IFS Packaging Guideline

VERSION 2

ENGLISH

IFS would like to thank all members of the national working groups, international technical committee, IFS team and experts who have actively participated in the conception and review of this guideline.

We are particularly grateful to Thomas Gude (SQTS Switzerland), whose experience, knowledge and insights have made this guideline possible. Furthermore, we would like to thank the IK Industrievereinigung Kunststoffverpackunen e. V. for their valuable contribution and additional comments.

This guideline is a supporting document related to packaging material topics. It is not a normative document, and its implementation is not mandatory.

Packaging materials are subject to different regulations in different countries and regions, which must be taken into account.

In case of any queries regarding the interpretation of IFS Standards and Programs, please contact standardmanagement@ifs-certification.com

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1 Introduction

1 INTRODUCTION

The IFS Packaging Guideline provides support in the implementation of the requirements of the IFS Food Standard. The guideline primarily addresses suppliers of food products and contributes to better cooperation within the supply chain to deliver safe products. Also, it helps to define responsibilities in different areas.

Food packaging primarily protects the food product to ensure its properties are maintained during production, transport, and storage. It can also contain important information for the customer. At the same time, packaging or packaging materials can also pose a risk to the quality and safety of the products. For example, chemical substances can migrate from the packaging into the food. Food manufacturers must ensure that the packaging is safe for the respective product. In addition, they are confronted with requirements and expectations from customers and consumers who request packaging to be more sustainable.

New technologies and recycled or bio-based materials are increasingly used to achieve sustainability goals for packaging. Here, food suppliers must be aware of the potential food safety risks. When choosing the packaging for their product, they need to consider these aspects in their risk assessment. In the chapter on sustainability and trends of this guideline, you will find information and advice on the possible risks.

Our evaluations have shown that errors related to packaging are mostly due to a lack of understanding and time pressure on staff. Accordingly, adequate staff training is essential. This guideline will also help you with this aspect. It provides the professional knowledge required to ensure safe food packaging in daily working routines.

The requirements in IFS Food Version 7 and this guideline concern the suppliers of packaging materials (after this, referred to as packaging manufacturers) only indirectly. For them, the IFS PACsecure is relevant. Still, we have included conceptual information from the IFS PACsecure standard.

This guideline focuses on European Union (EU) legislation. You may need to consider additional national legislation in some EU member states. The guideline may also contain valuable hints and tips for readers outside the EU. Of course, you must then consider your relevant national legislation.

2 Introductory definitions

2 INTRODUCTORY DEFINITIONS

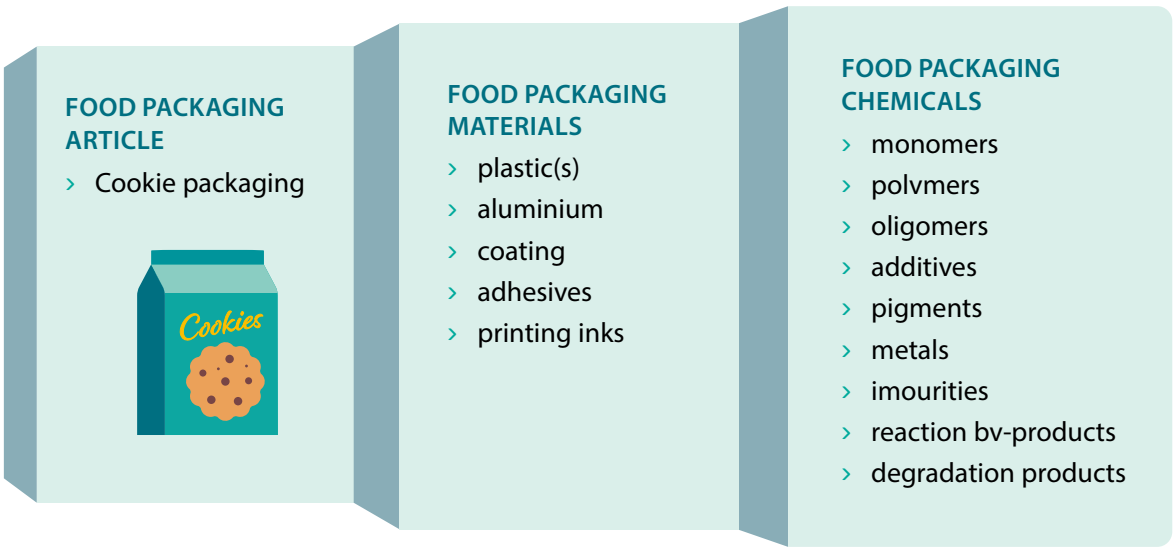
Food contact materials (FCM) cover a wide range of materials and applications, of which packaging is only one element. This guideline focusses only on packaging materials and issues related to it. Nevertheless, the approach and process described in this guideline can be transferred to other materials, applications and articles.

Food contact materials (FCMs) are materials and articles that the food comes into contact with during its production, processing, storage, preparation and serving prior to its eventual consumption. FCM are either intended to be brought into contact with food, are already in contact with food, or can reasonably be brought into contact with food or transfer their constituents to the food under normal or foreseeable use. This includes direct or indirect contact. Examples can include: containers for transporting food, machinery to process food, packaging materials, kitchenware and tableware.

Definition based on EU legislation

A distinction between **food packaging materials** and **food packaging articles** must be made: The packaging supplier might only deliver individual materials (like film or trays) which are combined or converted by the food manufacturer to a food packaging article. For example: a plastic film is the material but the printed film is the packaging article.

The food manufacturer must have assessed the final article and not just the individual layers. He is responsible to ensure that the food packaging article complies with current legislation.



Packaging material is any material used to:

- Contain the product, which depends on the product's physical form and nature
- Protect and prevent the product from mechanical damage due to the hazards of distribution
- Preserve the product, to prevent or inhibit chemical changes, biochemical changes and/or microbiological spoilage
- Inform and communicate about the product (e.g. legal requirements, product ingredients, usage, brand communication, etc.)
- Extend the shelf life or to maintain or improve the condition of the product (e.g. active food contact materials)
- Monitor the condition of the packaged product or the environment surrounding the product (e.g. intelligent food contact materials)
- Handling, delivery and presentation of products

Definition according to IFS PACsecure version 2

3 Supply Chain Communication and Responsibilities

3 SUPPLY CHAIN COMMUNICATION AND RESPONSIBILITIES

In principle, the food manufacturer should handle packaging materials in the same way as any other raw material regarding contracts, specifications and legal contamination limits.

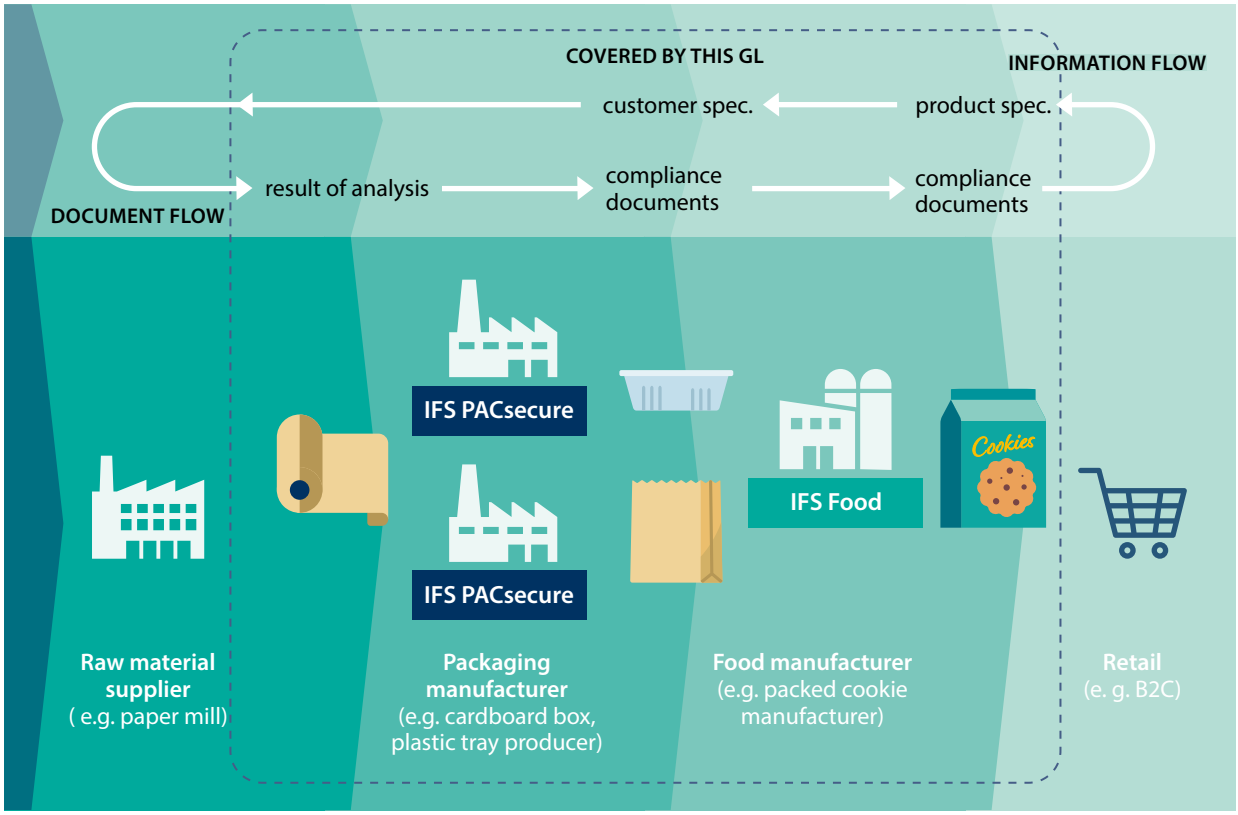
According to EU Regulation 1935/2004 article 3a) b) and c), substances shall not migrate from the packaging into the food in quantities hazardous to consumer health, that change the composition of the food in an unacceptable way, or affect organoleptic properties. This is applicable to all FCMs, including food packaging, regardless of whether the specific material is regulated by a separate EU legislation or not (e.g. metal, glass, paper, cork). The general food law principles (Regulation (EC) No 178/2002) state that the food business operators are responsible to verify that food is safe and compliant. This means that they shall not simply assume the safety of the packaging material but must be able to provide evidence. This requires everyone in the supply chain to be able to demonstrate this safety.

The food manufacturer must check whether the packaging is suitable for the specific type of food, as well as for the process, storage and distribution circumstances such as temperatures and contact times. This also includes the preparation conditions at the consumer. If the food manufacturer uses different materials (e.g. different films plus a label or a carton as outer packaging), they are responsible for checking the interaction between these materials and evaluation of the entire packaging (migration). The food manufacturer must develop, maintain and update the necessary in-house documentation and evaluate/approve the packaging suppliers based on criteria that include food safety and legal compliance. As part of the HACCP plan, possible migration must be considered as a chemical risk and appropriate control measures (e.g. tests and evaluations) must be defined and implemented.

The key is a fair and clear communication within the processing supply chain. Compliance with legal requirements and the safety of the final product can only be ensured if relevant information and documents are exchanged between the supplier and the customer and vice versa.

FIGURE 1

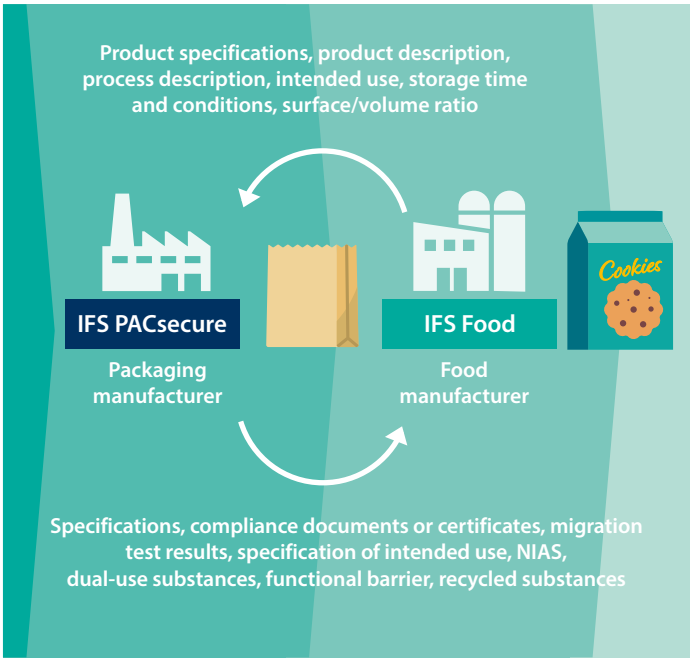
Flow of information from raw material supplier to retailer and vice versa
B2C – Business to Consumer



- **Food manufacturers** share information about product specification, process description, storage time and condition, contact conditions, intended use by consumers, surface/volume ratio and description of whole complete product packaging (see also chapter 6).
- **Packaging manufacturers** communicate the relevant chemical composition, the use of substances which may have a potential to migrate and provide information on any newly introduced substances intended to come into contact with the food as well as non-intentionally added substances (NIAS) generated during the manufacturing process.

FIGURE 2

Two-way communication between packaging manufacturer and food manufactures. Information which should be exchanged



Importance of defining responsibilities in supplier contracts:

A quality contract should be agreed between both parties in addition to the requirement for evidence of compliance (see also chapter 6.3). Within this contract it should be clarified which checks are performed by whom and who is informing the other party about relevant changes e.g. in the recipe or REACH updates among others (see definition below). Possible disclaimers by the packaging supplier stating that the material is compliant but transferring all responsibility to the food manufacturer shall be avoided.

REACH (Regulation (EC) No 1907/2006) aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. This is done by the four processes of REACH, namely the Registration, Evaluation, Authorisation and Restriction of Chemicals.

Source: https://ec.europa.eu/environment/chemicals/reach/reach_en.htm

Quality contracts can include:

- Supporting documentation of the supplier's compliance work (e.g. migration test, effectiveness of functional barrier etc)
- The level of GMP accepted (see also chapter 5.4)
- Responsibility of packaging manufacturer to inform food manufacturer of any changes to/in the packaging material and its related processes
- Frequency of the REACH statement update
- A clear definition of which documents are acceptable (see also chapter 6, Step 8). Please note:
  - just analytical reports do not replace any declaration of compliance (DoC) or similar documents
  - DoCs or similar statement must come from the legal business partner. Such statements cannot be issued by a 3rd party, (e. g. a broker).

Furthermore, effective communication concerning the compliance work, between all involved stakeholders, is key. Not only the communication between manufacturer and client is crucial, but also with contracted laboratories as well as internal communication between departments like purchasing, sales and marketing.

Migration test results (see also chapter 6):

Migration test results are not necessarily original test reports. The packaging manufacturer shall provide conclusive evidence of compliance and indicate the basis of the evidence or test (type of test and conditions). The tools to demonstrate compliance are listed in the Reg. 10/2011: Migration testing, residual content determination, worst case calculations, modelling or any other scientific explanation. However, it should not be accepted to make only a link to individual documents of suppliers without explaining, why the product should be compliant without one of the above cited tools.

FIGURE 3

Example of a bag with cookies: Information which is required for a food manufacturer to ensure the suitability of packaging

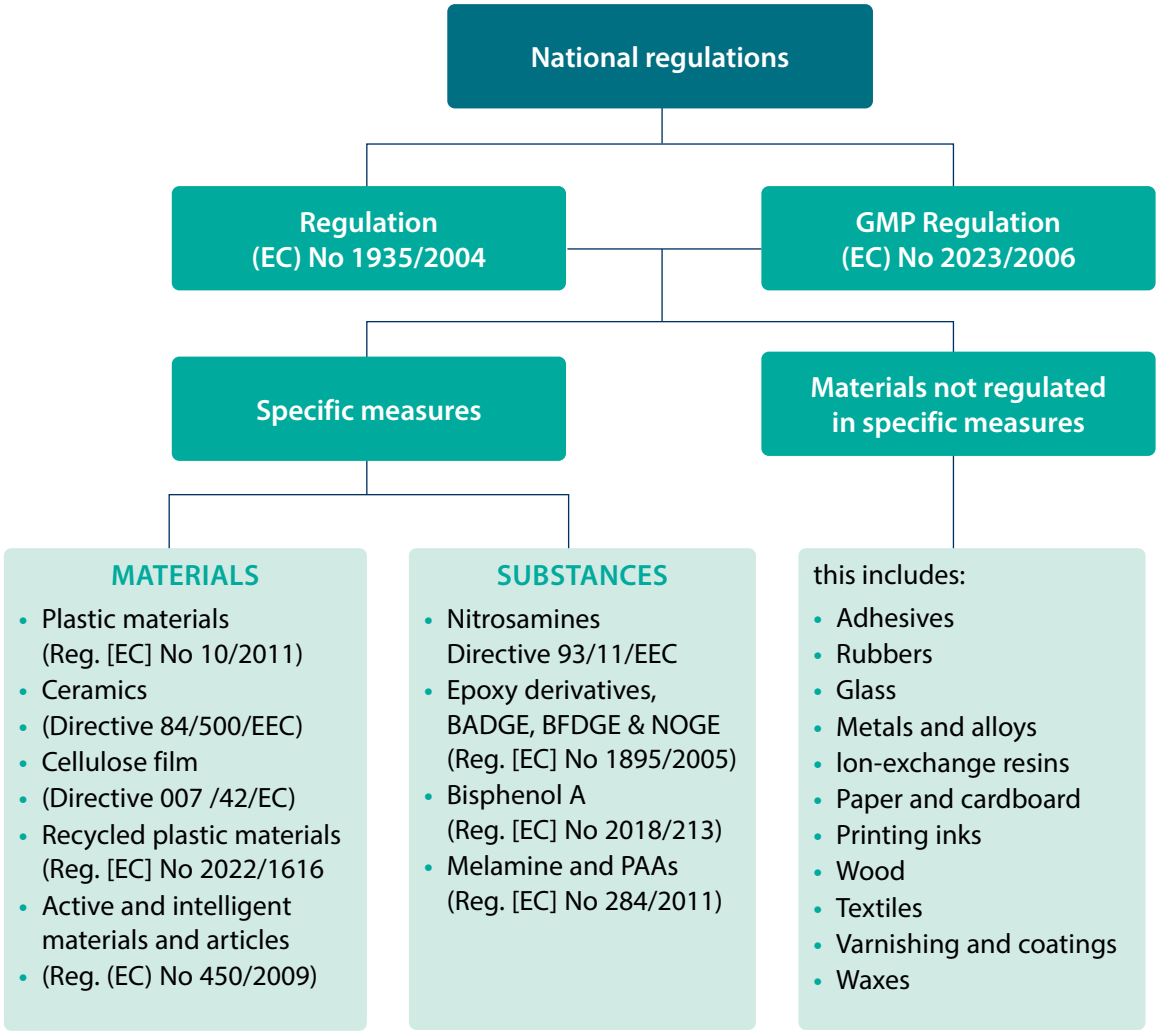
4 EU legislation

4 EU LEGISLATION

The summary of the current packaging legislation can be found in figure 4 below. Please also consider amendments and newly introduced laws. The latest version can be found on the website of the European commission at: *https://eur-lex.europa.eu*. The EU is currently evaluating the FCM legislation in order to harmonise regulations across the European Union.

FIGURE 4

Overview legislation in the EU



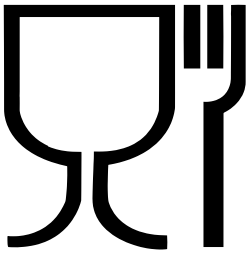
The framework Regulation (EC) No 1935/2004 requires that materials do not release harmful levels of components into foods and do not alter the taste, odour or composition of food to an unacceptable extent. It also requires food manufacturers and packaging suppliers to set up a system that traces FCMs from production to distribution and provides compliance documentation.

The framework regulation provides (amongst others): [1]

- rules on active and intelligent materials which monitor the condition of packaged food or the environment surrounding the food. [2]
- other EU measures for specific not harmonised materials (see figure 4 "materials not regulated in specific measures").
- the procedure to perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority.
- rules on labelling including an indication for use or by reproducing the appropriate symbol (see figure 5).

FIGURE 5

Symbol indicating that the product is suitable "for food contact", as defined in EC Regulation No 1935/2004, Article 15.



This legislation applies to all FCMs and consequently to both food and packaging material manufacturers. **From the standpoint of food manufacturers, they must comply with the legislation and check whether their suppliers do also.**

The framework Regulation No 1935/2004 and (EC) No 2023/2006, which regulates Good Manufacturing practice (GMP) for FCM manufacturers, are the basis for the compliance work. GMP guidelines are a quality assurance tool that assures retailers and consumers that their food packaging is safe (see also chapter GMP 5.4).

1 based on source: https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/legislation_en

2 Further information for active and intelligent materials to (EC) No 450/2009: https://eur-lex.europa.eu/legal-content/DE/LSU/?uri=CELEX:32009R0450

The plastics Regulation (EU) No 10/2011 is the most comprehensive specific EU measure for plastic FCMs and regulates the following: [3]

- Compositional requirements e.g. Union list (positive list) of authorised substances that can be used in the manufacture of plastic FCMs
- Specific Migration Limits (SML) for the substances on the Union list
- Overall Migration Limit (OML)
- Detailed migration testing rules and simulants categorisation
- Declaration of Compliance (DoC)
- Appropriate documentation (supporting documents)

Besides the mandatory framework regulation (EC) No 1935/2004, additional national legislations exist in most EU Member states, regulating various materials and chemicals. Legal compliance to EU and national regulations is mandatory for the country of the production site as well as for the product destination country.

Furthermore, general non-food packaging legislation, such as the REACH legislation, should be applied (see also definition for REACH in chapter 3).

Declarations of compliance (DoC) (see also chapter 8.2)

DoCs are required for plastic and recycled plastic materials under the Reg.(EU) No 10/2011 as well as for ceramics, epoxy derivatives, cellulose film, Bisphenol A coatings and active/intelligent materials. The required content and scope of the DoC can differ significantly for these specific materials and the requirements are defined in the relevant EU regulations (see also the materials/substances regulated under "specific measures" in figure 4).

Non-EU-harmonised materials (in the EU) are materials, for which no specific EU regulated measures exist (see figure 4). There is currently no formal legal requirement for a declaration of compliance on the EU level for these materials. Here the Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food can be used for orientation.

IFS uses the term "certificate of conformity" (CoC) in order to allow worldwide applicability and to include all materials (also the non-EU-harmonised ones).

3 Further information on EU No 10/2011 (guidance document): https://food.ec.europa.eu/system/files/2016-10/cs_fcm_plastic-guidance_201110_reg_en.pdf

5 IFS Implementation

5 IFS IMPLEMENTATION

IFS Food standard has set up requirements to ensure that a food manufacturer is able to produce products that are safe, legal and in compliance with customer specifications. Food packaging materials are addressed in several chapters, but the core requirements are found in chapter 4.5 Product packaging and requirements, 4.18.1 and 4.2.1.3. They are presented in the following section.

Requirement 4.5.1

Based on hazard analysis, assessment of associated risks and intended use, the company shall define the key parameters for the packaging materials in detailed specifications complying with the current relevant legislation and other relevant hazards or risks. The company shall check and verify the suitability and existence of functional barrier(s) of the consumer unit packaging material for each relevant product test / analysis, such as:

- organoleptic tests
- storage tests
- chemical analyses
- migration test results. (see also chapter 3: Migration test results)

Interpretation:

For all packaging materials used, the company must determine the key parameters and define specifications for them through a hazard analysis/risk assessment.

Legal limits and relevant hazards/risks with an impact on the suitability of the packaging material, according to the intended use must be considered in the hazard analysis/risk assessment.

The suitability of all packaging materials (including glue and ink when applicable) and the existence of functional barriers must either be proven by adequate compliance information (e.g. CoC) or the food manufacturer must determine the relevant test/analysis to demonstrate this. The test/analysis used must be one of those listed in the requirement.

Example questions:

- Does a risk assessment exist for packaging and the suitability of the materials?
- Are specifications available for all packaging materials in use?
- How is it ensured that packaging material complies with current relevant legislation?
- Does it include material without direct contact to food, ensuring no direct negative influence on the product?
- Is the interaction between different materials checked? How?
- Who develops, reviews new packaging material?
- Which test(s) is/are necessary to confirm the suitability?

Requirement 4.5.2

For all packaging materials which could have an impact on products, certificates of conformity shall exist which attest compliance with legal requirements. In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that packaging materials are suitable for use. This applies for packaging materials which could have an influence on raw materials, semi-finished and finished products.

Interpretation:

The suitability of packaging materials must be proven by the CoC. The Declaration of Compliance, if applicable as required by EU legislation, can be used instead of a CoC and in the case the packaging material is not modified by the food manufacturer. In case of packaging modification, the food manufacturer must determine and initiate the relevant test/analysis to demonstrate suitability.

Example questions:

- Are all certificates of conformity available?
- Are they up to date and matching with the product characteristics (including the intended and foreseeable use)?
- Are CoCs available for intermediate packaging?
- How can suitability be demonstrated if no CoC exists?
- Is the packaging modified on site?

Requirement 4.5.3

The company shall ensure that the used packaging and labelling correspond to the product being packaged and comply with agreed customer product specifications. This shall be regularly checked and documented.

Interpretation:

Packaging and labelling must correspond to the product and comply with specifications. Records have to be available and checked regularly.

Example questions:

- Which process is in place to ensure conformity?
- How is it ensured that the right packaging is used for the right product?
- How is it ensured that the packaging complies with customer specification?

Requirement 4.18.1 KO N° 7

A traceability system shall be in place that enables the identification of product lots and their relation to batches of raw materials and primary packaging materials. The traceability system shall incorporate all relevant records of:

- receipt
- processing
- use of rework
- distribution.

Traceability shall be ensured and documented until delivery to the customer.

Interpretation:

Each batch of the finished product must be fully identifiable and linked to the batch of primary packaging materials that has been used until delivery to the customer in accordance with the traceability procedure and the supplier list. To achieve this, the food manufacturer must use appropriate labelling and identify the packaging material as well as maintain clear production records (according to the list in the requirement).

Example questions:

- How is traceability ensured?
- Which products come from which supplier?
- Is there a list available with all current suppliers?
- Can the CoC be clearly assigned to the materials and articles?

Requirement 4.2.1.3 KO N° 4

Specifications shall be available and in place for all raw materials (ingredients, additives, packaging materials, rework). Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if existing, with customer requirements.

Interpretation:

All packaging materials must be accompanied by their specifications. The specifications have to be up to date (latest version), comply with the legal requirements and meet customer requirements. It must be possible to link the specifications to the relevant packaging material. Each type and variety has to have its own specification, no matter if it is similar to other packaging material. Under certain circumstances articles/materials can be grouped ("family" approach).

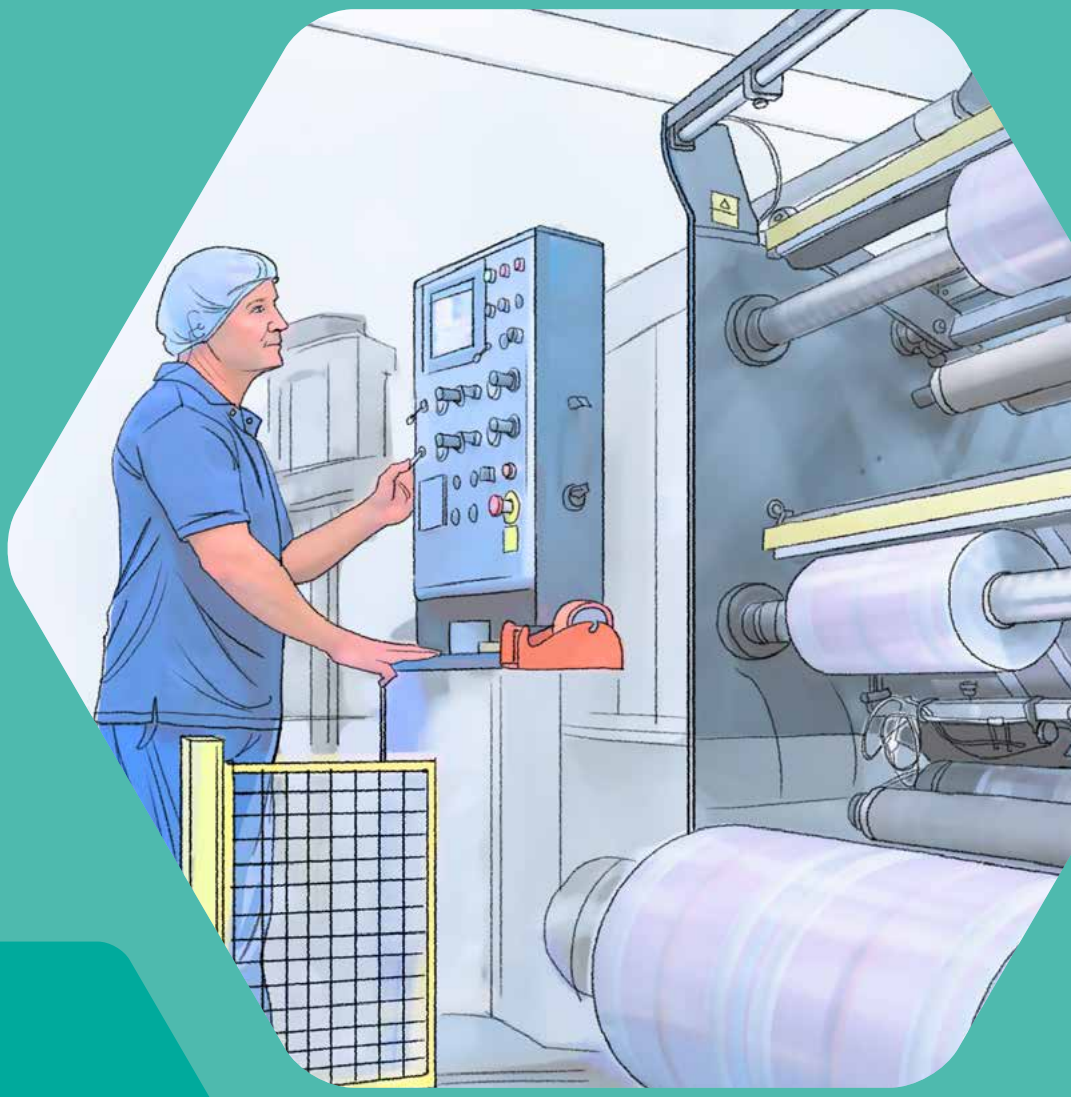
Example questions:

- Are specifications available for all packaging materials and rework?
- Which evidence is given that specifications are followed?
- Which evidence is given that specifications are in compliance with legal requirements?
- Who writes, checks and approves specifications?

Most common issues detected by auditors in relation to conformity work:

- documents from supplier or lab are not being read or understood
- conformity work is therefore not delegated or completed
- product is not being evaluated in an overall context
- no test on the final product
- strategy for analysis is non-existent
- the validity period of the certificate has expired
- legal requirements/references in CoC are not up to date
- missing and incomplete information in the CoC
- certificate cannot be allocated to the product or sample
- test conditions of Specific Migration Limits (SML)and Overall Migration Limit (OML) do not match
- certificate is not passed on in the chain
- certificate has the date of the audit/request
- contradictory information (e.g. conditions of use don't match test conditions)

6 Compliance work



6 COMPLIANCE WORK

6.1 What are the food manufacturer's tasks?

The main task of the food manufacturer regarding compliance work is to carry out all relevant processes and tests and to compile documents which provide evidence that the packaging materials in contact with food do not adversely affect or modify it. It must be ensured that the consumers health is not negatively affected, the composition not changed in an unacceptable way and that the organoleptic characteristics do not deteriorate.

The tasks can be structured in nine consecutive steps, which are explained in the following subchapters. All steps must be carried out according to the current applicable legislation and should be recorded, which results in two summary documents: firstly, certificate of conformity (CoC) and secondly, the in-house documentation of all confidential documents.

STEP 1 **Define food specifications**

The food product specifications are required to understand the food and all the intrinsic parameters that can influence the suitability of the packaging for the specific food product. The intended and the foreseeable uses must also be taken into account.

Essential and relevant aspects must be defined and communicated by the food manufacturer to the packaging material supplier. However, the specific product characteristics should be added for any product checked. The following example checklist may be used as a basis for a product specification checklist.

Food name/food category/food characteristic

- Aqueous foodstuff
- Alkaline or acidic foodstuff (pH)
- Alcoholic foodstuff
- Fatty foodstuff (fat content %)
- Dry foodstuff
- Shape/surface

Food processing

- Heat treatment
- other processing

Packaging process

- Thermo forming
- Thrinking
- Other procedures

Preservation process

- Deep-freezing
- Heat treatment
- Spraying with alcohol
- Filling temperature
- Modified atmosphere
- Air tightness
- Other procedures

Storage conditions of the finished product

- Ambient temperature
- Cool storage
- Deep-freeze storage
- Other storage conditions

Preparation of the finished product

- Microwave
- Oven
- “Bain-marie”/steamer
- Other method of preparation

Consumer target group

- Baby/Children
- Adult
- Other vulnerable group

Destination country

- Legal requirements
- Climate condition

Surface/Volume ratio

Other packaging parts

- Closures
- Trays
- Labels
- Straws, spoons

STEP 2 Identify the packaging materials and relevant legal framework

The results of the food product specification checklist should be used to identify suitable packaging materials in collaboration with the packaging material supplier. The time and resources required for this step depend on the degree of food-packaging interaction identified with the specification checklist.

The selection of potentially appropriate packaging materials can include single or multiple materials (e. g. plastic tray, printed film, paper label), possibly from different suppliers. For the relevant legal framework see also chapter 4, EU legislation.

When the food packaging article and materials are defined, the packaging specifications are required to define the properties of these individual packaging materials.

STEP 3 Inspect the specifications/certificates of conformity (declarations of compliance)

The **packaging manufacturer** must produce a safe packaging material based on the food specifications received.

Food packaging specifications should have a clear structure and include information on the material, its composition, list of materials and substances, technical details, tests conducted, analysis performed, and legal requirements.

After receiving the specifications for food packaging, the following points below should be checked. These points apply to all types of materials, but are in most cases already covered for plastics by Regulation (EC) No 10/2011:

- type of food it is intended for contact with
- time and temperature of treatment and storage in contact with the food
- the highest food contact surface area to volume ratio for which compliance has been verified e.g for plastics according to Article 17 and 18 of Regulation (EU) No. 10/2011 or equivalent information;

Especially the surface to volume-ratio needs to be very well defined as a downgrading based on documents is always possible, but not an upgrading. This is important for all kind of materials.

"The setting of migration limits takes into account a conventional assumption that 1kg of food is consumed daily by a person of 60 kg bodyweight and that the food is packaged in a cubic container of 6 dm^2 surface area releasing the substance. For very small and very large containers the real surface area to volume of packaged food is varying a lot from the conventional assumption. Therefore, their surface area should be normalised before comparing testing results with migration limits."

Excerpt article 17 and 18 of Regulation (EU) No. 10/2011

Some of the information is provided as "supporting documents", which shall include all the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance. These shall be made available to the competent authorities at their request. The passing on of "supporting documents" should always be regulated in bilateral agreements.

STEP 4 Hazard analysis and risk assessment (see also 6.2)

The food manufacturer first needs to identify and analyse the hazards (for example chemical, microbiological and allergen contamination, foreign body and fraud risk) and secondly assess the risk for the consumer (likelihood of occurrence and in case of occurrence, the severance of negative health effects).

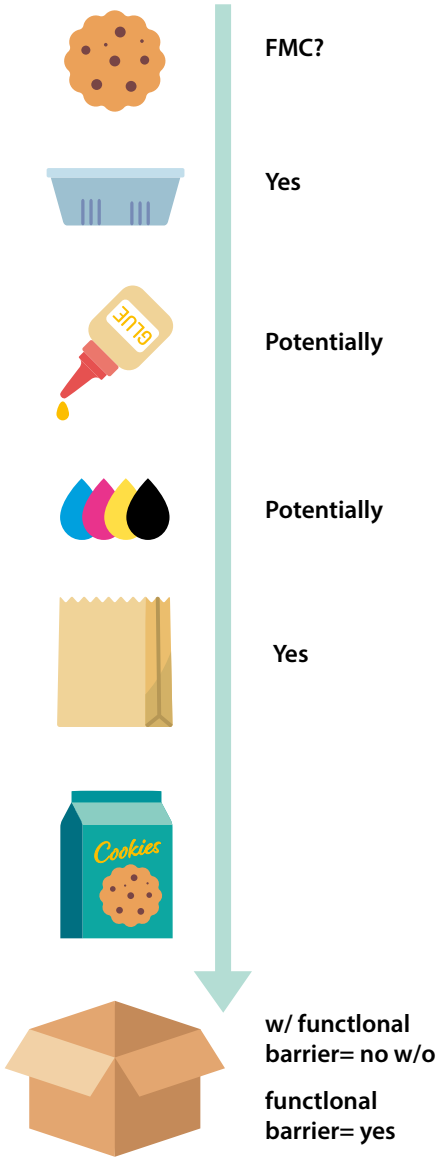
The interaction of the packaging materials shall be taken into account, e.g. between film and printing inks, functional barrier properties, migration through the gas phase, closures, staples or additionally applied labels as well as abrasion during transport (interaction of product and packaging).The use of recycled materials and possible contamination in their production process must be considered in the risk assessment. To prevent the interaction of some materials (such as recycled paper) with the food, a functional barrier can be used and their effectiveness shall be proven (see figure 6).

Some packaging which initially does not have direct contact with the food, might have contact during later handling by the consumer. For example, margarine packaging equipped with a sealing film. When the film is removed, the lid may come in direct contact with the margarine. Foreseeable use cases shall be considered and need to be assessed in the hazard analysis (regulatory requirement of Regulation (EC) No 1935/2004).

Substances that might migrate to the specific type of food need to be recognised in this step. The HACCP review needs to be done annually and in case of changes or new information and technologies.

FIGURE 6

Example: Cookie packaging to showcase the complexity for decision making if an material or article is a food contact material (FCM) or not



STEP 5

Food manufacturer checks whether the packaging supplier is capable of providing all the relevant and necessary information

The food manufacturer may have identified during the HACCP and risk assessment that additional information from the packaging supplier is needed to complete the compliance work. The manufacturer of the packaging material shall share all relevant information required by the buyer for their compliance work and demonstrate the safety of the known substance capable of migration. A distinction is made between IAS (intentionally added substances) from the formulation and NIAS (non-intentionally added substances) that may occur due to production factors in the form of degradation products, fission products, impurities etc. For IAS a list of used substances should be provided and it should be highlighted in the quality contract to what extent information can be provided. NIAS are subject to own investigations of the party who introduces these substances into the product. Non-intentional contaminations like NIAS introduced either from raw materials, recycling or due to process reasons should be limited as far as possible by suitable GMP measures. When using packaging materials, the requirements of the European evaluation of chemicals (REACH) are to be considered as well. If these substances (NIAS) are known and they occur systematically, a risk assessment is required (see step 4).

Delegation:

Every packaging manufacturer introducing a substance is responsible for its impact (possible contamination, migration) and reaction products occurring during processing, as long as it is in their control. Afterwards the food manufacturer is responsible. Especially at early manufacturing stages it is often impossible to confirm the compliance for the finished product since the migration might not be foreseeable. The one introducing a substance is obliged to delegate legal responsibility, e. g. to pass on the unfinished work to the next user. It is not possible to reject responsibility in general without listing specific delegated tasks. This way the food manufacturer knows what kind of compliance work they burden themselves with when dealing with a product and may opt for alternatives, if appropriate.

Delegation means that the tasks to ensure the status of a substance/product regarding food legislation are transferred to a downstream level. This might be the case if substances are used:

- where a toxicological assessment was not yet carried out, or
- which might migrate in unacceptable quantities and shall be controlled by the next step

Additional compliance work, e.g. identification and toxicological assessments of certain contaminations and potential reactive products or sensory test may also be delegated. For tasks that are not delegated (either in the declaration of compliance or another written statement) the signatory automatically assumes responsibility.

STEP 6

Food manufacturer checks whether the requirements, limits, and analyses stated comply with the data given by the packaging suppliers/manufacturers

For the food manufacturer to confirm that the food packaging does not transfer any harmful substances to the food, relevant migration tests should be performed. This procedure can also be carried out using modelling or calculations. For the latter, the worst-case scenario should always be used. Migration tests from packaging suppliers or their CoC can be used instead, as long as they were performed under the same conditions. Finally, if the results of the compliance work show that migration does not occur in the specific packaging, a CoC can be issued by the packaging supplier.

The final step in demonstrating the adequacy of the packaging is a shelf-life test. According to IFS Requirement 4.3.3, the food manufacturer is responsible to check and ensure the suitability of the product's shelf-life. The shelf-life test may include organoleptic, microbiological and other tests.

Information about SVHC (substances of very high concern) are updated regularly and it seems unpractical to include this data in the CoCs, as they need to be amended with each change. Instead, both parties should define "who is informing who" in the quality contract, if any relevant new substances are detected.

STEP 7

Ensure traceability

IFS defines a KO requirement for the implementation of a traceability system including primary packaging materials. One of the main purposes of traceability is to enable recalls and withdrawals of non-conforming products at all stages of production, processing and distribution. As a result, relevant documentation is required in all parts of the food packaging chain.

A traceability system shall be in place for all food contact packaging materials which may have an impact on food.

The food manufacturer must use appropriate labelling or identification of all packaging material, so batch numbers of the raw material used can be linked to the finished product. Traceability must be ensured and documented until the product is delivered to the customer and the CoC must be clearly attributable to the FCM.

STEP 8 Conduct regular packaging supplier evaluation

The IFS Food Standard requests a general supplier evaluation which also includes the packaging suppliers and intermediate brookers, if present in the value chain.

There are numerous criteria for evaluation, including food safety, product quality, logistical, commercial and/or environmental criteria, among others. Food safety should be prioritised in the criteria hierarchy because it is critical and a legal requirement.

Collaboration between Purchasing Department & Quality Assurance Department is required to obtain an efficient supplier evaluation.

Some example questions specifically oriented towards supplier evaluation are given below:

- Does the packaging supplier have an implemented HACCP system?
- Is the packaging supplier IFS PACsecure certified or certified to another recognised standard?
- Does the packaging supplier provide a CoC for the packaging materials?
- Does the packaging supplier provide specifications for the packaging materials?
- Does the packaging supplier provide documented evidence (appropriate testing) that the packaging materials are suitable for the intended use?
- Does the packaging supplier manage allergens?
- Does the packaging supplier comply with GMP?
- Does the packaging supplier have a traceability system in place?
- Does the packaging supplier comply with the EU legislation for FCM and the additional national legislation if is applicable?

The supplier should be able to provide a CoC under his own name and not just forward documents from their supplier; analytical reports from laboratories are also not valid replacements for a CoC. The supplier is obliged to provide the quality statement with their own business letter head. From a legal point of view only signed documents from the direct business partner should be accepted.

By working for example with IFS PACsecure certified suppliers, the certificate shows that the packaging manufacturer has implemented functioning product safety and quality processes. As a result, the food manufacturer can adjust their own suppliers' performance measures (supplier approval and monitoring procedures).

Under the umbrella of IFS, IFS PACsecure covers requirements on product safety, quality and compliance for packaging material. All of the above-mentioned points that need to be ensured by the packaging manufacturer, e.g. GMP, specifications and traceability of products, are regularly checked during the 3rd party certification assessments performed by a professional certification body.

The IFS PACsecure Standard is used to assess whether the processes of a packaging manufacturer are able to produce products that are safe, legal and in compliance with customer specifications. That is why both product safety and quality are essential components of all IFS Standards.

It is built upon general aspects of a product safety and quality management system. However, the main emphasis is to instil confidence in the products and processes, meaning that safety, quality, legality and compliance with specified customer requirements are ensured via an on-site evaluation and documentation review and inspection.

IFS PACsecure is a product and process certification. Requirements from the areas management systems, resources, planning and production process, measurements/analyses/improvements and food defence are checked, among others.

The focus here is on fulfilling customer requirements in addition to safety. IFS PACsecure provides the company with the opportunity to develop individual solutions for implementing the Standard requirements based on a risk analysis, just like all other IFS Standards. IFS PACsecure helps the company to comply with the regulation and meet customer expectations regarding product safety and quality. It reduces operating costs and increases efficiency by improving your processes and reducing waste and costs related to recalls, complaints, or rejected products and rework, while improving production and giving a competitive advantage.

STEP 9 **Perform self-control analysis based on own HACCP system**

See also point 6.2 Further explanation on hazard analysis and risk assessment and 6.3 Certificate of conformity regarding plausibility checks. Nevertheless, it should be addressed as an independent step in this approach.

Based on the information provided by the packaging supplier, "critical substances" should be verified in real food samples, especially in those cases, where the supplier is not able to provide all requested relevant information e.g. own migration tests show deviations or non-compliances. Especially for high-risk products described in the risk assessment, specific migration testing of the food (or other testing – *see 6.3 plausibility check*) is sometimes the only way to verify the compliance of the packaging article within the framework of the monitoring program.

6.2 Further explanations on hazard analysis and risk assessment

Example questions that can be asked as part of the hazard analysis and risk assessment:

- What hazards exist at which process step?
- Are all potential conditions and interactions registered?
- How high is the risk potential (risk assessment)?
- Which control measures are carried out?
- Is there a CCP at the hazard point?
- Are materials considered to act as a functional barrier?
- Which materials are excluded due to (a) functional barrier(s)?

Resulting measure:

- Review of the declarations of compliance and/or certificates
- Review of packaging material specification
- Chemical or physical analyses
- Modelling/ calculating maximum migration based on worst-case-scenarios (e.g. of complete migration)
- Organoleptic tests, e.g. Robinson test (very easy and at a low price to implement)
- Introduction of control measures (e.g. leak test) and control devices in the process
- Optimising/modifying storage conditions for packaging materials
- Replacing packaging materials or packaging aids (e.g. adhesives, varnish)

FIGURE 7

Risk matrix for migration of substances from food packaging materials to food and vice versa

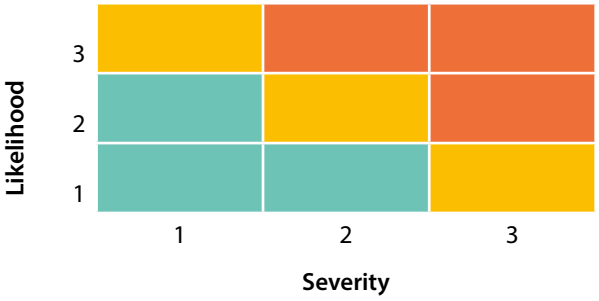


FIGURE 8

Example: Risk matrix of cookies and chocolate coated cookies (shelf life 2 years). The cookies are classified as dry food, while the chocolate cookies are classified as fatty food.

Important note: This is only an example; each user should create a risk matrix for themselves based on the packaging material and the type of food they are processing.

	Type of food	
Materials and processing steps	Cookies	Cookies covered with chocolate
PET tray		
Multi-layer films with functional barrier UV labels		
Paper in recycled cardboard		
Migration related processing steps.		
Risk of whole packaging		

The risk matrix shown in figure 8 can be used in order to evaluate packaging materials. The likelihood and severity determination shall be based on scientific and technical data (figure 7).

The risk shall be evaluated for the whole packaging including all packaging materials and the migration related processing steps. A possible approach is shown in figure 8.

Following the risk assessment, control measures must be defined according to the risk level. Organoleptic, storage, chemical, or migration tests, as well as other tests can be used as control measures. Results of migration tests which are provided by the suppliers and cover the intended use of the packaging material may be accepted. **Verifications on the food shall be carried out in defined cases, according to the risk matrix.**

According to article 18/6 of Reg. (EU) 10/2011: *"The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches"*

This means checks of potentially "critical" substances identified, especially those named by suppliers as potentially problematic, should be checked in real food applications as part of the HACCP system of the food manufacturer.

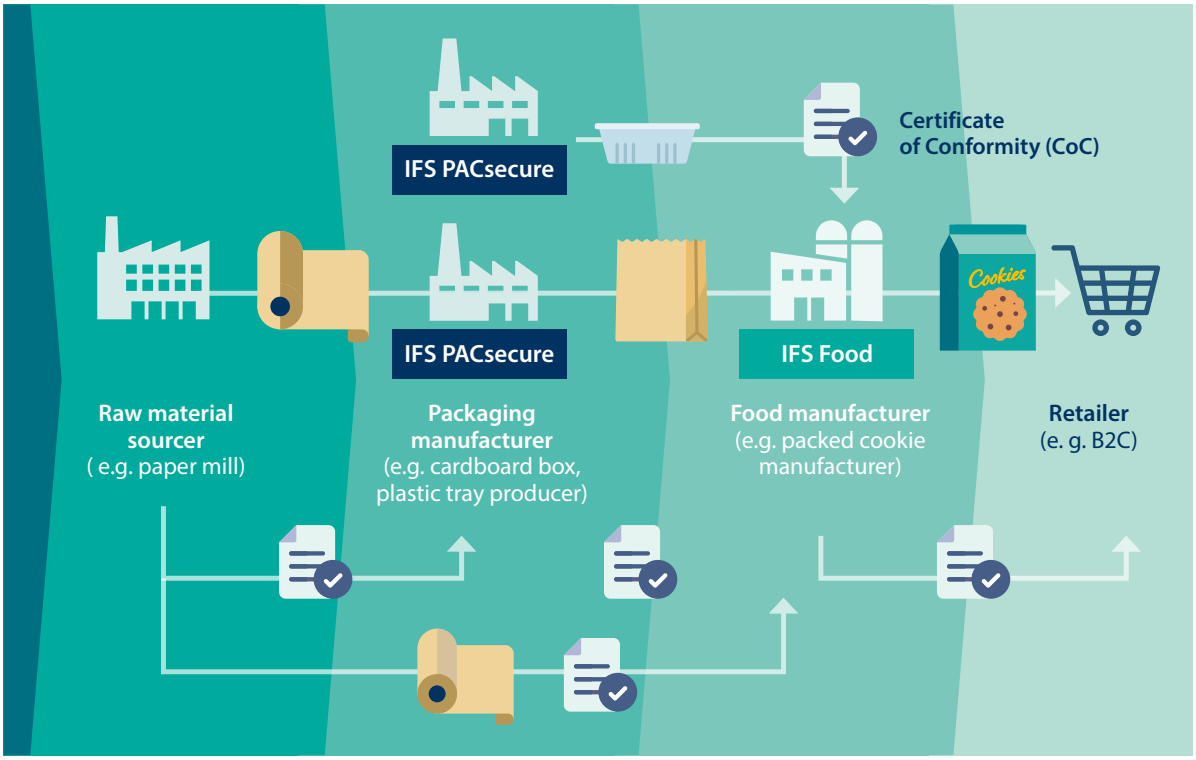
6.3 Certificate of conformity (Declaration of Compliance)

All packaging articles which come or are intended to come in contact with the food product should have an appropriate confirmation or certificate of compliance which indicates that the packaging complies with the existing regulations and is suitable for the intended use (see also chapter 4, declaration of compliance). In case of non-specific regulation, the CoC shall provide evidence of suitability of the packaging material for the intended use and accompany the packaging at each step. The *CM/Res(2020)9 on the safety and quality of materials and articles for contact with food* can be used for orientation for such materials.

The food manufacturer is entitled to receive a DoC or CoC from the packaging supplier.

FIGURE 9

An example who issues the CoC in each processing step



Packaging suppliers often provide a DoC/CoC just for single materials but food manufactures must ensure the safety of the whole packaging article and as a consequence confirm compliance for the entire product. The food manufactures need to carefully check the documentation from the packaging supplier to determine whether it covers all aspects of the product that it will be used for.

To demonstrate, if a CoC fits the needs, the attached checklist Annex 2 may help to identify potential gaps.

In case of missing information due to further processing of the packaging, additional compliance work is needed to meet the legal requirements. This also applies if the food manufacturer transforms the material himself (e.g. thermoforming). In case of food packaging being imported from non-EU countries, the importer is legally equal to the manufacturer and thus the one who first places the materials on the EU market and therefore is also responsible for the CoC.

A general statement that "statutory requirements are met," is not sufficient. Meaningful certificates of conformity or other conclusive evidence should show the basis for the compliance work. Here it is important that specific references to the laws are mentioned.

The CoC has to be renewed in the following cases at minimum:

- changes occur in the composition or
- changes occur in the production or
- new legislation or changes in legislation (e.g. changes in limits) become available or
- new or updated scientific data becomes available.

Packaging manufacturers shall inform the food manufacturer of any changes, so it can be re-evaluated in the risk assessment, if required. This information policy can be defined in contractual agreements (see also chapter 3 supply chain communication).

Plausibility checks

In some cases, a packaging supplier cannot demonstrate that relevant tests have been performed and the food manufacturer is not able to obtain reliable documentation. The food manufacturer has to define how to demonstrate suitability and is left two options:

- Not using the materials with missing documentation
- Performing own test (plausibility check)

The term plausibility check is not mentioned in the EU food contact material legislation, however article 18/6 of Reg 10/2011 clearly gives the following advice:

> "The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches.".

Performing own tests could mean a full extraction on final products/ final food packaging article to identify substances of concern. The identified/unidentified substances can then be cross-checked via migration studies or analysed in the real food stored up until the end of shelf life.

As end of shelf life testing is not feasible in certain cases, e.g. in ambient stable products, accelerated testing may be an option (e.g. 10 days 60° C for long term storage applications). If the food of interest cannot be tested under accelerated conditions (e.g. chocolate), other so-called model food can be used (infant food milk powder or similar).

The type of plausibility check can be both individually defined and also used for high-risk products described in the risk assessment. These checks are a way to fill gaps when adequate information is missing, or a higher level of safety is required. Data from real food outweighs any simulation test and since it's quite common to test for pesticides and other contaminants, it might be useful to include such tests for FCMs in the HACCP plan.

6.4 Good Manufacturing Practice (GMP)

The GMP Regulation (EC) No 2023/2006 applies to all FCM, including intermediate materials (printing inks, surface coatings, etc.) and in all stages of manufacture, processing and distribution of packaging materials.

GMP needs to be implemented by both the food and packaging manufacturer: The **food manufacturer** needs to implement and follow GMPs when handling and storing food packaging materials e.g. to protect food packaging from dust and other potential pollutants while being stored.

The **packaging manufacturer** must develop and implement appropriate, effective, and documented safety and quality assurance and control systems. **To ensure that the production of food packaging is suitable for food contact, the critical steps in the manufacturing process should be controlled, and corrective actions implemented in the event of non-conformances and failures. All of these aspects shall be monitored and documented** (*see also 6.1 Step 2*).

All measures taken, specifications, results, staff training, flow charts, critical control points, etc. shall be documented. The packaging material supplier should assure their customers that GMP is followed and declare this on the food packaging material specifications.

Documentation following the GMP Regulation (EC) No 2023/2006 must be made available for authorities (on request) for:

- Specifications
- Manufacturing formulations and processes
- Details of the individual production stages
- Information and results of quality controls
- Information from the previous stages
- Possible worst-case calculations and mathematical modelling
- Risk assessment for non-regulated substances

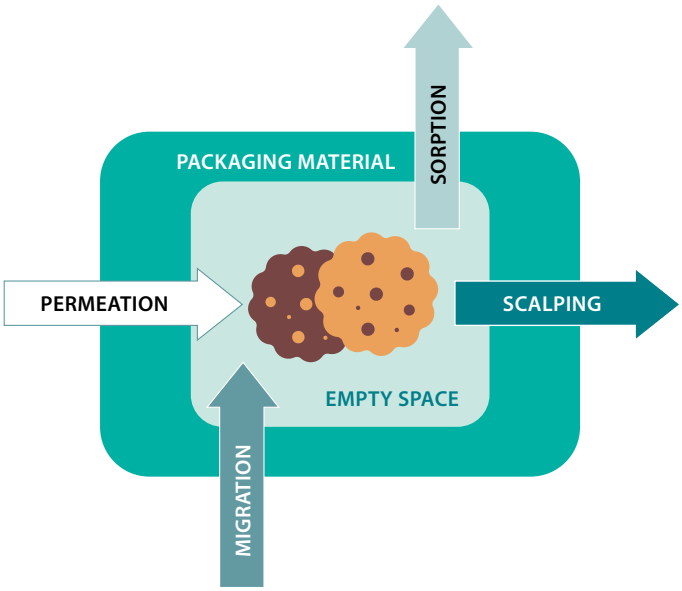
It is highly recommended that the food manufacturer and packaging material supplier specify the level of GMP accepted in a quality contract, as the GMP regulation is fairly unspecific. The clear expectations on GMP should be signed by both parties in a quality contract.

6.5 What to consider with reference to migration?

The interaction of food packaging with the food can be described using the following figure 10.

FIGURE 10

Interaction between food packaging and food



Permeation is the exchange of substances from the outside to the inside of a package. This is for example, when solvents of printing ink, gas or moisture enter from outside the packaging and into the food, compromising the protective function of the packaging. This phenomenon can harm food quality and shelflife in packaged foods, as well as transfer harmful substances.

Sorption is the exchange of food components such as flavours, lipids, and moisture into the packaging material. This can cause changes in flavour and odour of the food. Furthermore, food components that migrate into plastic (e.g. fat) can increase the mobility of plastic components, accelerating the migration from the food packaging to food.

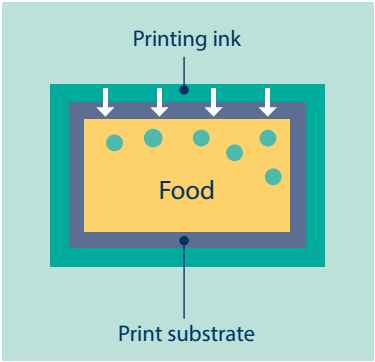
Scalping is the escape of food components outside of the packaging, resulting in loss of aroma and a decrease in the organoleptic quality of the food.

Migration occurs when chemicals and/or components pass from the packaging and into the food. Since these particles can be hazardous to human health, migration is regulated in most countries for this reason.

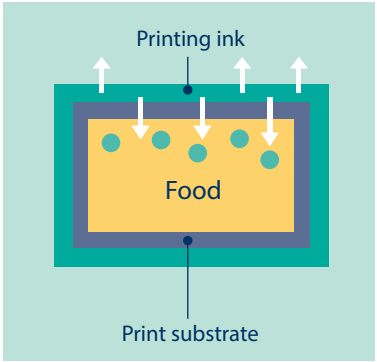
FIGURE 11

Migration below describes the ways that migration may take place

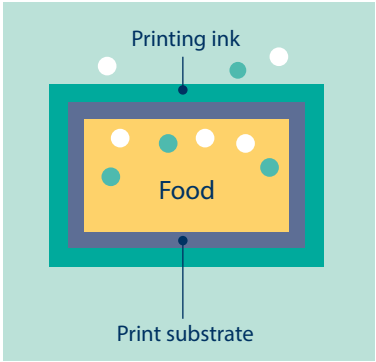
SET-OFF MIGRATION
Set-off (contact): migration from the printed surface to the blank reverse side of the printing substrate in stacks or in the reel (and from there into the foodstuff). Set-off can also occur with lacquers, other plastics etc.



PENETRATION MIGRATION
Transfer of a substance from the packaging into the food, and vice-versa



GAS PHASE MIGRATION
Migration through evaporation of volatile substances during heating (e.g. cooking, baking or cooking frozen products in the original packaging)



DISTILLATION MIGRATION
Migration through steam distillation during cooking, baking or sterilisation process

Although food contact is needed in order for the substances to migrate from the packaging material to the food, food contact does not necessarily mean physical contact. Migration may also take place by means of evaporation (in the packaging) and re-condensation (in the food).

The extent and rate of migration is influenced by a variety of factors. The most important factors are:

- the nature of the food (fat, acids etc.)
- the type of contact (direct, indirect, barrier properties)
- the time of contact
- the temperature during contact
- the nature of the packaging material
- the characteristics of the migrant
- The amount of the migrant in the packaging material

In multilayer food packaging, a substance can originate from several layers and compliance for the final article should be ensured by accounting for contributions from all layers.

A distinction is made between overall migration and specific migration or extraction. The quantity of migrated substances can be identified by testing with food simulants or real food (only specific migration) under precisely defined testing conditions such as time, temperature and room humidity.

Overall migration test

An overall migration test determines the sum of all migratable substances released from the packaging (per unit area of packaging). The overall migration limit (OML) is non-specific (no separation into different substances) and only shows the overall quantity of all migrated substances. It is a measure of the inertness of a material and does not allow any conclusions to be drawn on the health-related evaluation of individual substances.

Overall migration testing is currently only required for plastic materials covered by Regulation (EU) No. 10/2011and sometimes in national regulations for other materials like paper (i.e. French and Dutch Regulations). Nevertheless, a total migration value for non-plastic layers could also indicate inertness as a first sign. The test conditions for non-plastic materials need to be carefully discussed as not all materials can be treated like a plastic, e.g. cardboard exposed to vegetable oil at 40 °C for 10 days would not work. Testing the overall migration is only feasible in food simulants and not in real foods.

Specific migration test

A specific migration test searches for specific substances and shows how much of an individual substance has migrated. For specific migrants, a distinction must be made between known targets and partly unknown non-targets (such as NIAS). Test procedures are usually based on chromatographic, e.g. mass spectrographic principles (e.g. GC/MS [separation using gas chromatography], LC/MS [separation using liquid chromatography]). Standards and accredited methods do not exist for all migratable substances. Accredited laboratories usually also have a quality control for the determination of substances with non-accredited methods, so these laboratories are preferable.[4]

The regulation (EU) No 10/2011 recognises **modelling** as an alternative method for calculating migrated substances. The initial concentration and packaging structure must be known for this calculation. The parameters should be estimated considering the worst-case scenario. Several software programmes are available and the European Commission has published a practical guide on the application of migration modelling *(JRC Practical guidelines on the application of migration modelling for the estimation of specific migration)*.

4 See also: Guidance in selecting analytical techniques for identification and quantification of non-intentionally added substances (NIAS) in food contact materials (FCMS), Food Additives & Contaminants: Part A, 39:3, 620-643, DOI: 10.1080/19440049.2021.2012599 by Cristina Nerín, Siméon Bourdoux, Birgit Faust, Thomas Gude, Céline Lesueur, Thomas Simat, Angela Stoermer, Els Van Hoek & Peter Oldring (2022)

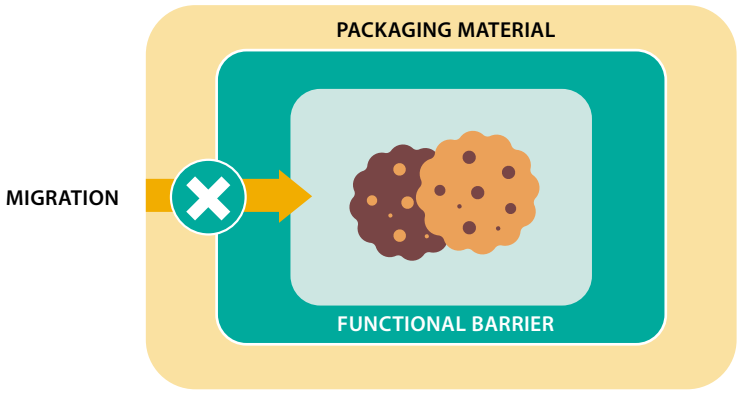
If there is no processing step relevant to migration, the food manufacturer can make worst-case calculations to determine migration. If a migration-related processing step exists (which can include changing the shape of the starting material such as deep drawing foils or forming PET bottles, printing or gluing on packaging or assembling several parts such as a plastic tray with sealing film) modelling or migration testing on simulants or on food is required to ensure the safety of packaging.

Functional barrier

According to EU Regulation 10/2011 'functional barrier' means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation No 1935/2004 and with the provisions of this regulation. In other words, a functional barrier is a layer (or multiple layers) that prevents migration into the food from behind (outside) the barrier.

FIGURE 12

Interaction between food packaging and food



Behind a functional barrier, non-authorised substances may be used, provided they fulfil the criteria below:

- confirmation that the non-authorised additives and monomers are not classified as CMR substances (= Carcinogenic, mutagenic and reprotoxic chemicals) according to the Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP).
- confirmation that the non-authorised additives and monomers do not have a nanostructure according to the EU Commission Recommendation for nanomaterials.
- confirmation that according to the intended conditions of use the integration of the non-authorised substances are not detectable in food or food simulants at a detection limit of 0.01 mg/kg.

If such an indication is not possible, the identity of the substances and other necessary information must be provided to allow the downstream food manufacturer to define the functional barrier and to verify that no migration is detectable (see also the information provided concerning delegation).

7 Improving sustainability of packaging materials

7 IMPROVING SUSTAINABILITY OF PACKAGING MATERIALS

European Green Deal

To reduce the environmental impact of human consumption and production, the European Commission created the European Green Deal with the goal of achieving a climate neutral Europe in 2050. The European Green Deal is an outline for a transformational change and will result in numerous legislative changes.

In the food sector, the Farm to Fork Strategy is at the heart of the Green Deal and strives for a sustainable food production system without compromising food safety.

Food packaging plays a key role in food sustainability. The aim is to improve food safety and public health by reducing the use of hazardous chemicals and promoting innovative and sustainable packaging solutions through environmentally friendly, reusable and recyclable materials. At the same time, food waste should be reduced and the environmental footprint minimised. To achieve this, the EU legislation on FCMs will be revised as part of the European Commission's Farm to Fork Strategy including the packaging and waste directive. A legislative proposal for a framework for a sustainable food system will be presented in the near future.

Trends in food packaging

Food packaging plays a dual role in sustainability. It has a positive impact on the environment by preventing spoilage and reducing food waste, but it can also have a negative impact due to the energy and water used in their production, the materials it is made of and the pollution that can occur during disposal. A more sustainable approach to food packaging can lead to the solutions described below.

Challenges with sustainable materials such as biobased polymer

Biobased polymer are either bio-based materials derived from plants, biodegradable materials that can be converted into natural substances by microorganisms or a combination of both. They are used as a more sustainable alternative to oil-based plastic, which has caused serious environmental problems due to its non-degradability and depletion of fossil resources.

New issues arise with biobased polymers, like allergenicity or presence of unknown nature-based substances with unclear toxicological potential (heavy metals, pesticides, natural toxins). These risks have to be addressed in the risk assessment.

Furthermore, biobased polymer has the potential to contaminate recycled plastic materials because it frequently ends up with other plastic when disposed. A collection and recycling system still needs to be established for biobased polymer. In countries where packaging is disposed of in landfills, biobased polymer can have advantages.

More information about biobased polymer is available (in English and German) on the website of IK Industrievereinigung Kunststoffverpackungen e.V.:

https://kunststoffverpackungen.de/presse-informationen/publikationen/

Reduction of packaging

Reducing packaging is the most common and straightforward environmentally friendly solution. Packaging should contain as little material as possible without compromising the protective function. This can be achieved by minimising the weight and volume of packaging materials, thereby reducing raw material consumption, energy use and waste volume. The use of lighter packaging, increase in surface/volume ratio or bulk packaging are examples of packaging reduction. However, thinner materials may lose their barrier properties. This fact should be carefully considered.

Reuse

Another sustainable solution is to reuse the packaging either for the same purpose or for a new one. Glass bottles in the beverage industry are an example of reusable packaging. The packaging should be refillable, reusable and durable. However, it should be noted that contamination of food packaging can occur through consumer misuse or during collection and transport. The washing process is critical to food safety, as is the use of technology to detect non-compliant packaging.

Recycle

Recycling is a common method to reduce the environmental impact of packaging. Metals and glass, as well as paper and plastic, are recyclable. Recycling is defined as the collection, sorting, processing, and marketing of materials that have been used previously. However, if any of these steps fails, recycling fails as well, and a new type of waste is produced.

The use of recycled packaging materials raises the risk of chemical contamination and accumulation that can migrate from the packaging to the food. Contamination can occur as a result of consumer misuse of packaging, improper sorting, or the recycling process itself. Flavour, aroma and odour compounds are also common contaminants.

During processing, metal and glass are melted at extremely high temperatures, hence avoiding contamination because most organic materials are destroyed. Paper is not separated into food grade and non-food grade streams before recycling. As a result, chemical compounds such as additives, printing inks, adhesives, solvents, plasticisers, and pigments can end up in recycled paper and should therefore not come into direct contact with food. Chemical compounds are also frequently found as contaminants in recycled plastic packaging. These compounds are residues from dyes, inks and additives and during the synthesis process of recycling plastic, additional oligomers can be formed, which can then migrate into the food.

Currently, there is a strong emphasis on high recyclability, which in principle is in line with the EU strategy on FCMs. However, it must be evaluated and demonstrated that high recyclability does not lead to a loss of barrier functionality. This should be addressed in the food manufacturer's risk matrix.

Which legislation applies when dealing with recycled materials?

Any FCM is covered by Regulation (EC) No.1935/2004, which also includes recycled materials, new materials and combinations of the two. As this is an increasingly important issue, food manufacturers need to consider it in their risk assessment (matrix). The use of recycled packaging is to be clearly mentioned in the food packaging specification.

Recycled plastic

Regulation (EU) No 2022/1616 states that food packaging shall only contain recycled plastic obtained from an EFSA authorised recycling process. A challenge test or other scientific evidence should demonstrate that the process is capable of reducing any contamination of the plastic input to a concentration that does not pose a risk to human health. The DoC shall state that only recycled plastic from an EFSA authorised recycling process was used and also mention the EC Register number of the authorised recycling process. Significant changes can be expected in this area, so food manufacturers should carefully follow the ongoing legislative activities, especially on approval processes and their transferal into national and EU Regulations. The most relevant information can currently be found in EFSA opinions on the submitted cleaning concepts, which are mainly for recycled PET.[5] It is imperative to check if up to 100% recycled material can be used without restriction or not. Especially in the latter case, food manufacturers must take this into account by introducing suitable barrier materials/layers.

5 EFSA: Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food

In the EU, only PET material is currently well described; other plastics have not yet been approved for food contact. This does not necessarily mean it cannot be used, but the user must then carry out their own tests demonstrating safety acc. Reg. (EU) No 1935/2004 based on internationally recognised risk assessment principles.

Recycled Paper

The EU has not yet harmonised legislation regarding the use of paper and recycled paper for FCMs. As a result, national legislation must be considered in addition to Regulation (EU) No. 1935/2004 and Regulation (EC) No. 2023/2006. Most national legislations require an adequate barrier layer to avoid any direct contact between food and recycled paper.

Various substances that can originate from non-food grade paper, printed materials, adhesives, coatings of the base paper, the recycling process, etc. shall be evaluated in a risk assessment. The input materials shall be suitable, and if necessary, a cleaning process must be used. All aspects of the recycling process must adhere to GMP and be mentioned in the supporting documentation. A certificate of compliance must be provided together with the recycled paper food packaging.

8 Annexes

8 ANNEXES

Annex 1: Questions and answers

1. Who is responsible for issuing the Certificate of Conformity (CoC) in the case of products imported from third countries?

Any products placed on the EU market from third countries have to comply with EU legislation. Product compliance is the responsibility of the business operator who places the product on the EU market.

In case of importing FCMs and articles, importers are deemed to be equal to the manufacturer and are responsible for compliance with the legislation, as well as the CoC. In the case of pre-packed food imports to the EU, the FCM of pre-packed food must comply with EU legislation.

2. What is required by REACH/SVHC legislation?

The requirements of the European evaluation of chemicals (REACH) have to also be considered with respect to packaging materials. The Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) aims to improve human health and environmental protection by establishing requirements for the use of chemicals.

This legislation requires that all substances of quantities greater than one tonne per year be registered with the Agency. The substance will be assigned a registration number once the registration has been submitted. This number must be communicated all the way down the supply chain. Non-registered products cannot be manufactured or imported to the EU and should not be placed on the EU market.

Substances of very high concern (SVHC) can be identified on the basis of containing intrinsic properties hazardous to human health or the environment and they are included in the "Candidate list". Such an identification is made without regard for the risk. This does not imply that these substances are prohibited, but rather that they are under consideration to be on the authorisation list. Substances from the candidate list may be added to the authorisation list (Annex XIV) if it can be determined for specific uses through a risk assessment. These substances can only be placed on the EU market for the time period specified.

If a candidate list substance is sold directly or is found to be present at >0.1% by weight in another substance or product, the presence of the substance must be communicated to the customer, including information to allow safe use. This obligation extends all the way down the supply chain to the final requirement that a retailer shall be able to provide such information to a consumer inquiring about the presence of SVHCs in consumer articles within 45 days of receiving the request.

The stricter limit needs to be followed for substances that appear on both the REACH and FCM lists. For example, DEHP (diethyl hexyl phthalate) is on the SVHC list and thus subject to notification at 0.1 % (1,000 mg/kg). Simultaneously, the substance is listed in Regulation (EU) No 10/2011 with an SML of 1.5 mg/kg for certain applications.

Example: If you have a film with a grammage of 0,2 g/dm^2 which has less than 0,1% DEHP the migration can be estimated as followed assuming complete migration:

< 0,1% of 0,2 g/dm^2 are < 0,0002 g/dm^2 (<0,2 mg/dm^2).

With a s/v ratio of max. 6 dm^2/kg food the migration will be <1,2 mg/kg food and therefore below the limit of 1,5 mg/kg food.

REACH/SVHC statement should not be mixed with CoCs as the updating frequency is different. Mandatory safety data sheets under REACH also do not replace any CoC.

3. Can substances that have not been included on the EU Regulation 10/2011 Union list be used in packaging?

Article 6 of Regulation (EU) No 10/2011 states that substances other than those on the Union list may be used as polymer production aids. Colorants and solvents, polymerisation aids (APs), non-intentionally added substances (NIAS), and other substances are examples of exempted substances. Non-listed substances that do not require authorisation may only be used if a risk assessment demonstrates that they are safe and this is recorded in the supporting documents. Every known substance capable of migrating must be proven safe.

Every manufacturer introducing a substance is responsible for this, as well as the impact (possible contamination, migration) and reaction products that occur during processing. If the procedure for verifying compliance is not known in detail, the manufacturer of the packaging/raw materials should share all information required by the buyer for their compliance work. The manufacturer needs to assess the risks in accordance with internationally recognised scientific principles. This risk assessment for these substances is required as part of the supporting documentation along with the DoC for plastic material.

4. What are Dual-Use-additives (plastic materials)?

Dual-use additives are substances that have been approved as food additives but can also be used in the packaging materials sector. According to Article 11(3) of Regulation (EU) No 10/2011, additives that are also approved as food additives or flavourings (Regulation (EC) No 1333/2008 and Regulation (EC) No 1334/2008, respectively) shall not migrate into food in quantities that can affect the final product. These substances should not exceed the limits set by the food additive regulations. Food manufacturers need to be aware of these substances in order to assess the total amount in the final product.

5. Which legislation applies to printing inks?

Although printing inks are typically applied on the non-food contact side of food packaging, migration through the food contact layer is possible and substances can be transferred via set-off from outside to inside. The broad rules in Regulation (EC) No. 1935/2004 and Regulation (EC) No. 2023/2006 on Good Manufacturing Practice apply to printing inks. According to these regulations, a risk assessment of the chemicals used in the composition of printing inks is required, as well as an assessment of any potential migration or set-off from these chemicals into food.

Printing inks are also subject to national regulations. The Swiss regulation on printing ink is the basis of a list of substances given by EuPIA (European Printing Ink Association). This regulation requires that substances used for the manufacturing of packaging inks shall be evaluated and have to comply with the restrictions. Non-evaluated substances shall not be detected in food simulants in amounts higher than 10 µg/kg. Similarly, the German regulation (in force since December 2021, amendment to BedGgstV) on printing ink includes a list of approved substances and sets limits of 10 µg/kg for substances that have not been assessed and are not carcinogenic, mutagenic, or reprotoxic.

Annex 2: Example checklist for evaluation of the declaration of compliance

The green marked questions are optional but can be used for detailed discussions with suppliers to help to set-up a quality contract for food packaging (national interpretations are possible, especially for NIAS)

Based on SVI checklist

Mandatory | Mandatory for plastic, but recommended for other materials | Optional

			Yes	No	N/A
0.	Title	0.1. Instructive title such as "declaration of compliance "or similar?			
		0.2. Title = „declaration of compliance"?			
1.	Identification and address of issuer and receiver	1.1. Identification and address of issuer (importer, manufacturer)* existent?			
		1.2. Identification and address of receiver existent?			
2.	Identification of additional companies	2.1. Further indications regarding identification and/or additional addresses existent?			
3.	Identification of food packaging	3.1. Food packaging clearly described and identifiable?			
		3.2. Does declaration of compliance encompass all parts of the food packaging?			
		3.3. Does composition of the food packaging encompass all parts (completeness)?			
4.	Date of declaration	4.1. Is the issuance date of declaration mentioned?			
5.	Confirmation of obser-vance of regulatory framework	5.1. Is suitability for food contact according to EU 1935/2004 confirmed? Special consideration shall be given to Article 3, 5, 11, 15 and 17.			
		5.2. Is it confirmed that production observes GMP acc.to EU 2023/2006?			
		5.3. Confirmation of any quality standard applied during production?			
		5.4. Is compliance with specific measures confirmed in case such measures are applicable according to EU regulatory framework (EU 10/2011, EU 2022/1616, EU 450/2009, EU 84/500/EEC, EU 2007/42 /EC)?			
		5.5. Is the observance of relevant national regulatory frameworks confirmed?			
		5.6. Confirmation of any specific industry sector reference?			
		5.7. Is it clearly stated for what the issuer does accept responsibility?			

6. Sufficient information about substances applied (SML/ migration)	6.1. Is information provided about substances applied in the food packaging sufficient?			
	6.2. Is unequivocal information concerning substances with (SML) available?			
	6.3. Is information about NIAS available?			
	6.4. If set-off from printed surfaces possible - unequivocal information given?			
7. Dual-use Additives	7.1. Is information about usage of dual-use additive available?			
8. Specification about the intended usage of the food packaging	8.1. Are allowable type or types of foodstuffs indicated?			
	8.2. Are indications concerning duration and temperature during treatment and storage of food stuffs available?			
	8.3. Is information about highest surface to volume ratio available?			
	8.4. Are conditions of storage for food packaging provided?			
	8.5. In case a restriction of application has to be observed, is it clearly indicated?			
9. Functional barrier	9.1. In case a functional barrier is applied, is a confirmation about its efficacy available?			
10. Date and signature	10.1. Is the document signed with a valid signature?			
	10.2. Is the job description of the signatory indicated?			
	10.3. Has the document been countersigned by the receiver			
11. Detailsabout compliance work already made	11.1. Are details about compliance work already made available?			
	11.2. Are details about continuative documents available?			
	11.3. Are details about third parties documents available?			
Summarising the evaluation: shall the document be accepted?				☒

- Trading companies must name the actual manufacturer or importer of the food packaging in the declaration.
- The criterion for the acceptance: **zero "No"**
- n/a means "not applicable" and has be defined by the receiver of the Declaration of Compliance

Annex 3: Further reading and links

- European Commission- EU legislation on Food Contact Materials legislation https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials_en
- Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food Council of Europe
- Food Packaging Forum https://www.foodpackagingforum.org/
- Council of Europe (EDQM)- Publications of Food contact materials https://www.edqm.eu/en/food-contact-materials-and-articles
- https://www.efsa.europa.eu/en/topics/topic/food-ingredients-and-packaging
- Guidance in selecting analytical techniques for identification and quantification of non-intentionally added substances (NIAS) in food contact materials (FCMS), Food Additives & Contaminants Volume 39, Issue 3
- 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 (updated 12.01.2016)
- EFSA: Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food EFSA Journal 2011;9(7):2184
- Industrievereinigung Kunstoffverpackung e.V. , Publikationen https://kunststoffverpackungen.de/presse-informationen/publikationen/

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