demand for set-off testing is not expressed explicitly and if the printed outer layer of the paper sack is not in direct contact with food the risk is lower for migration over limitations. Set-off testing is done for specific migration with Tenax. It is up to the sack producer if he should test to make sure that there is no set-off or not.

Other tests on free plastic layers or plastic tubes are only necessary if the supplier has not conducted them according to his DoC or AI.

It is easier to look for substances if the supplier has done the material testing and if the ink supplier has identified the critical substances.

The table below summarizes the different testing needs. If the supplier has not conducted the migration tests in TYPE IV and V this has to be done by the paper sack manufacturer.

Table 5 - Type of testing needed for Type I to V

Basic sack type	If printed	Overall migration	Specific migration to Tenax
TYPE I	Set off	-	-
TYPE II	Set off	Voluntary	Voluntary
TYPE III	Set off	Voluntary	Voluntary
TYPE IV	Set off	Performed on plastic layer	Performed on plastic layer
TYPE V	Set off	Performed on tube	Performed on tube

As these multi-materials multilayer constructions are not part of the scope of the regulation for plastics L 10/2011 as a whole we don't have specific rules on testing at EU level. In this case you have to do what you do with all materials for which no specific measures are in place at EU level according to mutual recognition. If it is not in place it is up to the manufacturer to find the most appropriate way to demonstrate compliance with 1935/2004. To ensure that the paper sack construction is in line with Regulation No 2023/2006 it is appropriate to implement specific migration tests and use in this case Tenax, but only for substances with limitations in L10/2011.

Overview of overall migration tests follows the Regulation (EC) No 10/2011 for plastics and plastic multi-layer materials which can be applicable for the paper sack.

The tables below show the different simulants for migration testing.

Table 6 Simulants for overall migrations test, on plastics or plastics multilayers.

Simulant	A	B	C	D2
	10% Ethanol	3% Acetic acid	20 % Ethanol	EX; Olive oil or alternative

Table 7 Simulants for testing of specific migrations from plastics.

Simulant		B	C	D2	E
		3% Acetic acid	20 % Ethanol	Olive oil	Tenax

Table 8 Simulant for testing of Set-off.

Simulant				E
	Tenax is the poly (2,6-diphenyl-p-phenylene oxide), PPPO particle size 60-80 mesh, pore size 200 nm (L 10/2011). (C18H12O) <sub>x</sub> molecular formula			Tenax

Table 9 Testing simulant of migration of the components to dry and frozen foods .

Simulant			E
Tenax is the poly(2,6-diphenyl-p-phenylene oxide), PPPO particle size 60-80 mesh, pore size 200 nm (L 10/2011). (C <sub>18</sub> H <sub>12</sub> O) <sub>x</sub> molecular formula			Tenax

#### **STEP 8. Document which show compliance of the specific paper sack construction with the regulations and recommendations**

As stated in the introduction, this Guideline has the intention to propose a structured way to the paper sack manufacturer to handle food contact issues. To decide upon measures regarding testing and compliance documentation for the final paper sack composition based on collected documentation and data collection regarding temperatures, storage times, etc, it needs someone with knowledge about food contact legislation.

Producers of paper sacks have to write their own statement based on both collected documentation as well as of any own testing results.

In the documentation from the paper sack manufacturer he should draw conclusions and evaluate both test results and state which regulations and measures he is using as a reference. This means that the paper sack manufacturer states what the paper sack is in compliance with and why.

## Labeling

The labelling requirements of the Framework Regulation, Article 15 requires that materials and articles not yet in contact with food should be, if necessary, accompanied with special instructions for safe and appropriate use. E.g. by the words ‘for food contact’,



Or a specific indication as to their use, such as coffee machine, wine bottle, soup spoon, or the symbol reproduced in Regulation (EC) No 10/2011.

L 1935 /2004 state that:

Without prejudice to the specific measures referred to in Article 5, materials and articles, which are not yet in contact with food when placed on the market, shall be accompanied by: the words ‘for food contact’, or a specific indication as to their use, such as coffee machine, wine bottle, soup spoon, or the symbol reproduced; and if necessary, special instructions to be observed for safe and appropriate use; and the name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market established within the Community; and adequate labeling or identification to ensure traceability of the material or article, as described in Article 17.

There are no recommendations or demands on size of the symbol. The labelling does not have to appear on the sack itself but can be provided on accompanying documents too.

## Annex I - Description of foodstuffs according to Regulation (EC) No 10/2011 and resulting type of simulant in testing

Ref no.	Description of the foodstuff	Ref no.	Description of the foodstuff
01	Drinks		
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 6% vol.	06.03	Meat of all zoological species (including poultry and game)
01.01	A. Clear beverages: Water, cider, fruit or vegetable juice of normal strength or concentrated, fruit nectar, lemonade, boiled juice, bitters, herbal teas, coffee, tea, beer, soft drinks, energy drinks and similar, flavoured water and liquid coffee extract	06.03	A.Fresh, chilled, salted or smoked
01.01	B. Opaque beverages: Juice, nectar and soft drinks with fruit pulp, must with fruit pulp and liquid chocolate	06.03	B.Processed meat products (e.g. ham, salami, bacon, sausages and other) or in pasta or cream form
01.02	Alcoholic beverages of an alcoholic strength of 6-20% vol.	06.03	C.Marinated meat products in an oily medium
01.03	Alcoholic beverages of an alcoholic strength of more than 20% vol. and all cream liqueurs	06.04	Preserved meat:
01.04	Other: undenaturated ethylalcohol	06.04	A.In a fatty or oily medium
02	Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares	06.04	B.In an aqueous medium
02.01	Starches	06.05	Whole eggs, egg yolks, egg whites
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)	06.05	A.In powder form, dried or frozen
02.03	Fine and coarse flour of cereals	06.05	B.Liquid and cooked
02.04	Dry pasta, e.g. macaroni, spaghetti and the like, fresh pasta	07	Milk products
02.05	Pastry, biscuits, cakes and other bakers' wares, dry	07.01	Milk
02.05	A.With fatty substances on the surface	07.01	A.Milk and milk based beverages, whole milk, condensed milk, and skimmed/partly skimmed milk
02.05	B.Other	07.01	B.Milk powder incl. infant formula (based on whole milk)
02.06	Pastry, cakes, loaves, dough and other bakers' wares fresh:	07.02	Fermented milk such as yoghurt, buttermilk and the like
02.06	A.With fatty substances on the surface	07.03	Cream and sour cream
02.06	B.Other	07.04	Cheese:
03	Chocolate, sugar and products thereof, confectionery products	07.04	A.Whole, with inedible rind
03.01	Chocolate, chocolate coated products, substitutes and products coated with substitutes	07.04	B.Cheese without rind or with an edible rind (Gouda, Camembert and similar) and processed cheese
03.02	Confectionery products:	07.04	C.Processed cheese (spread cheese, cottage cheese and similar)
03.02	A.In solid form	07.04	D.Preserved cheese:

03.02	I. With fatty substances on the surface	07.04	I. In an oily medium
03.02	II. Other	07.04	II. In an aqueous medium (feta cheese, mozzarella and similar)
03.02	B. In semi-solid form:	08	Miscellaneous products
03.02	I. With fatty substances on the surface	08.01	Vinegar
03.02	Moist	08.02	Fried or roasted foods:
03.03	Sugar and sugar products	08.02	A. Fried potatoes, fritters and the like
03.03	A. In solid form: crystals or powder	08.02	B. Of animal origin
03.03	B. Molasses, sugary syrup, honey and the like	08.03	Preparations for soups, broths, in liquid, solid or powder form (extracts, concentrates); homogenized composite foods, preparations, prepared dishes, including yeast and rising agents
04	Fruit, vegetables and products thereof	08.03	A. In powder form or dried
04.01	Whole fruits, fresh or chilled, unpeeled	08.03	I. Of a fatty character
04.02	Processed fruit:	08.03	II. Other
04.02	A. Dried or dehydrated fruit, whole, sliced or in the form of flour or powder	08.03	B. In other forms than powder or dried:
04.02	B. Fruit in the form of purée, preserves, paste or in its own juice or syrup (jam, compote and the like)	08.03	I. Of a fatty character
04.02	C. Fruit preserved in a liquid medium:	08.03	II. Other
04.02	I. In an oily medium	08.04	Sauces:
04.02	II. In an alcoholic medium	08.04	A. Aqueous
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and other):	08.04	B. Of a fatty character, e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil in water emulsions, e.g. sauces from coconut milk
04.03	A. Shelled, dried, flaked or ground	08.05	Mustard (except mustard in powder form under 08.14)
04.03	B. Shelled and roasted	08.06	Sandwiches, toasts, pizza and the like with any kind of food
04.03	C. In paste or cream form	08.06	A. With a fatty surface
04.04	Whole vegetables, fresh or chilled, unpeeled	08.06	B. Other
04.05	Processed vegetables:	08.07	Icecream
04.05	A. Dried or dehydrated vegetables, whole, sliced or in the form of flour or powder	08.08	Dried food
04.05	B. Fresh vegetables, peeled or cut	08.08	A. With a fatty surface
04.05	C. Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine)	08.08	B. Other
04.05	D. Preserved vegetables:	08.09	Frozen or deep-frozen foods
04.05	I. In an oily medium	08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.
04.05	II. In an alcoholic medium	08.11	Cocoa
5	Fats and oils	08.11	A. Cocoa powder, also with reduced or very reduced fat contents
05.01	Animal and vegetable fats and oils, whether natural or treated (inklusive cocoabutter, lard and resolidified butter)	08.11	B. Cocoa paste

05.02	Margarine, butter and other fats and oils made from water emulsions in oil	08.12	Coffee, roasted or unroasted, decaffeinated or soluble, coffee substitutes, granulated or powdered
06	Animal products and egg	08.13	Aromatic herbs and other herbs, e.g. camomile, mallow, mint, tea, malva, mynta, te, linden flower and others
06.01	Fish:	08.14	Spices and seasonings in the natural state, e.g. cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and others
06.01	A.Fresh, chilled, processed, salted or smoked, including roe	08.15	Spices and seasonings in an oily medium, e.g. pesto and curry paste
06.01	B.Preserved fish:	08.11	B.Cocoa paste
06.01	I.In an oily medium	08.12	Coffee, roasted or unroasted, decaffeinated or soluble, coffee substitutes, granulated or powdered
06.01	In a waterbased medium	08.13	Aromatic herbs and other herbs, e.g. camomile, mallow, mint, tea, malva, mynta, te, linden flower and others
06.02	Crustaceans and molluscs (including oysters, mussels and snails)	08.14	Spices and seasonings in the natural state, e.g. cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and others
06.02	A.Fresh with shells	08.15	Spices and seasonings in an oily medium, e.g. pesto and curry paste
06.02	B. Shelled, processed, preserved or cooked with shells		
06.02	I.In an oily medium		
06.02	II.In a waterbased medium		

**Table showing the type of simulant that should be used for different foodstuffs**

Ref.	Description of the foodstuff	A	B	C	D2	Tenax
02	Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares					
02.01	Starches					x
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)					x
02.03	Fine and coarse flour of cereals					x
02.04	Dry pasta, e.g. macaroni, spaghetti and the like, fresh pasta					x
02.05	Pastry, biscuits, cakes and other bakers' wares, dry					
02.05	A. With fatty substances on the surface				x	
02.05	B. Other					x
02.06	Pastry, cakes, loaves, dough and other bakers' wares fresh:					
02.06	A. With fatty substances on the surface				x	
02.06	B. Other					x
03	Chocolate, sugar and products thereof, confectionery products					
03.01	Chocolate, chocolate coated products, substitutes and products coated with substitutes				x	
03.02	Confectionery products:					
03.02	A. In solid form				x	
03.02	I. With fatty substances on the surface					x
03.02	II. Other					
03.02	B. In semi-solid form:				x	
03.02	I. With fatty substances on the surface					x
03.03	Sugar and sugar products					
03.03	A. In solid form: crystals or powder					x
04	Fruit, vegetables and products thereof					
04.01	Whole fruits, fresh or chilled, unpeeled					
04.02	Processed fruit:					
04.02	A. Dried or dehydrated fruit, whole, sliced or in the form of flour or powder					x
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and other):					
04.03	A. Shelled, dried, flaked or ground					x
04.03	B. Shelled and roasted					x
04.04	Whole vegetables, fresh or chilled, unpeeled					
04.05	Processed vegetables:					
04.05	A. Dried or dehydrated vegetables, whole, sliced or in the form of flour or powder					x
04.05	B. Fresh vegetables, peeled or cut	x				
05	Fats and oils					
06	Animal products and egg					
06.01	Fish:					
06.01	A. Fresh, chilled, processed, salted or smoked, including roe	x				x
06.02	Crustaceans and molluscs (including oysters, mussels and snails)					
06.02	A. Fresh with shells					
06.03	Meat of all zoological species (including poultry and game)					
06.03	A. Fresh, chilled, salted or smoked	x				x
06.03	B. Processed meat products or in pasta or cream form	x				x
06.05	Whole eggs, egg yolks, egg whites					
06.05	A. In powder form, dried or frozen					x
07	Milk products					
07.01	B. Milk powder incl. infant formula (based on whole milk)					
07.04	Cheese:					
07.04	A. Whole, with inedible rind					x
07.04	B. Cheese without rind or with an edible rind and processed cheese				x	



08	Miscellaneous products					
08.02	Fried or roasted foods:				X	
08.02	A.Fried potatoes, fritters and the like				X	
08.02	B.Of animal origin					
08.03	Preparations for soups, broths, in liquid, solid or powder form; homogenized composite foods, preparations, prepared dishes, including yeast and rising agents					
08.03	A.In powder form or dried					
08.03	I.Of a fatty character				X	
08.03	II. Other					X
08.03	B.In other forms than powder or dried:					
08.03	I. Of a fatty character	X	X			X
08.03	II.Other		X	X		
08.06	Sandwiches, toasts, pizza and the like with any kind of food					
08.06	A.With a fatty surface	X			X	
08.06	B.Other					X
08.07	Icecream			X		
08.08	Dried food					
08.08	A.With a fatty surface				X	
08.08	B.Other					X
08.09	Frozen or deep-frozen foods					
08.11	Cocoa					
08.11	A.Cocoa powder, also with reduced or very reduced fat contents					X
08.11	B.Cocoa paste				X	
08.12	Coffee, roasted or unroasted, decaffeinated or soluble, coffee substitutes, granulated or powdered					X
08.13	Aromatic herbs and other herbs, e.g. camomile, mallow, mint, tea, malva, mynta, te, linden flower and others					X
08.14	Spices and seasonings in the natural state, e.g. cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and others					X
08.15	Spices and seasonings in an oily medium, e.g. pesto and curry paste				X	

## Annex II - List of regulations and recommendations

EEC regulation has been published in all EEC languages. The links show just the English version. Regulation official versions in EU are written in English, German and French, these documents can be used as reference if the regulation has not been published in another EU leagues.

### European level

Regulation (EC) No 1935/2004

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/framework\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/framework_en.htm)

Regulation (EC) No 2023/2006 – Good Manufacturing Practise

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

Regulation (EC) No 10/2011 + amendments

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

update 321/2011

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R1282:EN:NOT>

update 1282/2011

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R1282:EN:NOT>

### National level

#### Germany

Federal Institute for Risk Assessment (BfR) covers different type of materials. BfR system and § XXXVI is for paper and board.

[http://bfr.zadi.de/kse/faces/DBEmpfehlung\\_en.jsp?filter=clear](http://bfr.zadi.de/kse/faces/DBEmpfehlung_en.jsp?filter=clear)

There is the English version of BfR recommendations

Regulation on inks in Germany – <http://safepackaging.eu/details-german-draft-regulation-printing-inks> is not published yet, but is expected year 2014.

#### Switzerland

817.023.21 <http://www.admin.ch/ch/d/sr/8/817.023.21.de.pdf>

[http://www.admin.ch/ch/d/sr/817\\_023\\_21/index.html](http://www.admin.ch/ch/d/sr/817_023_21/index.html)

<http://safepackaging.eu/english-translation-swiss-ordinance-sr-81702321-packaging-inks>



Nordic Guide for printing inks

<http://www.norden.org/en/publications/publikationer/2012-521/>

## Others

CEPI Good Manufacturing Practice for papermaking published in 2010

<http://www.cepi.org/topics/foodcontact/publications/Industryguidelineissue2>

CEPI/CITPA Industry Guideline for the Compliance of Paper & Board materials and Articles for Food Contact, issue 2, September 2012.

<http://www.cepi.org/topics/foodcontact/> or <http://www.citpa-europe.org/library/industry-guidelines>

Commitments related to the manufacture and supply of food packaging inks, EUPIA

[http://www.eupia.org/EPUB/easnet.dll/ExecReq/Page?eas:template\\_im=10008E&eas:dat\\_im=05048E](http://www.eupia.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=10008E&eas:dat_im=05048E)

## Annex III - Definitions

Here are some definitions following the Regulation (EC) No 10/2011. The text is taken from legislative documents.

### Plastics

Plastics are made of monomers and other starting substances which are chemically reacted to a macromolecular structure, the polymer, which forms the main structural component of the plastics. The polymer additives are added to achieve defined technological effects. The polymer as such is an inert high molecular weight structure. As substances with a molecular weight above 1 000 Da usually cannot be absorbed in the body the potential health risk from the polymer itself is minimal. Potential health risk may occur from non- or incompletely reacted monomers or other starting substances or from low molecular weight additives which are transferred into food via migration from the plastic food contact material. Therefore monomers, other starting substances and additives should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.

Plastics can also be made by micro-organisms that create macromolecular structures out of starting substances by fermentation processes. The macromolecule is then either released to a medium or extracted. Potential health risk may occur from the migration of non- or incompletely reacted starting substances, intermediates or by-products of the fermentation process. In this case the final product should be risk assessed and authorised before its use in the manufacture of plastic materials and articles.

Plastic materials covered by the scope of the Regulation are based on synthetic polymers and synthetic or natural polymers that have been chemically modified. Natural polymers that have not been chemically modified are not covered by the scope of the Regulation. The Regulation also covers plastics based on polymers manufactured by microbial fermentation.

The Regulation covers bio-based and bio-degradable plastics if they are manufactured with synthetic polymers, chemically modified natural or synthetic polymers or polymers manufactured by microbial fermentation.

An “intermediate plastic material” which is referred to in Art. 15 of Regulation (EC) No 10/2011, as a “product from intermediate stages of manufacture” e.g. a plastic powder, granules or flakes (including “masterbatch<sup>3</sup>”), pre-polymer excluding Article 6(3)(d), any semi-finished material and article such as a film, sheet, laminate, etc. requiring further processing/re-formulation steps to become a “finished” material or article. In short this is any product which is not a basic chemical and not yet a finished plastic material or article.

For the purpose of this document the plastic layers intended to be used in multi-material multilayers but not yet part of it are regarded as intermediate materials.

An “**intermediate non-plastic material**” is an ink, a coating or an adhesive formulation applied in the printing or coating of plastic articles or in combining of plastic layers. They still require application on the plastics and may require drying or curing. The composition may change due to reaction and degradation the "*final plastic material or article*" ready to go into contact with food but not yet in contact with food. This can be:

- i. the finished plastic food contact material or article (e.g. packaging material, storage containers for food, bulk food or food ingredients, bottle, tray, kitchenware or utensil, plastic part in food-processing machinery, food preparation surface);
- ii. the plastic layers inside a finished multi-material multilayer ;( see the box)
- ii. finished components of the final food contact material or article which only need to be brought together or assembled, either during packing/filling or before, to make the final article (e.g. bottle and cap, tray and lid, parts of kitchenware or food processing machinery).

**Plastic multi-layer** means a material or article composed of two or more layers of plastic.

**MMML - multi-material multilayer** cover many materials as plastics, paper and board, aluminium, coatings, adhesives, inks which are linked together in one construction as a material. MMML - multi-material multilayer means a material or article composed of two or more layers of different types of materials, at least one of them a plastic layer.

### **Definitions of materials construction in line with Regulation (EC) No 10/2011**

Example of polymer types as plastic layer can be: HDPE- High Density Polyethylene, LDPE- Low Density Polyethylene, LLDPE- Liner Low Density Polyethylene, PP- Polypropene, PET- Polyethylenetherephtalate and EVOH- Ethylene Vinyl Alcohol copolymer.

Plastic multi-layer materials is a construction where the plastic is food contact material and the layers of adhesives, coatings, aluminium and inks are part of the multilayer's construction.

Multi-material multi-layer materials as used for the construction of the sack is the construction including other materials, which are not coatings, not inks, not adhesives but e.g. paper and board. In constructions like this the plastic part of the construction should follow the legislative request for the plastics multi-layers materials.

The multi-materials multi-layers materials are not regulated by L 10/2011; however the plastic layer in this material is the plastic material in context of L 10/2011. The paper and board materials are not covered by L 10/2011 as they are not plastics multilayers, however the paper itself is covered e.g. by BfR § XXXVI or other national regulation, and the total construction is covered by Regulation (EC) No 1935/2004 at EU market.

**Recycled plastic** materials and articles made from unused plastic production offcuts and/or process scraps in compliance with Directive 2002/72/EC that are recycled within the

manufacturing site or are used at another site. The recycled plastics can be used in materials in contact with foods if they have been produced at an authorized recycling process which is in the Register published by EU Commission.

### **Additional definitions**

‘Specific migration limit’ (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants.

‘Total specific migration limit’ (SML (T)) means the maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated.

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

‘Non-fatty food’ means a food for which in migration testing only food simulants other than food simulants D1 or D2 are laid down in Table 2 of Annex V to this Regulation.

‘Restriction’ means limitation of use of a substance or migration limit or limit of content of the substance in the material or article.

### **Examples of materials composition**

Example 1: *A film manufacturer produces a 3 layer film (PP/PE/PP).*

The polypropylene grade (the two PP layers are manufactured from the same PP grade supplied by the same supplier) does not contain any additive with SML. The PE supplier does not want to disclose the additive with an SML of x mg/kg present in the PE grade sold, but confirms that the SML will not be exceeded by worst case calculation (100 % migration) for a film thickness of 150 µ. The customer will be able to confirm compliance, with this respect as the thickness of the PE layer is 150 µ or less. If the customer wants to use it above 150 µ then additional communication with the supplier is necessary.

Example 2: *A film manufacturer produces a 3 layer film (PP/PE/PP). Same example as above, but now the PP supplier is confirming the use of an additive with an SML mg/kg.*

The customer can confirm compliance as he has the proof that the two additives with SML used by his two suppliers are different.

Example 3: *A film manufacturer produces a 3 layer film (PP/PE/PP). Same Example as 1, but this time the PE and PP suppliers have both indicated the same SML of x mg/kg for their respective additive.*



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It may or may not be the same additive. In this case the two suppliers will have to disclose a maximum level for the additive present. With that information, the customer can check compliance as a worst case scenario (same additive, both levels added together). If by calculation the SML is exceeded, then additional communication with the supplier is necessary to receive more detailed information.

## Annex IV - Recycled paper

Recycled paper has been described by BfR/Germany as following the Federal Institute for Risk Assessment Annex to recommendation § XXXVI.

Preconditions for the use of recycled fibres as raw materials for the production of paper are quoted below from BfR.

Generally products made from recycled fibres have to comply with all other requirements of recommendation XXXVI. Substances, such as ingredients of printing inks or adhesives, which can be in the recovered paper used as raw material, have to comply with additional requirements. Regarding conformity with the rules of the Good Manufacturing Practice the possible presence of these substances, depending on the use of the papers and boards manufactured from recycled fibres has to be considered by a careful selection of the grade of recycled paper and the use of suitable cleaning methods.

Moreover, with regards to the compliance with the requirements laid down in article 3 of regulation 1935/2004/EC, particular care has to be taken with the analytics of products with respect to the possible migration of substances of health-concern into foodstuffs.

According to the current state of knowledge, known substances which may be introduced by paper recycling and require specific inspections are listed below.

Content and migration of these substances into foodstuffs respectively have to comply with the specified limits.

Substance	Content in finished paper	Migration into foodstuff or simulant
Primary aromatic amines*		ND, non-detectable, (in the extract of the finished material, the detection limit for paper yet has to be defined)
4,4'-Bis(dimethylamino)-benzophenone*		ND (DL 0.01 mg/kg)
Phtalates <ul style="list-style-type: none"> <li>• Diethylhexyl phthalate</li> <li>• Di-n-butyl phthalate</li> <li>• Diisobutyl phthalate</li> </ul>		Max. 1.5 mg/kg Max. 0.3 mg/kg Max. 0.3 mg/kg The sum of Di-n-butyl phthalate and Diisobutyl phthalate must not exceed 0.3 mg/kg.
Benzophenone		Max. 0.6 mg/kg
Bisphenol A*		Max. 0.6 mg/kg



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Diisopropylnaphthalene	As low as technically feasible	
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\* Verification of the specifications is only required if the finished products are intended for use with moist and fatty foodstuffs.



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