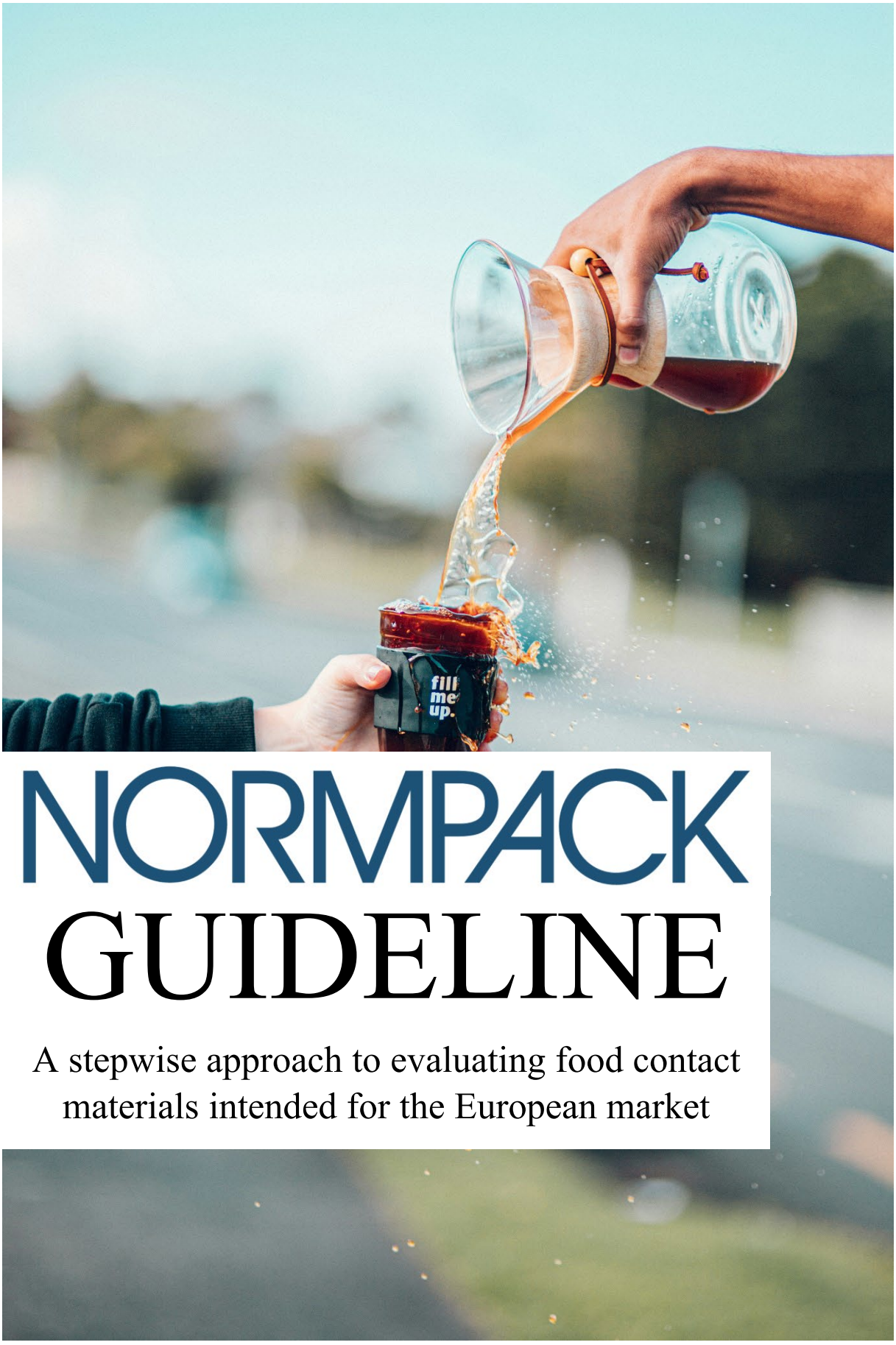

NORMPACK GUIDELINE

A stepwise approach to evaluating food contact materials intended for the European market

Version 1.0

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1 Introduction

All materials that are intended to be in contact with food are defined as food contact materials and articles (FCMs), and they cover both food contact materials and the articles made from these materials. FCMs must be safe and not transfer hazardous substances in levels that may endanger the safety of the food that will be consumed.

As a producer or supplier of FCMs, it is your responsibility to ensure that the products you put on the market are safe for their intended use. The FCM legislation is a group of requirements that includes the Framework Regulation (EC) No 1935/2004 and other laws at the EU or national level that are specific to FCMs. Each actor in the value chain is obliged to perform an assessment of FCMs at their stage in the value chain. There is no official entity at EU or member state level that approves FCMs.

Navigating the FCM legislation can be complicated, and questions can arise as to which legislation is relevant. Therefore, this guideline can be used to help you understand the requirements for FCMs and to guide the evaluation of FCMs to ensure their safety and regulatory compliance.

This guideline introduces a stepwise approach for evaluating FCMs intended for use within the EU, with the Swedish market as the main focus.

The use of this guideline is voluntary, as there may be other ways of demonstrating compliance with the FCM legislation.

This guideline is based on experiences collected by Normpack, a Swedish trade and industry association founded in 1981 to support companies in fulfilling their FCM obligations. Over the years, the association has gained extensive practical knowledge of how to work safely and effectively. The Normpack Norm, which outlines the requirements for FCMs based on EU legislation, provides the framework for Normpack primarily for the Swedish market. This guideline includes a separate chapter that describes the Normpack Norm.

The FCM legislation is continuously updated for the EU market. It is therefore important as an actor in the FCM value chain to follow the discussions and proposals put forward by legislators. There are also ongoing efforts from the EU Commission on how to revise the entire FCM legislation in the coming years.

1.1 Scope

The scope of the Normpack Guideline is limited to the requirements for food contact materials and articles as defined under the Framework Regulation (EC) No 1935/2004 as well as the ancillary/subordinate material-specific legislation on EU or national level. The scope includes legal requirements for all producers and suppliers as well as FCM importers. However, different entities will occasionally have differing requirements. Therefore, all parts in this guideline might not be relevant for all entities. The geographic scope focuses on the Swedish market but might be relevant for other markets, mainly EU ones. The most frequently used FCMs in food packaging are covered, including paper and board, plastic, recycled plastic, printing inks, and adhesives. Multi-material, multi-layer structures are also covered. Normpack intends to expand the scope with more materials in future updates of this guideline.

1.2 Purpose

The Normpack Guideline aims to help actors who produce and handle FCMs to understand the legal requirements for FCMs and to demonstrate compliance with them in a robust yet resource-efficient way.

The guideline can also be used as a source for finding relevant rules and recommendations.

This guideline:

- **Explains** the FCM legislation by outlining overarching rules and the material-specific legislation and recommendations on EU level.
- **Recommends a common practice** for assessing FCMs by introducing a stepwise approach.
- **Guides** the assessment of different FCMs, including multi-material, multi-layer FCMs.

The guideline can also help stakeholders like FCM producers and authorities to gain a common understanding of the interpretations of the legislation. Examples of such issues are the suitable level of detail in supporting documentation, evaluations (calculations, migration modelling, and migration analysis), and documentation for communicating between downstream users and producers.

1.3 Who should read this guideline?

This guideline is intended for members of the Normpack industry association, which represents companies producing or handling FCMs as defined in the EU Framework Regulation (EC) No 1935/2004. It is intended to provide insight when there is a need for guidance in how to demonstrate compliance with the legislation.

The guideline primarily benefits small and medium-sized enterprises that need guidance in their compliance efforts. However, it must be stressed that food contact legislation is complex, and compliance should be managed by a person familiar with the topic.

1.4 Limitations

This guideline focuses on interpreting the Framework Regulation (EC) No 1935/2004 for the most common FCMs or combinations of them. It does not focus on (EU) No 2023/2006 on Good Manufacturing Practice (GMP). For guidance on GMP, see the links in the annexes for sector-specific guidance.

Food contact materials can also be affected by other legislation not covered by this guideline.

Due to limited resources, the guideline does not cover the following types of FCMs in detail. Its aim is to include guidance for more of these FCMs in future updates. Some of the FCMs below are covered by EU common legislation. In such cases, the legislation number is given after the name.

- Active and intelligent materials, Regulation (EC) No 450/2009
- Regenerated cellulose, Directive 2007/42/EC
- Coatings and varnishes, unless covered by substance specific legislation for epoxy derivatives and bisphenol-A
- Metals
- Ceramics, Directive 84/500/EEC
- Silicones
- Rubber and elastomers
- Glass
- Wood
- Textiles
- Ion exchange resins

1.5 Responsible organisation

Normpack is responsible for writing and updating this guideline. Its contents have been endorsed by the members via Normpack's steering committee.

The FCM producer or user of this guideline is responsible for their products, materials, and processes. Normpack does not take any responsibility for the use and interpretation of this guideline.

1.6 Updating routines

The guideline is updated when there are major changes in legislation or other referred guidelines. The need for updates will be assessed at least once a year.

1.7 Distributing this guideline

The Normpack Guideline is exclusively for use and distribution by Normpack members.

2 Description of the FCM regulatory landscape

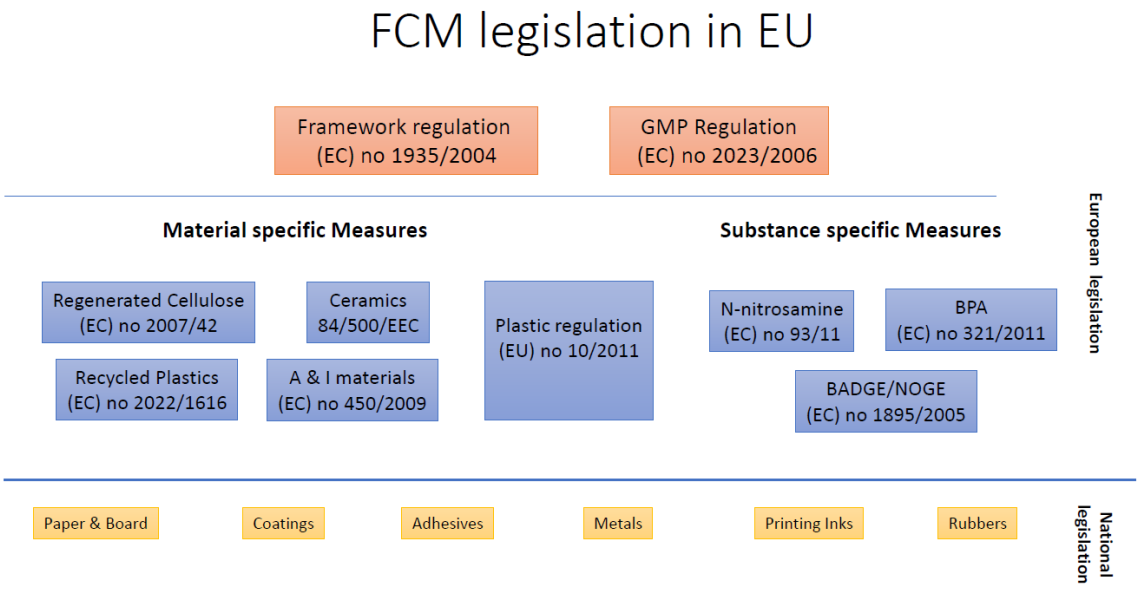

Figure 1

There are two general EU regulations for FCMs that apply to all FCMs regardless of the material type:

- Framework Regulation (EC) No 1935/2004, which describes general safety requirements.
- Good Manufacturing Practice Regulation (EC) No 2023/2006, which describes quality assurance and control in manufacturing, processing and distribution.

These two regulations are interrelated and serve as the legal foundation for all types of materials and articles that come into contact with food. They are intended to stipulate material-specific measures,

which entail more detailed and specific legislation for each material type at EU level, also known as material-specific EU harmonised legislation. However, only EU-specific legislation is available for FCMs made of plastic, ceramic, regenerated cellulose, active and intelligent materials, and recycled plastic. For materials that are not yet covered by a material-specific measure on EU level, such as for paper and board, printing inks, and adhesives, national legislation or recommendations apply. These materials are covered by mutual recognition law. According to the principle of mutual recognition, a material legally put on the market in one EU member state can also be sold in all other EU member states. See Section 3.6.

The EU's harmonised legislation and guidance is available on the EU Commission website, which is managed by the Directorate for Health and Food Safety.[1] The Swedish Food Agency also has a website for FCMs[2] (in Swedish). Regulatory measures for materials lacking EU harmonised legislation, such as legislation on a national level or guidelines, have been summarised by the commission's Joint Research Centre (JRC) in a study published in 2017[3]. This study provides a comprehensive description of the current situation concerning FCMs for which there are no specific measures at EU level.

The term FCM is defined in the framework regulation as materials and articles, including active and intelligent materials, that in their finished state:

- are intended to be brought into contact with food (e.g., kitchen utensils and tableware),
- are already in contact with food and are intended for that purpose (e.g., food packaging),
- can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use (e.g., napkins and table mats).

The reason for dividing the materials and articles covered by the legislation like this is both to cover all aspects of FCMs and to serve as a basis for verifying the compliance of the materials and articles. For FCMs already in contact with food, the control from authorities must be based on substances migrated into the packaged food. For the two other groups of materials and articles, the control can be performed by verifying the possible migration into food simulants. Actors who place the materials on the market assess compliance with legislation by using food simulants rather than food.

Fixed water supplies, antiques and coverings, or coating materials that form part of the food and can be consumed together with this food are clearly exempt from the FCM legislation.

As a dominating principle, only officially evaluated and authorised substances must be used as starting substances when manufacturing FCMs. A substance can have certain restrictions on possible use, for example being limited to use only with certain types of food, or not migrating into the food beyond a specific limit. This often referred to as the "positive list" approach, meaning that the allowed substances are listed for the type of material. When EU-specific measures include a positive list of authorised substances for use in manufacturing materials and articles intended to come into contact with food, the substances must undergo a safety assessment prior to their authorisation. One example is Annex I in the plastics regulation, (EU) No 10/2011.

[1] Food Contact Materials (europa.eu)

[2] Kontaktmaterial, Livsmedelsverket

[3] Non-harmonised FCM in the EU: Regulatory and market situation

The evaluation should also take the contact time and temperature into account. In most cases, FCMs are intended, optimised, and evaluated for a specific use. This calls for close communication in the value chain. The user must provide the intended use to the supplier. The manufacturer must state that the materials are made of suitable substances and evaluated for the intended use.

2.1 The framework regulation

The EU Framework Regulation (EC) No. 1935/2004 is the overarching legislation on FCMs. It affects all actors in the value chain, from raw material producers to food business operators and retailers. It describes the requirements on general safety, documentation, traceability, and labelling.

2.1.1 General safety requirements (Article 3)

The general safety requirements are given in Article 3, which states that:

Materials and articles, including active and intelligent materials, 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:

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

Furthermore, it is stated that consumers must not be misled by the labelling, advertising, or presentation of an FCM.

2.1.2 Labelling (Article 15)

The framework regulation also specifies labelling rules for FCMs.

The food contact material or article shall be accompanied by either:

- the wording ‘for food contact’,
- a name describing the use with food (such as coffee machine, wine bottle, soup spoon) or
- the glass/fork symbol[4].

The information should be conspicuous, clearly legible, and indelible. Within its own territory, the member state in which the FCM is marketed may stipulate that the labelling should be given in one or more specific languages.

At marketing stages other than the retail stage, the required information may alternatively be displayed on the accompanying documents or on labels or packaging.

2.1.3 Declaration of compliance (Article 16)

The framework regulation also establishes the principle that documentation must demonstrate that the FCMs comply with applicable requirements. For this, a declaration of compliance (DoC) must be issued. However, the framework regulation does not specify what the DoC must contain. Such descriptions are intended to be specified in each of the material-specific measures. As described

[4] (EC) No 1935/2004, Annex II

above, specific measures for all material types do not yet exist. Some EU member states have instead put the DoC requirement in their national legislation. For example, in Norway and Denmark all FCMs, regardless of material, must be covered by a DoC. For more guidance on DoCs, see Annex 6.8.

2.1.4 Traceability (Article 17)

A system for traceability must be maintained by FCM actors for control and possible recall of defective FCMs. The system must allow for tracing the FCM one step backwards and one step forwards in the value chain. The requirement for traceability is given in Article 17 of Regulation (EC) No 1935/2004.

2.2 Regulation on good manufacturing practice, GMP

The Regulation (EC) No 2023/2006 on Good Manufacturing Practice (GMP) describes the requirements for quality assurance and control in manufacturing, processing, and distribution.

The regulation states that actors must have a quality system (which includes quality assurance, quality control, and documentation) and keep documentation in order. The requirements apply to everyone involved in the manufacture, processing, and distribution of FCMs. The quality system must be adapted to the company's size and stage in the value chain. While there is no strict requirement for a quality system to follow a defined standard or be certified by a third party, many FCM actors use common standards for their quality systems.

The focus of the GMP regulation is quality-assurance and control. Additionally, it also lays down some product-specific rules for printing processes, as well as specific requirements on quality assurance systems for plastic recycling processes. More information on these topics is available in the annexes for printing inks and recycled plastics.

This guideline does not cover quality assurance and control requirements. Instead, we refer you to other guides, such as a report issued by the Italian Instituto Superiore di Sanita[5] and sector-specific guidance. See the annexes for additional information.

2.3 Material-specific measures and legislation at EU level

Article 5 of the EU Framework Regulation (EC) No 1935/2004 states that specific measures, hereafter referred to as legislation, may be adopted or amended by the Commission. Annex 1 lists seventeen different materials. To date, only five of these materials are regulated by material-specific legislation at EU level. For all other types of FCMs, national legislation or recommendations apply. See Section 3.5.

Ceramics and regenerated cellulose are covered by EU directives. Since EU directives are transposed into national law in each EU member state, each country can have interpreted the requirements in different ways.

The material-specific legislation for plastics as FCMs is a regulation and therefore directly applicable in all EU member states. It is also the most comprehensive of the material-specific legislation. The plastics regulation (EU) No 10/2011 is designed to follow the framework regulation's intentions. The

[5] Report ISTISAN 11/37

regulation specifies compositional requirements for plastics and provides a detailed description of how to evaluate a material.

There is material-specific legislation for recycled plastics, (EU) No 2022/1616, which applies to all types of recycled plastic and recycling technologies. This regulation includes mechanical recycling, recycling of products from a closed and controlled product chain, the use of recycled plastic behind a functional barrier, and some forms of chemical recycling.

The mode of recycling must be defined in a suitable technology that has been authorised and listed in the regulation. There is also a defined workflow for assessing a novel recycling technology before having it authorised as a suitable technology.

EU Regulation (EC) No 450/2009 for active and intelligent materials and articles is also available but is not covered by this guideline.

2.4 Substance-specific measures and legislation at EU level

For some substances or groups of substances, EU substance-specific legislation is also in place. See Figure 1.

2.4.1 Nitrosamines, or nitrosatable substances

Commission Directive 93/11/EEC controls these materials and articles concerning the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers. In Sweden, the implementation of the European directive is found in regulation LIVSFS 2023:5[6] (in Swedish). The Bundesinstitut für Risikobewertung (BfR) recommendation XXI/2 covers these products.

The following limits apply:

- 0.01 mg in total of N-nitrosamines released/kg
- 0.1 mg in total of N-nitrosatable substances/kg

2.4.2 Epoxy derivatives

Regulation (EC) No 1895/2005 restricts certain epoxy derivatives from being used in FCMs.

The regulation prohibits the use and presence of substances grouped as BFDGE and NOGE. The use of BADGE and some of its derivatives may be used if the given migration limits are met. For details, see the regulation.

Regulation (EC) No 1895/2005 refer to the older legislation covering plastic FCMs on how to perform migration testing. This should now be understood as following (EU) No 10/2011 instead.

2.4.3 Bisphenol A in coatings and varnishes

Regulation (EU) No 2018/213 lowered the specific migration limit of bisphenol A (BPA) from plastic FCMs to 0.05 mg/kg from 0.6 mg/kg. At the same time, its scope was also extended to cover coating and varnishes, such as coated metal. At the time of writing, there is a likely ban ahead for using bisphenol A and possibly other bisphenols in FCMs.

[6] livsmedelsverket.se

2.5 Materials not covered by specific measures and legislation at EU level

To demonstrate compliance with the Framework Regulation (EU) No 1935/2004 for FCMs not regulated by EU-specific legislation, national laws, recommendations or Council of Europe (CoE) guidelines can be applied. Article 6 in the framework regulation is open to this option, in fact, by stating that "in the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty." This can be seen as a pragmatic approach to handling the situation given the complexity of FCM risk assessment and risk management. Still, all FCMs must comply with the entire framework regulation, and more specifically with Article 3.

National legislation is in place in many EU member states that establishes individual rules on different materials and substances. These can differ from one member state to another. Below, the German BfR recommendations, the Dutch Warenwet, and the Council of Europe guidelines and resolutions are briefly described.

Germany: Bfr

The German Federal Institute for Risk Assessment (BfR) publishes recommendations for different materials used in FCMs that are often referred to as good practice, but they do not have strict legal status. The BfR Recommendations on Food Contact Materials do, however, represent the current state of scientific and technical knowledge for the conditions under which consumer goods made of high polymer substances, such as silicones, paper, and rubber, meet the requirements of § 31, Para 1 of the German Food and Feed Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch, or LFGB) as well as those of Article 3 of the Framework Regulation (EC) No 1935/2004 in respect to their health and safety. Most paper and board FCM manufacturers follow the BfR recommendations, which state both compositional and testing requirements. The compositional requirements state which substances are allowed for use, and many of them also have threshold amounts that may be used in the material. Depending on the chemicals used and testing results, the use of the FCM can be limited to certain foods, and maximum time and temperature in contact with the food.

There are almost 50 different BfR recommendations for many types of FCMs. The BfR recommendations are published and updated in the "Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz"[7] as notifications. The actual recommendation is updated shortly after.[8]

Netherlands: Warenwet

In the Netherlands, the Warenwet[9] lists legal requirements for several different material types including, but not limited to, metal, glass, textiles, and wood. Warenwet is also based on substances that are allowed to be used. However, there are requirements for both overall and specific migration testing for the majority of the materials covered. Results from overall migration testing may be recalculated in some cases.

Council of Europe

The Council of Europe (CoE) has issued resolutions on metals and alloys, paper and board, substances migrating from printing inks, and general principles on the safety and quality of materials and articles

[7] Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

[8] BfR Recommendations on Food Contact Materials

[9] Warenwet

for contact with food[10]. These CoE resolutions can also be used in risk assessment of FCMs, even if they do not have the status of national legislation.

For printing inks, a German law is currently in place that is still under implementation and does not need to be followed in full until early 2026. Switzerland also has legislation on printing inks, which is often referred to by ink manufacturers. See Annex 6.4 for more information on printing inks.

In 2017, the European Commission's Joint Research Centre (JRC) published a study[11] that comprehensively describes the current situation concerning FCMs for which there are no specific measures at EU level. The study is outlined for the different materials, rather than for each EU member state. Even if the study was published in 2017, the situation is more or less the same at the time of writing.

2.6 Mutual recognition regulation (EU) 2019/515

One of the EU's guiding principles is that it should be a common market, with mutual recognition allowing products that meet the requirements in one member state to be put on the market in all other member states. This principle is regulated in Regulation (EU) 2019/515.

A product lawfully put on the market in one EU member state may be put on the market in any other EU member state, unless there is a specific authorisation requirement for that product in that member state. As a result, FCMs may be generally marketed throughout the EU.

The EU Joint Research Center (JRC) has published a document containing questions and answers about regulation (EU) 2019/515. To learn more, visit the EU Commission webpage on mutual recognition[12].

[10] Food contact materials and articles - European Directorate for the Quality of Medicines & HealthCare

[11] Non-harmonised FCM in the EU: Regulatory and market situation

[12] Mutual recognition of goods

3 The Normpack Norm

The Normpack Norm was introduced during the early stages of Normpack activities as a means of addressing the legal situation in which there is a lack of EU-specific measures for certain FCM types. The Norm incorporates the German BfR recommendations, the Dutch Warenwet legislation, and the US FCM legislation under the FDA (Food and Drug Administration) as a last resort. This ensures that most possible FCM materials are covered and a risk assessment can be carried out.

The Normpack Norm consists of four paragraphs.

Paragraph 1 lists Swedish and European harmonised legislation relevant for food contact materials. The Swedish legal acts establish the requirements for FCM actors in Sweden and incorporate the EU directives on, for example, ceramics in the national legislation. The EU Framework Regulation (EC) No 1935/2004 on Food Contact Materials and Articles are, together with the GMP Regulation (EC) No 2023/2006, the core requirements. The EU General Food Law, (EC) No 178/2002, provides definitions that are also relevant for FCMs. The two regulations (EC) No 1333/2008 on food additives and (EC) No 1334/2008 on food flavourings are also listed in the Normpack Norm, as they are referenced in the FCM legislation. The material- and substance-specific EU FCM legislation is also part of Paragraph 1.

Paragraph 2 lists regulations and recommendations to use for materials lacking EU material-specific measures. These are the national legislation or recommendations in the Netherlands, Germany, and the US. However, fulfilling the US FDA regulation does not automatically mean that the material or article demonstrates compliance with the European legislation. FDA and European FCM laws are constructed in different ways, so there can be a need for additional risk assessment to comply with EU regulations even though FDA compliance has been established. The US FDA regulation's inclusion in the Normpack Norm should be understood as a possible reference in a broader risk assessment under the EU Framework Regulation (EU) No 1935/2004. The actual situation must be assessed case by case, and a dialogue with the relevant authority might be needed, if FDA regulations are used in the risk assessment.

Paragraph 3 is important as the proper use, handling, and manufacturing of FCMs require clear communication among stakeholders in the value chain. In most cases, FCMs are intended, optimised, and evaluated for a specific use. Therefore, the user must provide the intended use to the supplier. The manufacturer must only use starting substances and materials that are legally possible to use for the intended application and keep limitations in dosage, content, and analytical testing results. Downstream communication of limitations is required.

Paragraph 4 clarifies that for the evaluation of migration of substances from an FCM, mathematical calculations, migration modelling, or chemical analysis can be utilised.

NORMPACK NORM

§ 1 Materials and articles in contact with food shall meet the demands of Swedish or EU harmonised regulations, as amended:

Swedish regulations	EU regulations – all materials	EU regulations - specific materials
SFS 2006:804 SFS 2006:813 LIVSFS 2023:5 (Contact with Foods)	(EC) 1935/2004 (Framework reg.) (EC) 2023/2006 (GMP) (EC) 178/2002 (General Food Law) (EC) 1333/2008 (Additives) (EC) 1334/2008 (Flavourings)	(EC) 450/2009 (A&I packaging) 84/500/EEC (Ceramics) 2007/42/EC (Cellophane) 93/11/EEC (N-nitrosamine) (EC) 1895/2005 (Epoxi) (EU) 10/2011 (Plastic) (EU) 2022/1616 (Recycled plastic) (EU) 2018/213 (Plast-BPA)

§ 2 For material not covered by Swedish or EU harmonised food contact material regulations, one of the following regulations should be used:

Warenwet	BfR	FDA	CoE (metals)
The Dutch Packaging and Food-Utensils Regulation (Warenwet), Netherland	Empfehlungen des Bundesinstitutes für Risikobewertung (BfR), Germany. Recommendations on Food Contact Materials	Code of Federal Regulations, Title 21 Food and Drugs, (FDA), USA §§ 174, 175, 176, 177, 178, 180, 181, 182, 184, 186 and 189	Council of Europe resolution CM/Res (2013)9, Metals and alloys used in food contact materials and articles

§ 3. To ensure correct use, suppliers and purchasers throughout the value chain shall confer about the suitability of the material/article for the intended purpose.

§ 4. The transfer of constituents from the food contact material to food shall be assessed.
If there is a limit regulating materials/articles, the following alternative methods are suggested to establish whether the material/article meets the demands:

a) Worst-case calculations

b) Migration modelling

c) Laboratory measurements

4 Workflow

When evaluating a material for food contact applications, it is important to follow a step-wise approach. This chapter presents the necessary steps, which do not necessarily have to be taken in a specific order but are all important and must be included in the evaluation. The workflow is also described in more detail in each material-specific annex.

4.1 Define the intended use

The type of food that will be in contact with the material influences the migration rate of substances to the food. Therefore, information on the type of food that will be in contact with the FCM, such as dry, fatty or acidic, is needed.

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

Actions:

- *Define the food type that will be in contact with the material.*
- *Define the temperature at which the contact will take place.*
- *Define the storage time.*

4.2 Define type of material and legislation

Different material types are regulated under different material-specific laws or recommendations. By defining the material type, a list of applicable legislations can be produced. Note that (EC) No 1935/2004 and (EC) No 2023/2006 are mandatory for all FCMs regardless of material type.

To determine the applicable regulations for a specific material type, refer to the annex for that material. In an FCM containing different material types, each component must be evaluated against the corresponding regulation. All components, including materials like adhesives and printing ink, must be considered.

Action:

- *Make a list of all material types in the FCM and their corresponding regulation.*

4.3 Collect compliance information from suppliers

Information exchange between supplier and customer is crucial for enabling a correct risk assessment. The supplier must provide a statement for their product as it relates to the applicable legislation. This statement has two main objectives:

a) It confirms to the customer that the material and production process comply with the relevant requirements of regulation (EC) No 1935/2004, (EC) No 2023/2006, and other applicable regulations and recommendations.
b) It provides the customer with relevant information necessary for them to establish FCM compliance.

Materials that are covered by material-specific legislation must be accompanied by a declaration of compliance (DoC). For materials not covered by a specific measure there is no EU requirement for a DoC, though requirements can 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.

Action:

- *Collect statements for all components in the FCM.*

4.4 Perform calculations and analyses

Based on the requirements in the applicable legislation and the information received from suppliers, the FCM might need to be tested.

For the migration of specific substances, mathematical calculations or migration modelling can replace chemical analysis.

The testing programme must be adapted to the conditions of use defined in the first step of this workflow.

Actions:

- *Define possible calculations or modelling.*
- *Perform possible calculations or modelling.*
- *Define the necessary analyses.*
- *Perform the analyses.*

4.5 Compile the results

The collected information from suppliers, calculations, migration modelling results, or test reports and information on intended use make up the supporting documentation for compliance of the FCM with applicable regulations.

- Based on the supporting documentation, a statement that confirms FCM compliance should be written. This statement is used to communicate the suitability of the material for food contact with customers along the value chain, and possible obligations to be fulfilled by the downstream user. The statement can be a declaration of conformity, food contact statement (FCS), or statement of composition (SoC). Annex 6.8 contains further guidance.

Actions:

- *Compile the supporting documentation.*
- *Create the statement (DoC, FCS, SoC or equivalent).*

i. Annexes

The following annexes should be consulted and related workflows followed when you evaluate an FCM. The actual construction will determine which annexes you choose. See also the annex for multi-material, multi-layers where relevant. The annex on NIAS should be consulted for all types of FCMs, as should the DoC annex.

Annex 1. Paper and board

Food contact materials made of paper and board are not yet covered by a material-specific measure on the EU level. Instead, national legislation applies. In the EU, the German BfR recommendations are often referred to for paper and board, which is why this guide focuses on assessing compliance via BfR XXXVI. As an introduction, the BfR recommendations for paper and board are described. After that, the annex is divided into two main sections. The first is intended for converters or downstream users of paper and board. The second is intended for paper and board manufacturers.

German recommendations BfR XXXVI.

The BfR recommendations establish compositional requirements through positive lists. This means that every substance added to produce paper and board intended for contact with food must be in the positive list in order for the material to comply with the recommendation. The recommendations apply to the following components:

- Raw materials.
- Production aids.
- Special paper-refining agents.
- Preservatives used to prevent microbial spoilage of formulations and slimicides.

The recommendations do **not** apply to:

- Substances used to keep manufacturing devices clean and protect them from corrosion.
- Production of pulp or cellulose fibres.
- Substances that are used for manufacturing paper raw materials or for formulating active ingredients (e.g., stabilisers and pH-modifiers).

These substances and materials do not have to be listed in the positive list of recommendations but may still be used given the exceptions. However, it is important to assure that their use does not compromise the safety of the final material. The Framework Regulation (EC) No 1935/2004 must still be fulfilled, and the end product must be safe for the intended use according to Article 3 of (EC) No 1935/2004. See also Chapter 3.1 about the framework regulation.

In addition to the compositional requirements, the recommendations also set limits for the transfer of substances from the material to the food, in some cases as dosage limits, total content in the material, extraction limits or as migration limits.

The recommendations consist of the following four parts. The intended end use of the material determines which part of the recommendation applies:

- XXXVI – For single and multi-layered materials and articles made of paper and paperboard, including fibre casting and coating slips for use at temperatures up to 90°C.
- XXXVI/1 – For paper that will be subject to hot extraction, such as boil-in-bag packages, teabags, and hot filter papers.

- XXXVI/2 – For paper, paperboard, and board that are intended for use during baking and microwaving.
- XXXVI/3 – For absorber pads based on cellulosic fibres.

EU Regulation (EC) No 2023/2006 on Good Manufacturing Practice (GMP) must also be fulfilled. See Chapter 3.2 on GMP. For guidance on GMP for the production and handling of paper and board, see, for example, the CEPI (Confederation of European Paper Industries) Good Manufacturing Practice Guideline.[13]

Annex 1.a. Workflow for downstream users of paper and board

When assessing an FCM based on paper and board, start with defining the intended end use. Define the type of food that will be in contact with the material or article, as well as the contact time and contact temperature. These factors will affect which material should be chosen and secure a correct evaluation of the material. The assessment is then done on the finished construction, including for example printing inks and adhesives. For a multi-material, multi-layer FCM, see Section 6.6. State the applicable legislation or recommendation. In most cases for the Swedish market, the BfR recommendations can be chosen.

Workflow, step 1: Define the intended end use and applicable legislation.

- *Define the time and temperature under which the food will be in contact with the material.*
- *Define the type of food that will be in contact with the material.*
- *State the applicable legislation or recommendation for the material.*

Next, start gathering documents from the supplier for the material. The documentation must include references to the applicable legislation and any obligations the user must fulfil.

Workflow, step 2: Collect information from suppliers.

- *Make sure that the documentation includes references to applicable legislation and that the intended use is covered by the risk evaluation done by the producer.*

A paper or board material that is not converted more than through cutting or forming into a finished FCM does not need to be further assessed or tested in principle, as the material's producer should have already done this. A risk assessment might be needed for any addition of, for example, process lubricants. If the paper or board material is further converted through printing and gluing, additional assessment and tests might be needed.

Workflow, step 3: Perform calculations and analyses.

- *Perform a worst-case calculation (WCC) if possible.*
- *Perform migration modelling if needed.*
- *Perform migration testing if needed.*

[13] Publications | www.cepi.org

After these steps are completed and compliance is confirmed, a statement should be written in order to communicate compliance with the applicable legislation. This statement should clearly define the suitable food types and conditions of use for the final material. If the evaluation results in a restriction in the surface-to-volume ratio, this must also be included.

For information about compiling the statement, see Section 6.8 on DoCs in this annex.

Workflow, step 4: Compile the results.

- *Summarise your compliance efforts in a statement in order to communicate compliance and intended end use of the final material to the customer. Annex 6.8 contains further guidance on compiling such a statement.*

Annex 1.b. Workflow for paper and board manufacturers

Workflow, step 1: Define the intended end use and applicable legislation.

- *Define the time and temperature under which the food will be in contact with the material. Based on this, define which part of the BfR XXXVI recommendation is applicable.*
- *Define the type of food that will be in contact with the material. BfR XXXVI divides food types into dry, non-fatty, moist, and fatty food. Foodstuff can have one of these characteristics or a combination of them.*

Steps for assessment according to BfR XXXVI.

A paper or paperboard intended for food contact below 90°C must fulfil the requirements of BfR XXXVI. Substances and raw materials added during production must be listed in the positive list under the correct category (intended use). This is ensured by gathering information for each component from that component's supplier.

Workflow, step 2: Collect information from suppliers.

- *Make sure that the substances and raw materials included in production are listed on the positive list of the correct part of the recommendation by gathering information from the suppliers.*

The final material must then fulfil the analytical requirements mentioned in the preamble and limits for specific substances in the positive list (if the substance is used in production). A collection of analytical methods gathered by the BfR is available on their webpage.[14]

[14] https://www.bfr.bund.de/de/methodensammlung_papier__karton_und_pappe-32620.html.

The following analysis must be performed on the paper or paperboard:

- The finished paper and paperboard must have no preserving effect on the food. This is assessed by performing DIN EN 1104: Determination of the transfer of antimicrobial constituents.
- Cold water extraction[1] of lead and cadmium. The content of lead must be below 10µg/l and the content of cadmium below 5 µg/l. Testing is not necessary when the material is intended for contact with only dry and non-fatty foods.
- Aluminium must not migrate into foodstuff in quantities above 1mg/kg food. This requirement is checked by performing a cold water extract[1]. Testing is not necessary when the material is intended for contact exclusively with fatty foods, such as butter, and dry food.
- When optical brighteners are used in production, they must not migrate to the foodstuff. This is analysed by performing DIN EN 648, whereby a value of 5 must be reached on the evaluation scale. Depending on the intended conditions of use for the material, different test fluids and testing conditions apply that are specified in the standard.
- There must be no migration of colourants to the foodstuff from coloured papers. Testing is conducted according to DIN EN 646, whereby grade 5 on the grey scale must be reached.
- When primary aromatic amines (PAAs) are part of the formulation or if there is a risk that PAAs will be formed, you must ensure that these are not released to the food. An analysis is performed through cold water extraction[1]. The sum of all PAAs must not be identified over a limit of 0.01 mg/kg of food. Individual PAAs listed as CMR 1A and 1B in the CLP Regulation (EC) 1272/2008 must not be identified over a limit of 0.002 mg/kg.

Depending on the substances added, additional analysis might be needed. If the substances used are listed with a limitation in the positive list, you must demonstrate fulfilment of that limitation. A limitation can be in the form of a dosage limitation, total content in the final material, or a limitation of migration/transfer to the foodstuff. How compliance with these limitations is demonstrated depends on the nature of the limitation:

- Total content is analysed through cold water extraction.[15]
- Migration/transfer is analysed by using a suitable food simulant. Modified polyphenylene oxide (MPPO) is used for contact with dry foodstuff. A migration analysis simulating contact with moist and/or fatty foodstuff cannot be performed using the current methods. Instead, extraction is used to estimate the migration. Water extraction is used for contact with moist foodstuff and extraction with an organic solvent is used for contact with fatty foodstuff.[16] It should be noted that extraction tests can result in an overestimation of migration compared with a real-life scenario.

Workflow, step 3: Perform calculations and analyses.

- *Perform the analysis specified in the preamble of the recommendation. Further analysis is also needed if the used substances are listed with a limitation in the positive list.*

[15] A cold water extract is prepared according to DIN EN 645

[16] SS-EN 15519:2007

Since paper and board are not regulated under a material-specific measure, there is no legal requirement to create a declaration of compliance (DoC) for the final material. But in order to communicate compliance with (EC) No 1935/2004 and (EC) No 2023/2006 to the customer, a statement need to be written. This statement should clearly define the suitable food types and conditions of use for the final material.

Workflow, step 4: Compile the results.

- *Summarise your compliance efforts in a statement in order to communicate compliance and intended end use of the final material to the customer. Annex 6.8 contains further guidance on compiling a DoC.*

Steps for assessment according to XXXVI/1.
Papers intended for hot extraction, such as boil-in-bag packages, teabags, or hot filter papers, must comply with BfR XXXVI/1. Substances and raw materials used in the production must be listed in the positive list of BfR XXXVI/1 under the correct category (intended use). This is ensured by gathering information for each component from that component's supplier.

Workflow, step 2: Collect information from suppliers.

- *Make sure that the substances and raw materials included in the production are listed on the positive list of the correct part of the recommendation by gathering information from the suppliers.*

The final material must also meet the analytical requirements mentioned above (under BfR XXXVI) but the conditions must be adapted to the intended use, hot extraction. When water extraction is used, hot water extraction[3] must be performed. When the migration/transfer is analysed using an organic solvent, this is done at 60°C. If analysis of 1,3-dichloro-2-propanol and 3-monochloro-1,2-propanediol is needed according to the material's composition, it must be done in cold water extraction despite the intended end use.

In addition to the above analytical requirements, there is a requirement for the total dry residue in the water extract:

- For materials used for hot applications, the total dry residue in the hot water extract must not exceed 10 mg/dm^2 or 10 mg/g for filter layers with a maximum total nitrogen content of 0.1 mg/dm^2 and 0.1 mg N/g for filter layers, respectively.
- For materials used for cold applications, the total dry residue of the cold water extract must not exceed 5 mg/g filter layer, with inorganic components a max. of 3 mg/g. Total nitrogen content of the extract must not exceed 3 mg/g filter layer. Formaldehyde must not exceed 0.3 mg/g.

Workflow, step 3: Perform calculations and analyses.

- *Perform the analysis specified in the preamble of the recommendation. Further analysis is also needed if the substances used are listed with a limitation in the positive list.*

When analyses are performed and compliance is confirmed, a statement should be written in order to communicate compliance with (EC) No 1935/2004 and (EC) No 2023/2006 to the customer. This statement should clearly define the suitable food types and conditions of use for the final material.

Workflow, step 4: Compile the results.

- *Summarise your compliance efforts in a statement in order to communicate compliance and intended end use of the final material to the customer. Annex 6.8 contains further guidance on compiling such a statement.*

Steps for assessment according to XXXVI/2.

Paper, paperboard, and board that are intended for use during baking and microwaving must fulfil BfR XXXVI/2. Substances and raw materials used during production must be listed in the positive list of BfR XXXVI/2 under the correct category (intended use). This is ensured by gathering information for each component from that component's supplier. The positive list in the BfR XXXVI/2 is substantially shorter than the one in the BfR XXXVI, so it important to make sure that all substances are listed in the positive list in the BfR XXXVI/2.

Workflow, step 2: Collect information from suppliers.

- *Make sure that the substances and raw materials included in production are listed on the positive list from the correct part of the recommendation by gathering information from the suppliers.*

The final material must also meet the analytical requirements mentioned above (under BfR XXXVI) but the conditions must be adapted to the intended use, baking. When water extraction is used, hot water extraction[17] must be performed. When the migration/transfer is analysed using an organic solvent, this is done at 60°C. If analysis of 1,3-dichloro-2-propanol and 3-monochloro-1,2-propanediol is needed according to the material's composition, this must be done in cold water extraction despite the intended end use.

Paper and paperboard complying with BfR XXXVI/2 must not be used at temperatures above 220°C. The paper and paperboard must be able to withstand a temperature of at least 220°C for the intended duration of time without decomposing. For paper and board intended for microwave use, a maximum of 150°C applies.

Workflow, step 3: Perform calculations and analyses.

- *Perform the analysis specified in the preamble of the recommendation. Further analysis is also needed if the substances used are listed with a limitation in the positive list.*

When analyses have been performed and compliance is confirmed, a statement should be written in order to communicate compliance with (EC) No 1935/2004 and (EC) No 2023/2006 to the customer. This statement should clearly define the suitable food types and conditions of use for the final material.

Workflow, step 4: Compile the results.

- *Summarise your compliance efforts in a statement in order to communicate compliance and intended end use of the final material to the customer. Annex 6.8 contains further guidance on compiling such a statement.*

[17] A hot water extract is prepared according to DIN EN 647.

Steps for assessment according to XXXVI/3.

Absorber pads based on cellulosic fibres must comply with the compositional requirements set by BfR XXXVI/3 for the substances used in the absorbent core. Substances used in the absorbent core must be listed in the positive list from BfR XXXVI/3 under the correct category (intended use). This is ensured by gathering information for each component from that component's supplier. Other materials used in the absorber pads, such as paper, plastics and glue, must comply with their applicable legal requirements.

Workflow, step 2: Collect information from suppliers.

- *Make sure that the substances and raw materials included in production are listed on the positive list from the correct part of the recommendation by gathering information from the suppliers. Ensure that other components in the final product comply with their respective laws by collecting information from the suppliers.*

For the final product, no more than 10 µg/l lead and 5 µg/l cadmium must be detectable in the cold water extract.

Workflow, step 3: Perform calculations and analyses.

- *Perform the analysis specified.*

When analyses are performed and compliance is confirmed, a statement should be written in order to communicate compliance with (EC) No 1935/2004 and (EC) No 2023/2006 to the customer. This statement should clearly define the suitable food types and conditions of use for the final material.

Workflow, step 4: Compile the results.

- *Summarise your compliance efforts in a statement in order to communicate compliance and intended end use of the final material to the customer. Annex 6.8 contains further guidance on compiling a DoC.*

Paper and board made of recycled fibres.

Recycled fibres can be used in paper and paperboard for food contact under BfR XXXVI, but only for applications below 90°C. BfR recommendations do not allow the use of recycled fibres for other applications, such as microwave heating and baking.

The grades of recycled paper must be carefully selected, considering the risk of contamination from prior use and from the presence of harmful substances. The standard EN 643, the European List of Standard Grades of Paper and Board for Recycling,[18] can be used as a reference for excluding those sorting grades not suitable for use in paper and board for food contact.

The analytical requirements of the preamble in BfR XXXVI applies (see above under BfR XXXVI). Additionally, migration of the substances mentioned in the table of the BfR XXXVI annex must be under the limit.

Further resources.

CEPI, CCB, CITPA, ACE, ETS and ECMA have issued more detailed guidelines, such as the Food Contact Guidelines for the Compliance of Paper and Board Materials and Articles[19] as well as a responsible sourcing guideline.[20]

[18] Standard - Papper och kartong - Europeisk förteckning över standardkvaliteter för pappersåtervinning SS-EN 643:2014

[19] Food-Contact-Guidelines_2019

[20] Guidelines for Responsible Sourcing and Supply of Recovered Paper

Annex 2. Plastic

Plastic FCMs are regulated by the plastics regulation (EC) No 10/2011, which merged earlier EU Directives into one regulation in 2011 and was fully implemented in 2013. The process of rewriting and implementing the rules for plastic FCMs was called a "Plastic Implementing Measure (PIM)". The plastics regulation is regularly updated, and a consolidated version with the latest amendments is available.[21]

Three Union Guidelines have been published and one is being planned that will provide guidance on applying the rules as an actor in the plastic FCM supply chain.

A. Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
B. Technical guidelines for compliance testing, in the framework of Regulation (EU) No 10/2011 on plastic food contact materials (not officially published; a presentation from 2016 describing it is publicly available).
C. Applicability of generally recognised diffusion models for the estimation of specific migration in support of Directive 2002/72/EC.
D. Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain.

The Normpack Guideline is not intended to replace these Union Guidelines, but rather to provide recommendations on how to meet the requirements. It is recommended that this chapter be read together with Union Guideline "A" and the plastics regulation.

Regulation (EU) No 2022/1616 regulates recycled plastic for contact with food, and addresses the decontamination of the used plastic material. The composition of the plastic should fulfil requirements for composition according to (EU) No 10/2011.

The workflow described in this annex is intended to help producers of plastic articles evaluate their materials. For producers of plastic raw materials, we refer you to Plastics Europe[22] for guidance.

Annex 1.c. Workflow when assessing a plastic FCM

Workflow, step 1: Define the intended end use.

- *Define the types of food that will be in contact with the material.*
- *Define the time and temperature during which the food will be in contact with the material.*

[21] Legislation (europa.eu)

[22] Food contact, • Plastics Europe

The plastics regulation stipulates that the test parameters should be based on the worst foreseeable use of the material.

An FCM is often assessed for use with all types of food, thus covering a worst foreseeable use in this aspect. However, it is also possible to limit the use of an FCM to all types of food except acidic ones or fatty foods. This might be needed due to the use of mineral fillers or additives with restrictions on possible use.

Table 2 of Annex III in the plastics regulation must be used when choosing a specific food type and the food simulants that represent that food type. The table also includes correction factors that can be used when assessing the results obtained. Food simulants and correction factors are described in more detail further down.

When defining the temperature and contact time between the plastic and food, it is important to include the full use of the material. The most common time and temperature for use of plastic FCM packaging is long-term storage at room temperature or below. Additionally, the food may be hot or warm when it is filled into the packaging. This so-called hot fill is defined in the plastics regulation as "the filling of any article with a food with a temperature not exceeding 100°C at the moment of filling, after which the food cools down to 50°C or below within 60 minutes, or to 30°C or below within 150 minutes."[23]

Room temperature is generally defined as 25°C.[24]

When choosing storage time, long-term storage is defined as more than 30 days.

It is important that the producer of a plastic FCM communicate with the user so that they can clearly understand the intended use for all the following aspects:

- Type of food.
- Temperature at which the contact will take place.
- Time in contact with the food.

> ***Workflow, step 2: Define the material and state whether and how the plastics regulation applies.***
>
> - *Define the material or materials in the scope of the regulation, and what parts should be included in the assessment.*

Plastic is defined as the following in the plastics regulation:

'plastic' means (a) polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles.

A plastic layer that is in theory possible to separate from another material falls within the scope of the regulation. A coating or lacquer that must be applied onto another substrate to maintain its structural

[23] (EU) No 10/2011 Article 3, point 19

[24] (EU) No 10/2011 Annex V, 2.1.4 (f)

integrity is not considered to be within the scope of the regulation unless it is described specifically. For example, a dispersion is generally not within the scope, but a co-extruded polyethene layer is within the scope.

A plastic can either be a so-called mono-layer or a plastic multi-layer.

- A mono-layer consists of one type of polymer, for example polyethylene (PE), with the possible addition of additives.
- A plastic multi-layer consists of different layers of plastic, which can be different polymer types. The layers can be held together by adhesives, be co-extruded, or be held together by so-called tie layers.

Both plastic mono-layers and multi-layers can be coated, printed or both.

Multi-material multi-layers (MMML) are covered in a separate annex of the guideline, Annex 6.6.

In all cases, plastic layers must fulfil the rules for composition according to the plastics regulation. The monomers and additives used must be listed in the Union list[25]. There are derogations from this requirement, and polymer production aids (PPAs) other than those listed in the Union list may also be used. Colourants and solvents may also be used even if not listed. Recommendations from BfR may be used as a reference for assessing PPA and colourants.[26]

Coatings, printing inks, and adhesives used with plastic FCMs might contain chemical substances beyond those listed in the Union list. If a substance used in a coating, printing ink, or adhesive is listed in the Union list, the final material or article must comply with the migration limit of this substance, even if the substance is only used in the coating, printing ink, or adhesive. The Union list does not include substances used only in printing inks, adhesives, and coatings because these layers are not subject to the compositional requirements of the plastics regulation. However, substances used in coatings which form gaskets in closures and in caps are exceptions.

Ion exchange resins, rubbers, and silicones are not covered by (EU) No 10/2011, since these materials are made up of different substances and have different physio-chemical properties than plastics. Therefore, other specific rules apply to them.

Workflow, step 3: Collect information from suppliers.

- *Collect and make sure that the declarations of conformity for all components are up to date with current legislation and latest amendments, and that there are clear statements for substances that are used and have migration limits, or are present as dual-use substances.*

As a manufacturer, when assessing a plastic material, make a list of all material types in the plastic. Include colourants, solvents, PPAs, adhesives, and printing inks if used.

Collect the declaration of compliance (DoC) or equivalent for each of these materials. For materials other than plastic, these documents may be referred to as a statement of compliance, statement of composition or similar.

[25] (EU) No 10/2011 Annex I,

[26] BfR Recommendations on food contact materials - BfR (bund.de)

For recycled plastic, DoCs must be issued and provided for each batch.

All documents must indicate at a minimum that the material is suitable for use in an FCM and that it is possible to meet the requirements in the EU framework regulation.[27] If the material is plastic, the composition must meet the requirements in the plastics regulation. DoCs for starting materials need to state the identity of substances with specific migration limits, other restrictions, and dual-use substances.

The statements for coatings, adhesives, and printing inks must contain information on substances included in the Union list if they also have specific migration limits.

In some cases, suppliers may only provide information under a non-disclosure agreement. In these instances, it might be necessary to consult with a third-party testing laboratory or similar to ensure that the finished material meets the necessary standards.

When assessing a final food contact article that consist of several components, make a list of them and collect the DoCs for each of them.

Workflow, step 4: Perform calculations and analyses.

- *Perform an assessment of compliance as specified in Chapter V in the plastics regulation.*
- *Overall migration must be tested.*
- *Specific migration can be calculated, modelled or tested.*

The plastic FCM must be assessed according to the rules in Chapter V of the plastics regulation.

The inertness of the plastic is tested as overall migration.

The plastic's safety is assessed through specific migration, which ensures that the material does not release substances beyond the limits set for the substances during the intended use.

The general food types are described in the plastics regulation as the following. Instead of testing with real foods, they are replaced by food simulants, each with an abbreviation.

Food type	Food simulants	Abbreviation
Hydrophilic.	10% Ethanol (v/v)	A
pH <4.5, hydrophilic and acidic.	3% Acetic acid (w/v)	B
Alcohol content of up to 20%, and foods which contain a relevant amount of organic ingredients that render the food more lipophilic.	20% Ethanol (v/v)	C
Lipophilic. alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions.	50% Ethanol (v/v)	D1
Lipophilic foods which contain free fats at the surface.	Vegetable oil * or	D2

[27] (EC) No 1935/2004

	95% Ethanol and isooctane (v/v) as substitute	
Dry, frozen fruit and vegetables.	Poly (2,6-diphenyl-p-phenylene oxide = MPPO ('Tenax ®')	E

*Any vegetable oil containing less than 1% unsaponifiable matter

Overall migration.

Overall migration (OM) must be done to cover the use defined earlier in the process. There is a table of standardised conditions for testing the overall migration.[28] The conditions span from OM0, which is the least severe condition, to OM9, the most severe. A test at a more severe OM covers the less severe ones in most cases.

OM2, testing with food simulants at 10 days at 40°C, is the most common condition when testing overall migration from a plastic packaging for long-term storage.

Overall migration must be tested through analysis, not through a calculation.

The general overall migration limit (OML) is 10 mg/dm^2, with the exception of plastic FCMs intended for handling food for infants and small children (0 to 3 years of age), which is 60 mg/kg. This is because infants and small children are a vulnerable consumer group, and foods for them often are packaged in small packages. These packages have a high surface-to-volume ratio, and the risk assessment must not underestimate the migration.

Caps, gaskets, stoppers, or similar sealing articles can often be used on containers of different sizes. If the final use is not known by the producer, the OM may be reported in mg/article. It is the responsibility of the user of the sealing article to recalculate the migration to the final construction, when the complete surface area of both container and the sealing article is known.

OM tests to food simulants A, B and D2 will cover all food types.

OML covers non-volatile substances and therefore testing in food simulant E is not necessary.

Specific migration.

Approximately 400 of the substances in the Union list have SML values. Additionally, some groups of similar substances are regulated by group restrictions. For these groups, there is a total specific migration limit (SML (T)) for the sum of substances applicable to the group.

For substances with the SML set as not detected in food, a generic detection limit is set as 0.01 mg/kg unless stated differently in the Union list.

For substances with no SML value given, the generic overall migration limit and testing applies. There is no requirement to test the specific migration for these substances.

Specific migration values must be expressed in mg of the substance per kg of food (mg/kg) and apply the real surface-to-volume ratio in actual or foreseen use.

Assumptions can be made to simplify testing of an FCM that has not yet been in contact with food. These assumptions will underestimate migration from small food containers and packaging and

[28] (EU) No 10/2011, Annex V, Chapter 3, Table 3

overestimate migration from large containers. This is considered an acceptable practice in risk management for adults and older children, but not for infants and young children.

The surface-to-volume ratio is assumed to be 6 dm^2/kg, which is often referred to as the "EU-cube". It is estimated that a person consumes 1 kg of food, which is packed in a cube with a side of 1 dm^2. The surface area of the cube is then 6 dm^2. It is also assumed that the density of the food is 1 kg/dm3. Therefore, the surface-to-volume ratio is 6. Based on this, the unit used is dm^2/kg, even if it is described as surface to volume and not surface to weight.

Caps, gaskets, stoppers, or similar sealing articles can often be used on containers of different sizes. If the final use is not known by the producer, the specific migration may be reported in mg/article. It is the responsibility of the user of the sealing article to recalculate the migration to the final construction.

Worst-case calculation.

If the concentration of a substance is known in the material, a worst-case calculation can be made, assuming that all of the substance migrates into the food from the given material thickness, at the applied surface-to-volume ratio of the construction. The density of the food must also be considered.

Migration modelling.

If the worst-case calculation indicates that the SML is exceeded, migration modelling that applies generally recognised diffusion models can be used. The model must never underestimate real levels of migration. See the EU Guidance document "C": "Practical guidelines on the application of migration modelling for the estimation of specific migration" for more information.

Several migration modelling software products have been developed: FACET, MIGRATEST lite, SFPP3, AKTS-SML, and the most recent VERMEER FCM.

Migration testing.

Selection of simulants for testing specific migration.

The selection of food simulants is recommended based on the rule "similar solves similar". This means that the closer the polarity of the migrant and the screening food simulant, the better the solubility of the migrant will be in the food simulant. As a measure of polarity, the octanol to water partition coefficient (log Po/w) can be used. However, any swelling effect of the food simulant on the FCM, at the chosen time and temperature must also be considered. The following information is given as guidance and might not be applicable in all situations and for all polymer types. The interaction between the chemical substance and the food simulant might also need to be taken into account.

Specific migration must be done to one of the following food simulants based on the following list as most severe. Substances not covered in this list must be evaluated case by case.

A, 10% Ethanol.

Chemical substances with octanol/water partition coefficient equal to or lower than 0 log Po/w.

B, 3% Acetic acid.

Metals listed in Annex II.

Primary aromatic amines listed in Annex I and Annex II.[29]

[29] JRC: Technical guidelines on testing the migration of primary aromatic amines from polyamide kitchenware and of formaldehyde from melamine kitchenware

95% Ethanol.

Chemical substances with octanol/water partition coefficient equal to or higher than 3 log Po/w[30]

Lipophilic substances as indicated in column 7 in table 1, Annex I in (EU) No 10/2011.

Selection of time and temperatures.

Table 1 and 2 in Annex V must be used to assign specific migration testing conditions for an FCM used in contact with food up to 30 days, and at temperatures above room temperature.

For a contact period longer than 30 days at room temperature and below, there are specific conditions given in Section 2.1.4.

For plastic as a packaging material, it is common practice to test for specific migration from an FCM at **10 days at 60°C.** This also corresponds to the common practice for testing OM2.

Situations where use of food simulant D2 (oil) is not feasible.

If the testing is not technically feasible in food simulant D2, migration tests must be done using 95% ethanol and isooctane. For temperatures of 100°C and higher, testing must also be done using food simulant E. The test that results in the highest specific migration must be used to establish compliance.

Testing migration to vegetable oil cannot be replaced with 95% ethanol and isooctane for economic reasons. Situations that are not technically might include the following:

- The test sample has absorbed too much oil, resulting in a high uncertainty of the analytical measurements.
- Difficulties in recovering the absorbed oil.
- Physical changes in the test sample.
- Reaction of the substance with the food simulant vegetable oil.
- It is not possible to isolate the substance from the oil for quantification.
- Interference from the vegetable oil.
- Insufficient analytical detection limit of the substance in vegetable oil.

Since 95% ethanol and isooctane cannot be used for migration tests at temperatures above 60°C, the time applied must be adjusted. At the same time, the potential swelling of the plastic has to be taken into consideration. Nonpolar polymers like polyethene and polypropene will potentially swell more in contact with the nonpolar solvent isooctane compared to the more polar 95% ethanol. Therefore, the time and temperature require adjusting, since both simulants must be used if replaced in migration tests for vegetable oil. See guidance B as listed in the introduction of this annex.

Workflow, step 5: Compile the results.

- *Compile the supporting documentation.*
- *Summarise your compliance efforts in a declaration of conformity in order to communicate compliance and intended end use of the final material to the customer. Annex 6.8 contains further guidance.*

[30] Opinion of the SCF on the introduction of a Fat (Consumption) Reduction Factor (FRF)

When the assessment is done, the documentation and results must be compiled. This is the supporting documentation mentioned in the plastics regulation. It must be provided to a controlling authority if requested by them. There is no legal obligation to share the supporting documentation with a customer receiving the FCM. The customer must get the declaration of compliance for the FCM as delivered.

The supporting documentation consists of:

- A table or list of the different components.
- A DoC from suppliers of the listed components.
- Calculations.
- Test reports.

How to create and update the DoC is described in a separate annex, Annex 6.8. Note that for FCMs containing recycled plastics, detailed requirements apply. DoCs must be issued using mandatory templates, relevant registration numbers must be provided, and DoCs must be issued for each batch of materials or articles. See EU Commission guidance.[31]

[31] Resources for plastic recyclers

Annex 3. Recycled plastic

Recycled plastic as an FCM is covered by regulation (EU) No 2022/1616. This regulation replaced a previous one from 2008, and some of the older rules are maintained in the new regulation. However, the new regulation is intended to cover new recycling technologies.

The bearing principle is that plastic FCMs must comply with the general regulation (EU) No 10/2011 on plastic material composition. Regulation (EU) No 2022/1616 outlines the rules for recycling and decontaminating the plastic material in recycling processes to make it suitable for food contact again. There are also requirements for registration for different actors in the recycling value chain. The requirements for documenting compliance are stricter for recycled plastic compared to new FCM plastic. A declaration of compliance (DoC) for recycled plastic must be issued for each batch produced, and mandatory templates must be used.

This guideline only covers the use of recycled plastic as a converter.

The EU Commission has a FAQ page about the implementation of (EU) No 2022/1616.[32] The Swedish Food Agency has also published information in Swedish.[33]

The EU Commission plans to publish guidance on the requirements for recycled plastics.

Workflow when assessing recycled plastic.

In principle, the workflow described in the annex for plastic FCMs, Annex 6.2, must be followed.

Step 3 in the workflow must be adjusted, since a DoC must be obtained for each batch of recycled plastic. The assurance of FCMs made from recycled plastics is more of a continuous process. A workflow for managing batch numbers on incoming recycled plastic materials and stating them in the DoCs issued for the finished products must be in place.

[32] Plastic Recycling (europa.eu)

[33] Återvunnen plast (livsmedelsverket.se)

Annex 4. Printing inks

The composition of printing inks for FCMs are not regulated by EU material-specific measures. As stated in the framework regulation (EC) No 1935/2004 Article 6, national provisions may be used instead. However, there is still no clear national legislation in force in any EU member state for printing inks.

A German printing ink ordinance, which was published in December 2021,[34] is still in the implementation phase until 31 Dec. 2025. After this date, FCMs for the German market must comply with the legislation. The German Printing Ink Ordinance has a positive list of risk-assessed substances. Under this German legislation, it may be possible to make and apply the printing ink on the side of the FCM that is intended to be in contact with the food.

Outside the EU, Swiss legislation is in force for printing inks based on positive lists.[35] This legislation is commonly referred to by printing ink manufacturers. Annex 10[36] contains a list of risk assessed substances. Previously also non risk assessed substances were included, but these are now removed from listing.

The Dutch Warenwet mentions printing inks in Chapter XI for colourants and pigments. These requirements cover the purity of the pigments, but there is no list of allowable substances.

The handling, not the composition, of printing inks applied to the non-food contact side (the side not directly in contact with food) of FCMs is regulated in (EC) No 2023/2006 on Good Manufacturing Practice (GMP) for FCMs. A set-off assessment is necessary to ensure that substances in the printing ink are not be transferred to the food through set-off in the stack or reel, or via transfer through the FCM, in concentrations that are not in line with the requirements from Article 3 of Regulation (EC) No 1935/2004. See also Section 3.23.2 on GMP.

In short, a set-off evaluation is performed by assessing three different samples and the differences between results:

a) Printed sample: A sample that has not been stored in a stack or reel. This sample is used to detect substances that may be transferred through set-off.
b) Control sample: An unprinted sample that is otherwise identical to the printed sample. Has not been stored in a stack or reel. Substances originating from this sample are detracted from substances found from the printed sample in (a).
c) Set-off sample: A sample that has been stored in a stack or reel for a given time and at a certain pressure to allow potential set-off to take place. The printed side has been in contact with the food contact side.

The European Printing Ink Association (EuPIA) has issued policies and guidance for FCM printing ink materials and processes. There is no positive list, but rather an exclusion list of substances that

[34] Bundesgesetzblatt BGBl.

[35] Swiss Bedarfsgegenständeverordnung

[36] Annex 10 of Swiss printing ink ordinance

must not be used.[37] Current practice for FCM printing inks for the EU market is to follow the EuPIA guides for composition and evaluation of production and use.

The basis for the EuPIA commitments is described in a guideline.[38] EuPIA has also published guidance for converters and end users of printed FCMs.[39]

The print of a printed FCM is assessed together with the construction that is printed. Substances with restrictions used in other parts of the construction and present in the printing ink must be assessed for migration from the entire construction. As always, the intended use must be included in the assessment.

Workflow for assessing a printed FCM.

Define the intended use.

The type of food that will be in contact with the material affects the migration rate of substances to the food. Therefore, information on the type of food is needed, such as whether it is dry, fatty or acidic.

The storage time and temperature also influence the migration of substances to the food. Therefore, the composition of the materials, including printing inks used, must be designed for this purpose. Higher temperature and longer storage time require more demanding test protocols.

In general, three different cases can be identified for printed FCMs.

Case 1

Printing inks are applied to the outside, the non-food contact side of the FCM. The print can be on the outside as a final layer. The print can also be covered by a lacquer or by a transparent plastic layer, referred to as sandwich printing or reverse printing.

Intended use at room temperature and below, including hot fill. The product is not intended to be used for heating the food.

Examples include most of the food packaged for retail to consumers.

Case 2

Printing inks applied to the outside, non-food contact side of the FCM. The print can be on the outside as the final layer. The print can also be covered by a lacquer or by a transparent plastic layer, referred to as sandwich printing or reverse printing.

More demanding use that also includes heating of the material together with the food. Examples include printed baking paper or print on plastic packaging for cooking or heating in an oven or microwave.

Case 3

Printing inks applied to the food contact side of the FCM. Examples include print on paper drinking straws that are intended to be immersed in the beverage.

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[37] EuPIA Exclusion Policy for printing inks and related products

[38] EuPIA_Guideline_on_Printing_Inks_applied_to_Food_Contact_Materials

[39] EuPIA_Customer_Guidance_Note_for_Using_Statements_of_Composition

Workflow, step 1: Define the intended use.

- *Define the food type that will be in contact with the material.*
- *Define the temperature at which the contact will take place.*
- *Define the storage time.*

Define the material, the production process and the applicable legislation.

Define the construction and all layers in the printed FCM. The print might also be covered by a lacquer. Substances with migration limits may be present in several of the FCM layers, and all the sources for potential migration must be taken into consideration. Note also if there is a functional barrier in the construction that might be part of the product's safety compliance.

State whether there is a risk for set-off in the production process through stacking or rolling of the printed product.

The applicable legislation in the EU for printing inks is the EU Framework Regulation (EC) No 1935/2004. Additionally, the Swiss or the Dutch Warenwet or the coming German legislation may be referred to. Even if the EuPIA guidance does not have legal status, it is advisable to choose printing inks that fulfil the EuPIA exclusion list.

Workflow, step 2: Define the material, the production process and the applicable legislation.

- *Define which side is printed.*
- *Define if there is a functional barrier.*
- *Define the risk for set-off.*

Collect compliance information from suppliers.

Compliance information from the printing ink supplier can be given at different levels of detail.

In all cases, a general statement is needed confirming that the FCM printed with the ink fulfils (EC) No 1935/2004 if applied and used as intended. It should also state the intended use of the printed material. For more demanding cases, like heating of the printed material or direct food contact, this should be stated as possible use.

Printing ink suppliers following the EuPIA guidance can also supply a statement of composition (SoC). A non-disclosure agreement (NDA) is often needed between the supplier and the user, or between the supplier and a third party like a testing lab, if the printing ink supplier will provide the SoC.

Workflow, step 3: Collect information from suppliers.

- *Declaration of compliance, including the intended use.*
- *Statement of composition.*

Perform calculations and analyses.

The statement of composition (SoC) containing the identities of the substances used can also provide worst-case calculations (WCCs). In such cases, the SoC states the possible maximum amount of printing ink defined as dry weight of printing ink per printed surface area. For energy curing printing inks, the SoC can state the formed substances in the cured product. These should be assessed through migration testing.

Case 1

The assessment starts by comparing the used amount of printing ink with the WCC in the statement of composition. If the product to be assessed has a higher surface-to-volume ratio than the ratio applied on the WCC provided by the ink supplier, the possible values have to be adjusted. If all the substances meet the limits, the assessment for them is completed. However, migration testing based on the other layers in the material might be needed.

If a substance is found to be above the WCC limit, migration modelling or migration testing should be performed. For selecting the migration parameters, see the EuPIA guidance.[40]

For energy curing printing inks, the SoC states the starting substances. Since the chemical state of the cured printing ink is different, WCC is not possible for these substances, but has to be assessed through migration testing.

If the documentation from the printing ink supplier does not include any WCC and the amount of each substance is not given, a migration test should be performed.

The migration of metals should be tested. This test is set up based on requirements for the relevant material being printed (i.e. plastic or paper).

Primary aromatic amines should be tested if the documentation indicates that they pose a risk. This test is set up based on requirements and available methods for the relevant material being printed (i.e. plastic or paper).

If there is a risk for set-off during processing or handling, a set-off analysis is needed.

Case 2

In addition to the assessment outlined for Case 1, the assessment for possible non-intentionally added substances (NIAS) formed at elevated temperature is assessed. See specific EuPIA guidance on NIAS[41] and guidance for Inks and Coatings for High Temperature Applications.[42] It is advisable to seek assistance when assessing these types of materials.

Case 3

The assessment should follow the setup for Case 1 except for set-off testing, which is not needed since the printing ink is on the food contact side. Note that the documentation provided by the ink supplier might contain other requirements for assessment and testing.

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[40] EuPIA_Guidance_on_Migration_Test_Methods

[41] EuPIA_NIAS_Guidance

[42] EuPIA_Info_Note_Inks_and_Coatings_for_High_Temperature_Applications

Workflow, step 4: Perform calculations and analyses.

- *Perform WCC.*
- *If possible, perform migration modelling if needed after a worst-case calculation (WCC).*
- *Perform migration testing if needed after a WCC.*
- *Perform a metal test.*
- *Perform PAA tests.*
- *Perform a set-off test, if relevant.*
- *Perform a NIAS assessment or test (Case 2).*

Compile the results.

The information collected from suppliers, calculations, migration modelling results, or test reports as well as information on intended use make up the supporting documentation for assessing compliance of the printed FCM with applicable regulations.

Based on the supporting documentation, a statement should be written that confirms FCM compliance. This statement is used to communicate the suitability of the material for food contact with customers along the value chain. See the section on DoCs in Section 3.1.3 of this guideline.

Workflow, step 5: Compile the results.

- *Compile the supporting documentation.*
- *Create the DoC. See Annex 6.8 for further guidance.*

Annex 5. Adhesives

Adhesives are frequently used in food contact materials and articles, but there is currently no material-specific measure for this component. As for all FCMs, adhesives must be safe for the intended application and must comply with the requirements in (EC) No 1935/2004.

Adhesives can be used on many different substrates, such as paper and plastic, and the evaluation of the adhesive must be adjusted for the application. The wide variety of adhesives must also be taken into consideration. There is no single approach that applies for all adhesives and all applications.

There is no positive list for components allowed to be used in adhesives for food contact. Therefore, whenever possible, adhesive suppliers often refer to the positive list in the plastics regulation (EU) No 10/2011. For components not listed in a positive list, a risk assessment based on potential hazard and exposure must be performed (see Annex NIAS for more information on risk assessment). The risk assessment can, for example, be based on opinions from the European Food Safety Authority (EFSA).

The European Adhesive and Sealant Industry (FEICA)[43] has published guidance on adhesives for FCMs.

An FCM's adhesive is assessed together with the entire construction. Substances with restrictions used in other parts of the construction and present in the adhesive must be assessed for migration from the entire construction. As always, the intended use must be included in the assessment.

Risk assessment for FCMs containing an adhesive.

When doing a risk assessment of an FCM containing an adhesive, start by defining the intended end use. Choosing the right kind of adhesive for the application is important. The contact temperature and type of food will influence the adhesive's performance and thus the safety of the final FCM.

> ***Workflow, step 1: Define the intended end use and applicable legislation.***
>
> - *Define the time and temperature under which the food will be in contact with the material.*
> - *Define the type of food that will be in contact with the material.*

Also define the substrate on which the adhesive will be applied. The substrate will influence how the final FCM will be analysed. Next, start gathering documents from the supplier of each component of the final FCM. Each layer of the FCM must comply with its respective legislation (see the corresponding annex for specific material types). The documentation for the adhesive must refer to (EC) No 1935/2004 and (EC) No 2023/2006 at a minimum. It must also include information on substances with the potential to migrate including their respective migration limits.

> ***Workflow, step 2: Collect information from suppliers.***
>
> - *Make sure that the documentation includes references to applicable legislation and information about substances with the potential to migrate.*

[43] FEICA

Based on the information gathered from the suppliers, a testing program is set up. For the substances in the adhesive with a potential to migrate, the migration must be assessed. If the supplier has provided information on the amount of each substance contained in the adhesive, an assessment can be performed by making a worst-case calculation (assuming that everything in the material of a defined area will migrate to a defined amount of food). If the calculation results in a migration over the migration limit, migration modelling can be performed using software for this purpose. If both the calculation and modelling results exceed the migration limits, or if the amount of the substances is not known, migration analysis should be performed.

When performing migration analysis for an adhesive, the type of substrate has to be considered. If the substrate is a plastic, migration analysis according to plastics regulation (EU) No 10/2011 can be applied. If the substrate is paperboard, migration to MPPO is preferable since liquid simulants might dissolve the adhesive if it is only separated from the simulant with a paper layer.

The time and temperature for the migration testing must be chosen based on the expected conditions of use. Certain care must be taken when analysing adhesives, since elevated temperatures might affect the adhesive. For guidance, consult the guidelines from the FEICA (Association of the European Adhesive and Sealant Industry) for adhesive migration testing.[44]

The results of the migration assessment, whether through calculation, modelling or analysis, is then compared to the migration limits specified in the positive list. In the case of a non-listed substance, the result must be compared with the limit derived from the risk assessment.

Workflow, step 3: Perform calculations and analyses.

- *Perform a worst-case calculation (WCC) if possible.*
- *Perform migration modelling if needed.*
- *Perform migration testing if needed.*

When analyses are performed and compliance is confirmed, a statement should be written for the customer communicating compliance with (EC) No 1935/2004 and (EC) No 2023/2006. This statement should clearly define the suitable food types and conditions of use for the final material.

Workflow, step 4: Compile the results.

- *Summarise your compliance efforts in a statement in order to communicate compliance and intended end use of the final material to the customer. Annex 6.8 contains further guidance on compiling a DoC.*

Annex 6. Multi-material, multi-layer FCMs

Multi-material multi-layer (MMML) means a material or article composed of two or more layers of different types of materials, such as a paperboard laminated with a plastic layer. There is no material-specific measure for all MMMLs since an MMML can consist of several different material types.

[44] Paper & Packaging: Feica

Instead, each layer in an MMML must comply with its respective material-specific measure or national regulation. The final construction must comply with (EC) No 1935/2004 as a whole.

For guidance on how to evaluate the individual layers, see the annex for each specific material type. How the final construction should be evaluated depends on the type of materials that are involved, but in general each layer must comply with its respective material-specific measure or national regulation. If a substance with a migration limit is present in more than one layer, the combined migration from each layer should be evaluated. This can be done either through mathematical calculation, modelling, or chemical analysis. If a functional barrier is present in the construction, layers outside of this barrier might also be composed of substances not listed in the respective material-specific measure or national regulation. For more information on functional barriers, see the technical guidelines for compliance testing in Chapter 5.2: Guidance B.

Risk assessment of an MMML.

When assessing an MMML, start by defining the intended end use. The type of food that will be in contact with the material or article, as well as the contact time and contact temperature, will affect how further analysis should be performed. Also define the different material types in the construction and their corresponding material-specific measure or national legislation.

Workflow, step 1: Define the intended end use and applicable legislation.

- *Define the time and temperature under which the food will be in contact with the material.*
- *Define the type of food that will be in contact with the material.*
- *Define applicable legislation for each layer.*

Next, start gathering documents from the supplier of each component of the final FCM. Each layer of the FCM must comply with its respective legislation, if not outside of a functional barrier. See the technical guidelines for a description of functional barrier. The documentation must include references to the applicable legislation and information on substances with the potential to migrate including their respective migration limits.

Workflow, step 2: Collect information from suppliers.

- *Make sure that the documentation includes references to applicable legislation and information about substances with the potential to migrate.*

Based on the information in the gathered documentation, a test programme can be set up. If a substance that has a migration limit is present in more than one layer, migration must be assessed for the final construction. According to the plastics regulation (EU) No 10/2011, a plastic layer in an MMML is exempt from the migration analysis requirement. However, you must demonstrate that the final MMML is safe, so migration studies are usually performed. The migration can be assessed through a worst-case calculation (assuming that everything in the material will migrate to the food). If the calculation results in a migration exceeding the migration limit, migration modelling can be performed using software for this purpose. If both the calculation and modelling results exceed the migration limits, or if the amount of the substances is not known, migration analysis should be performed.

Migration evaluation studies also need to be performed if there are substances with migration limits in one of the layers and the supplier has not evaluated the migration of that substance for the individual layer.

If migration analysis must be performed, the test setup must be adjusted to the type of layer included in the final construction. If the food contact layer is a plastic, the conditions specified in the plastics regulation can often be applied. Preferably, migration tests should be done on the final material. However, you might not be able to perform migration testing if the material as a whole does not withstand the food simulant without decomposing or wetting. This may happen if there are so-called pinholes in the food contact layer. If this is the case, migration might need to be tested for each layer separately.

Workflow, step 3: Perform calculations and analyses.

- *Perform a worst-case calculation (WCC) if possible.*
- *Perform migration modelling if needed.*
- *Perform migration testing if needed.*

When these steps are completed and compliance is confirmed, a statement should be written in order to communicate compliance with the applicable legislation. This statement should clearly define the suitable food types and conditions of use for the final material. If the evaluation results in a restriction in the surface-to-volume ratio, this must also be included.

See the chapter on DoC in the guideline.

Workflow, step 4: Compile the results.

- *Summarise your compliance efforts in a statement in order to communicate compliance and intended end use of the final material to the customer. Annex 6.8 contains further guidance on compiling a DoC.*

Annex 7. Non-intentionally added substances

Background.

Non-intentionally added substances (NIAS) in FCMs can mean any of the following:

- Impurities in the substances used (for example, traces of heavy metals).
- Reaction intermediates (for example, formation of nitrosamines).
- Degradation or reactions products (for example, oxidised stabilisers).

The presence of NIAS in food contact materials is unavoidable, and in principle all substances migrating from FCMs must undergo a risk assessment. As for all potential migrants, the risk assessment includes both defining the potential hazard and the exposure.

Legal foundation.

The term 'non-intentionally added substance' is stated in the plastics regulation in Article 6, point 4. In fact, NIAS is not mentioned as such in the Framework Regulation (EC) No 1935/2004, other than as possible impurities associated with substances for which an application exists.

Article 19 in the plastics regulation (EU) No 10/2011 states that substances not included in the Union list (Annex I of (EU) No 10/2011) must be assessed "in accordance with internationally recognised scientific principles on risk assessment".

However, Article 3 of regulation (EC) No 1935/2004 states that FCMs must not transfer their constituents to food in quantities which could endanger human health, bring about an unacceptable change in the composition of the food or bring about a deterioration in the food's organoleptic characteristics.

Therefore, NIAS can be understood as being part of the constituents and should therefore, in principle, also undergo a risk assessment if migrating from an FCM, regardless of type of material.

Recommendations and guidelines.

The assessment of NIAS migrating from an FCM is challenging, and no standard approach for assessing them is currently available. A recent report from ILSI Europe, "An Overview of Approaches for Analysing NIAS from different FCMs",[45] provides a comprehensive overview of this topic. It also lists recommendations and industry guidance for non-harmonised FCMs (ones that still lack EU-specific measure) as well as considerations for sampling, general steps for NIAS analysis, or alternatives like worst-case calculations or migration modelling. It also recommends different approaches and best practices.

Guidelines on risk assessment of non-listed substances and non-intentionally added substances[46] is available from the Food Contact Additives group within the European Chemical Industry Council (Cefic).

[45] An Overview of Approaches for Analysing NIAS from different FCMs | Zenodo

[46] Home - FCA- Food Contact Additives (cefic.org)

Practical considerations and approaches.

Information on possible NIAS is given in DoCs for some materials. When this is the case, they can be assessed using the results of calculations or tests.

Testing for NIAS can be done through non-target screening tests. The first step is the migration or extraction of substances from the FCM. Migration from FCM like plastic should in principle estimate the real exposure of migrating substances. Extraction, and the following determination of the content of substances in the material, might be the only option for some materials like paper and board. In these cases, a worst-case calculation assuming full migration of all the substances might overestimate exposure.

In screening tests, it can be challenging or even impossible to identify all substances. Gas chromatography-mass spectrometry (GC-MS) is the most widely used analytical technique, but in principle it only detects volatile and semi-volatile substances. There are libraries of spectral data to compare the signals obtained. For a fuller assessment of all potential NIAS, liquid chromatography (LC) should also be performed since it will capture non-volatile migrating substances. Until now, the libraries of spectral data for them have been less comprehensive. For volatile substances, headspace GC-MS might also be used. See the ILSI guidance[47] or Nerin et al.[48] for more information on selecting analytical techniques for NIAS identification and quantification.

The results from these analyses should then be evaluated. As a general limit, substances larger than 1000 Da (1500 Da for fluorinated substances) can be omitted, as they are assumed to not pass through the intestinal mucosa. Also, substances with migration less than 0.01 mg/kg can be omitted, based on prevailing interpretation that this is the generic detection limit in screening analyses. However, the plastics regulation (EU) No 10/2011, Annex IV, states that substances for which genotoxicity has not been ruled out must not migrate above 0.00015 mg/kg. In practice, this level of reporting is not possible with the current analytical capabilities. Instead, the statement must be based on information from suppliers earlier in the value chain.

The European Food Safety Authority (EFSA) has developed a definition for a threshold of toxicological concern (TTC)[49]. This method addresses substances found to be present in low or very low concentrations in food that lack sufficient toxicological data.

Non-target screenings may result in different cases.

In the most favourable case, all substances are possible to identify, are listed in FCM legislation and are fully evaluated with limits for migration. The results can then be assessed against this data.

Alternatively, substances found are possible to identify, and some toxicological data is available for all substances found. The first step of the assessment will be to exclude genotoxicity based on the available data.

In the least favourable case, one or several substances cannot be identified. Hopefully, this might be resolved by getting more compositional information from suppliers of the starting materials. Further

[47] Guidance on Best Practices on the Risk Assessment of Non-Intentionally Added Substances (NIAS) in Food Contact Materials and Articles

[48] Guidance in selecting analytical techniques for identification and quantification of non-intentionally added substances (NIAS) in food contact materials (FCMS)

[49] Threshold of toxicological concern

assessments, also with targeted analysis to rule out suspected substances, might be needed. A change in the composition of the material might also be needed.

For more information, see the FCA guidance,[50] EFSA guidance on submission on a dossier on a substance to be used in FCM,[51] and the EFSA guidance on the TTC concept.[52]

Further considerations.

NIAS should be assessed in plastic FCMs at a minimum by assessing the supporting documentation and building the assessment on what is stated for the used materials.

The need for analysing NIAS in FCMs made from less complex materials, for example with no printing ink or adhesives included and with less demanding intended use, is in practice today low. The situation might change when EU FCM legislation is updated.

However, with more demanding intended use such as heating or cooking the food in the packaging, and with more complex constructions including printing inks and adhesives, the need for evaluating potentially formed NIAS is greater. See the annex on printing inks for more information.

Some types of materials have been identified as more prone to containing or producing NIAS. Examples include polyamides,[53] silicones,[54] heated printing inks,[55] and recycled fibres.[56]

Workflow for assessing NIAS in FCMs.

The following are suggested steps for assessing NIAS in an FCM. The assessment should be done in addition to the assessment for the material-specific requirements. The workflow steps described here are for clarification only and list any additions to the steps described in the annexes for each base material. See the relevant annex.

Define the intended use.

This step is the same as for the base material.

> ***Workflow, step 1: Define the intended use.***
>
> - *Same as described for each base material.*

Define the material and the applicable legislation.

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[50] FCA- Food Contact Additives

[51] Note for Guidance for the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials

[52] Threshold of toxicological concern

[53] Polyamide - BfR

[54] Migration of siloxane oligomers in foodstuffs from silicone baking moulds

[55] EuPIA_Info_Note_Inks_and_Coatings_for_High_Temperature_Applications

[56] Mineral oil hydrocarbons

This step is the same as for the base material, with the addition of possible recommendations, reports or opinions relevant for the material. The presence of a functional barrier in the construction should also be considered. The evaluation of NIAS in FCMs on the part outside of the functional barrier is limited to the exclusion of genotoxic substances.

Workflow, step 2: Define the material and the applicable legislation.

- *Define all materials.*
- *Define applicable legislation or recommendations.*
- *Define if there is a functional barrier.*

Collect compliance information from suppliers.

Compliance information from the FCM supplier can be given at different levels of detail. The DoC for the raw material might list possible NIAS, and these may be evaluated as known NIAS. The documentation can also list possible unwanted NIAS as degradation products, like primary aromatic amines, nitrosamines, or oligomers.

For information on NIAS in the case of printed FCMs, see Annex 6.4 for printing inks.

Workflow, step 3: Collect information from suppliers.

- *Declaration of compliance, including the intended use.*
- *Statement of composition.*
- *Compile the information given on NIAS in the documentation.*

Perform calculations and analyses.

Based on the compilation, perform worst-case calculations if possible. The surface-to-volume ratio (S/V) applied should be 6 dm^2/kg (plastic, MMML) or 13.3 dm^2/kg (paper and board) if the final S/V ratio is not known.

Targeted tests can be done to rule out the migration of suspected formed NIAS.

Non-target screening of migration might be done to assess if there is migration of any substances above a detection limit. This limit is normally 0.01 mg/kg. If there is a migration, hopefully the pattern of the signal can be compared to a library for an approximate identification and quantification. In some cases, however, patterns cannot be identified. In these cases, the assessment must rely more on the supporting documentation and possible tests for absence of unwanted but possibly formed NIAS.

Workflow, step 4: Perform calculations and analyses. Can be done in a tiered approach.

- *Perform worst-case calculations if possible.*
- *Test for absence of unwanted but possibly formed NIAS.*
- *Perform non-target screening to assess if there is migration of NIAS.*

Compile the results.

The results from the NIAS assessment should be included in the declaration as outlined for the assessed material.

Workflow, step 5: Compile the results.

- *Include the results from the assessment in the Declaration of Compliance. Annex 6.8 contains further guidance.*

Annex 8. Declaration of compliance

To summarise the evaluation and to inform the user of the intended use of the FCM, the supplier or distributor of an FCM or an intermediate material creates a declaration of compliance (DoC). The legal basis for a DoC can be found in the Framework Regulation (EC) No 1935/2004, which states that a material covered by a specific measure must be accompanied by a DoC. Currently, these FCMs are: plastic, recycled plastics, active and intelligent materials, regenerated cellulose, and ceramics. The details on the content of such declarations is found in the corresponding specific measure for that material type. This means, though, that there is no obligation to issue a DoC for a material not covered by a specific measure. Nevertheless, some countries have adopted national legislation requiring a DoC for all FCMs. For example, Norway and Denmark have legislation requiring a DoC for all FCMs regardless of material type. Sweden has not adopted such legislation.

However, since clear communication –a statement containing detailed information needed by the downstream user – is required for FCMs, Normpack recommends that a DoC or similar be issued for all FCMs. The document does not necessarily need to be called a DoC but can be called an FCS (food contact statement), SoC (statement of composition) or similar. The point of this document is to enable those who use an FCM to fulfil their obligations and use the FCM in the intended way.

The documentation on which the DoC is based is called supporting documentation. This can include DoCs from suppliers, test reports, mathematical calculations for migration, modelling of migration and so on. A producer or distributor of an FCM is not obliged to disclose the supporting documentation to their customers but must make the supporting documentation available to the authorities on request. The DoC is the only document that must be submitted to the customer.

Specific rules on what a DoC must contain are specified in the specific measures for the different material types. Annex IV of the plastics regulation contains a list of 9 points to include in the DoC. For recycled plastics, the specific measure (EU) No 2022/1616 states that a DoC must be issued according to a fixed format found in the regulation. For a material not covered by a specific measure, the DoC can be designed more freely in a suitable way. Several guidelines are available on how to write a DoC, including the Nordic checklist for food contact materials published by the Nordic Council of Ministers[57]

The plastics regulation (EU) No 10/2011 states that a DoC must be available at all marketing stages except for the retail stage for an FCM made of plastic. The same is valid for active and intelligent FCMs and for regenerated cellulose. Although the rules for issuing DoCs are more complex for recycled plastics, they aim to ensure compliance between business operators. DoCs for ceramic products must be available at all marketing stages, including the retail stage.

[57] Nordic checklist food contact materials

When writing a DoC, it is important to keep in mind that its purpose is to help recipients use the FCM in a correct, safe way. Information to include in the DoC should include the following at a minimum:

- Identification of the product or material.
- Identification of the producer or distributor of the FMC.
- DoC date of issue.
- Legal compliance – the regulations and recommendations the DoC complies with.
  - (EC) No 1935/2004 and (EC) No 2023/2006 must always be stated regardless of the material type.
  - Material-specific measures or recommendations. If these are not available, other guidelines can be mentioned.
- Intended use of the FCM – based on how the FCM was evaluated.
  - Food types.
  - Contact time and temperature.
- Restrictions and limitations – if there are any restrictions on the FCM's use, for example only for dry foods or temperatures up to a certain level.
- If intermediate materials are present – information needed by the downstream user to perform their assessment of the final material. The presence of substances with migration limits etc.