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IFS Food
Packaging Guideline

Guideline to implement the requirements
for "product packaging" in IFS Food, Version 6
Chapters 4.5 and 4.18.1

Version 2
September 2013

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IFS Food Packaging Guideline Version 2

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1 Introduction

Guideline to implement the IFS Food requirements for "Product packaging"

Scope of the guideline

The development of the first IFS Food Packaging Guideline dates back to the year of publication of the IFS Food, Version 5 in 2007. The legislative changes in packaging, especially of the Regulation (EC) No 1935/2004, were reason to develop requirements concerning product packaging in IFS Food. The particular interest of these requirements is to secure currently the private label products of retailers. Additionally, all products covered by the scope of the food manufacturer shall be secured and inspected accordingly.

The second edition of the IFS Food Packaging Guideline now includes the adjustment to Version 6 of IFS Food as well as the new legislative regulations and the latest developments of the market. This guideline relates to the existing requirements of IFS Food, Version 6 concerning product packaging only, including an interpretation thereof and does not contain additional requirements.

The implementation of the requirements in the food business caused more questions and problems than expected, since considering the legal requirements apparently requires a need to differentiate responsibilities within the supply chain. Some of the questions of IFS Food have been directly passed to the packaging industry, without considering whether those issues fall within their area of responsibility.

IFS Food Packaging Guideline provides help and support for implementing the requirements of IFS Food for product packaging. The guideline is primarily intended for the food industry and secondly for manufacturers of food packaging as well as other interested parties (auditors, certification bodies). Parts of it may also be applied to the IFS HPC Standard.

Furthermore, it shall also contribute to an understanding of the IFS Food requirements in up- and downstream sectors (suppliers, suppliers of packaging materials, food retailers …) including a clarification of responsibilities in various areas. The requirements in IFS Food, Version 6 for product packaging and this guideline concern the suppliers of packaging materials (hereinafter referred to as packaging manufacturers) only indirectly. The distinction from IFS PACsecure will be given as well.

This guideline focuses on the legislation of the EU. It may be applied, however, outside the EU considering the national legislation.

Purpose of this guideline is to increase the safety of product packaging in companies certified according to IFS Food. In addition, the professional knowledge associated with IFS Food shall be improved so that product packaging is practical and meaningfully ensured.

Berlin,
Stephan Tromp
IFS Managing Director

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3 Contents

4 General product packaging requirements

The legal requirements (see chapter 6) and of course the state of the art and science are the most important basis of the IFS Food requirements for product packaging. IFS Food requires compliance with all legal requirements (e.g. IFS Food requirements 1.2.10, 2.2.1.1, 4.2.1.2, 4.5.2, 4.5.3, 4.17.2) related to the products and production processes. This also includes the Product Liability Act, but this will not be further discussed at this point.

This guideline is primarily intended for the food industry and secondly for manufacturers of food packaging and other interested parties (auditors, certification bodies), intended to ensure that all partners involved in the process chain know and carry out their duties while preparing safe packaging. Behind this is the initiative to systematically ensure compliance which so far worked only badly and to make compliance work as simple and efficient as possible.

The key is fair and clear communication within the process chain. Food manufacturers are aware of the high demands of consumers:

Substances shall not migrate from the packaging into the food in quantities hazardous to consumers' health or affecting organoleptic properties. The manufacturing chain shall not simply assume this safety but provide evidence. Providing evidence of safety requires that everybody in the manufacturing chain contributes to this. The Good Manufacturing Practice (GMP) required by law is based on the understanding the every relevant aspect of the manufacturing process is systematically reviewed.

Verifying packaging materials delivered to the food industry is often very complex. This should start at the introduction of every new substance partly due to a lack of information from upstream suppliers and completed at the earliest possible production level. Newly introduced substances shall therefore be tested with regard to their suitability for food contact. Interactions between substances, however, might sometimes only be shown in the finished product which therefore requires a mandatory assessment. This assessment should then be verified in the food based on a risk-based approach.

Using the previous procedure allows only for a very difficult compliance work. Including the whole production chain and having a clear regulation of responsibility should help in reaching the goal. Migration reviews shall take place where they are sensible, be reduced to the essential aspects and carried out in the manufacturing chain as early as possible. The source materials shall be selected such that the work regarding conformity is as easy as possible (no or little delegation). This allows for offering safe and harmless products. Everybody in the manufacturing chain should be aware of their responsibility and their share in the knowledge transfer, shown in the example in figure 1.

Figure. 1: Flow of information in the value chain – current estimate

Knowledge about raw materials and substances (incl. contaminations) used that might migrate into the food.	Stage in the production chain	Responsibility according to legislation (will be held accountable by the Food Authority)
Comprehensive knowledge	Suppliers of raw materials	No responsibility
Limited knowledge	Packaging manufacturers	Minor responsibility
Little knowledge	Food manufacturers and packing and filling companies	Major responsibility
Generally very little knowledge	Retailers and other placers	Ultimate Responsibility

5 Guidance on the procedure of implementing the IFS Food requirements for product packaging

To implement the IFS requirements for product packaging, the recommended approach is to meet points 1 to 5 (Table 1). Through this structured approach it will be possible to identify hazard points, and to analyse and take measures to minimize those identified hazards.

The term declaration of compliance that will be used hereinafter is first and foremost a kind of declaration. A declaration of compliance is mandatory for specific materials that are specifically regulated, e.g. plastics. Written declarations are required for materials that are not specifically regulated, e.g. paper. Therefore, the term declaration of compliance will be used for reasons of simplicity, but does not always mean the legally required declaration of compliance. Details can be found in chapter 10.

Table. 1: Recommendations on how to proceed

Recommended actions	Reference to IFS Food Standard Version 6
Gathering information: • Inventory of all packaging materials and packaging aids of food manufacturers. • Investigation of completeness and latest updates of packaging specifications and process descriptions when handling packaging materials. • Determination of the structure of the packaging, from the inside (food contact side) to the outside (no direct contact, but transfer via gaseous phase possible, set-off • Review of the existing documentation using a checklist	Chapter HACCP (2.2.1.2, 2.2.3.1) Chapter Specifications (4.2.1.2, 4.2.1.6) Chapter Product Packaging (4.5.2)
Categorisation: • Establishing a risk matrix, e.g. material properties such as a) material with direct contact or b) material without direct contact but gaseous phase transfer c) existing functional barriers and d) pieces of packaging that may potentially interact with the food, e.g. set-off (when used according to their designated purpose, see also Reg. (EC) 1935/2004) • Comparing properties of food. Properties not covered by compliance have to be ensured using additional analyses. The categorisation provides a working tool for subsequent hazard analysis. Categories a) and c) should then be the focus of the hazard analysis.	Chapter Product Packaging (4.5.1 and 4.5.3)
Hazard analysis Conducting a hazard analysis and risk assessment for the product packaging according to IFS Food requirements in Chapter 2.2 – see also section 11 of the Packaging Guideline	Chapter HACCP (2.2.1.2, 2.2.3.1) Chapter Product Packaging (4.5.1 and 4.5.4)

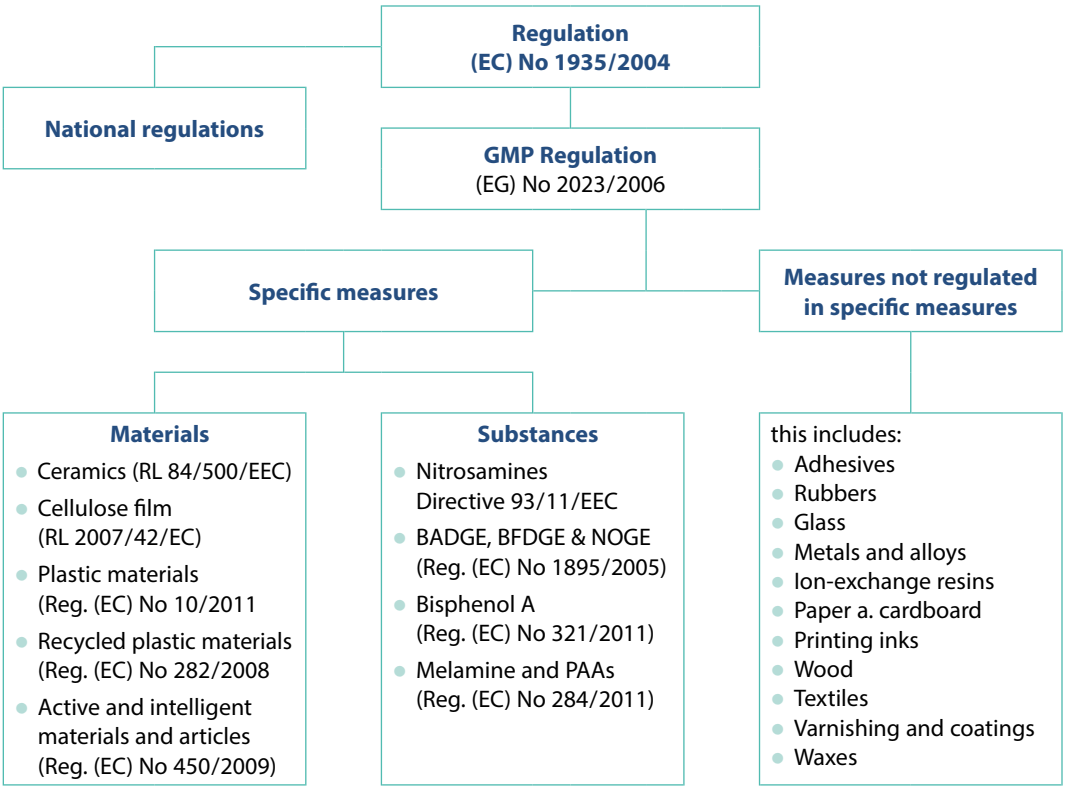
Recommended actions	Reference to IFS Food Standard Version 6
Actions: Defining the required actions considering the IFS Food Packaging Guideline and the IFS Food Standard	Chapter HACCP (2.2)
Periodical review a) Implementing the measures (e.g. during internal audits) b) Sustainability of the measures (assessment of complaints, scientific findings, information from the early warning system etc.) c) Re-assessment when replacing materials for packaging or changes to the production process of the food	Chapter Internal Audits (5.1) Chapter Management of Complaints from Authorities and Customers (5.8)

6 Legal and normative product packaging requirements

6.1 Food contact materials

The current legal packaging requirements and their relation can be found in the overview following below. Please note that this description does not reflect the latest status if new legal requirements have been released. The latest version can be found on the website of the European commission at (http://ec.europa.eu/food/food/chemicalsafety/foodcon-tact/index_en.htm). The current status is presented in Figure 2.

Fig. 2: Overview EC legislation



The EC framework regulation No 1935/2004 requires in section 3: "Materials and articles … shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- endanger human health or
- bring about an unacceptable change in the composition of the food or
- bring about deterioration in the organoleptic characteristics thereof." (colour, odour, taste)

Executive legislations such as the EC Regulation 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food are specific measures as

provided for in Art. 5(1) of Regulation 1395/2004. In absence of such specific legislations (e.g. for paper/cardboard, glass, metals etc.) the manufacturing chain itself is responsible for providing evidence on compliance with Article 3.

The same Regulation 1935/2004 requires a product-related declaration (binding statement about the suitability for food contact) for the next step of the manufacturing chain. Ann in-house documentation of the compliance work that shall be made available to the competent authorities only. The EC GMP Regulation 2023/2006 emphasises the process-oriented compliance work. It shall be applied as a horizontal specific measure to all food contact materials and lists necessary means in Articles 5, 6 and 7:

- Quality assurance and control system (Art. 5 and 6)
- Adequate and competent personnel (Art. 5)
- Specification of starting materials with regard to the intended use (Art. 5)
- Written documentation (Art. 7)

All parties involved in the manufacturing chain are jointly responsible and shall document their input (on paper or in electronic format) and this shall be made available to the competent authorities at their request. Only substances and components intended to be used for applying them in food packaging shall be used, this means, those for which the manufacturer conducted the compliance work for appliances in the food sector.

Furthermore, national authorities, such as the Federal Institute for Risk Assessment, Germany (BfR) make available other publications for areas not controlled by specific measures. There are also country-specific recommendations such as the Swiss Ordinance on Materials and Articles regarding printing inks. These documents may be used for problems and risk assessments. Further information can be found in Chapter 14 (Literature).

Other useful information, especially for the plastic materials sector can be found in future in the EU guideline for the Regulation (EC) No 10/2011 and in the publications of the BLL which also explain correlations in the value chain; for example in the previous publication "Declaration of Compliance", August 2012.

6.2 Dual-Use-Additives

Still open is the legislative issue concerning the use of dual-use additives. This means substances that are used in the packaging materials sector as well as approved as additives in the food sector. Especially food manufactures should know of these. Currently, a final overview is missing. Failing this, it is recommended to refer to the food additives regulation of the EU (Regulation (EC) 1333/2008, including last amendment No 1129/2011). This regulation lists all additives approved for the food sector including their restrictions.

6.3 Nanomaterials

In October 2011, a recommendation of the Commission on the definition of nanomaterial was published (2011/696/EU). This recommendation does not regulate the use of nanomaterial in detail. According to the Regulation on Plastic materials (EC) No 10/2011, substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I of the Regulation.

6.4 REACH/SVHC

When using packaging materials the requirements of the European evaluation of chemicals (REACH) shall be considered as well.

It is absolutely imperative, however, that the confirmation of absence (< 0.1 %) of SVHC substances (substances of very high concern) in packaging material does not allow a statement whether a migration in a lower range of concentration is possible or not. This shall be assessed separately. For example, DEHP (diethyl hexyl phthalate) is on the SVHC list and therefore with 0.1 % (1,000 mg/kg) subject to notification. At the same time the substance is listed in the Regulation (EC) No 10/2011 with a SML of 1.5 mg/kg.

7 Background

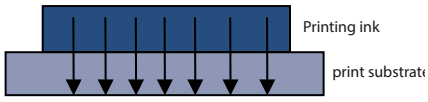
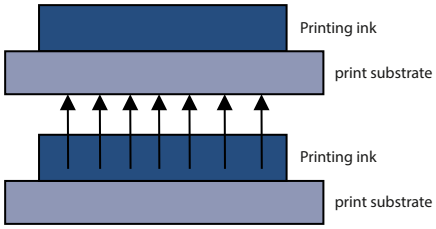
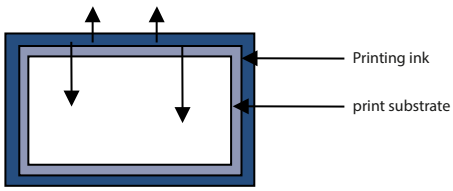
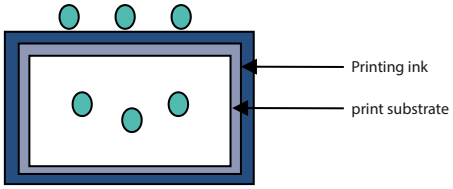
7.1 About food contact

Where a migration from the packaging into the food cannot be excluded there is food contact. 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).

7.2 What is migration?

Migration is the transfer of substances between the filling material and the food packaging. The following interactions may take place:

Fig. 3: Migration

Penetration Migration: **Transfer of a substance from the packaging into the food, and vice-versa**	
Set-off migration **Substance may transfer from the printed surface onto the side of food contact due to the pressure in the stack or on the reel subsequent to printing.**	
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**	

7.3 Test procedures

7.3.1 Modelling

Modelling is a recognised alternative method of compliance assessment (Reg (EC) 10/2011.

Article 18). This is a (quick) calculation for different applications, especially for long storage periods. For this, the initial concentration and the structure of the packaging must be known. The parameters should estimate the actual migration slightly too high (in the sense

of "worst case"). Several software programmes are available for free or commercially for mono- and multi-material layers. Currently, estimations for the most important plastic materials can be made. Basis is the guidance for choosing parameters for modelling: EU-Report 2010 EUR 24514 EN (http://ihcp.jrc.ec.europa.eu).

7.3.2 Chemical analysis

Simulants or real foodstuffs are used to identify the quantity of migrated substances. Simulations share comparable characteristics with the food to be packed. They are tested for migrated components after a determined exposure time under precisely defined conditions such as temperature and room humidity. A distinction is made between overall migration and specific migration or extraction.

7.3.2.1 Overall migration

The overall migration limit (OML) shows the maximum permissible quantity of non-volatile substances to transfer from materials or articles to food simulants. The value is non-specific (no separation into different substances) and only shows the overall quantity of all migrated substances. It is only a measure of the inertness of a material and does not allow any conclusions on the health-related evaluation of individual substances. Strictly speaking, overall migration is only valid in the plastics segment. Alternative, state-of-the-art test procedures for non-plastic materials are permitted showing the inertness of a food contact material.

7.3.2.2 Specific migration/extraction

This test searches for specific substances and shows how much of an individual substance migrated. But only if it is known. So-called screening tests provide an alternative. Numerous substances are detected using one method. These procedures are usually based on chromatographic, e.g. mass spectrographic principles (e.g. GC/MS [separation using gas chromatography, analysis using mass spectrometry], LC/MS [separation using liquid chromatography, analysis using mass spectrometry]).

7.3.3 Organoleptic analysis

The packaging is tested for migrated substances that have an adverse effect on either the odour of the taste of the food. For this, samples from production with suitable foodstuffs are brought into contact with the packaging materials for a defined period of time. Then the sample is tested and assessed for any changes to odour or taste by trained personnel.

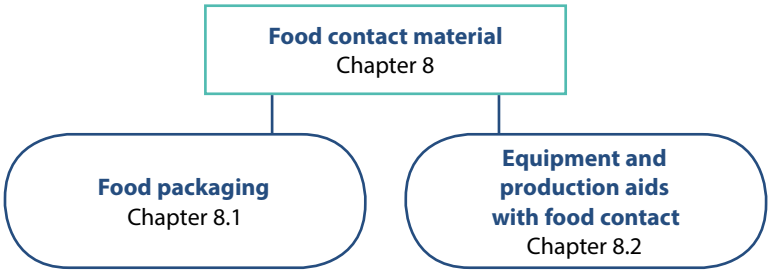
7.3.4 Microbiological analyses

Currently, there are no general legal requirements for packaging but only for the foodstuff. Food manufacturers shall consider a possible impact by the packaging in the risk analysis. If a risk is assumed the microbiological parameters should be agreed bilaterally between the food manufacturer and the packaging manufacturer.

8 IFS Food requirements related to product packaging in chapter 4.5 – Design and interpretation

During the assessment in the company a distinction must be made between packaging materials and those materials that come into contact with food during production or product processing, see also figure 4. The following chapter 8.1 deals with food packaging, whereas chapter 8.2 deals with equipment and production aids. This distinction is necessary since a varying risk assessment may be available.

Fig. 4: Classifying food contact materials



8.1 Food packaging

The following chapter indicates in detail the product packaging requirements of the IFS Food. The details presented provide an interpretation of the requirements. Each product packaging and each packaging material should be checked against relevant requirements. Legislative requirements have been mentioned at various points where it is deemed appropriate. These lists, however, have no claim for completeness.

4.5 Product packaging

4.5.1 Based on hazard analysis, assessment of associated risks and intended use, the company shall determine the key parameters for the packaging material.

Interpretation (see also risk matrix chapter 11)

- As a food manufacturer it is necessary to ensure that the used packaging has no negative interaction with the product. Health risks for the consumer are excluded when used according to regulations and foreseeable use. The product packaging must be compliant with legal requirements.
- A food manufacturer has to verify that the packaging manufacturer or the supplier meets the legal requirements of the packaging materials supplied.
- The objective of complying with all relevant legal provisions is to prevent health hazards.

- It must be assumed that migration-free materials do no exist. Generally, simulation tests only cover common cases.
- Even during simulation tests carried out specifically on the individual product it is possible that substances exceed a limit. Here verification in the food is required.
- Verifications in the food shall be carried out in defined cases, according to the prepared risk matrix. The marker substances to be used here should result from simulation measurements or other risk assessment tools.
- Which key parameters should be assessed? Pressure, temperature, time, contact surface, food characteristics (sour, fatty, dry), barrier etc.

4.5.2 Detailed specifications shall exist for all packaging materials which comply with the current relevant legislation.

Interpretation

- The food manufacturer has validated and sufficiently detailed specifications for all packaging materials available.
- These include among others: technical parameters, technical parameters in relationship to products and intended use, material, processing information, application area (not mandatory in the specification), storage instructions (not mandatory in the specification), and best before (use by) dates, if appropriate.
- The customer requirements are taken into account.
- Specifications of the packaging materials shall be regarded as an essential part of compliance work. They form the basis on which the manufacturer of packaging materials issues the compliance.
- Ideally, packaging material specifications have been agreed between the packaging manufacturer and the food manufacturer.

The packaging manufacturer needs the following information (key parameters/specifications) from the food manufacturer to optimise the selection and testing of the packaging materials:

- Storage conditions of the packed foodstuff
- Product description (fatty, watery, dry, etc.)
- Process conditions, filling conditions (pasteurisation, microwave pasteurisation etc.)
- Intended use: e.g. forms of preparation (microwave suitability, oven suitability, "bain-marie"/water bath suitability)
- Surface/volume ratio
- Description of the complete product packaging (important for interactions of the different packaging materials of a product)

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

Interpretation

For reasons of simplicity the term "certificate of compliance" will be used in general, also for "evidence of suitability of the packaging material for the intended use", but does not always mean the legally required declaration of compliance.

- Declarations of compliance, as mentioned above, are available for product packaging that may have an impact on raw materials, semi-finished and finished products.
- Evaluation reports of third parties are not declarations of compliance as mentioned above. These only support issuing another evidence.
- Suppliers shall always provide declarations of compliance for the material/packaging.
- If packaging materials delivered to the food industry are assembled by the food manufacturer (e.g. top and bottom film, or stretch blow moulding of PET bottles etc.) they shall provide a risk assessment.

With respect to raw materials, they are meant to be classified as food.

It is important to note that according to the GMP Regulation (EC) No 2023/2006, each packaging manufacturer shall have so-called "appropriate documentation" or "supporting documents" in order to demonstrate their compliance work to the competent authorities. Declarations of compliance are derived from the supporting documents which do not need to be passed to the downstream step. The "supporting documents" remain at the product packaging manufacturer. Transferring these documents is subject to bilateral agreements.

Additional information

A general statement that "statutory requirements are met," is not enough. There should be meaningful conformity certificates or other certificates that verify this. Here it is important that a specific reference to law is mentioned. More details and examples can be found in chapter 10 (Compliance work)

The IFS Food auditor assesses at the food manufacturer whether the food-law specifications are met in the final product. For this, he shall have access to the in-house documentation of the food manufacturer showing the estimated risk.

4.5.4 Based on hazard analysis and assessment of associated risks, the company shall verify the suitability of the packaging material for each relevant product (e.g. organoleptic tests, storage tests, chemical analysis, migration tests).

The tasks to fulfil the requirement 4.5.4 are shared between the packaging manufacturer and packaging user or food manufacturer (GMP).

Interpretation for the food manufacturer:

- Packaging users are also responsible under Regulation (EC) No 178/2002 for the suitability of the product packaging.
- Especially, if the food manufacturer buys different packaging materials and combines these to a food packaging himself, e.g. top and bottom films or stretch blow moulding of PET bottles. The user of packaging materials is responsible to evaluate the documents and the state of the matter. Based on a hazard analysis, it is necessary to determine which proficiency test and quality control the food manufacturer has to carry out himself or has to source out to a third party (this strongly depends on the product). These proficiency tests and quality controls can include incoming goods inspections, visual and organoleptic controls, storage tests as well as dimensional accuracy and analytical testing (possibly microbiology and migration) depending on the intended use.
- If food products or procedures/applications are used which are not covered by the test simulant and test conditions stated by the packaging manufacturer, i.e. if the scope of simulants strongly deviates (e.g. microwave capability, stability in the baking process, etc.) investigations against these products and the procedures (conditions) shall be carried out. If necessary, these studies should be performed with the real product in use. In order to clarify these points, a constructive communication between packaging manufacturers and users is essential.
- If the risk assessment implies that test reports are required these shall be up-to-date.

Up-to-date means that reports of the food manufacturer concerning proficiency test and quality controls for the packaging materials currently in use and the intended use are available. If packaging and product are not altered the up-to-date nature remains unaffected.

- The frequency of the proficiency test and quality controls is determined using the hazard analysis.
- Especially for new editions of packaging, it is necessary to insure the relevancy of the test reports. Specifications and declarations of compliance should be reviewed in detail.
- The IFS Food requirement of 4.5.4 does not imply that any combination of packaging and product must be examined individually, but that both food and packaging can be grouped together. This is only true if the properties of the products are so similar that the test result applies to the entire group. Under certain conditions, a calculation/modelling is sufficient.
- The hazard analysis and risk assessment of the suitability (fitness) shall include among other things these following characteristics:
  - *organoleptic:* (sensory focus: Does the contact to the packaging lead to taste/visible deterioration of the product?)
  - *microbiological:* Is the packaging exposed to a microbiological contamination during production, transport or storage? Are there any changes to the packaging material and/or the product?
  - *physical:* e.g., testing of tightness should be performed or the seal strength should be tested, etc.
  - *chemical:* the food manufacturer shall carry out additional tests if the food is insufficiently represented by the simulants or further inspections. Conducting the analyses should comply with the specifications of IFS Food 6, requirement 5.6.2.

  The interaction of the packaging components shall be taken into account (interactions, e.g. between film and printing inks, barrier properties, migration through the gas phase, transportation packaging of the product packaging).

Under the risk-based approach all other packaging materials have been reviewed (e.g. outer packaging and protective packaging) to prevent negative interactions. If negative effects are present, it is also necessary to take care of regulatory requested diligence for packaging in direct contact with food. Packaging aids are closures, staples, adhesives and similar items. Negative interactions should also be excluded when using printing inks and additionally applied labels. When using recycled paper, the possible interactions should be prevented by a functional barrier, e.g. made of aluminium or PET, or by any other barrier for which evidence on the effectiveness was provided.

Supporting services of the packaging manufacturer

- Every packaging manufacturer is subject to the regulations 1935/2004 and 2023/2006. Thus, they can only put packaging products on the market having no adverse interactions with the food product, where known.
- The testing conditions should include the actual use, if known. The packaging manufacturer, however, decides on which samples, when and in which laboratory these proficiency tests shall be conducted.
- The test reports prepared by the packaging manufacturer may be exchanged between food manufacturer and the supplier of packaging material where contractually agreed. Accessing these "supporting documents" is desirable where in-depth inspections in the foodstuff are required according to the risk assessment of the food manufacturer.
- The packaging manufacturer ensures the suitability of the materials using migration analyses or other suitable procedures (e.g. calculations) based on their risk assessment. Analyses are carried out according to the state-of-the-art and technics using their inspection plan or customer requirements.

4.5.5 The company shall ensure that the packaging used corresponds to the product being packed. The use of correct packaging shall be regularly checked and checks shall be documented.

Interpretation:

Traceability for the packaging and the related product (food) shall be ensured at all times. A mix-up shall be prevented by regular sampling when combining the food and the packaging. Sampling intervals and related documentation shall be determined during the risk assessment (e.g. manual vs. automatic packing).

4.5.6 Labelling information shall be legible, indelible and shall comply with agreed customer product specifications. This shall be regularly checked and checks shall be documented.

Interpretation:

The packaging materials received by the food manufacturer and the packed foodstuffs are cross-checked with the specifications at random (regarding labelling, declaration, legibility etc.). Sampling intervals and related documentation shall be determined during the risk assessment.

Additional requirements of IFS Food regarding product packaging other than mentioned in chapter 4.5

4.18.1 (KO) A traceability system shall be in place which enables the identification of [...] packaging in direct contact with food, packaging intended or expected to be in direct contact with food. [...]

Interpretation for the food manufacturer:

- The food manufacturer ensures traceability of the packaging using a suitable labelling or identification of the packaging material.
- The assignment of product and packaging is controlled.
- The traceability of the packaging material concerns primarily those that are in direct food contact.

  However, based on results of a hazard analysis this may not be sufficient. Packaging materials where it may be predictable that they come into contact with food (i.e. the intended use at the consumer is important here, e.g. snap-on-lids to reseal) shall also be considered.

Additional IFS Food requirements relating to product packaging are, e.g. 4.2.1.2, 4.14.1, 4.14.2 und 4.14.3, whose interpretation is mostly covered by the procedure explained in this packaging guideline.

8.2 Equipment and production aids with food contact

4.17.2 For all equipment and tools with direct food contact, certificates of conformity shall exist which verify compliance with current legal requirements. In case no specific legal requirements are applicable, evidence shall be available to demonstrate that all equipment and tools are suitable for use. This applies for all equipment and tools in direct contact with raw materials, semi-processed and finished products.

So far, the guideline for product packaging primarily addressed the packaging itself. According to the IFS Food requirement 4.17.2, tools, equipment and components as well as containers for transport with direct food contact shall also be checked for hazards and interactions. Equipment and components should be assessed during a hazard analysis and risk assessment for this. The same requirements apply to all materials in use as to food packaging. Evidence on the suitability of the materials in use are available (production certificates, analyses, scientific recommendations etc.). It is also possible to verify by tests in the final product that there is no risk of, e.g. substance transfer from equipment or components. The final product shall be examined for possible contaminants (e.g. migration) from equipment, components and containers for transport.

You should always consider the fact that some of the times of contact are very short when assessing such materials. This issue should be considered adequately in the respective risk matrix (see also chapter 11).

8.3 Handling packed raw materials

For packaging of raw materials, potential risks of contamination shall be determined based on HACCP studies. The following aspects shall be considered:

a) Origin of the packaging of raw materials.
b) One-way or reusable; for reusable items the usual cleaning/disinfection operations (e.g. for burlap bags),
c) Transportation of raw materials

The concerns also supplier's requirements that may be communicated and verified as part of the raw materials specifications with specific agreements on product packaging requirements.

The suitability shall either be proven by a declaration of compliance as specified in this guideline or the food manufacturer shall use suitable procedures verifying that the food contamination risk is minimised.

9 Specifications

Specifications are prepared on one hand for the foodstuff to be packed (related to requirement 4.2.1.1) and on the other hand for the packaging materials according to requirement 4.5.2.

9.1 Food specifications

A specification is a description of the foodstuff and the related manufacturing processes. It is important to note that the customer (here the food manufacturer and packer) transfers all necessary information to the supplier of the packaging material, so that they are able to assess which kind of packaging, which raw materials etc. are acceptable in the first place to keep migration of substances as low as possible. The compliance work preferably refers to the specifications or, if the food manufacturer cannot provide these sufficiently, clarifies the statement/declaration of the supplier of packaging materials stating for which application the product is suitable (scope of application, application conditions) and its limits. Simply said: a statement/declaration is always specific, i.e. refers to a defined application purpose and a specific packaging material.

Essential aspects of a specification that should be defined by the food manufacturer for the manufacturer of packaging materials:

- Food name/food category
  - Aqueous foodstuff
  - Alkaline or acidic foodstuff
  - Alcoholic foodstuff
  - Fatty foodstuff
  - Dry foodstuff
- Food processing
  - Heat treatment
  - other processing
- Packaging process
  - Thermo forming
  - Shrinking
  - Other procedures
- Preservation process
  - Deep-freezing
  - Heat treatment
  - Spraying with alcohol
  - Modified atmosphere
  - Air tightness
  - Filling temperature
  - Other procedures
- Storage conditions of the finished product
  - Ambient temperature
  - Cool storage
  - Deep-freeze storage
  - Other storage

- Shelf life of the finished product
  - Maximum shelf life
  - Desired humidity level
- Preparation of the finished product
  - Microwave
  - Oven
  - "Bain-marie"/steamer
  - Other method of preparation

9.2 Packaging material specifications (related to the IFS Food requirement 4.5.2)

The packaging manufacturer, on the other hand, should make every effort to produce a safe product (packaging material) based on the food specifications received. As an example, the most important measures, also for packaging materials specification, can be found in the list below. Some of them are "supporting documents". These shall be made available in total to the competent authorities at their request. Reality, however, shows that referring to a disclosure to competent authorities only does not always serve the purpose. Therefore, passing on "supporting documents" should always be regulated in bilateral agreements.

The companies involved in the production of food packaging should consider the following for the manufactured product:

- final application (type of packed foodstuff, filling and storage conditions, shelf-life and other important characteristics)
- which substances might migrate
- which substance may cause problems in the foodstuff

In addition the following should be taken into account:

9.2.1 Raw materials

- Selecting raw materials according to specifications determined in advance with the customer
- If possible, using low-migration components (e.g. low-migration printing inks) or components with a known low-level of toxicity, where the conformity can be verified without migration measurement.
- Requesting up-to-date declarations of the suppliers
- No acceptance of declarations with general disclaimers (general denial of responsibility)
- Traceability of raw materials

9.2.2 Processing, storage, distribution

- Implementing suitable quality management systems
- Appointing a quality manager
- Comprehensive documentation of the processes

9.2.3 Hygiene measures

- Rigorous compliance with the hygiene measures in the processes
- Hygiene requirements for production sites, e.g. securing and cleaning premises, buildings, work materials etc.
- Contamination control, e.g. cleaning, pest control, waste treatment, storage
- Personnel hygiene, e.g. work clothing, dining rooms, sanitary facilities
- Strengthening hygiene awareness of staff members

9.2.4 Information sharing

The manufacturer of the packaging/raw materials shall share all information required by the buyer for their compliance work if the application for verifying the compliance is not known in detail. The safety of every known substance capable of migration shall be proven. Differentiate here between IAS (intentionally added substances) resulting from the formulation and NIAS (non-intentionally added substances) that may occur due to production factors in the form of degradation products, fission products etc. For IAS, for example, you may refer to a list of the substances authorised in the EU. NIAS, however, are subject to own investigations of those who introduce these substances into the product. Unintentional contaminations (NIAS) introduced either from raw materials or due to process-reasons should be limited as far as possible by suitable GMP measures. Provided these substances are known and occur regularly, a safety assessment is required.

Safety assessment shall also be carried out for unknown substances detectable during migration tests, if possible. This, however, is nearly impossible due to missing structural information.

There are different ways to identify the conformity with migration limits:

- calculating maximum migration based on worst-case-scenarios (e.g. complete migration)
- mathematical modelling of migration
- analyses, some of them are time-consuming and expensive.

Every manufacturer introducing a substance is responsible for this, its impact (possible contamination, migration) and reaction products occurring during processing. Especially at early manufacturing steps it is often impossible or not desirable to apply the compliance for the finished product since, for example, the migration is not foreseeable. The one introducing a substance is obliged to delegate legal responsibility, i.e. to pass on the unfinished work to the next user (see point 10).

Then, the user knows what kind of compliance work they burden themselves with a product and may opt for alternatives, if appropriate.

This system does not allow any alternatives: the respective issuer is fully legally responsible for all substances and tasks not stated in the declaration. It is not possible to reject responsibility in general without listing specified delegated tasks.

10 Declaration (Confirmation) of Compliance (conformity assessment and written declaration of compliance with food laws)

Compliance work requires a product-accompanying declaration for the next step in the value chain. The compliance is based on an in-house documentation, the "supporting documents".

A declaration should always describe on what it is based. The checklist mentioned in point 10.7 and listed in the annex is a good tool to verify the declaration. It can be applied to declarations of compliance as well as other written statements. The declaration shall be clearly distinguished from the "supporting documents". These are in-house documentations and shall be made available in total to the competent authorities at their request. To what extent declaration and in-house documentation differ when passing them on within the value chain is subject to agreements under private law.

In principle, there is the obligation to declare for every material that it complies with the framework regulation (EC) No 1935/2004.

There are detailed requirements for the declaration of compliance for certain materials, e.g. in Regulation (EC) No 10/2011.

Whereas for other materials a written declaration of compliance with the specifications is required. The term declaration will be used hereinafter for the declaration of compliance and also for any other written statement.

The declaration shall always refer to the EU Framework Regulation (EC) No 1935/2004, to the GMP Regulation (EC) No 2023/2006, to a specification (see point 9) and to a necessary delegation (see point 10.4) of tasks, if required.

10.1 Declaration of compliance

A declaration of compliance indicates that the item or product for which the declaration of compliance is issued complies with existing regulations. For packaging materials, for which specific measures have been adopted requiring a declaration of compliance, the manufacturer shall put such a document at disposal. Structure and content of the declaration are set out in the individual measures, but not appropriate for business-to-business operation. Therefore, it is more advisable to use the checklist listed in the annex as a basis.

For materials not currently regulated by specific measures a declaration of compliance is not required by law. The general requirements under Article 3 of Regulation (EC) No 1935/2004, however, shall be met. This shall be confirmed (this guideline also calls this written statement a declaration of compliance for reasons of simplification).

Recommendation: A confirmation or another declaration for materials can be agreed under private law between supplier and customer. The content is not determined by law; it is, however, advisable to orient the agreement on the legally regulated areas. Further regulations may be agreed separately (see also the checklist in the annex).

Other written statements may replace declarations of compliance if they are not legally required. These confirm that a packaging material is suitable for food contact.

These statements may only be issued by the delivering point (manufacturer or placer) since a legal responsibility is assumed. Signing declarations of compliance or other written statements is not required by law but a signed declaration underlines the importance of such a document many times over. Demanding a signature should be resolved in advance during bilateral agreements.

A general issuance by third parties (e.g. specialist laboratories or institutes) is not equivalent. They may only contribute to the "supporting documents".

10.2 Analytical reports/expert's reports

These documents serve as supporting documents within the compliance work only, i.e. they are often forwarded as accompanying documents of the declaration of compliance/other written statements. They are included in the "supporting documents", which are usually available at the packaging manufacturer and remain there. The used specialist laboratories should be accredited accordingly.

10.3 In-House-Documentation

The in-house documentation demonstrates to authorities the compliance work performed as resulting from legal requirements and Good Manufacturing Practice. It lists the substances that possibly migrate:

- those added by the manufacturer,
- those substances for which the upstream supplier delegated an noted the compliance work,
- for which the compliance work is completed and its reasons,
- for which the work must be delegated.

Most often, the manufacturer will restrict the range of application for their product. They take over responsibility only within these specifications (ideally agreed with the customer). They may delegate the compliance work for other applications or application conditions.

10.4 Delegation

Delegation means passing on the tasks for ensuring the status of a substance/a product regarding food law to a downstream step.

This might be the case if substances are used:

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

Additional compliance work, e.g. identification and toxicological assessment of certain contaminations and potential reaction products may also be delegated.

For tasks that are not delegated (either in the declaration of compliance or another written statement) the signatory automatically (tacitly) assumes responsibility.

Attention: The issuer bears the responsibility for their product for every compliance work not delegated (tacit declaration of compliance). Packaging manufacturers should make the provision of a declaration regarding the substances composition by their suppliers mandatory. Named substances shall be investigated further; substances not named are considered to comply.

10.5 Disclosure or confidentiality

If the compliance of specific substances is guaranteed the confidentiality according to EU law is largely ensured. The in-house documentation justifying the compliance work shall be provided to the authorities at their request only. However, the incomplete compliance work, meaning substances where a final declaration cannot be taken shall be delegated to the customer.

10.6 Validity of documents

If packaging and product are not altered, the up-to-date nature of the documentation remains unaffected. A time limit on the validity of these documents is usually not appropriate. Where there are changes, e.g. composition, specification, legislative changes etc. the issuing company (packaging manufacturer) shall inform their customers within a reasonable period of time so that the customer may carry out a necessary revaluation within the frame of their risk assessment, if required.

10.7 Checklist for evaluating declarations

The checklist in the annex may be used for compliance work. The points of the checklist shall be defined by the user in such a manner as they shall be applied to the respective product. If this is not the case, "n/a" shall be ticked off in the appropriate column; indicating that it will not be used for the final evaluation of the presented document. All other questions for the presented documentation should then be answered "yes" or "no". The user of the checklist shall take appropriate measures if questions were answered in the negative, whether rejecting a material, initiating own analyses/gathering information etc. The cover sheet of the checklist may be regarded as part of the compliance work by the user. The checklist itself is annexed with a commentary for better understanding the questions.

The latest checklist sample can be downloaded from the IFS website (www.ifs-certification.com).

11 Hazard analysis for product packaging

IFS Food-certified food company – how to proceed:

4. Identifying the relevant legal framework for the packaging materials in use,
5. Inspecting whether the specifications/declaration of compliance available refer to this legal framework,
6. Checking whether the requirements, limits, analyses stated comply with the data given by the packaging suppliers/manufacturers,
7. Checking whether additional data from the packaging supplier/manufacturer is required to control additional identified hazard within the HACCP.

As described in chapter 5 of the guideline, the food producer shall conduct a hazard analysis with a risk assessment as part of the HACCP for packaging materials. This is particularly true for the suitability of the used packaging materials regarding IFS Food requirement 4.5.

The hazard analysis can be carried out analogue to all other hazard analyses.

Tab. 2: Example of a matrix for hazard analysis
(Source: HACCP documentation, course "HACCP from the perspective of the IFS", IFS Academy)

No.	Step/ Product	Hazard	Type (p, c, b)	Mea-sure	L	S o L	R	Q1	Q2	Q3	CCP (Y/N)

P, c, b: Physical, chemical, biological
L: Likelihood
S o I: Severity of Impact
R: Risk
Q1: Does this step involve a hazard of sufficient likelihood of occurrence so that control is no longer assured?
Q2: Does a control measure for the hazard exist at this step?
Q3: Is control at this point necessary to prevent, to eliminate, the likelihood of occurrence of the hazard to the consumer?

Notes:

In principle, the packaged food shall be assessed considering the composition of the food, storage conditions, best-before-date and the complete production process. The packaging material in use shall be examined for negative impacts, hazards and interactions regarding the stated parameters of the product.

Questions for the procedure:

a) What hazards exist at which process step?
b) Are all potential conditions and interactions registered?
c) Which control measures are carried out?

d) How high is the risk potential (risk assessment)?
e) Shall further measures be introduced?
f) Is there CP or CCP at the hazard point?

Resulting measures:

a) Review of the declarations of compliance and/or certificates
b) Review of packaging material specification
c) Chemical or physical analyses
d) Microbiological analyses
e) Organoleptic tests, e.g. Robinson test (partially very easy and at a low price when implementing)
f) Introduction of control measures (e.g. leak test) and control devices in the process (e.g. "bottle inspector")
g) Optimizing/modifying storage conditions for packaging materials
h) Replacing packaging materials or packaging aids (e.g. adhesives, varnish)

The manufacturer shall also check the use of the packaging material with the food: e.g. opening the packaging, performance of packaging under deep freezing conditions, performance of packaging during transport/storage (e.g. cans).

Storage/handling of packaging, which initially do not have direct contact with the food, but have direct contact due to later handling by the consumer (e.g. sealing film of margarine is removed by the consumer, so that the closure lid comes in direct contact with the margarine later on). This foreseen use is to be taken into account and shall be assessed in the hazard analysis (regulatory requirement of Regulation (EC) No 1935/2004).

We abstain from presenting a general overview of potential hazards for packaging materials at this point, since the potential for hazards needs to be assessed individually for each packaging and application/use in the facility. Figure 5 shows an example of such a risk matrix.

After preparing a risk matrix, it is also vital to note the frequency of the in-house review. A revaluation in the risk matrix should be carried out at every modification (e.g. revaluation of the risk, changes to materials etc.). Suitable measures, such as analyses etc. should be initiated if this results in a high level of risk according to the own classification.

Preparing a risk matrix does not mean that all combinations evaluated with high risk shall be reviewed once per year. Materiality criteria should be kept instead, such as change of suppliers, product modifications, if known, that automatically lead to a revaluation. Sample planning is therefore a combination of risk and materiality criteria. The following overview may be used as an example.

Fig. 5: Risk matrix – example
(every user shall prepare a risk matrix for themselves)

Conditions / Material	major FI, high fat	mayor FI, medium fat	major FI, low fat	medium FI, high fat	medium FI, medium fat	medium FI, low fat	small FI, high fat	small FI, medium fat	small FI, low fat	ele-vated Temp.
Glass										
Tinplate with varnish										
Aluminium with coating										
Aluminium without coating										
Film polyethylene in recycled card-board										
Multi-layer films without barrier										
Multi-layer films without barrier in RC										
Multi-layer films with UV or mineral-oil-based ink										
Multi-layer films without barrier UV labels										
Multi-layer films with barrier UV labels										
Dimensionally stable plastics in RC										
Dimensionally stable plastics with UV labels										
Dimensionally stable plastics with recycling cardboard										
Paper/Cardboard from virgin fibre in RC										
Paper/Cardboard with UV or mineral-oil-based ink										
recycling card-board or paper										
Paper/aluminium in recycled card-board										

FI = Food impact, RC = returnable container, UV = UV printing
This example uses the traffic light system (green = low risk, yellow = medium risk, red = high risk)

12 Selecting suppliers of packaging materials

The IFS Food Standard requests a general supplier evaluation. This includes also the packaging suppliers. The following list shows the current systems, standards, certification programs and legal provisions, which a packaging manufacturer has to respect or can undergo. This overview is designed to assist IFS Food-certified companies when evaluating these suppliers.

Tab. 3: Overview of the current systems, standards, certifications and legal provisions

	Reg. (EC) 2023/2006	Reg. (EC) 1935/2004	IFS PACsecure	BRC IOP	FEFCO GMP	GMP Guideline	HACCP/Codex	DIN EN 15593	DIN EN ISO 9001	DIN EN ISO 14001	DIN EN ISO 22000
Mandatory by law	X	X									
Voluntary			X	X	X	X	X	X	X	X	X
Product certification			X	X	X						
System certification							X	X	X	X	X
Hygiene			X	X	X	X	X	X			X
HACCP/Codex			X	X	X	X	X	X			X
Declarations of compliance mandatory		X	X	X		X					
Specific requirements for packaging	X	X	X	X	X	X		X			

Table 3 shows a graphic overview of the different systems, standards and certifications and their content. Supplier selection should be based on the question how packaging manufacturers or packaging suppliers prove their commitment to the GMP Regulation. This can be demonstrated either by an appropriate quality management certificate or by how certificates of compliance are issued. The checklist in the annex may be used for the assessment. A qualified supplier also distinguishes himself by having a profound knowledge about the migration problem. This is reflected in the selection of raw materials, intermediate products with regard to the migration potential among other things. Proceeding according to this guideline is intended to establish a uniform terminology and understanding between food and packaging manufacturer.

Since the term "GMP" is not protected by law and does not give any detailed specifications it is recommended, as a food manufacturer, to write down own specifications and forward them to the upstream supplier to implement these.

What the food manufacturer recognises as GMP at his supplier shall be predetermined and binding and communicated to the supplier. This notice is subject to an agreement under private law. The following standards may be considered:

IFS PACsecure

The IFS PACsecure Standard is used to assess manufacturers and converters of packaging materials. It resulted from the cooperation of IFS and the Packaging Association of Canada (PAC) and adopts elements of the established PACsecure standard developed with the support of leading manufacturers of food and packaging materials in North America.

A certification according to IFS PACsecure is a product and process certification. Requirements from the areas management systems, resources, planning and production process, measurements/analyses/improvements and food defense are checked among others. The checklist of the Standard includes also exemplary questions that may be asked the company during the audit and examples of KO or Major evaluations. 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 like all other IFS Standards do.

The IFS PACsecure Standard picks up the requirements of Reg. 2023/2006. For example, the requirements for a „Quality assurance system" (Article 5), „Quality control system" (Article 6) und „Documentation" (Article 7) are addressed in the IFS PACsecure chapters 2 (Quality and Packaging Material Safety Management System), 4.2 (Specifications and formulas/configuration) or 5.11 (Corrective actions). The requirements of the annex of this EU regulation regarding printing ink are also covered by the IFS PACsecure Standard, e.g. implicitly in chapter 4.14 (Receipt of goods and storage) and 5.6 (Product analysis).

BRC IOP

This standard has been developed by the UK retail organisation BRC and the Institute of Packaging (IOP) for manufacturers of packaging and packaging materials. It focuses on the hazard and risk management system (based on HACCP) as well as prerequisite programs (pest control, cleaning, avoiding foreign body contaminations etc.). Due to the different hygiene risk the materials are divided into two categories. There is a designed catalogue of criteria for each category to ensure hygiene during production and transportation.

BRC IOP was developed in addition to BRC Food (food safety standard for food manufacturers).

DIN EN 15593
Management of hygiene in the production of packaging for foodstuffs

European norm focussing on packaging hygiene during the production of packaging materials. Requirements are defined within the frame of a management system ensuring hygienic production of food packaging.

The legal conformity of packaging regarding food contact is not integrated. The manufacturer is responsible for implementing legal provisions to that effect. During an audit, however, the fulfilment of legal requirements as well as customer-specific requirements is reviewed. Particular importance was placed on the compatibility of this norm with DIN EN ISO 9001 (and DIN EN ISO 22000). Main subjects of the norm are: the management system, prerequisite programs, hazard analysis and risk assessment. Certifications according to this standard are possible since 2006.

DIN EN ISO 9001

Internationally recognised and globally used standard applied in all industry sectors. The company demonstrates a functioning quality management system. It is a system certification with an emphasis on customer focus and a continual improvement process. A management system according to DIN EN ISO 9001 is often the foundation for so-called integrated systems. This means that it is possible to well integrate requirements of other standards, legal obligations, customer demands etc. into this management system. Hygiene aspects/HACCP etc. are not mentioned in the DIN EN ISO 9001 but can be integrated by the company on a voluntary basis in the existing quality management system. However, this is not compulsory.

DIN EN ISO 14001

Internationally recognised and globally used standard applied in all industry sectors. The company demonstrates a functioning environmental management system. It is a certification system with emphasis on environmental orientation. The company has to determine all significant environmental aspects and define environmental objectives where necessary. The continual improvement process should be focused on environmental issues. This standard is rather unsuitable for integrating a hygiene management system and HACCP.

HACCP (Hazard Analysis Critical Control Point)

Contrary to the norms mentioned above, this is not an international standard but a guideline prepared by an international commission. The title of this guideline is: RECOMMENDED INTERNATIONAL CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE, CAC/RCP 1-1969, Rev. 4-2003.

In Europe, HACCP is a legal requirement for all business operators handling food. This is regulated in the hygiene regulation 852/2004 and others. The monitoring or implementation are under the responsibility of the national authorities. Certificates according to HACCP, however, are requested more and more frequently so that many certification bodies offer HACCP certificates. All organisations within the food chain can be certified. The interpretation for the individual levels is left to the certification bodies. A quality reference is the accreditation of the Certification Body for this program by a recognised accreditation body.

International Good Manufacturing Practice Standard (GMP) for Corrugated and Solid Board Packaging (FEFCO Standard)

Standard for the manufacturers of cardboard packaging and corrugated board. The list of criteria is shorter than that of the BRC IOP.

Hazards are identified and preventive measures determined based on a hazard analysis. These measures are anchored in GMP (Good Manufacturing Practice). The standard assumes that all potential hazards can be controlled using these GMP measures; critical control points are not identified.

The legal compliance of packaging regarding food contact is not integrated. The manufacturer is responsible for implementing legal provisions to that effect.

GMP Guideline draft standard "Packaging – Good Manufacturing Practice (GMP) for manufacturers of food product packaging" – Recommendation

Based on Regulation (EC) No 2023/2006, a GMP standard is under development by a European standardisation body. The standard is aimed at manufacturers of food product packaging and their suppliers (including warehousing and transport). Based on a management

system, other aspects concerning food safety are taken into account (food manufacturing and packaging process). The requirements for GMP are set out in detail. A special feature is the chapter on legal compliance, in which the issue of declaration of compliance/proof of suitability according to food law is integrated. The date of adoption of this standard is not yet known.

DIN EN ISO 22000

International norm with requirements for a food safety management system. The scope of this standard applies to all organisations involved in the food chain. Consequently, this norm is applicable for the organisations in the food chain itself (e.g. agriculture, manufacturers, processors, retail) and in the businesses associated to the food chain (e.g. manufacturers of equipment, service providers, producers of cleaning materials and disinfectants, manufacturers of packaging materials). Individual organizations are always subject to the criteria of DIN EN ISO 22000, but these shall be interpreted by the respective auditor with regard to the specific sector. The individual steps are divided into categories. For packaging materials suppliers the category "M" is applicable. Certifications are possible since 2005. Particular importance was placed on the compatibility of this norm with DIN EN ISO 9001. Main subjects of this standard are:

- Interactive communication
- System management
- Prerequisite programs
- HACCP principles

13 Glossary

Compliance work

Compliance work includes all work, documents, processes and tests providing evidence that materials and articles coming in contact with food do not adversely affect or modify the food so as not to adversely affect the health of the consumer. This evidence of compliance (accordance) is carried out with reference to the food law currently valid. The complete compliance work shall be recorded in writing. There are two categories of these documents: the first is the product-related declaration (written declaration of compliance), the second in the in-house documentation of all confidential documents.

Delegation of compliance work

As a general rule, every step of the manufacturing chain is responsible for all materials, substances and the related effects of the product.

A general delegation of responsibility is not possible. The compliance work, however, may be delegated to downstream steps under specific (i.e. precisely defined materials/substances) conditions.

Disclaimer

The term disclaimer is used as the technical term for excluding liability. This is often used to tone down the declaration of compliance in such a way that, although a material complies with the law, the liability, however, for all kinds of potential usage is refused.

Dual-Use-Additive

Substance which usage is limited in foodstuffs, e.g. as food additive.

Exposure analysis

An exposure analysis is an experimental set-up that provides answers to the question if and how a substance is damaging health. The experimental set-up may include experiments on living beings. Only using exposure analyses can help identifying if and in which quantities substance are toxic.

Food contact material

This means every substance coming directly or indirectly into contact with a foodstuff.

Food contact materials and articles

Food contact materials and articles, in some national legislations also called utilities, are those designated to come into contact with food during production, usage or packaging of the food. A food packaging is a food contact material. In the EU terminology materials and articles are food contact materials (FCM).

HACCP

HACCP means Hazard Analysis and Critical Control Points and is a system that identifies, evaluates and controls hazards that are significant for safety.

Hazard analysis

The procedure of collecting, assessing and evaluating information on hazards and situations that these may cause in order to decide which present a safety risk and therefore shall be included in the HACCP plan.

IAS (intentionally added substances)

Intentionally added substances are those substances that are an essential part of the formula of a material.

Migration

Migration is the transfer of substance between the packaging and the foodstuff (filling material). There are different forms of migration.

- *Penetration migration:* migration from the printed surface through the printing substrate to the blank reverse side (and from there into the foodstuff)
- *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)
- *Gas phase migration:* migration through evaporation of volatile substances in printing/packaging substrate due to heating (e.g. cooking, baking or cooking frozen products in the original packaging)
- *Distillation migration:* migration by steam distillation during cooking, backing or sterilisation procedure

NIAS (not intentionally added substances/incidental substances)

Not intentionally added substances: these may be reaction products occurring when two or more substances in a product react or contaminations originating from a raw material for which it is impossible to find out (different reasons possible) where the substances come from and what kind of substances they are (e.g. foreign substance in waste paper).

Packaging

Product for packaging other products. The terms "packaging" and "packaging materials" are used as synonyms in this guideline.

Placer on the market

According to Regulation (EC) No 1935/2004 Article 2(1)(b) the placer on the market is someone who holds materials and articles for the purpose of sale, offers for sale, distribution or any other form of transfer. This includes offering for sale and any other form of transfer, whether free of charge or not.

Product-accompanying declaration (Declaration of compliance/written statements)

The product-accompanying declaration is a written statement given to the buyer along with the product. It serves as a proof for materials and articles coming into contact with food that these materials and articles are in compliance with the respective food laws. Synonymous terms for product-accompanying declaration are "certificate of compliance" or "declaration of compliance". The declaration of compliance refers to the issued specifications of the food manufacturer, where possible.

Self-regulation

According to European law as well as national European food law every manufacturer and placer of food and utilities shall ensure that the goods comply with the legal requirements. The obligation for self-regulation is the basis for compliance work.

Set-Off

Set-off migration may occur when storing the products in stacks or reels, among other.

SML (specific migration limit)

The specific migration limit (SML) is the maximum permissible quantity of a certain substance that may transfer from a material or article into food or food simulants.

Specifications

A specification is a description of the foodstuff and the related manufacturing processes as well as details of the packaging. This includes especially information on how to store the foodstuff, how long it is stored, how to prepare it etc. The declaration of compliance of a packaging refers to the specification, i.e. it states (including) the areas of application, the conditions of use or states (excluding) where it should not be used.

Supporting documents

Suitable documents provided to the competent national authorities at their request. They are used to prove that the materials and articles, products from intermediate stages of production as well as the substances intended for the manufacturing of these materials and articles comply with the requirements.

These documents include a description of the conditions and results of checks, calculations, including model calculations, other analyses as well as certificates of harmlessness or a justification proving compliance.

TDI

This value (tolerable daily intake) states the maximum quantity of a substance that may be taken on a daily basis without causing poisoning or toxicological interferences. The TDI results from examinations on living cells, animals or humans.

14 Literature

Please find a selection of links to the following documents/sources on our website (www.ifs-certification.com). The documents are mostly in English.

1. European Commission, Health & Consumers: "References of the European and National Legislations", 2009
2. Federal Institute for Risk Assessment, Germany (Bundesinstitut für Risikobewertung – BfR): "General analytical methods for paper and cardboard articles" (in German)
3. Central Association for Food law and Food science, Germany (Bund für Lebensmittelrecht und Lebensmittelkunde e.V. – BLL): "The 'Declaration of Compliance' for food contact materials and articles according to the German Commodity Ordinance", 2009 (in German)
4. German Retail Federation (Handelsverband Deutschland – HDE): "Compliance Solution", 2009
5. European Chemical Agency (ECHA): "Candidate List of Substances of Very High Concern for authorisation", 2008
6. List of Regulations & Directives (important requirements for the implementation of the IFS Packaging Guideline)
   a) EU Framework Regulation (EC) No 1935/2004
   b) EU Plastics Directive (EC) No 10/2011
   c) GMP Regulation (EC) No 2023/2006
   d) National legal requirements of the country of production and destination
   e) Food Safety – Regulation 178/2002/EC
   f) Food Hygiene – Regulation 852/2004/EC
   g) REACH – Regulation 1907/2006/EC
   h) Product Safety – Directive 2001/95/EC
   i) Liability for defective products – Directive 85/374/EC
   j) Heavy metal waste – Directive 94/62/EC
7. National guidelines (Recommendations)
   a) Germany: BfR Recommendation XXXVI
   b) France: Guide de bonnes pratiques
   c) The Netherlands: Warenwet
8. Global level, non-European countries
   a) UN (WHO, FAO)
   b) Council of Europe
   c) Codex Alimentarius
   d) USA: Regulations of the FDA (U.S. Food and Drug Administration)
9. BLL: "Specifications in the food packaging chain"
10. EFSA: www.efsa.europa.eu/de
11. www.foodcontactmaterials.com
12. European Federation for paint and ink manufacturers, EMPAC – European association of metal packaging manufacturers, "Code of practice for coated articles where the food contact layer is a coating", 2009

13. EMPAC: "Guide to good manufacturing and hygiene practices for metal packaging in contact with food"
14. Sustainable Packaging of organic food: a guideline for companies (Nachhaltige Verpackung von Bio-Lebensmitteln: Ein Leitfaden für Unternehmen (Cordula Binder, Renate Dylla, Alexander Gerber, Kathrin Seidel, Ralph Weishaupt. BÖLW (ed.), FiBL (Sales) 2011), in German
15. IFS Food
16. IFS PACsecure

Further information and examples can be found in the following publications:

Central Association for Food law and Food science, Germany (Bund für Lebensmittelrecht und Lebensmittelkunde e.V. – BLL): The "declaration of compliance" for plastic materials and articles intended to come into contact with food according to Commission Regulation (EU) No 10/2011 (Plastics Implementation Measure, PIM), as of September 2012

The German industry association IK Industrievereinigung Kunststoffverpackungen e.V. (German Association for Plastics Packaging and Films) – Guideline for manufacturers of plastics packaging for food from the view of the commodities law

Annex

Assessing declarations of compliance (example)

This checklist pursues several approaches. Firstly it shall help checking and evaluating declarations of compliance according to a uniform, systematic approach, if possible. Furthermore, it can be used as a base for discussing bilateral agreements between buyer and seller of a material – "who provides which information and who is responsible for what".

Before applying the checklist users should ask themselves which questions are relevant, especially since some questions are optional and go partly beyond legislation. Questions to be excluded may be marked in the column "n/a" (not applicable). Then, the remaining questions may be answered with "yes" or "no" depending on the information of the document to be checked. In the end, a final evaluation may be conducted. In order to better understand the individual questions short explanations were included. The declaration of compliance does not always contain all final information. Therefore, references to additional documents that shall also be subject to the review, if required, may be included.

This checklist is an example only. The current version can be downloaded from the IFS website.

		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 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 the product	3.1 Material clearly described and identifiable?			
	3.2 Does declaration of compliance include all components?			
	3.3 Does composition of the product include all parts?			
4. Date of declaration	4.1 Is the issuance date of declaration mentioned?			
5. Confirmation of observance of regulatory framework	5.1 Is suitability for food contact according to EU 1935/2004 confirmed?			
	5.2 Is confirmed that production observes GMP according to EU 2023/2006?			
	5.3 Confirmation of any quality standard (e.g. IFS PACsecure) applied during production?			
	5.4 Is compliance with specific measures confirmed, in case such measure is applicable according to EU regulatory framework?			
	5.5 Is the observance of relevant national regulatory frameworks confirmed?			
	5.6 Confirmation of observance of any specific industry sector reference?			
	5.7 Is there any unacceptable exclusion of liability (disclaimer)?			
6. Sufficient information about substances applied	6.1 Is general information provided about substances applied available?			
	6.2 Is clear information concerning substances with specific limits (e.g. SML) and statement regarding acceptance of responsibility (delegation) available?			
	6.3 Is information about NIAS available?			
7. Dual-Use Additives	7.1 Is information about usage of dual-use additive available?			
8. Specification about the intended usage of the material	8.1 Are allowable type or types of foodstuffs indicated?			
	8.2 Are indications concerning duration and temperature during treatment and storage when in contact with foodstuffs available?			
	8.3 Is information about surface and volume ratio available?			
	8.4 Are conditions of storage for the product provided?			
	8.5 Are indications of a restriction of application available?			
9. Functional barrier	9.1 In case a functional barrier is applied, is a confirmation about its efficacy available?			
	9.2 Is information about possible set-off 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. Details about compliance work already made	11.1 Are details about compliance work already made available?			
	11.2 Are details about continuative documents (by the issuer) available?			
	11.3 Are details about continuative documents (by third parties) available?			
Summarizing the evaluation: shall the document be accepted? The criterion for the acceptance: zero „No"				

* n/a means "not applicable" and shall be defined by the receiver of the declaration of compliance.

Remarks
Date and signature

Explanations to the checklist

Explanatory notes

The structure of the checklist follows the structure of the written declaration for plastic products according to Art. 15 of Regulation 10/2011 Appendix IV.

0. Title

0.1 Does an explanatory title exist in the document such as declaration of compliance or declaration of conformity?

Commentary: a title is needed.

0.2 Has the notion "declaration of compliance" been used?

Commentary: the term is obligatory in conjunction with materials that are subject to specific measures according to EU rules, such as plastics, ceramics and active and intelligent materials.

1. Identification and address of issuer and receiver

1.1 Is the identification and address of the company known that issued the declaration of compliance?

Commentary: an indication is obligatory.

1.2 Is the identification and address of the receiver (the company receiving the declaration of compliance) known?

Commentary: this point is an issue of mutual agreement and not obligatory.

2. Identification and address of additional companies

2.1 If point 2 is not fully covered by the information submitted in point 1: are further details concerning identification and addresses of companies available that produce materials or products made out of plastic or food contact materials made out of intermediates or produce and/or import substances that are used in the production of materials and products mentioned in point 3?

Commentary: only products that fall under Regulation (EC) 10/2011 shall fulfil this requirement. The requirement shall only be met in cases information under point 1 is missing.

3. Identification of product covered by this document

3.1 Is it possible to clearly describe and identify the material either by name or article number?

Commentary: the denomination of the material must be traceable in all supporting documents (internal documentation), like analysis reports.

An indication of reference article number of the supplier and/or of the reference article number of the food producer facilitate the traceability.

3.2 Does declaration of compliance include all components?

Commentary: a declaration of compliance shall include and describe all parts of the product as delivered. See also 3.3.

3.3 Does composition of the product include all parts?

Commentary: it shall be obvious for which layers the declaration is valid. If necessary, a sketch explaining the composition would be helpful. This point, however, should be decided bilaterally in advance.

4. Date of declaration

4.1 Is the issuance date of declaration mentioned?

5. Confirmation of observance of regulatory framework

5.1 Does the declaration confirm that the product is fit for use in contact with foodstuffs?

Commentary: this requirement is fulfilled if compliance with Regulation (EC) 1935/2004 is confirmed.

In principle, it can be assumed that the product complies with the national legislation if compliance with Regulation (EC) 1935/2004 is confirmed.

In addition or alternatively, a reference can be made to Swiss law (LMG – SR 817.0 and LGV – SR 817.02) in case the product is sold in Switzerland only.

If the declaration is issued for a non-EU country and/or Switzerland a reference to the regulatory framework of the country of destination should be made.

5.2 Does the declaration confirm that the product has been produced according to GMP following Regulation (EC) 2023/2006 for food contact materials?

Commentary: Swiss law does not require observance of the EU GMP Regulation but this may be derived from Art. 49 of LGV, the demand for self-regulation.

5.3 Is a confirmation available stating that a quality standard has been applied during production (e.g. industry guidelines, IFS PACsecure)?

Commentary: Such standards are presented in the chapter "Supplier selection".

5.4 If the product is subject to specific measures according to the EU regulatory framework, is compliance guaranteed?

Commentary: following materials are subject to EU specific measures:

- Plastic materials: Regulation (EC) No 10/2011
- Ceramic articles: Directive 84/500/EEC
- Active and intelligent materials: Regulation (EC) No 450/2009
- Recycled plastic materials: Regulation (EC) No 282/2008
- Regenerated cellulose: Directive 2007/42/EC

5.5 Is confirmed that the product complies with the national regulatory framework?

Commentary: if there are no harmonised EU rules applicable, a reference to the regulatory framework of the country where the product shall be placed on the market should be made.

F. e. printing inks in Switzerland: Bedarfsgegenstände-Verordnung: 817.023.21 Abschnitt 8 b (Ordinance of the FDHA on Materials and Articles RS 817.023.21, section 8b

5.6 Is confirmed that – provided that the above mentioned declaration is valid – the product is complying with specific industry references that have no legal quality?

Commentary: in the absence of national or EU harmonised rules, references may be made to sector specific industry recommendations, examples are:

- Paper: Recommendations of the Bundesinstituts für Risikobewertung (BfR): No. XXXVI
- Metals and alloys: Technical Document Council of Europe, 13.02.2002

5.7 Is it clearly stated for what the issuer of the declaration does accept responsibility?

Commentary: a declaration of compliance without a clear statement about responsibility is problematic. A declaration must clearly state who is responsible for what.

While rejection of responsibility in the small printed bottom paragraph, such as by stating general disclaimers, is possible, the disclaimer is not the basis for a transparent and confidence-building collaboration between the issuer and the receiver of a declaration of compliance. A tacit acceptance of any declaration with a general disclaimer implies that the receiver accepts full responsibility for the product.

For substances mentioned in the declaration both ways are possible: taking on or delegating the responsibility. For any substance that is not mentioned the issuer takes on the full responsibility anyway.

Unacceptable disclaimers are those that make no indication to any substance but reject the responsibility globally.

If the issuer does not take on (= does delegate) responsibility (for a specific substance) this means for the receiver of the declaration that he must exert himself for further clarifications in his own compliance work.

6. Sufficient information about substances applied

6.1 Does the issuer provide sufficient information about substances applied with no restrictions?

Commentary: indications following the format underneath would facilitate the transfer of information.

CAS No.	Name	Criteria for purity

The term "sufficient" orients itself on the customers' need for information so that they are enabled to perform their own compliance work. This need for information should also be clarified bilaterally, if required.

The limits for allowable migration of any substance with no SML for plastic materials (and in Switzerland for silicones as well) are defined by the threshold value of the global migrate.

Example:
Antioxidants Irgafos 168 (CAS 31570-04-4 – Tris(2,4-di-tert-butylphenyl) phosphide – listed in Reg. (EC) 10/2011, but no SML defined.

There are often decomposition products from this substance in materials: e.g. 2,4-di-tert-butylphenol (CAS: 96-76-4). This decomposition product is not listed in Reg. (EC) No 10/2011. In general, a manufacturer does not list the decomposition products of Irgafos 168. Therefore, it is mostly impossible to allocate decomposition products with the potential to migrate, as found in chemical analyses.

6.2 Is clear information concerning substances with specific limits (e.g. SML) available?

Commentary: the denomination of all substances with specific migration limits is required (provision of sufficient information). A renouncement of mentioning substances (or a single substance) means that the issuer takes on full responsibility.

For every substance evidence must be given whether the issuer of the declaration carried out tests (analysis, modelling, worst-case calculations) by himself. If such tests are available the receiver may exclude these substances from further risk analysis. Consequently, it is understood that the issuer takes on full responsibility for any substance he did not delegate responsibility.

The delegation should always relate to a single substance, the format being given in the blueprint underneath.

CAS No.	Name	Restriction (such as SML or any other limit applied)	Delegation

If e.g. based on one's own tests (analysis, modelling, worst-case calculations) a transgression of the restriction can be excluded a delegation would be unnecessary. Abstinence from delegation would minimise unnecessary costs. A documentation about these tests shall be available and is part of the supporting documents. In any case, competent authorities have the right to get access to these supporting documents.

6.3 Is information about NIAS available?

Commentary: indications following the format underneath would facilitate the transfer of information.

CAS No.	Name

A declaration should give evidence whether the issuer has made some research/fact finding about NIAS (such as decomposition or reaction products) and evaluated these as far a possible.

6.4 Is there any indication in the declaration if set-off is possible?

Commentary: set-off is defined as the transfer of substances from the outer side of the product to the inner side of the material that is in direct contact with the food. If the product will be delivered in reels or in stapled sheets, further indications and/or explanations are expected, e.g. suitable GMP measures preventing this.

Are there any indications mentioned concerning substances that could migrate as consequence of a set-off process from the food contact side of the packaging.

7. Indication concerning dual-use additives

7.1 Are there any indications concerning dual-use additives?

Commentary: indication is mandatory if the food contact material is subject to the Regulation (EC) 10/2011, for all other materials indications are desirable and welcomed.

For the time being there is no definitive list of dual-use additives. The EU ordinance on additive substances 1129/2011 may serve as an auxiliary tool in the meantime.

8. Specification about the intended usage of the material

8.1 Does the declaration make any statement as to what type or classes of foodstuff the product may get into contact with?

Commentary: indication is mandatory if the food contact material is subject to the Regulation (EC) 10/2011. But as a basic rule, every declaration should make reference to a specification, independent of the material in use. Specifications are useful to restrict and narrow down the application of the product and the responsibility related to this application. Should the receiver deviate from these specifications he is bound to accept the responsibility and commission further clarifications. In case the receiver has issued specifications that are not compatible with the general specifications issued by the issuer of the declaration (e.g. separate specifications for packaging and/or foodstuff), further comments taking into account these specifications are expected.

8.2 Does the declaration make any statement about duration and temperature during treatment and storage in case of food contact?

Commentary: see 8.1.

8.3 Are there any indications available that take into account the relation of surface of the product and the volume of foodstuff affected, based on which compliance of the material or the article might be assessed?

Commentary: indication is mandatory if the food contact material is subject to the Regulation (EC) 10/2011. For all other materials indications are desirable and welcomed.

8.4 Are conditions for the storage of the food contact material indicated?

Commentary: explanations are necessary especially in cases where materials have been used that are subject to deterioration during storage.

8.5 In case there are prescriptions for the restriction of application fields are these remarks clear?

Commentary: as an example for clear restriction of application may serve: "not to be used for fatty food".

An obligatory remark must be made in case the product is only applicable in combination with a barrier (such as advertising the product as "only fit for indirect food contact").

9. Indications concerning the application of functional barrier materials

9.1 Is there any conformation available that a functional barrier is effective in case a multilayer material with barrier function is applied?

Commentary: each plastic layer in a multilayer material or article must be complying with Regulation (EC) 10/2011.

A deviation from the principle is only allowed if a plastic material layer does not have direct contact with the food and is separated by a functional barrier. Under these circumstances the plastic material may be made of substances that are not part of the union list or the preliminary directory.

10. Date and signature

10.1 Is the document signed with a legally valid signature?

Commentary: legally valid means in this context that the signatory must be legally entitled according to the authorization list of his company. Declarations without signature are invalid and not accepted for further evaluation. If documents shall have a legally valid signature should be clarified bilaterally in advance.

10.2 Is the function of the signatory indicated?

10.3 Has the document been countersigned by the receiver?

Commentary: A countersignature is not mandatory (subject to the agreement between issuer and receiver). A countersignature might be favourable especially in cases of critical combinations of food and packaging, just to underline the mutual responsibility. It will be an assurance for the issuer too.

11. Indications relating to any compliance work already done

11.1 Are details about compliance work already done available?

Commentary: just from the legal perspective there is no need to expose compliance work already done. However, such information will certainly build up confidence in the partnership between issuer and receiver.

It should be possible to derive information from the declaration on what has been done already to gather the essential knowledge in preparing the declaration.

11.2 Are there any indications as to documents available with further information?

Commentary: such documents with further information could be statements of sub-suppliers, declarations of harmlessness, expertise and analysis reports. These are not part of the declaration of compliance but part of the supporting documents. Their disclosure is a topic of separate agreements.

11.3 In case there are links to third-party documents mentioned, are there any indications who that might be and what kind of documents they are?

Commentary: it should be possible to establish a traceable reference between product and further documents (expertise, analysis tests). If analyses reports are mentioned it might be helpful to indicate the type of test and the name of the laboratory.

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The Swiss Packaging Institute (Schweizerisches Verpackungsinstitut, SVI) is the overarching trade association for the packaging industry in Switzerland. The SVI spans all packaging types and has the role of representing and promoting the interests of all companies involved in the packaging life cycle – from packaging production and filling to recycling. SVI thus supports the advancement of the packaging industry as a whole in functional, ecological and economic aspects, and highlights its innovative strengths.

Joint Industry Group

The Joint Industry Group on Packaging for Food Contact (JIG) is an SVI project. JIG is an initiative bringing together Swiss industrial partners that operate in the food, food contact materials/FCM (packaging) and food/FCM marketing industries. These stakeholders aim to perform compliance work throughout the supply chain to ensure they fulfil the mandates set forth in food legislation (self-regulation, risk management, legal compliance).

Specific objectives of JIG:

- Build expertise along the supply chain for efficient management of compliance within the industry
- Provide a platform for exchange of information throughout the supply chain as a whole
- Provide a meeting-point where entrepreneurs and executive authorities can come together and dialogue can take place between „inspectors and inspected“

JIG‘s work focuses on three areas:

- Mutual exchange of information at two plenary meetings of JIG (JIG Platform)
- Provision of continuing training (courses and workshops) on the topic of compliance
- Development and provision of a toolbox for performance of professional compliance work in practi ce

JIG offers an extensive range of continuing training services in the field of compliance, covering not only the packaging industry, but also – and particularly – the food industry. JIG courses and workshops teach the requisite legal foundations, methods of food contact materials analysis and how to use the JIG Checklist, as well as the basic principles of compliance work and the reasons why it is necessary.

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