eurosac

CEPI EUROKRAFT
European Producers of Sack Kraft Paper and Kraft Paper

FOOD CONTACT GUIDELINE

2025 UPDATE

FOREWORD

The objectives of the European Paper Sack Research Group (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 to handle food contact legislation as a support to the paper sack manufacturer. It should be emphasised though **that food contact legislation is very complex and should be handled by a knowledgeable person** in the company.

The scope of the guideline is limited to legislations and recommendations covering the safety of food contact materials and articles. Legislation dealing with environmental matters, such as the REACH regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) are not within the scope of this guideline. Furthermore, the guideline covers legislations and recommendations in place on the European market.

The ESG Food Contact Guideline has the objective to make the sack producer understand his responsibilities in relation to different regulations. The guideline shows how and when these different regulations are needed to be met depending on the composition of the paper sack, type of food product, temperatures and time during storage, input materials, etc. It clarifies who is responsible for what and when in the "lifetime" of a paper sack, from production of input materials to emptying of the food product contained within the paper sack.

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

The revised CEPI/CITPA Food Contact Guideline was published on April 9th, 2019. In some cases, this guideline and the ESG Guideline are overlapping but should be seen as complimentary documents.

PRODUCED BY

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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ESG Food Contact Guideline, 4th edition, Eurosac, Paris and CEPI Eurokraft, Stockholm, May 2025.

Copies can be downloaded from Eurosac and CEPI Eurokraft websites.

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CHAPTER 1

Introduction to the guideline

The main component in a paper sack is paper, to a large extent based on virgin fibres, combined with plastics, metals, inks, adhesives, glue, etc. In addition, chemicals to enhance process or packaging performance are needed to provide today's paper sacks with properties that meet the various demands. When food comes into contact with paper sacks 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.

There are regulations and recommendations in place to ensure that materials are safe to use in contact with food.

Food contact materials are defined as:

- **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 and cutlery**
- **materials that can reasonably be expected to be brought into contact with food such as food preparation areas or the inner walls and shelves of refrigerators.**

Food products which will be in contact with the material can be of varying character: they can be fatty on the surface, they can contain fat, they can be dry or moist. The migration of substances from the food contact material to the food is dependent on several parameters, for example type of food, characteristics of the chemicals as well as the time and temperature during storage. Migration of chemicals can be investigated through migration testing with simulants. A food simulant is a test medium that mimics food in its behaviour. The food simulant is used to mimic migration from food contact materials into the food. The amount of substances in the packaging material which might migrate can be investigated by extraction testing.

CHAPTER 1

The European community regulation (EC) No 1935/2004 covers all materials and articles intended to come into contact with food and sets the basic requirement for these materials. Regulation (EC) No 2023/2006 on Good Manufacturing Practices also applies to all food contact materials. In addition, there are material specific measures for some types of materials, for example regulation (EU) No 10/2011 on plastic food contact materials. For those materials not covered by specific measures on a European level, for example paper and board, there are in some cases national regulations or recommendations.

A paper sack intended for food products can be constructed in many different ways, with different materials, so called multi-material multi-layer (MMML). 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 like 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, can in some cases be seen as having a functional barrier towards migration. The paper sack can be printed on the outside layer and also glue can be a part of the final construction.

As many input materials are present in the paper sack and different foods can be packed in a particular paper sack construction, there is a need for information from suppliers of all used materials in the paper sack as well as information on the type of food that will be packed in the sack. There is a need to clarify who is responsible for fulfilling food contact requirements linked to materials, paper sacks and food, during the "lifetime" of the sack.

The food producer has to fulfil Regulation (EC) No 178/2002 on food which ensures the quality of foodstuffs intended for human consumption and animal feed. In order to do so the food producer needs information on the food contact compliance of the paper sack.

We have established the "ESG/Key Seven Steps" which will help to facilitate the process of ensuring compliance with the legislation for the paper sack manufacturer. **We strongly recommend establishing a good dialogue between the supplier, the customer and the paper sack filler, in these matters.**

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

CHAPTER 2

Introduction to food contact regulations

An understanding of the regulations applicable to food contact materials and articles (FCM) is crucial in order to be able to ensure the safety of a paper sack. This chapter will give a brief introduction to some important elements of the legislation.

Food contact legislation in the European Union

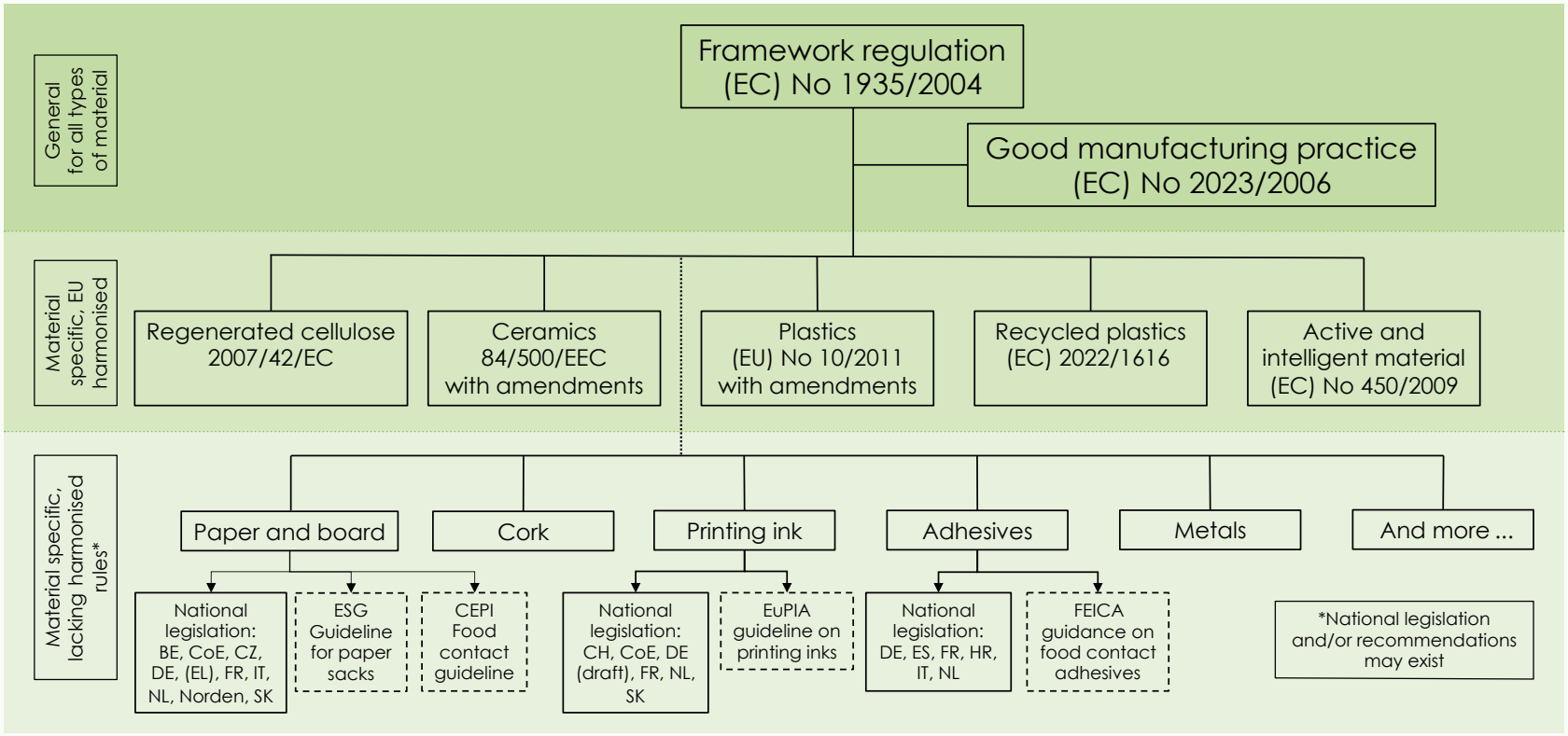

Figure 1: Overview of relevant FCM-legislations and recommendations in the EU.

CHAPTER 2

EU regulations

All materials and articles for food contact are covered by regulation (EC) No 1935/2004 and (EC) 2023/2006, these are so called "horizontal" legislations. Material specific legislation exists for some types of food contact materials but is lacking for others.

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

Regulation (EC) No 1935/2004 concerns all parties of the supply chain, from producers of raw materials, chemicals, inks, adhesives, packaging materials to food packers and retailers. The regulation sets the basic requirement for food contact materials and is often referred to as the framework regulation.

The regulation applies to all food contact materials and articles, including active and intelligent food contact materials, which in their finished state:

a) are intended to be brought into contact with food

b) are already in contact with food and were intended for that purpose

c) can reasonably be expected to be brought into contact with food or to transfer their constituent to food under normal or foreseeable use.

The main principle is that any material or article intended to come into contact with food, directly or indirectly, must be sufficiently inert to avoid substances from being transferred to food in unwanted quantities.

CHAPTER 2

Article 3 of regulation (EC) No 1935/2004 states that:

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

   b) bring about an unacceptable change in the composition of the food

   c) bring about a deterioration in the organoleptic characteristics thereof.

2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

Article 17 of regulation (EC) No 1935/2004 sets requirements on traceability and requires that traceability of materials and articles intended to come into contact with food shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

The European Framework Regulation (EC) No 1935/2004 must always be met and a company shall always be prepared to show compliance with it.

CHAPTER 2

Regulation (EC) No 2023/2006 on good manufacturing practice

Regulation (EC) No 2023/2006 lays down the rules on Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food. The regulation applies 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.

Beyond setting requirements for quality assurance system, quality control system and documentation, the regulation includes an annex dealing with the migration of chemicals from printing inks due to the lack of specific measures for printing inks on a European level. The GMP regulation states that:

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 either:

   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 either:

   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.

3. The printed surfaces shall not come into direct contact with food.

CHAPTER 2

Regulation (EU) No 10/2011 on plastic materials and articles for food contact

This regulation establishes the specific rules for plastic materials and articles and repeals Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs.

The regulation applies 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 on the sack construction, the plastic layer of paper sacks intended for food contact can belong to category C, when the plastic layer construction is not laminated or coated to paper. If the construction of the sack has plastics and paper laminated or coated together, the plastic layer is covered by E.

Annex I of regulation (EU) No 10/2011 contains a positive list with substances allowed to be used in the manufacture of food contact plastics. The regulation also sets requirements on the inertness of the material, introducing an overall migration limit and specific migration limits for a number of substances.

As the plastics regulation is usually amended several times a year, it is important to use the latest version of the regulation, and to check for subsequent amendments.

CHAPTER 2

National recommendations on paper and paperboard

There is no specific measure for paper and paperboard on a European level. The German recommendations, Bundesinstitut für Risikobewertung (BfR), are often referred to.

German Bundesinstitut für Risikobewertung (BfR) Recommendation XXXVI

The BfR recommendations cover several different types of materials, BfR XXXVI covers paper and paperboard. Since 1958 the 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.

BfR XXXVI consist of a preamble setting general requirements on paper and board. The recommendation also includes a positive list of substances permitted for use in the manufacture of paper and paperboard as well as maximum quantities of use for some of these substances.

The recommendations also cover paper and paperboard for:

- cooking papers, hot filter papers and filter layers (BfR XXXVI/1)
- baking purposes (BfR XXXVI/2)
- absorber pads based on cellulosic fibres for food packaging (BfR XXXVI/3).

CHAPTER 2

National recommendations on printing inks

There are packaging inks, preparations from printing inks and varnishes, intended for printing on food contact materials and articles. They are manufactured from binders (monomers), colourants, pigments, plasticisers, 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. As of today, there are no EU-specific measures for printing inks, although national regulations exist in Switzerland and Germany. France regulates mineral oils in printing inks for food contact applications, see annex I.

Since there is no EU-harmonised specific measure for printing inks, the compliance work should be based on an open communication between the printing ink manufacturer and the converter. It is important to choose the correct printing ink for the intended application and perform an analysis based on the information received from the printing ink manufacturer.

Swiss ordinance, 817.023.21

Ordinance of the FDHA (Federal Department of Home Affairs) on articles and materials (RS 817.023.21) of 16 December 2016, Section 12 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 transfer via a gas phase can be excluded.

The ordinance states that packaging inks may only be manufactured from substances set out in annex 2 and annex 10 of the ordinance, under the conditions laid down therein.

Note that the ordinance is valid for Switzerland and since Switzerland is not a member of EU, mutual recognition does not apply.

CHAPTER 2

21st Amendment to the consumer goods ordinance, Germany

In December 2021, Germany published an amendment to the consumer goods ordinance regulating printing ink and varnishes. The amendment covers both printing inks indirectly in contact with food (non-DFC inks) but also inks directly in contact with food (DFC inks).

The amendment contains a positive list for monomers, additives, colourants, solvents and photo initiators that are allowed to be used in the production of printing inks for food contact. However, the list is incomplete and contains inconsistencies.

During a transition period of 4 years the list will be finalised. Only after the transition period has ended can compliance with the amendment be established.

The regulation allows for non-listed substances to be used in non-DFCs as long as migration does not occur above 0.01 mg/kg.

Adhesives

Adhesives in food contact applications are not regulated by an EU-harmonised specific measure as of today, but as with all other food contact materials, the adhesive must comply with the requirements of the framework regulation, (EC) No 1935/2004 and the regulation for good manufacturing practice (EC) No 2023/2006. Adhesive manufacturers often refer to the plastic regulation (EC) No 10/2011 since many components of adhesives are listed in the positive list of this regulation.

The compliance work for adhesives should, much like that for printing inks, be based on an open communication between the manufacturer and the converter. It is important to choose an adhesive intended for food contact applications and perform an analysis based on the information received from the adhesive manufacturer.

CHAPTER 2

Guidelines

CEPI/CITPA Food Contact Guideline on paper and paperboard

The Food Contact Guideline for the compliance of paper & board materials and articles, by CEPI and CITPA, was first published in March 2010, it was then revised in 2012 and further revised in 2019. The objective of the Food Contact Guideline is to provide a methodology to demonstrate the suitability of paper and paperboard materials and articles for a variety of food contact applications.

European Printing Ink Association (EuPIA) Guideline on printing inks

The European Printing Ink Association (EuPIA) has, in the absence of European specific measures for printing inks, compiled a number of documents to support their members and their customers in the assessment of printing inks for food contact materials. Amongst other, there is a guideline on printing inks applied to the non-food contact surface of food packaging materials and articles as well as a guideline on migration test methods.

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.

CHAPTER 3

National regulations and mutual recognition

Due to the lack of EU harmonized specific measures for many types of food contact materials, several countries have implemented national legislation. For a non-exhaustive list of national legislation see the table in annex V.

The national legislation can differ and cause a barrier to trade, for example some countries require a Declaration of Compliance (DoC) for all types of food contact materials while some may not (more on DoCs in chapter 4). Other differences can be the level of tolerated migration for certain chemicals.

In order to avoid this barrier to trade the rule of mutual recognition is important. Mutual recognition is defined thus:

"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."

Source: https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition_nn

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.

CHAPTER 4

ESG/Key Seven Steps to food contact compliance

The ESG/Key Seven Steps describe the necessary procedure of information collection, evaluation, documentation and compliance for any specific paper sack material composition. By following the ESG/Key Seven Steps, the paper sack producer can build up the information and data collection required for the evaluation of a specific paper sack material composition in line with the regulations and recommendations applicable for that paper sack.

As mentioned in earlier chapters, all paper sack material compositions are covered by regulation (EC) No 1935/2004. To fulfil this regulation, the paper sack manufacturer shall apply the specific rules and recommendations applicable for each of the different components of the paper sack.

It is important to combine the evaluation with the food type for which the paper sack is intended and the conditions of use, temperature and storage time.

CHAPTER 4

There are three parts of the ESG/Key Seven Steps:

E – Establish background prerequisites

STEP 1 – Collect information on the type of food that will be packed in the paper sack

STEP 2 – Define time and temperature during storage of the filled paper sack

S – Specify sack construction and applicable legislation

STEP 3 – Describe the paper sack material composition

STEP 4 – Find applicable regulations and recommendations for the paper sack material composition

G – Generate compliance with legislation

STEP 5 – Collect documentation for each layer of material and other components in the specific paper sack material composition

STEP 6 – Find out the testing needed for the specific paper sack and perform testing

STEP 7 – Generate statement which show compliance with the regulations and recommendations applicable to the specific paper sack construction

On the next page you will find a workflow visualizing step 1-7 of the ESG/Key Seven Steps, on the following pages you will find a more detailed description of each step.

CHAPTER 4

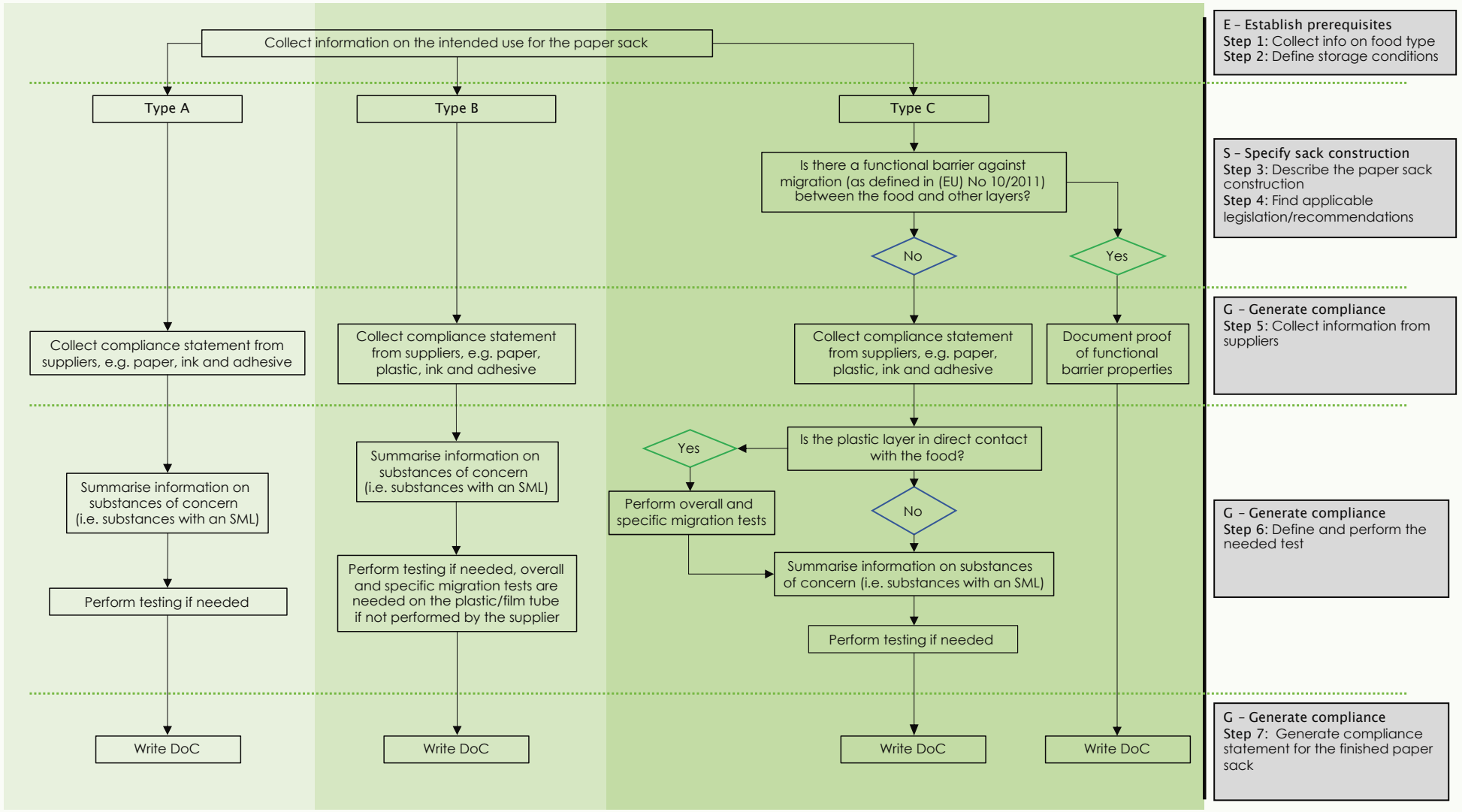

Figure 2: Workflow describing the ESG/Key Seven Steps. For the description of type A, B and C, see table 1 on page 21.

CHAPTER 4

E – Establish background prerequisites

The main objective of the first part of the ESG/Key Seven Steps is to collect information on the intended use of the paper sack. The information is then used as a basis for the testing in step 6.

STEP 1 – Collect information on the type of food that will be packed in the paper sack

The type of food that will be packed in the paper sack influences the migration rate of substances to the food. Therefore, information on the type of food, for example dry, fatty or acidic, that will be packed in the paper sack is needed.

Action: Document information on the type of food that will be packed in the paper sack

STEP 2 – Define time and temperature during storage of the filled paper sack

The storage time and temperature also influence the migration of substances to the food. Higher temperature and longer storage time require more demanding test protocols.

Define the storage time and temperature of the filled paper sack as a basis for selecting parameters for testing.

Action: Document information on the intended use, time and temperature for storage

If the sack producer does not know anything about the food type, temperature and storage time, worst-case testing can be used.

CHAPTER 4

S – Specify sack construction and applicable legislation

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

STEP 3 – Describe the paper sack material composition

Describe the composition of the sack and classify it according to types A, B and C described in table 1. Document whether the paper sack consists of layers of paper only or if there are other layers as well, such as a plastic layer.

Table 1: The table describes three types of paper sack compositions

Sack type	Description
Type A	Paper sack consists of one or more paper layers
Type B	Paper sack consists of one or more paper layers and a free-standing plastic layer/tube
Type C	Paper sack is a multi-material multi-layer (MMML)

Further details to consider are:

Is the paper sack printed or not?
This is important as there are specific requirements for printed FCM in the GMP regulation (EC) no 2026/2006. The ink might also contain substances that need to be considered in the evaluation of the finished paper sack.

Are adhesives used?
This is important because the adhesive might contain substances that need to be considered in the evaluation of the finished paper sack.

CHAPTER 4

Does the paper sack contain a functional barrier against migration of chemicals?
This is important as the presence of a functional barrier against migration of chemicals (as defined in (EU) No 10/2011) can reduce the testing needed to show compliance since this layer prevents migration of substances from the outer layers. Examples of materials that can act as a functional barrier are aluminium and in some cases PET.

Action: Describe and classify the construction of the paper sack

STEP 4 – Find 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 types of paper sacks.

Table 2: The sack types (A, B and C) and applicable regulations/recommendations

Regulations	Type A	Type B	Type C
European regulations			
(EC) No 1935/2004	X	X	X
(EC) No 2023/2006 (GMP)	X	X	X
(EU) No 10/2011 with amendments		X	X
(EC) 2022/1616		X*	X*
National recommendations on paper			
BfR § XXXVI (paper)	X	X	X
BfR § XIV, § XLI (organic coating)			X**
National legislation on ink			
L 817.023.21 (Swiss ordinance on inks, only applicable in Switzerland)	X	X	X
21st amendment of the Consumer Goods Ordinance (applicable in Germany)	X	X	X

*If recycled plastic is used
**If plastic dispersion

CHAPTER 4

A paper sack can consist of several different components: paper and board, plastics, other barrier materials, adhesives, glues, coatings, varnish, printing inks etc. At present, besides the European specific regulations on materials, there are national standards, recommendations and regulations in place for various materials. Depending on the composition of the paper sack, these might also be applicable to the paper sack besides the ones shown in the table above.

If recycled plastic is used, additional regulations are applicable, see annex III.

Action: Find applicable regulations and recommendations

CHAPTER 4

G – Generate compliance with legislation

The objective of the following steps is to **collect relevant information about the paper sack material components, perform any necessary testing and finally make the Food Contact Statement (FCS).**

STEP 5 – Collect documentation for each layer of material and other components in the specific paper sack material composition

Information exchange between the supplier of raw materials and the customer, in this case the paper sack manufacturer, is crucial in order to enable a correct risk assessment of the final paper sack. The supplier shall provide a statement in relation to the applicable legislation to the paper sack manufacturer. The statement has two main objectives:

- It confirms to the paper sack manufacturer the compliance of the material and the production process with the relevant requirements of regulation (EC) No 1935/2004, (EC) No 2023/2006 and other applicable regulations and recommendations.

- It provides the paper sack manufacturer with relevant information necessary for them to establish the compliance of the final paper sack.

Materials that are covered by a specific measure must be accompanied by a statement called Declaration of Compliance (DoC) according to framework regulation (EC) No 1935/2004. Plastic materials and articles are covered by regulation (EU) No 10/2011 and shall therefore be accompanied by such a DoC. The information to be included in a DoC for plastics is defined in annex IV of the regulation.

For materials not covered by a specific measure there is no requirement for a DoC on a European level, but requirements may exist on a national level. **Even though no harmonised legal requirement exists, a statement with enough information to facilitate an appropriate risk assessment should be delivered to the customer.** Such a statement is often referred to as a Declaration of Compliance (DoC), but is also referred to by many other names, such as Statement of Compliance, Statement of Composition, etc.

CHAPTER 4

For clarity, this guidance will refer to a statement for materials not covered by a specific measure as a Food Contact Statement (FCS).

The FCS for a material not covered by a specific measure should include the following as a minimum:

- Identity and address of the business operator issuing the FCS
- Identity of the material
- Date of the document
- Information on compliance with applicable national legislations or recommendations, such as (EC) No 1935/2004, (EC) No 2026/2006 and BfR XXXVI for paper and board
- Information on relevant restrictions such as migration limits
- Information on the intended use, such as food types and time and temperature for storage.

The table below shows a summary of information that would typically be requested by the paper sack manufacturer from the suppliers.

Table 3: Type of requested documentation depends on the construction of the paper sack

Layers	TYPE A	TYPE B	TYPE C
Paper layer, BfR § XXXVI	FCS	FCS	FCS
Plastic layer/tube, (EU) No 10/2011	Not applicable	DoC	DoC
Plastic dispersion, (EU) No 10/2011	Not applicable	Not applicable	DoC*
Polymer dispersion, BfR § XIV	Not applicable	Not applicable	FCS**
Adhesive, national recommendations if any	FCS	FCS	FCS
Ink, national recommendations if any	FCS	FCS	FCS

* If the dispersion is based on chemicals present in (EU) 10/2011, a DoC shall accompany the dispersion
** If the dispersion is based on chemicals listed in BfR XIV, and not present in (EU) 10/2011, a FCS is sufficient.

CHAPTER 4

TYPE A – Paper sack consists only of paper and/or inorganic coated paper

- Food Contact Statement for paper based on national recommendations for paper and paperboard
- Food Contact Statement on adhesives, inks etc.

TYPE B – Paper sack consists of paper and a free-standing plastic layer/tube

- Food Contact Statement for paper based on national recommendations for paper and paperboard
- Declaration of Compliance (DoC) for plastic layer/tube, including information on chemicals with specific migration limits (SML), according to (EU) No 10/2011
  > Overall and specific migration tests are mandatory for the plastic layer/tube
- Food Contact Statement for adhesives, inks etc.

TYPE C – Paper sack is a multi-material multi-layer (MMML)

- Food Contact Statement for paper based on national recommendations for paper and paperboard
- Declaration of Compliance (DoC) for plastic components, including information on chemicals with specific migration limits (SML), according to (EU) No 10/2011
  > Overall and specific migration tests are mandatory if the plastic layer is the food contact layer (for more information see annex IV)
- Food contact statement on adhesives, inks etc.

Action: Collect DoC and/or FCS from suppliers

CHAPTER 4

STEP 6 – Find out the testing needed for the specific paper sack and perform testing

The need for the paper sack manufacturer to do testing of the specific paper sack construction is based on the background information that has been collected during step 1-5.

In principle, the one producing the different components of a paper sack is responsible for the compliance of that specific component, but it is the paper sack manufacturer who has the responsibility for the final paper sack composition. Good quality and completeness of collected information simplifies the task for the paper sack manufacturer to show compliance for the paper sack.

Based on the information collected from the suppliers a test program can be created. For example, if the adhesive or print contains any critical substances to monitor. Compliance with migration limits can be shown by migration testing, migration modelling or mathematical calculations assuming 100 % migration.

Free standing plastic layer/tube

A free-standing plastic layer or tube shall comply with the compositional requirements of (EU) No 10/2011. It shall also comply with the requirements for overall and specific migration. Tests on a free-standing plastic layer/tube shall be performed by the manufacturer of the plastic layer/tube.

Multi-material multi-layer (MMML)

The plastic layer in a MMML shall also comply with the compositional requirements of (EU) No 10/2011. Testing for overall and specific migration from the plastic layer is mandatory also for a MMML if the plastic layer is the food contact layer. For more details on migration testing, see annex IV.

Printed paper sacks

If the paper sack is printed on the outside, the paper sack shall be designed in such a way that substances from the printed surface are not transferred to the food contact side in harmful amounts, either through migration or through set-off, according to the GMP regulation (EC) No 2023/2006. Set-off testing is often done by testing specific migration with modified polyphenylene oxide (MPPO, also called Tenax).

CHAPTER 4

Table 4: Type of testing needed for Paper sack type A, B and C

Tests	Type A	Type B	Type C
Tests according to BfR § XXXVI	Performed on paper layer	Performed on paper layer	Performed on paper layer
Overall migration	Not applicable	Performed on plastic layer/tube	Performed on final paper sack*
Specific migration	Not applicable	Performed on plastic layer/tube	Performed on final paper sack*
Set-off (if printed)	Performed on final paper sack	Performed on final paper sack	Performed on final paper sack

*Mandatory only if the plastic layer is the food contact layer

STEP 7 – Generate document which shows compliance with the regulations and recommendations applicable to the specific paper sack construction

As stated in the introduction, the aim of this guideline is to propose a structured way for paper sack manufacturers to handle food contact issues. **However, deciding on measures regarding testing and compliance documentation for the final paper sack composition still requires someone with knowledge of food contact legislation.**

Based on the information collected in step 1-6, the manufacturer of the paper sack issues his own statement regarding food contact for the final paper sack. The statement should clearly state which regulations and recommendations are applicable and used as reference for the evaluation of the final paper sack. The statement should also inform about the intended use of the paper sack, suitable food types, temperatures and storage time. As a minimum, the food contact statement should include the details mentioned under step 5. For further guidance on how to prepare a food contact statement the CEPI/CITPA food contact guideline is useful (note that the CEPI/CITPA food contact guideline uses the wording Declaration of Compliance for such a statement).

The producer of a paper sack should be prepared to show a statement of compliance (FCS, DoC or similar) to his customer since this is often a customer request. However, the producer is not obliged to show the supporting documentation, i.e. test reports, to his customers. Nonetheless, the producer may choose to do so if they wish. The supporting documentation shall be available upon request by authorities.

CHAPTER 5

Labelling

Article 15 of the framework regulation (EC) No 1935/2004 requires that materials and articles not yet in contact with food shall be accompanied with the words "for food contact" or a specific indication as to their use, such as coffee machine, wine bottle, soup spoon, or the symbol depicted below. If necessary, the label shall also contain special instructions for safe and appropriate use, such as restrictions on type of food to be packed in the material or article.

Figure 3: Article 15 of the Framework Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food specifies the labelling requirements. It says that food contact materials shall be accompanied by the words "for food contact" or the above symbol, unless it is obvious that the article is intended for food contact.

The label shall also include the name or trade name, address of the manufacturer, processer, or seller responsible for placing the material or article on the market. Adequate information to ensure traceability is also required.

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

ANNEX I

Regulation of specific substances
(not an exhaustive list)

Bisphenol A (BPA) and other bisphenols

BPA is a substance that is used in plastics and resins for coatings etcetera. The European Food Safety Authority (EFSA) published a re-evaluation on the safety of BPA in 2023, significantly reducing the tolerable daily intake (TDI) of the substance. Following this, the European commission set out to ban the use of BPA in food contact materials. The safety of BPA has been under scrutiny for some time and is already phased out in many applications.

The regulation to ban BPA was published on 31 of December 2024 and entered into force on 20 January 2025. The regulation, named (EU) 2024/3190, bans the use of BPA and other hazardous bisphenols in food contact plastics, varnishes and coatings, printing inks, adhesives, ion-exchange resins, silicones and rubbers.

Single-use final food contact materials manufactured with BPA may be placed on the market until 20 January 2026, when the transitional period of 18 month ends.

Food contact materials covered by the regulation shall be accompanied by a declaration of compliance at all marketing stages except the retail stage.

This new regulation amends the plastic regulation, (EU) No 10/2011, and repeals regulation (EU) 2018/213.

Per- and polyfluoroalkyl substances (PFAS)

PFAS are a big and complex group of substances consisting of several thousands of man-made synthetic chemicals. These substances are widely used in our society for varying applications. They are persistent and very difficult to break down and some PFAS have also been shown to have negative health effects on humans. Because these chemicals do not break down in the environment, background levels are often found in many materials and in water samples.

ANNEX I

REACH
A proposal for a universal restriction of PFAS was published in 2023. The proposal aims to ban the production and use of over 10,000 PFAS, under the REACH regulation.

The proposal is now being discussed in ECHA's scientific committees RAC (The Committee for Risk Assessment) and SEAC (The Committee for Socio-economic Analysis). An entry into force is not expected before 2027.

PPWR
At the same time, a ban of food packaging containing PFAS was recently published under the new Packaging and Packaging Waste Regulation (PPWR). The regulation bans the intentional use of PFAS in food packaging and says that:

…food contact packaging shall not be placed on the market if it contains per- and polyfluorinated alkyl substances (PFASs) in a concentration equal to or above the following limit values.

- 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)
- 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification).
- 50 ppm for PFASs (polymeric PFASs included)

PPWR, (EU) 2025/40, was officially published on 22 January 2025, and entered into force on 11 February 2025. The requirements on PFAS in food contact packaging apply from 12 August 2026.

Mineral oil hydrocarbons (MOH)

Mineral oil hydrocarbons (MOH) are a diverse group of chemical compounds and are divided into two main categories:

- Mineral oil saturated hydrocarbons (MOSH)
- Mineral oil aromatic hydrocarbons (MOAH)

ANNEX I

MOSH has the potential to bioaccumulate but does not pose a public health risk at current dietary exposure levels. MOAH, on the other hand, can contain substances that are genotoxic.

In 2021, Germany notified their intention to regulate the migration of MOAH from recycled paper and board. The draft regulation set a limit for MOAH migration into food to < 0.5 mg/kg and into food simulants < 0.15 mg/kg.

In 2022, the European Commission published recommended limits on the presence of MOAH in food:

- 0.5 mg/kg for dry foods with a low fat/oil content (≤ 4% fat/oil)
- 1 mg/kg for foods with a higher fat/oil content (> 4% fat/oil)
- 2 mg/kg for fats/oils

These limits are not legally binding and a more differentiated approach to regulate MOAH in food is being discussed.

In France, the use of mineral oils in packaging has been prohibited since January 2022. As of January 2025, it is now also prohibited to use mineral oils in prints for the general public. The ban applies when:

- Concentration of MOAH is greater than 0.1% or when the concentration of compounds with 3 to 7 aromatic rings are greater than 1 ppm
- Concentration of MOSH is greater than 0.1%

Analysing mineral oils is possible and many laboratories offers MOH analysis. But interpreting results from MOAH analysis should be done with caution. The analysis and quantification is complex due to the fact that MOH comprises a large group of substances that are eluted together. Compliance work regarding mineral oils should, in the first place, be based on documentation from suppliers.

ANNEX II

Non-intentionally added substances (NIAS)

Non-intentionally added substances (NIAS) may be present in all types of food contact materials. NIAS are defined in (EU) No 10/2011 as "an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product".
The International Life Science Institute (ILSI) guidance on risk assessment of NIAS expands the definition of NIAS by including contaminants from the surrounding environment during production, storage and transport, such as lubricants from the process equipment, but also unknown contaminants that are often unpredictable.

According to article 19 of (EU) No 10/2011, NIAS shall be risk assessed in accordance with internationally recognised scientific principles on risk assessment. All NIAS also have to comply with the general safety requirements of article 3 in (EC) No 1935/2004.

For guidance on how to risk assess NIAS see ILSI's "Guidance on Best Practices on the Risk Assessment of Non Intentionally Added Substances (NIAS) in Food Contact Materials and Articles" (2015).

ANNEX III

Recycled materials for food contact

Demands for using recycled material in packaging is increasing, this also includes food packaging. The use of recycled material in FCM is allowed according to the regulation but it requires careful consideration. Recycled material can contain contaminants from previous use, printing inks and so on. The recycled material may also have an increased batch variation compared to virgin material.

When using recycled material, care needs to be taken to ensure that the material fulfils the requirements for that specific material. It is also wise to update the supporting documentation on a regular basis for the recycled material.

Recycled paper and board

Recycled paper and board are allowed to be used in the manufacture of paper and board according to BfR XXXVI. Careful selection of the grade of recycled fibres and the use of suitable cleaning methods shall take place before using recycled fibres.

Materials and articles made from recycled fibres shall comply with the requirements set out in recommendation XXXVI. Due to the risk of contamination by substances originating from printing inks, glues etc., there are additional requirements for specific substances. For example, the migration of certain phthalates is regulated. The migration limits for these phthalates were recently lowered. The current limit values can be found in the annex of BfR XXXVI.

Recycled plastic

Recycled plastic can be used in food contact materials under regulation (EU) 2022/1616. The regulation entered into force in 2022 and is still being implemented. A union register is being set up that consists of recyclers, recycling processes, recycling installations, the facilities where these installations are located, recycling schemes and novel technologies.

Recycled plastic to be used in FCM must come from a suitable technology (a registered recycling technology that has been evaluated by EFSA) or a novel technology (a registered recycling technology that is under evaluation by EFSA). Recycled plastic under (EU) 2022/1616 shall be accompanied by a batch-specific DoC following pre-established templates.

ANNEX IV

Migration testing

It is mandatory to perform an assessment of overall migration and specific migration for a free-standing plastic layer or tube according to the plastic regulation (EU) No 10/2011. This is usually done by the plastic manufacturer.

Previously, the plastic layer in a multi-material multi-layer (MMML) was exempted from migration testing.

But the recently published amendment to (EU) no 10/2011, the so-called quality amendment ((EU) 2025/351), has made it mandatory to analyse overall and specific migration from the plastic layer also in a MMML, if the plastic layer constitutes the food contact layer. This can be done on the final paper sack.

Food simulants

Migration testing can be performed using real food but is mostly performed using food simulants intended to mimic real food. For both overall and specific migration, a combination of food simulants is used to cover the intended use. The simulants used are listed below. To cover all types of food migration to simulants A, B and D2 is performed. Simulant E is used when testing specific migration. For details on categories of food types and assignment of food simulants see annex III of (EU) No 10/2011.

ANNEX IV

The standardized food simulants are:

- Simulant A – 10 % ethanol
- Simulant B – 3 % acetic acid
- Simulant C – 20 % ethanol
- Simulant D1 – 50 % ethanol
- Simulant D2 – olive oil*
- Simulant E – modified polyphenylene oxide (MPPO, also called Tenax)

*if testing with D2 is not technically feasible 95 % ethanol and isooctane can be used instead.

Testing conditions

Testing shall be performed using standardized testing conditions representing the most extreme conditions of time and temperature foreseeable in actual use.

The standardized testing conditions can be found in annex V of (EU) No 10/2011.

ANNEX V

Presence of national legislations, recommendations and standards for materials with no EU harmonised specific measure

Below is a non-exhaustive list on the presence of national legislations, recommendations and standards for food contact materials not regulated under an EU harmonised specific measure. The table is based partly on the information in the Joint Research Centre's (JRC) report "Non-harmonised food contact materials in the EU: regulatory and market situation" from 2016. For links to some of the legislations and recommendations see annex VI.

	Paper and paperboard	Adhesive	Printing ink
France	x	x	x
Netherlands	x	x	x
Croatia	x	x	x
Czech Republic	x		x
Germany	x	x	x
Italy	x	x	x
Slovakia	x		x
Spain		x	
Switzerland			x
Belgium	x		
Greece	x		
Nordic Co-operation	x		
Poland	x		
Romania			x
USA	x	x	
China	x	x	x

ANNEX VI

Links

Below are links to some of the regulations mentioned in the guideline and other useful information.

Legislations and recommendations

European level

European harmonised regulations can be found on the European Commission's website on food contact materials

https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en

National level (not an exhaustive list)

German BfR recommendations on several types of material for food contact

https://empfehlungen.bfr.bund.de/recommendations?locale=en

Switzerland, 817.023.21 Ordonnance du DFI sur les matériaux et objets destinés à entrer en contact avec les denrées alimentaires

https://www.admin.ch/opc/fr/classified-compilation/20143393/index.html

France, DGCCRF Matériaux au contact des denrées alimentaires

https://www.economie.gouv.fr/dgccrf/Materiaux-au-contact-des-denrees-alimentaires

Italy, MOCA Materiali ed Oggetti a Contatto con

http://www.salute.gov.it/portale/temi/p2_6.jsp?id=1173&area=sicurezzaAlimentare&menu=chimica

Dutch Commodities Act Regulation on Packaging and Consumer Articles Coming into Contact with Foodstuffs (Warenwet)

https://wetten.overheid.nl/BWBR0034991/2017-01-01

Guidelines

CEPI/CITPA Food contact guidelines for the compliance of paper and board materials and articles

http://www.citpa-europe.org/sites/default/files/Food%20Contact%20Guidelines_2019_final.pdf

CEPI Guideline on good manufacturing practice for the manufacture of paper and board for food contact

https://www.cepi.org/updated-good-manufacturing-practice-gmp-guidelines-for-the-manufacture-of-paper-board-for-food-contact/

EuPIA documents on the use of printing inks on food contact materials and articles

https://www.eupia.org/key-topics/food-contact-materials/general-overview-of-fcm/

ANNEX VI

Links

Legislations and recommendations

Guidelines

ILSI Guidance on best practices on the risk assessment of non-intentionally added substances (NIAS) in food contact materials and articles

https://ilsi.eu/publication/guidance-on-best-practices-on-the-risk-assessment-of-non-intentionally-added-substances-nias-in-food-contact-materials-and-articles/

The Nordic Co-operation has published several guidelines on different types of food contact materials

https://www.norden.org/en/publications

Other

JRC report on "Non-harmonised food contact materials in the EU: regulatory and market situation" (2016)

https://publications.jrc.ec.europa.eu/repository/handle/JRC104198

Packaging and Packaging Waste Regulation, (EU) 2025/40

https://eur-lex.europa.eu/eli/reg/2025/40/oj/eng

ANNEX VII

Glossary

Term	Meaning
BfR	Bundesinstitut für Risikobewertung (German Federal Institute for Risk Assessment)
CEPI	Confederation of European Paper Industries
CITPA	International Confederation of Paper and Board Converters in Europe
DoC	Declaration of Compliance
EFSA	European Food Safety Authority
ESG	European Paper Sack Research Group
EuPIA	European Printing Ink Association
FCM	Food Contact Materials and Articles
FCS	Food Contact Statement
Food simulant	A test medium mimicking food, used in migration testing
FDHA	Federal Department of Home Affairs
Functional barrier	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
GMP	Good Manufacturing Practice, those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use
ILSI	International Life Science Institute
JRC	Joint Research Centre
Migration	The transfer of chemical substances from food contact material to food
MMML	Multi-Material Multi-Layer – a material or article composed of two or more layers of different types of materials, at least one of them a plastic layer

ANNEX VII

Glossary

Term	Meaning
MPPO	Modified polyphenylene oxide, Poly (2,6-diphenyl-p-phenylene oxide)
NIAS	Non-Intentionally Added Substances
OML	Overall Migration Limit
PET	Polyethylene terephthalate
REACH	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
SML	Specific Migration Limit

MORE INFORMATION

For more information on paper sacks, contact your sack producer or either of the two organisations below.

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Publication date: May 2025