

## 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)

### 1. Introduction and objective

It is common usage in the marketing and distribution of food contact materials to issue declarations or certificates on the suitability and the compliance with established food law requirements.

Since 1997, a detailed and binding stipulation has been in place on **materials and articles intended to come into contact with food (synonym: food contact materials) made from plastic**, namely to make available in writing information about the compliance with current legislation as well as to provide information about the producer or importer ("declarations of compliance"). Within the process of implementing European Regulations into the national Consumer Goods Ordinance in 2008, it was found that there was some need for further information on the declaration of compliance. In 2011, these stipulations were transposed into the new European Regulation on plastic materials and articles (EU) No 10/2011 which basically continues the concept of the declaration of compliance. Due to their exceptional position, this paper brings plastic materials into focus.

This paper aims at informing all stakeholders within the **food packaging chain** about the current European regulations, at contributing to their application in conformance with the legislation, and at answering queries from the industries (the FAQs are directly linked to the respective answers). The information shall assist those responsible for designing individual declarations of compliance.

Furthermore, this information is aimed at a common understanding, a restrictive use of declarations of compliance within the supply chain and also in respect of contact with competent authorities. The information is strictly guided by legal requirements (minimum requirements). Any additional requirement requested by the respective business partners or industrial recommendations can still be used as a basis for voluntary agreements, but they shall be differentiated accordingly (e.g. as "specification recommendations").

In general, this information has to be considered within the context of other information for the food packaging chain provided by the BLL (BLL's information leaflet "Specifications in the Food Packaging Chain" of June 2010, <http://www.bll.de/themen/bedarfsgegenstaende/>).

The German Federation of Food Law and Food Science (BLL) has coordinated this information with other food industry representatives and industrial associations involved, including

- *PlasticsEurope Deutschland e.V. - (PlasticsEurope Germany)*
- *Industrievereinigung Kunststoffverpackungen e.V. (IK) - (German Association for Plastics Packagings and Films)*
- *Verband der Druckfarbenindustrie (VdD) - (German Printing Ink Industry Association) (VdL)*
- *Gesamtverband der Aluminiumindustrie e.V. (GDA) (Federation of the aluminum producing and processing industry)*

## 2. Regulations regarding the declaration of compliance for plastic materials

The general and fundamental requirements for materials and articles intended to come into contact with food (according to the definition of the German food law, LFGB<sup>1</sup>) are laid down in Framework **Regulation (EC) No 1935/2004**<sup>2</sup>. In general, all food contact materials and articles have to comply with these requirements; they *“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 (...) or bring about a deterioration in the organoleptic characteristics thereof”*. (Article 3, Regulation (EC) No. 1935/2004).

The general requirements for the so-called “Good Manufacturing Practice” in relation to the production process of food contact materials are supplementarily stipulated in Commission Regulation (EC) No 2023/2006<sup>3</sup>.

According to Article 16 of the Framework Regulation, the “declaration of compliance” is the written confirmation that the food contact materials comply with the rules applicable to them. Such a document is obligatory as long as this has been stipulated in so-called “specific measures”, i.e. specific rules on materials. Moreover, Article 16 states that the declarations of compliance shall be supported by appropriate documentation to demonstrate the compliance. That documentation shall be made available to the competent authorities on demand.

Specific measures as referred to in Framework Regulation (EC) No 1935/2004, i.e. specific rules and specifications for individual materials, are not in place for all groups of food contact materials, but for example for materials made from ceramic, regenerated cellulose and for the large group of plastic materials. As far as specific measures were available in form of an EU directive, they have been transposed into the national Consumer Goods Ordinance<sup>4</sup>; EU Regulations are directly applicable and do not require national transposition.

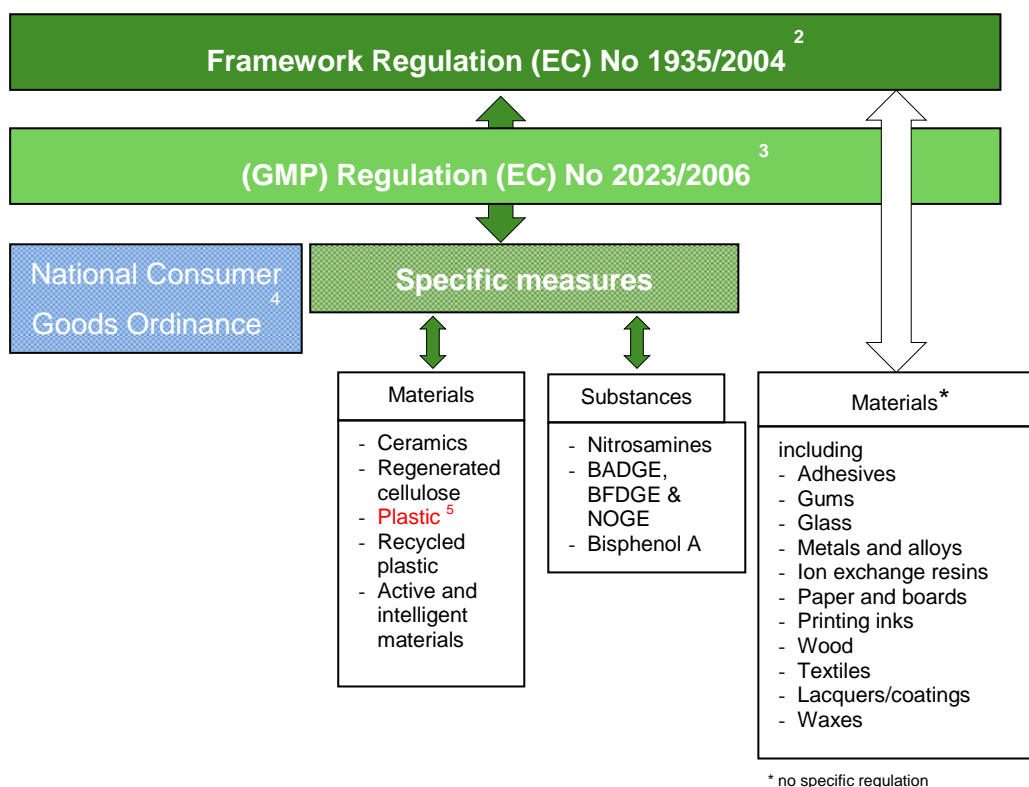
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<sup>1</sup> German Food and Feed Law (LFGB)

<sup>2</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC [Official Journal of the European Union L 338/4 of 13.11.2004] (see also [Anwendung der Verordnung \(EG\) Nr. 1935/2004](#) (in the German language) at the BLL website)

<sup>3</sup> Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food [Official Journal of the European Union L 384/75 ff. of 29.12.2006]

<sup>4</sup> German Consumer Goods Ordinance (last amended on 13 December 2011)



**Fig. 1: Regulatory approach for food contact materials**

The main focus of the following discussion and interpretation are the requirements for specific measures in the field of plastic materials. Already existing requirements in European and national legislation for ceramic, regenerated cellulose and epoxy derivatives are supplementarily raised (see sections 4 and 5).

**The new Commission Regulation (EU) 10/2011 on plastic materials and articles:**

Since 1 May 2011, the new **Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food**<sup>5</sup>, whose abbreviation **PIM** results from the former working title “Plastics Implementation Measure”, applies to all plastic food contact materials and articles. This EU-Regulation is a specific measure within the meaning of Framework Regulation (EC) No 1935/2004; among others, it replaces Plastic Directive 2002/72/EC and also includes raw materials in its scope. The regulatory approach for plastic materials and their specifications (restrictions and overall migration limits) has not changed. Predominantly, the rules for migration tests have been revised as to their structure and updated; in particular with regard to the use and assignment of food simulants and test conditions.

Chapter IV, **Articles 15 and 16** of the EU Plastic Regulation deal with the declaration of compliance and documentation; the new wording states that *“at all marketing stages other than the retail stage, a written declaration (...) shall be made available (...)”*. This also applies to intermediate products and raw materials.

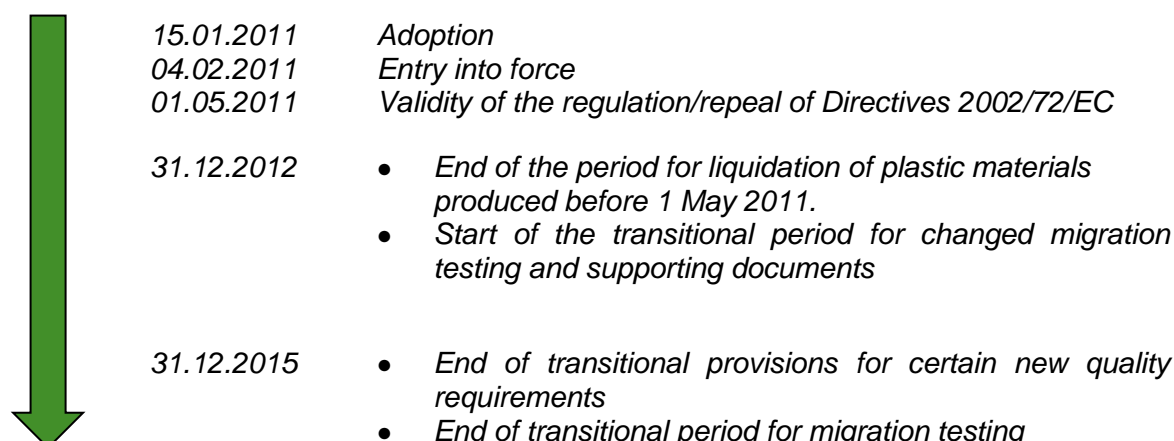
<sup>5</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food [Official Journal of the European Union L 278/13 of 25.10.2011]

The declaration shall be issued by the business operator and shall contain **the information laid down in Annex IV of the Regulation**. The business operator shall make available to the national competent authorities upon request appropriate documentation (supporting documents) (see 3.1.7) that demonstrates compliance (“*conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance*”).

The wording of Article 15 and 16 and Annex IV are included in the Annex of this information leaflet.

### Transitional provisions of Regulation (EU) No 10/2011:

The rules on the change-over to the new regulation are phased in over time and cover a period from 2012 to 2015. The application of the rules for migration testing shall be adjusted until the end of 2015. During the transitional period, the supporting documents required for the declaration of compliance may be based on the basic rules set out in the Annex to Directive 82/711/EEG<sup>6</sup> in combination with Council Directive 85/572/EEC<sup>7</sup> or on the new rules for migration testing set out in Article 18 of Regulation (EU) 10/2011.



**Fig. 2: Transitional provisions of Regulation (EU) No 10/2011**

As long as no material modification for a plastic food contact material has to be taken into consideration and if no modification of the migration testing is required as a consequence of Regulation (EC) No. 10/2011, at least an editorial adjustment of the declaration of compliance will be necessary; the respective transitional period for this is until the end of 2015.

<sup>6</sup> Council Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (82/711/EEC) [Official Journal of the European Union L 297/26 of 23.10.1982]

<sup>7</sup> Council Directive of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (85/572/EEC) [Official Journal of the European Union L 372 of 31.12.1985]

### Guidance Document of the European Commission in the pipeline:

Currently, the European Commission together with experts from the Member States and industrial associations is preparing a comprehensive "Guidance Document"<sup>8</sup> on the implementation of Regulation (EU) No 10/2011 which will also explain the importance of declarations of compliance in the plastic supply chain, their contents, procedures and the tasks of all parties concerned (as of July 2012).

Upon publication of this EU Guidance Document, this BLL information leaflet will be revised and modified, if needed.

Added to that, European industrial associations have published related explanations<sup>9</sup>.

### Priority of the EU Regulation and amendment of the national Consumer Goods Ordinance:

The adoption of an overriding EU Regulation in combination with the repeal of EU Directives requires a harmonization of the currently applicable national Consumer Goods Ordinance as regards plastic related rules. Contents based on Directive 2007/19/EC have to be adjusted in favor of the EU Regulation; this affects among others the materials lists in Annex 3 and the rules of Article 10 (1) in combination with Annex 12 regarding the declaration of compliance.

The time of adjustment is still open (as of July 2012); in case of duplication of rules, the national regulations are subordinate to European Regulations and thus irrelevant.

Following the adjustment of the national Consumer Goods Ordinance, the rules for the declarations of compliance for plastic materials will be laid down exclusively in the European legislation and thus will be identically applicable within the entire European Union.

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<sup>8</sup> Draft Commission service working document in preparation of Union Guidelines on Regulation (EU) No 10/2011 (SANCO/E6/AS, EMB/1143) of 30.05.2012

<sup>9</sup> PlasticEurope and Food Contact Additives (FCA): "Explanatory views on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food"  
[http://www.plasticseurope.org/foodcontact\\_pim\\_explanatory\\_document\\_7\\_12\\_2011.pdf](http://www.plasticseurope.org/foodcontact_pim_explanatory_document_7_12_2011.pdf)

### 3. Declarations of compliance for plastic food contact materials

#### 3.1 Frequently asked questions

- 3.1.1 What are plastic food contact materials?
- 3.1.2 What is the purpose of a declaration of compliance?
- 3.1.3 Are declarations of compliance needed for the raw materials and intermediate products used in the production of plastic materials?
- 3.1.4 Are declarations of compliance requested for printing inks, lacquers and adhesives used in the final manufacturing process of food contact materials and articles?
- 3.1.5 What are plastic food contact materials?
- 3.1.6 Must the food packaging company pass on the declaration of compliance?
- 3.1.7 What is the difference between supporting documents and a declaration of compliance
- 3.1.8 What are GMP and “compliance work”?
- 3.1.9 What are suitable ways of communication?
- 3.1.10 What obligatory tests and due diligence have to be fulfilled by the downstream user?
- 3.1.11 What are the test conditions based on?

#### 3.1.1 What are plastic food contact materials?

**Plastic food contact materials** are

- materials and articles as well as parts thereof made exclusively from plastic;
- plastic multi-layer materials and articles held together by adhesives or by other means;
- that are printed and/or covered by a coating;
- this includes
  - plastic layers or plastic coatings forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
  - plastic layers in multi-material multi-layer materials and articles intended to come into contact with food; or already in contact with food; or which can reasonably be expected to come into contact with food.

- **Plastic** means

*polymer (= macromolecular substance obtained by a polymerization process, chemical modification of natural or synthetic macromolecules or microbial fermentation) to which additives or other organic substances may have been added, which is capable of functioning as a main structural component of final materials and articles.*

The following are **not** considered to be plastic:

- Ion exchange resins
- Rubber
- Silicones

*“Printing inks, adhesives and coatings to be used in plastic materials are not treated as plastic; they may contain other substances that are approved under the Regulation.*

**A functional barrier made from plastic is**

*a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with the provisions of the Plastic Regulation (EU) No 10/2011 and with Article 3 of Regulation (EC) No 1935/2004.*

[according to Articles 1, 2, and 3 of Regulation (EU) No 10/2011

**EXAMPLES:  
Plastic food contact materials**

- Materials intended to be used for food packaging;
- Plastic films, multi-layer films and film bags, composite films;
- Primary packaging coming into contact with the food products such as PET bottles, cups, plastic closures of packages as long as there is a contact with the food;
- Plastic bags as long as they are intended to come into contact with unpacked food products;
- Parts of food processing machines and equipment coming into contact with food;
- Containers, pipelines, water hoses, mobile water supply units, if made from plastic material;
- Gloves used in direct contact with food products;
- Household films;
- Plates and dishes, cutlery, any type of kitchen tools and utensils, storage boxes, parts of kitchen equipment coming into contact with food made from plastic material;
- Disposable plates, dishes and cutlery made from plastic material;
- Plastic surfaces, for example of tables and counters, which come into direct contact with food products;
- Non-edible wrappings (based on plastics);
- Sealing compounds and gaskets in closures made from metal or other materials (e.g. vacuum lids for glasses, crown caps, screw caps for bottles);
- Elastomers (e.g. gaskets).



**EXAMPLES:**

**Articles made from plastic that are not food contact materials and articles by definition**

- Secondary packaging, e.g. films that have **no** contact with the food;
- Labels and closures made of plastics, that have **no** contact with the food as long as used as intended;
- Bags and pouches made of plastic that have **no** contact with the food as long as used as intended;
- Crates, boxes, transport pallets made of plastics, that have **no** contact with the food as long as used as intended;
- Parts of processing lines and machines that have **no** contact with the food;
- Stationary water supply plants and pipelines according to the Drinking Water Ordinance.

If using plastic articles as part of food packaging or packaging systems, they are food contact materials if they are intended to or it is foreseeable that they will come into contact with the packed food.

Components of packaging which do not have any or any foreseeable contact with food if used as intended (e.g. labels to be applied on the outside, secondary packaging) are not per se food contact materials within the meaning of the regulations.

However, because such components can be essential for the overall functionality of the packaging or packaging system and their character or action may affect the filled food product, the principles of Article 3 of the Regulation (EC) 1935/2004 apply to the packaging system in total. The barrier properties of the entire system or of individual components are decisive for the analysis of a possible migration of substances.

### 3.1.2 What is the purpose of a declaration of compliance?

The declaration of compliance shall – according to the European legislators – prove to the downstream user of a specific material within the supply chain and to competent authorities that the relevant regulations have been complied with. According to the recitals, this shall *“strengthen the coordination and responsibility of the suppliers at each stage of manufacture, including that of the starting substances”*.

Nevertheless it is set out that, according to the general food law principles, the food business operators are required to verify that foods are compliant with the rules applicable to them.

To this end, however, and *“subject to the requirement of confidentiality, food business operators should be given access to the relevant information to enable them to ensure that the migration from the materials and articles to food complies with the specifications and restrictions laid down in food legislation”* (cf recital 31 of the Regulation (EU) No 10/2011).

This means that the declaration of compliance is predominantly a tool for customer information and quality assurance.

The declaration of compliance is attached to the material or article after its production or at the time of importation either as a paper document or as part of the shipping documents or by electronic means. It shall allow an easy identification and assignment.



According to the legal requirements, it “*shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available*”.

**Purpose of the declaration of compliance:**

- Corresponds to the principle of responsibility of each stage
- Supports the flow of information along the chain
- Helps to identify material
- Basis for specific assessment of suitability
- Basis for concluding assessment of compliance

**Target groups:**

- Customers, i.e. users and processors
- Surveillance authorities (upon request)

**Contents:**

- Confirmation of compliance with regulations relating to food
- Information on suitability with important specifications on possible use
- General information on compliance testing performed

**Point in time when information is needed:**

- When the material shall be used, e.g. in the packaging process

**Fig. 3: Declaration of compliance for plastic materials**

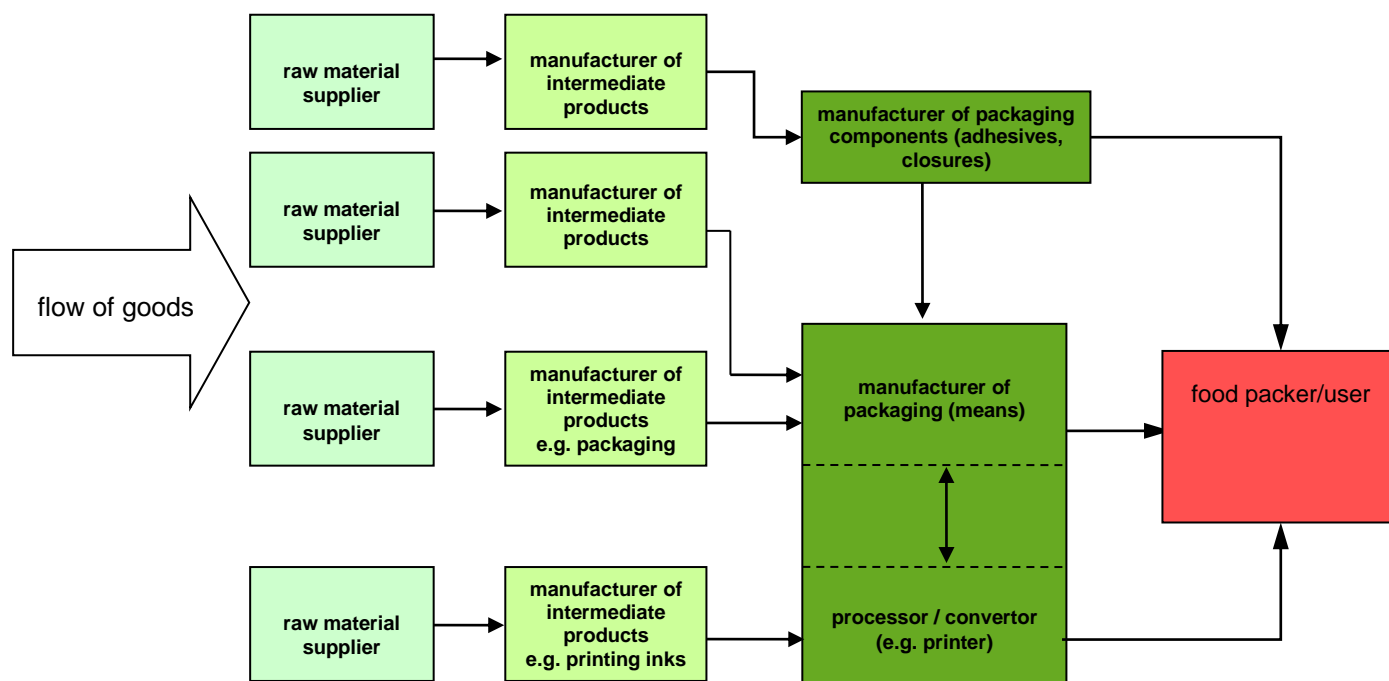
A declaration of compliance is not a product specification. The latter can be used as a supplement within the supply chain and contain further information on the product or on the division of tasks for the conformity assessment. The specification is predominantly a part of the customer-supplier relationship; it is not intended for third parties or competent authorities but could be provided in exceptional cases.

The individual elements included at minimum in a declaration of compliance are explained in detail in section 3.2.

**3.1.3 Are declarations of compliance needed for the raw materials and intermediate products used in the production of plastic materials?**

In general, plastic material is made from preliminary products (e.g. compounds and granules, additives, colorants) which are made from different raw materials. According to the wording in Article 15 of the Regulation (EC) 10/2011, in the future the obligation to issue a declaration of compliance applies also to the production and procurement of preliminary products within the meaning of Annex IV (“*products from intermediate stages*” as well as “*substances intended for the manufacturing*”).

The intended objective is that the manufacturer of a plastic food contact material needs relevant information from his suppliers in order to be able to issue a factually and legally conforming declaration of compliance as well for the internal documentation within the scope of the so called “supporting documents”. This applies in particular to the use of substances with restrictions (e. g. substances with specific migration (SML) or compositional (QM) limits) and to the approval and suitability situation of individual additives and components.



**Fig. 4: Supply chain for food packaging**

The changed scope of the new Plastic Regulation brings about complex practical problems, in particular regarding the required declarations within the supply chain.

The tasks and obligations to provide information concern various stages, i.e. the manufacture and processing of plastic materials in different companies, e.g.:

- Producer/supplier of raw materials
- Producer of starting products
- Manufacturer of (final) products/processor/convertor
- User of the product/packer of food products.

Depending on the individual stage, the substances and materials differ; therefore, the contents of the declarations of compliance are also different. Issuers at the beginning of the supply chain have only a limited way of testing and can confirm just certain conformity relevant aspects. Process-related material changes and reactions or reaction products have to be considered as well. Therefore, declarations of compliance cannot necessarily and completely comply with the stipulation in Annex IV of the Regulation (EU) No 10/2011 and its general requirements.

For the stage making the entry to comply with its co-responsibility, at least information on the identity of the respective material and the use of SML substances and "dual use substances" must be provided. Providing additional information on the active use of other potentially migratable substances which may affect the total migration (overall migration limit) for the food contact materials, would be beneficial.

Furthermore, all criteria affecting the determination of conditions of use and which are relevant for the declaration of compliance of the last stage of the supply chain are also important.

Information on performed or omitted tests may be relevant for the downstream stages to determine the scope of own testing needed for their compliance (principle of reference).

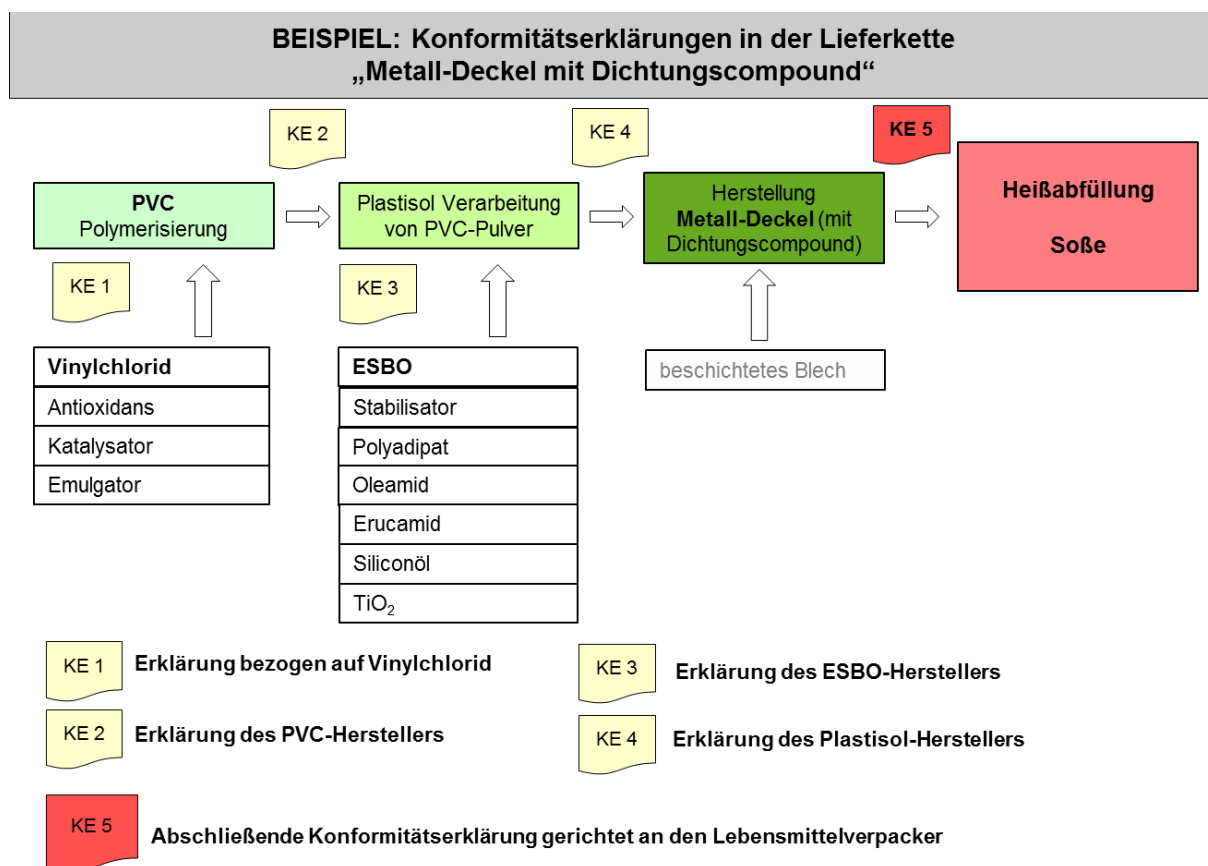
Food law relevant conformity testing used to verify the compliance with specific restrictions or otherwise overall migration limits can be done for the final food contact materials only or these can be simulated referring to predefined conditions of use and the intended good to be filled.

This principle of shared responsibility can be seen in conjunction with the request for adherence to and documentation of conformity-relevant quality assurance work at all stages of the supply chain (cf 3.1.8 “GMP” and “compliance work”).

The following EXAMPLE (Figure 5 Declaration of compliance within the supply chain “metal lid with sealing compound”<sup>10</sup>) is for illustration purposes only; it is not a template suitable for practical application.

Detailed suggestions for implementation may possibly be provided by the expected Guidance Document of the European Commission which will be incorporated here in due time.

<sup>10</sup> The example is an excerpt and is based on the article (in the German language only): “Gute Herstellungspraxis (GMP) und Konformitätserklärung für Lebensmittelbedarfsgegenstände: Konkretisierung der Anforderungen“, Altkofer, W., Brauer, B., Grob, K., Haffke, H. and Helling, R. (Journal of Consumer Protection and Food Safety, volume 5, issue 1 (2010) p.111ff.



- Essential information provided with the declaration of compliance for each stage:**
- information on identity of issuer, manufacturer or importer
  - validity information (date and signature)
  - identity of the material
  
  - information on use for the production of food contact materials
  
  - information on later compliance tests
    - detailed information on the use of substances subject to restrictions (in particular SML substances) and on relevant regulations
    - information on dual use substances including amounts
    - information on relevant reaction or by products
  
  - information on processes resulting in material changes (potential reactions)
  
  - information on tests performed including test results and methods

**Fig. 5: EXAMPLE declaration of compliance within the supply chain  
“Metal lid with sealing compound”**

### 3.1.4 Are declarations of compliance requested for printing inks, lacquers and adhesives used in the final manufacturing process of food contact materials and articles?

Coatings, printing inks and adhesives are not yet covered by specific EU legislation and therefore not subject to the requirement of a declaration of compliance. This means that the obligation to issue a declaration of compliance according to Annex IV of the Regulation (EU) No 10/2011 does not apply when placing such products for the production of plastic food contact materials on the market.

However, for coatings, printing inks and adhesives to be used in plastic materials and articles, adequate information should be provided to the manufacturer of the final plastic article that enables him to ensure compliance for substances for which migration limits have been established in the regulation (cf recital 30 of the Regulation (EU) No 10/2011).

The producer of a final food contact material can conduct the required tests and issue a comprehensive declaration of compliance, which is in line with legal requirements, only based on relevant and useful information. It is strongly recommended here that relevant information is provided for products such as printing inks, lacquers and adhesives along the supply chain. However, it must be taken into consideration that these products are generally formulated from several (raw) materials and may be complex systems for which the information relevant to their composition may be retrieved from the supply chain.

These recommendations apply to substances/products from the range of printing inks, lacquers and adhesives which, provided they are used as intended, become part of the food contact material but do not come into contact with the food; their intended use is on the side that is not facing the food product.

If this is not the case and if a direct food contact is given or foreseeable, then the requirements of Article 3 of the Regulation (EU) No 10/2011 including possibly applicable specific measures and corresponding declarations of compliance apply in full (cf section on lacquers).

In supporting the relevant suppliers, European and national industry associations have recommended model declarations which are referred to in the following.

Further information on coordination and information acquisition is available in the BLL Information leaflet "Specifications in the food packaging chain"<sup>11</sup>.

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<sup>11</sup> BLL information leaflet "Specification in the food packaging chain" (12/2010)  
<http://www.bll.de/themen/bedarfsgegenstaende/>

## Printing inks

The European Printing Inks Association (EuPIA) has compiled a model declaration regarding the composition of printing ink. The association recommends the following:

<b>Advice regarding the “information on the composition of printing inks and printing lacquers used in the production of food packaging materials”</b>
<ol style="list-style-type: none"> <li>1. Name and address of the manufacturer;</li> <li>2. Date of issue;</li> <li>3. Name/product code;</li> <li>4. Confirmation on the compliance with EuPIA guidelines<sup>12</sup> and EuPIA GMP;</li> <li>5. Confirmation that the intended use “food packaging” was taken into consideration during the formulation of the inks;</li> <li>6. Information on the substances used that are subject to restrictions according to Regulation (EU) No 10/2011;</li> <li>7. Information on known substances with potential migration properties;</li> <li>8. Information on dual use additives contained.</li> </ol>

It should be noted that the confirmation of the manufacturer about the compliance with EuPIA Guidelines refers to the composition of the printing inks. This is not the same as the confirmation that the stipulations of Article 3 of the Regulation (EU) No 1935/2004 on the prevention of transfer of constituents are being complied with. This compliance has to be verified individually – in consultation between the producer and the user.

## Coatings/lacquers

However, if products are used as coatings or lacquers for the production of plastic food contact materials and are not intended or foreseeable for direct food contact, the general remarks on the communication of information applies (see above).

For an intended food contact of coatings/lacquers, the stipulations of Framework Regulation (EU) No 1935/2004 and the specification of Regulation (EC) No 1895/2005 regarding the use of epoxy derivatives<sup>13</sup> apply. Apart from these there is no other relevant legislation.

The European Association CEPE (European Council of the Paint, Printing Inks and Artists' Colors Industry) in its Codes of Practice provides comprehensive recommendations on the properties of coatings/lacquers intended to come into contact with food and on the drafting of declarations of compliance with regard to the Framework Regulation<sup>14</sup>.

<sup>12</sup> Source: [www.eupia.org](http://www.eupia.org)

<sup>13</sup> Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food [Official Journal of the European Union Nr. L 302 of 19.11.2005]

<sup>14</sup> Code of Practice for Coated Articles where the Food Contact Layer is a Coating (several enclosures); Coated Articles Where the Food Contact Layer is a Coating - declaration of compliance (June 2009) Source: [www.cepe.org](http://www.cepe.org)

These CoPs can also be the basis for the provision of information within the supply chain when using coatings/lacquers in the production of plastic food contact materials.

Advice regarding the “information on the composition of coatings/lacquers used in the production of food packaging materials”
<ol style="list-style-type: none"> <li>1. Name and address of the manufacturer;</li> <li>2. Date of issue;</li> <li>3. Name/product code;</li> <li>4. Confirmation that the relevant rulebooks will be complied with:</li> <li>5. - CEPE-Code of Practice<sup>14</sup></li> <li>6. - Regulation (EC) No 1895/2005;</li> <li>7. Confirmation that the intended use “food packaging” was taken into consideration;</li> <li>8. Information on the substances used that are subject to restrictions according to Regulation (EU) No 10/2011 (SML substances);</li> <li>9. Information on known substances with potential migration properties;</li> <li>10. Information on dual use additives contained.</li> </ol>

### Adhesives

The German Association for Plastic Packaging and Films has compiled an information leaflet on the issue “Legal status of adhesives/raw materials for use with food<sup>15</sup>”. The information will enable the manufacturers of the finished food contact materials or articles to meet their obligation of issuing a declaration of compliance.

Information leaflet “Food contact status of adhesives/raw materials used in the production of food packaging”
<ol style="list-style-type: none"> <li>1. Name and address of the manufacturer;</li> <li>2. Date of issue;</li> <li>3. Name of the adhesive;</li> <li>4. Information on the substances used that are subject to restrictions according to Regulation (EU) No 10/2011 and/or according to relevant national regulations;</li> <li>5. If needed, verification of the harmlessness of the product when used with food provided by a specialist laboratory or institute.</li> </ol>

### 3.1.5 Who issues and who receives the declarations of compliance within the chain?

The new Regulation (EU) No 10/2011 did not change the requirements for composing a declaration of compliance significantly but specified in detail the group of issuers and recipients. Included now are “*substances intended for the manufacturing*” and “*products from intermediate stages*”.

As a basic principle, the business operator who places the product on the market is legally required to issue and pass on a declaration of compliance. In general, this will be the **manufacturer** of a raw material, intermediate product or a finished plastic food contact material, e.g. the producer of a plastic film sold to a food producer as packaging material. A business operator is also the importer importing respective materials from third countries (see below).

<sup>15</sup> Source: [www.klebstoffe.com](http://www.klebstoffe.com)



In practice these procedures are rather complex, in particular due to the integration of producers of raw materials and intermediate products. The different stages of the food supply chain have already been shown exemplarily (see Figure 6). However, there are even more stages e.g. if the food contact material or article is further processed or printed after the actual production process.

In these cases, the declaration of compliance must be issued by the manufacturer of the food contact material or article as the first one placing the product on the market. If in the downstream process (e.g. printer) the food contact material or article is modified and again placed on the market, the downstream operators must issue their own declarations of compliance based on the manufacturer's declaration. If the printer and possible other downstream processors are acting on behalf of the manufacturer, the latter one remains responsible for issuing a declaration of compliance for the finished food contact material or article as he is responsible for placing the product on the market (see Figure 6).

In case of **imports** of food contact materials and articles, the importer is deemed to be equal to the manufacturer; he is the first one placing the product on the market and with that responsible for the declaration of compliance. A food producer or retailer has the same obligation as an importer if he imports plastic food contact materials and articles that are subject to obligatory declarations of compliance.

There are also situations when a **food manufacturer** himself produces the food contact materials or articles to be used as packaging entirely or in parts immediately before or during the packaging process (e.g. deep-drawing of plastic cups from film, blowing of PET bottles). In this case it is required that the food manufacturer as a producer of the food contact material or article generates the required information on suitability and legality needed for the declaration of compliance and that he has the relevant supporting documents at his disposal (cf 3.1.7).

## Retail

Special situations may arise for businesses from the food retail trade<sup>16</sup> selling plastic food contact materials e.g. household or cooking utensils, disposable dinnerware or household films. According to the wording in Regulation (EU) No 10/2011, no declarations of compliance need to be made available at the retail stage.

The purpose of the regulation is to pass on necessary information along the supply chain. The information of the (final) consumer is not done via declaration of compliance but rather via special labeling elements that have to be applied to certain food contact materials and articles ("*symbol glass-fork*", "*for food contact*") and which indicate legality, compliance and suitability to the final consumer.

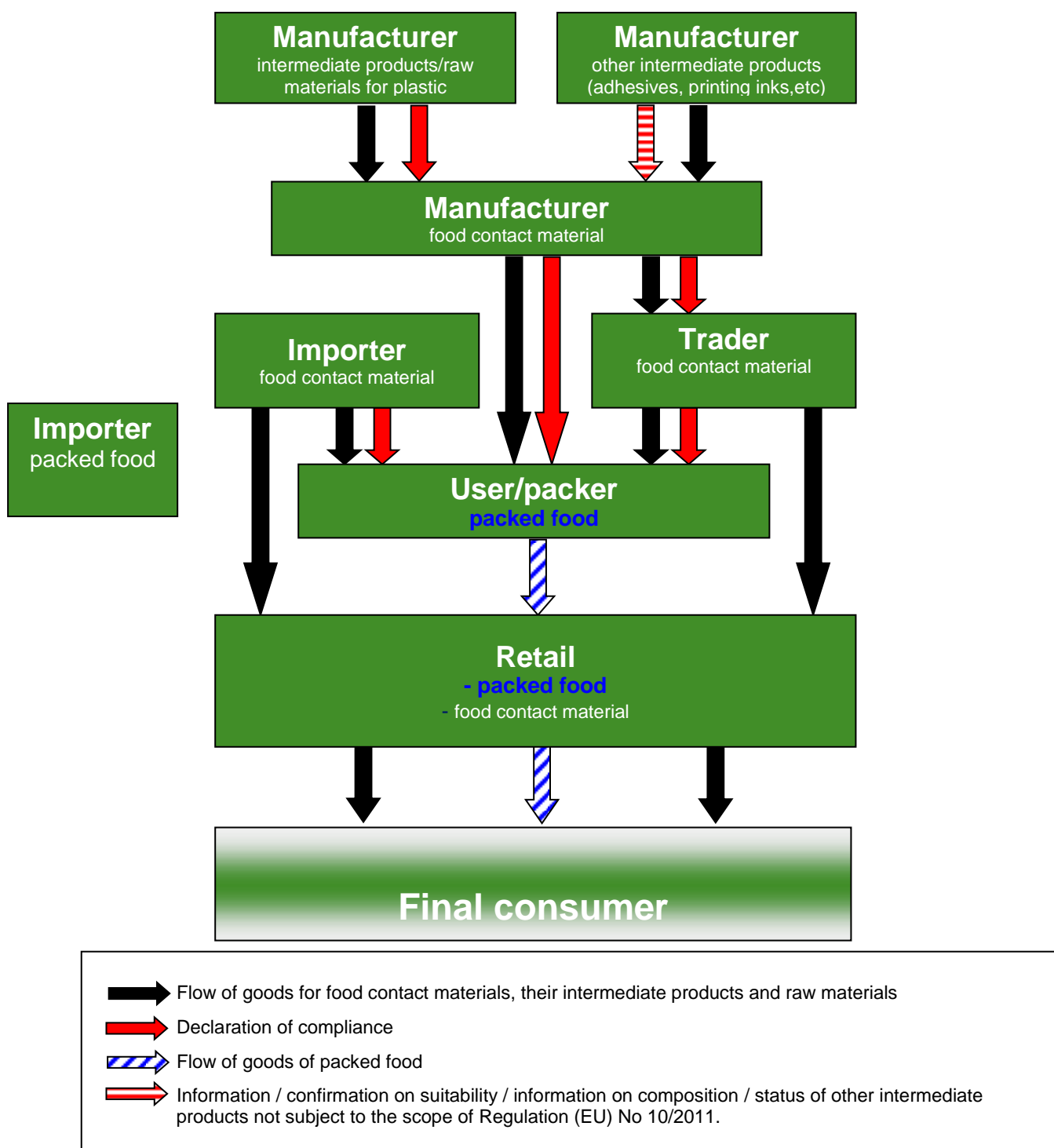
If a manufacturer supplies the relevant products to the retail business without intermediary trade stages, then he is the first one who places the product on the market and he has to issue a declaration of compliance for the retailer. If food contact materials and articles with compulsory declaration of compliance are traded via several stages, they have to be accompanied by the declaration of compliance until they reach the retail level (also distributors, wholesalers).

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<sup>16</sup> Definition: "retail" means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centers and wholesale outlets [Regulation (EC) No 178/2002 Art. 3 (7)]

There are situations in practice where commercial users of food contact materials and articles buy their products from retailers and then use them in activities that sometimes require information from the declaration of compliance, e.g. if a food producing company procures packaging materials for food products in cash and carry markets. Consequently, these users are dependent on receiving a specific declaration of compliance from the retail business. It might be appropriate to pass on the declaration to the user via the internet.

For certain activities, a retail business may be deemed to be equal to the importer or manufacturer regarding the obligation of issuing a declaration of compliance (e.g. direct import from third countries). Added to that, a retail business may be considered to be equal to a food packaging company for comparable activities (e. g. production of private label products, final packaging or pre-packaging of sales packs). In this case the retail business must take the declaration of compliance into consideration in the procurement and use of plastic packaging materials.



**Fig. 6: Issuers and recipients along the chain**

### 3.1.6 Must the food packaging company pass on the declaration of compliance?

For the food manufacturer who procures and uses a plastic food contact material or article e.g. as packaging material or part of a package, the declaration of compliance is a document and basic information which must be provided by the manufacturer of the packaging material or the first one who places the packaging material on the market along with the product.

The question on whether the declaration of compliance needs to accompany packaging materials “in use”, e.g. packed food, along the next distribution stages has not been clearly specified by the legislator.

With the new wording in Regulation (EU) No 10/2011 it becomes clearer that the availability of declarations of compliances at the marketing stages of the retail trade are not required (cf Article 15 of Regulation (EU) No 10/2011: “*At the marketing stages other than at the retail stage...*”).

This corresponds to the purpose of the concept according to which the declaration of compliance is a “customer information”; the essential information is relevant prior to use, e.g. before the packaging process, and shall serve the packer as a basis for decision-making. The information is not relevant for the consumer.

If a packaging material is used as intended and thus the final product, e.g. a packed food product is passed along the chain, it is neither required for compliance with the regulation nor useful when the declaration of compliance is also passed along with the packed product.

This applies to the transfer of a packed food product not only to other processors but also to the different marketing stages (wholesaler/retailers). In case of **importing packed food** from non-EU states, no declaration of compliance is required for the retail stage.

However, for imported goods the declaration of compliance must be available at the time of packing – in the third country – and also known to the importer.

### 3.1.7 What is the difference between supporting documents and a declaration of compliance

For the passing on of declarations of compliance, a distinction is made between the document “*declaration of compliance*” according to Article 15 in conjunction with Annex IV of the Regulation (EU) No 10/2011 and “*supporting documents*” within the meaning of Article 16. Later ones are described as “*appropriate documentation*” to demonstrate the compliance to the competent authorities on request.

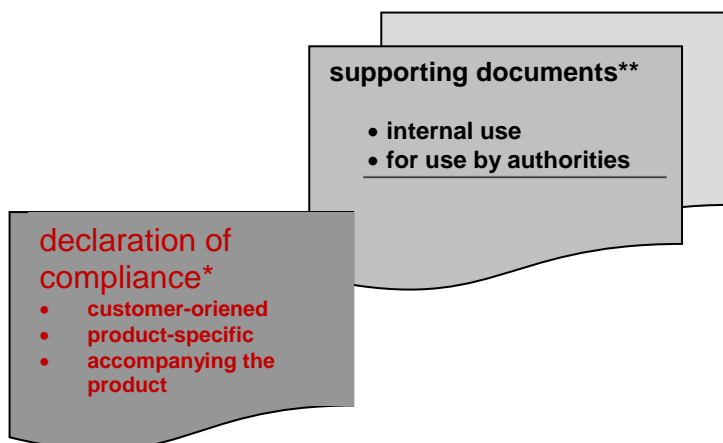
The documentation may include results of testing, calculations, and other evidence demonstrating compliance. Rules for testing to demonstrate compliance are also set out in Regulation (EU) No 10/2011.

Other than the declaration of compliance, the supporting documents will remain with the manufacturer and are not part of the declaration of compliance that has to be passed on. Their purpose is solely to substantiate the manufacturer’s compliance and to document legal compliance to competent authorities upon request.

Even though the external inspection of these specific documents (supporting documents and GMP documentation) is limited to competent authorities according to the regulations, it might be advisable under individual circumstances to provide access to such documents to customers at their request and to agree on a bilateral basis on the passing on of certain parts of the documentation under consideration of possible non-disclosure agreements with pre-suppliers and appropriate protection of proprietary knowledge.

**EXAMPLES:  
Supporting documents**

- Information about up-stream processing stages/pre-suppliers (“certificate of suitability”);
- Recipes/process data/GMP documentation;
- Test results/including third party test results;
- Calculations;
- Certificates from third parties;
- Analysis reports from third parties;
- Risk assessments;
- Worst case scenarios.



\* according to Art. 15 in conjunction with Annex IV of Regulation (EU) No 10/2011

\*\* according to Art. 16 of Regulation (EU) No 10/2011

**Fig. 7: Declaration of compliance and supporting documents**

### 3.1.8 What are GMP and “compliance work”?

For the production of food contact materials and articles, in principle the obligations from the so called **GMP Regulation (EC) No 2023/2006**<sup>17</sup> apply. This regulation refers to the stipulation of Article 3 of Regulation (EC) No 1935/2004 according to which food contact materials shall be manufactured in compliance with good manufacturing practice (GMP). It applies to the production of any food contact materials, i.e. for all types regardless of the specific legal description of requirements and also includes recycled materials.

In the GMP Regulation the rules for good manufacturing practice are specified and defined as *“those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use (...)”* (cf Article 3a of the GMP Regulation).

The GMP Regulation has to be applied to the manufacture of the groups of materials and articles listed in Annex I of Regulation (EC) No 1935/2004 (cf Figure 1), irrespective of whether they are manufactured in compliance with general or detailed rules, as well as for combinations of those materials and articles or recycled materials and articles.

Furthermore, it applies to all manufacturing, processing and distribution stages.

<sup>17</sup> Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food [Official Journal of the European Union L 384/75 of 29.12.2006]

### GMP rules as defined in Regulation (EC) No 2023/2006

- effective **quality assurance system** (Article 5)
  - personnel, material and organization
  - compliant, specified starting materials
  - system of instructions and procedures
- ⇒ **with due regard to proportionality!**
- 
- effective **quality control system** (Article 6)
  - monitoring of implementation of GMP
  - corrective and improvement measures
- appropriate **documentation** (Article 7)
  - with respect to specifications and manufacturing formulae
  - with respect to processing and various manufacturing operations
  - to be made available to competent authorities
- ⇒ **which are relevant to compliance!**

**Fig. 8: GMP rules for food contact materials**

In the meantime, the term “compliance work” has been introduced for relevant tasks within the businesses that aim at establishing an organizational basis for the verification of compliant processes and products as well as at ensuring and confirming compliance. In the ideal case, this shall support the downstream stages in exercising their responsibility with respect to the food law and shall also release them from certain tasks.

In the field of plastic materials, it is indisputable that a declaration of compliance has to be based on in-house GMP or QC documentation.

### “Compliance work” in the field of food contact materials

#### Principle:

- Co-responsibility of all stages participating in the manufacture of a compliant final product
- Stage-related partial product assessment(s) with regard to the specific use/application of the final product
- Optimization of test performance of all compliance-related aspects, in particular
  - potentially migrating substances
  - adherence to migration limits

#### Requirements:

- interactive flow of information along the supply chain
- agreement on how to conduct certain tests
- documentation and consolidation of results (certificates/declarations)

#### Objective:

- to enable the person responsible for food compliance to come to a final conclusion regarding the complete products (packed food) and to assume responsibility.

**Fig. 9: “Compliance work” in the field of food contact materials**



### 3.1.9 What are suitable ways of communication?

According to the wording of the Regulation (EC) No 1935/2004, “written” declarations of compliance are required (cf Art. 16). Subject to individual agreements, paper or electronic documents are considered to be the most common means of documentation. With regard to legally binding signatures, bilateral agreements shall be entered, if necessary. According to the regulation, no signature is required to confirm the declaration of compliance.

It is not explicitly requested that the declaration is passed on physically or shall be an immediate part of deliveries or even each delivery. This means that the declaration of compliance can be communicated through alternative channels, for example electronically.

Added to that, if the same recipient is supplied repeatedly with an unmodified product, a declaration of compliance is not required to be sent along with the food contact material or article each time. It is possible to deposit valid declarations of compliance with the recipient which have to be replaced only if the need arises. It is important that the recipient and the competent authorities are enabled to assign the declaration to the respective products beyond any doubt.

The regulation does not provide for an expiration date of the declaration of conformity. The declaration has to be renewed if the circumstances change, i.e. in the case of significant process modifications with effects on migration or amendments of the regulations or if new scientific findings are available. In practice, these instructions by the legislator regarding the control of documents can be implemented by respective document and material numbers and a validity statement, if necessary.

Since the Plastic Regulation (EU) No 10/2011 takes effect step-by-step, it may become necessary to issue a new declaration in due time if the material composition and type of migration testing have changed. If the composition of a certain product has not changed, a new declaration has only to be issued for editorial purposes at latest at the end of the transition period (31 Dec 2015) (cf section 2).

For the bilateral manufacturer-supplier relationship, it is recommended that the validity of the declaration of compliance is limited (e.g. to two or three years) resulting in a frequent renewal of the document and possible validation of the information provided.

#### Language

Referring to Article 15, paragraph 1 (a) (b) of Regulation (EC) No 1935/2004 and independent of specific measures, Article 10, paragraph 4 of the national Consumer Goods Ordinance (as amended) generally requests that the declarations are *issued in the German language*. This goes beyond the European legislation which does not have comparable stipulations.

In practice, this stipulation is not always easy to fulfill because the use of the English language has been established in international trade relationships and market structures. However, at least the translation of key information is recommended. When presenting foreign language documents to authorities it is important that they understand the document, are able to review its contents and identify the material.

### 3.1.10 What obligatory tests and due diligence have to be fulfilled by the downstream user?

In principle, the declaration of compliance provided by the manufacturer of a food contact material or articles does not release the downstream user from the exercise of due diligence. If e.g. a packaging material for a food product is in question, the food manufacturer/packer who places the packed product on the market is responsible for the product and has to reassure himself about the legality of the actual application. He has to guarantee that the specific application complies with the relevant migration limits until the expiration of the best-before date and he has to verify this on a random basis, if necessary, or have it tested in agreement with the supplier. In case of other uses, the user must verify the suitability of this application. All information and all test results provided apply to the specified product under consideration of the stated conditions of use.

The declaration of compliance is founded on trust in the presumption of legality but it does not cover all imaginable applications. The downstream user has to take into consideration that the declaration of compliance is only binding for the characteristics assured in the document. The information provided by the manufacturer is in general based on tests with simulants and thus on simulated applications within the scope of the product's suitability range.

The manufacturer is liable for the respective information; a general exemption from liability (disclaimer) is not possible.

### 3.1.11 What are the test conditions based on?

Within the scope of the declaration of compliance, the issuing manufacturer must state which applications (e.g. goods to be packed, packaging technologies and food contact conditions (volume/time/temperature)) are covered by the declaration based on the tests performed. Furthermore, it should be stated that in the case of other uses, the user himself has to verify suitability (cf **enclosure EXAMPLES**).

Up to now the Directives 85/572/EEC and 82/711/EEC for testing migration could be used as a guideline for selecting appropriate test conditions; these have now been replaced by the description of migration testing in Regulation (EU) No 10/2011 Articles 17 and 18 and in Annexes III (*food simulants*) and V (*compliance testing*). The Guidance Documents currently compiled by the European Commission will possibly contain further information on test conditions.

Until 31 Dec 2012, the tests have to be performed according to Directives 82/711/EEC and 85/572/EEC. After that date, tests based on these Directives may still be performed within the transitional period; from 1 Jan 2016 Regulation (EU) No 10/2011 takes exclusive effect and the declaration of compliance has to be adapted accordingly.

### 3.2 Information requested within the scope of the declaration of compliance

In the following the individual statements are explained which are obligatory according to the wording of **Annex IV of Regulation (EU) No 10/2011** (cf [Enclosure](#)) and which describe the minimum requirements for a declaration of compliance.

*“1. Identity of the issuer of the declaration”*

*“2. Manufacturer or importer of the materials declared”*

Manufacturer (point 2) and issuer (point 1) are identical as long as the declaration is a manufacturer’s declaration; in certain situations e.g. when food contact materials are imported or traded by different companies, the issuer has to identify the manufacturer or importer.

*“3. Identity of the materials”*

The food contact material or article, products from intermediate stages or raw materials shall be described in as detailed a way as possible (e.g. printed/colored), including material or specification numbers if available.

*“4. Date of the declaration”*

*“5. Declaration of compliance”*

The stipulation in Annex IV refers directly to the relevant legal regulations (Plastic Regulation (EU) No 10/2011 and Framework Regulation (EC) No 1935/2004). The confirmation of compliance can be kept brief and should be supported by the confirmation of adherence to the overall migration limit (OML). If required, the confirmation can be supplemented for the national market with references made to Articles 30 and 32 LFGB (German Food and Feed Law).

*“6. Adequate information relative to the substances used or products of degradation thereof with restrictions and/or specifications”*

Only such substances (additives/monomers) contained in the material have to be stated that are subject to SML or QM restrictions. If the regulation specifies restrictions for degradation products this has to be indicated as well.

Substances without restrictions must not be stated. The objective is to provide sufficient information for the downstream user so that all limiting values can be met in all subsequent processing operations.

Information on the SML/QM values can be made in the declaration of compliance as follows:

- Option a) No substances subject to SML or QM are used.
- Option b) Substances subject to SML or QM are used and named; the compliance of the limits is confirmed for the stated types of food and conditions of use. These statements are based on the documentation of the issuer of the declaration of compliance (supporting documents).

The disclosure of the individual substances that are subject to restrictions is not mandatory within the scope of the declaration of compliance. As an alternative, in special situations it is possible to agree on the disclosure of the required information on individual substances to third parties (e.g. test laboratories) which then confirm the compliance of the limits for the respective application to the customer.

*“7. Information on dual use substances”*

Substances approved as additives for plastic materials and as food additives (so called dual use substances) have to be stated separately in the declaration of compliance because their use in food is limited by legislation.

The objective is to make it compulsory to give the downstream user the necessary information on expected substances with possible migration properties (*“experimental data or theoretical calculations about the level of their specific migration”*) so that food-related regulations are not infringed in specific situations. Information on which substances are considered to be dual use substances can be found, among others, in the relevant European regulations on food additives.

*“8. Specifications on the use”*

The statements can be rather comprehensive, in particular for packaging materials. The goal is to support the user in his assessment as to whether a specific food contact material or article is suitable to be used or not. For food packaging, the ideal case would be to specify the food to be packed and also to provide information on storage periods and storage conditions.

The declaration of compliance must contain information on the suitability of the material/article derived from the standardized groups of goods to be packed, in particular regarding

- ”a)            *Type(s) of food”, e.g.*
  - physical condition
  - pH
  - suitable or tested simulants
  
- ”b)            *Time and temperature of food contact”, e.g.*
  - information on microwaveability
  - suitability for sterilization
  - freezer-proof
  
- ”c)            *Ratio of contact surface area to volume on which the determination of compliance is based”*

The comparison of the specific conditions of use of a packaging material or food contact material or articles with the correlating test conditions ideally requires communication between manufacturer and user. In this situation, a packaging specification is the method of choice.

If the manufacturer of the packaging material knows the precise application requirements such as type of food, contact period and temperature, he can adjust the test conditions pursuant to the relevant regulations (cf section 3.1.11 test conditions).

Alternatively, the maximum application conditions as tested by the manufacturer can be stated: e.g. olive oil, longest possible contact time, contact surface, highest possible contact temperature at which the overall migration limit will not be exceeded. The user can take these conditions as a basis for his decision about the suitability of this packaging material for its intended use. For films used as 2-dimensional packaging, the tests are based on a surface-volume ratio of six (standard cube).

*“9. Multi-layer material or functional barrier”*

When a *functional barrier* is used, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of Regulation (EC) 10/2011 is required in the declaration of compliance.

The description above and the **sample of a standard of a declaration of compliance** (cf Figure 10 **SAMPLE**) comply with the legally required scope (minimum scope).

Additional information, specifications or agreements relating to the respective customer-supplier relationship can supplement the declaration of compliance. This applies in particular if a packaging material has been developed or procured for a specific application. In this case the parties shall agree on further disclosure and confirmation issues.

**Declaration of compliance  
for materials made from plastic intended to come into contact with food**

*Name and address of the issuer;*

*if different from above  
Name and complete postal address of the manufacturer or importer;*

*Date:*

Hereby we declare that the product.....

complies with the legal regulations laid down in the Regulation (EU) No 10/2011 as well as in Regulation (EC) No 1935/2004, both as amended.

When used as specified, the overall migration as well as the specific migration does not exceed the legal limits.

The tests will be performed

- until 31.12.2012: according to Directives 82/711/EEC and 85/572/EEC
- until 31.12.2015: according to Directives 82/711/EEC and 85/572/EEC or  
according to Art. 17 and 18 of Regulation (EU) No 10/2011 in conjunction with Annex V
- from 1.1.2016. according to Art. 17 and 18 of Regulation (EU) No 10/2011 in conjunction with Annex V

The materials and raw materials used comply with Regulation (EU) No 10/2011.

The following substances subject to restrictions and/or specification are used in the above mentioned product:

Name of substance	Restriction
.....	.....

Information on dual use substances, if used, and on specific migration.

**Specification of the intended use or restrictions:**

- Type(s) of food intended to come into contact with the material:  
.....
- Conditions of use including duration and temperature of treatment or storage while in contact with the food:  
.....
- Ratio of food contact surface area to volume used to determine the compliance of the material or article:  
.....

Information on a “functional barrier”, if relevant, and confirmation.

If a functional barrier made from plastic is used in the above mentioned product, we confirm the compliance with the special stipulations set out in Regulation (EU) No 10/2011.

**Fig. 10: Minimum requirements for a declaration of compliance/standard declaration/sample**

Optionally the inclusion of further clauses regarding validity, traceability as well as use and liability exemptions can be included (see **Enclosure EXAMPLES**).

## 4. Declaration for other food contact materials (except plastic)

### 4.1 Regenerated cellulose, ceramics and materials containing epoxy derivatives

According to Framework Regulation (EU) No 1935/2004, a written declaration on legal compliance is only provided for materials that are also subject to individual regulations. Plastic Regulation (EU) No 10/2011 is the most comprehensive specific measure; however, other materials groups such as regenerated cellulose film and ceramics are subject to separate EU regulations which also stipulate written declarations. These certificates and their contents are not comparable with the declarations according to the Plastic Regulation because they do not stipulate form and scope in detail.

Due to the implementation of the EU regulations, the stipulations are found in Article 10 of the national Consumer Goods Ordinance. The declarations for the different material groups (plastic, regenerated cellulose, ceramic) are separately described in detail; this is due to various community legislation. The wording of Article 10 of the Consumer Goods Ordinance can be found in the **Enclosure** to this information.

#### Regenerated cellulose

When placing food contact materials and articles made from regenerated cellulose film on the market, they must be accompanied by a (not further specified) certificate in the German language that contains a confirmation of compliance according to Regulation (EC) No 1935/2004.

The declaration must not be presented when placing the goods with the retail trade and for articles that are obviously intended to be used as food contact material or articles.

#### Ceramic

The same applies to food contact materials and articles made from ceramic which are not yet in contact with the food; when placed on the market, the products must be accompanied by a written declaration in the German language certifying their legal compliance. Additionally, the following information must be provided:

- Name and address of the manufacturer or importer;
- Identity of the food contact material or article made from ceramic;
- Date of issue of the declaration.

Furthermore, the manufacturer or importer must have available further documents (supporting documents) for this group of materials to prove the compliance with the specific regulations on ceramic materials and articles to the supervisory authorities. These documents must at least state *“the results of the analyses performed, the test conditions, as well as name and address of the laboratory performing the analyses”*.

The presentation of the declaration for articles made from ceramic to the retail trade is not clearly defined in the Consumer Goods Ordinance; a complete analogy to the rules for regenerated cellulose cannot be drawn with the reference to paragraph 1a (1). According to the wording in Directive 2005/31/EC amending Directive 84/500/EEC<sup>18</sup>, *“at the marketing stages up to and including the retail stage”* ceramic articles shall be accompanied by a written declaration, this means not necessarily when the product is placed on the retail market or when the retailers sells the product to the final customer.

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<sup>18</sup> Commission Directive 2005/31/EC of 29 April 2005 amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs [Official Journal of the European Union L 110/36 vom 30.4.2005]



### Epoxy derivatives

“At the marketing stages other than the retail stages”, food contact materials and articles, including coatings and lacquers, containing epoxy derivatives (BADGE, NOGE) shall be accompanied by a written declaration demonstrating legal compliance with the restrictions laid down in Regulation (EC) No 1895/2005<sup>19</sup>.

Appropriate documentation shall be available to demonstrate such compliance to the competent authorities on demand; the declarations are not further specified.

### 4.2 Active and intelligent materials

The group of “active and intelligent materials” and articles intended to come into contact with food are regulated in the separate Regulation (EC) No 450/2009<sup>20</sup>. “Active” materials are substances capable of interacting with the food; basically they are not subject to the migration prevention rule. As far as such materials are based on plastic, the rules for plastic materials are unaffectedly applicable; the stipulations for the declaration of compliance are for the most part congruent with Regulation (EU) No 10/2011; Annex II of Regulation (EC) No 450/2009 corresponds to the wording in Annex IV of the Plastic Regulation. Therefore, the explanations in section 3.2 of this information leaflet apply.

Notwithstanding the Plastic Regulation, “at the marketing stages other than at the point of sale to the final consumer, active and intelligent materials and articles, whether or not they are in contact with food” shall be accompanied by a written declaration of compliance.

### 4.3 Other, not specified materials

No specific regulations are in place for other groups of materials than those described; for these and their application, the general requirements regarding their characteristics according to Regulation (EC) No 1935/2004 apply. In each case and referring to the intended purpose, the business operator placing the product on the market, e.g. the food manufacturer or retailer, is responsible for proper compliance.

The manufacturer or supplier and customer within the supply chain may agree on a specification and formulate a general or specific "declaration" on a voluntary base.

In the field of **paper and cardboard packaging** it is common practice to refer to the recommendations provided by the Federal Institute of Risk Assessment. The specifications are available in the database as “BfR Recommendations on food contact materials: XXXVI. paper and board for food contact”<sup>21</sup>.

Even without a concrete agreement with customers, manufacturers may provide unilateral declarations on the suitability and legal compliance of food contact materials that are not subject to specific legislation; however, this is legally not required. Such procedure does not release the users from their due diligence and their verification of suitability for the intended use.

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<sup>19</sup> Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food [Official Journal of the European Union Nr. L 302 of 19.11.2005]

<sup>20</sup> Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food [Official Journal of the European Union L 135/3 of 30.5.2009]

<sup>21</sup> Source: <http://bfr.zadi.de/kse/faces/DBEmpfehlung.jsp>

#### 4.4 Voluntary information and declaration

Voluntary standards aimed at food businesses such as the International Food Standard (currently IFS 6) exceed the relevant legal regulations regarding the demonstration of legality of the food contact materials used.

IFS 6, for example, requests in general, declarations (of “compliance”) or evidence of suitability for all types of packaging materials, for processing materials and non-food materials; it is left to the discretion of the individual business to comply with these standards and to meet these additional requirements on a voluntary basis.

In any case the communication on necessity and informative value of such certificates as well as a definition of priorities seems to be advisable. This can be done by explanations provided by the standard owners (cf. IFS Packaging Guidelines), bilaterally or during an audit.

A uniform linguistic usage would be desirable as would be the restricting of the use of the term "declaration of compliance" to legal situations. This could help the businesses within the supply chain to differentiate between the obligation to issue qualified declarations and voluntary certificates – also in the dialogue with official authorities.

#### 5. Other information obligations regarding plastic materials

Beyond the requirements from the food law, manufacturers and suppliers of plastic materials are obliged to provide further information to regulatory authorities or downstream processors. These, however, cannot be described in detail here.

A limited range of obligations for downstream processors may also arise from the REACH Regulation<sup>22</sup> as well as from the application of Directive 94/62/EC on packaging and packaging waste<sup>23</sup> which sets out the general requirements regarding composition, reuse and recycling of packaging. For example, for packaging made from plastic (not limited to food contact packaging) it must be demonstrated to the user that the products comply with the Directive’s requirements and that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium does not exceed 100 ppm. This confirmation may be issued and managed together with the declaration of compliance.

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<sup>22</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (...) [Official Journal of the European Union L 396/1 of 30.12.2006]

<sup>23</sup> European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste [Official Journal of the European Union L 365/10 of 31.12.1994]

## **ENCLOSURES**

### **Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food**

#### **Chapter IV DECLARATION OF COMPLIANCE AND DOCUMENTATION**

##### **Article 15 Declaration of compliance**

**(1)** At the marketing stages other than at the retail stage, a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.

**(2)** The written declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex IV.

**(3)** The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

##### **Article 16 Supporting documents**

**(1)** Appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Regulation shall be made available by the business operator to the national competent authorities on request.

**(2)** That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in Chapter V

#### **ANNEX IV of Commission Regulation (EU) No 10/2011)**

##### **Declaration of compliance**

The written declaration referred to in Article 15 shall contain the following information:

1. the identity and address of the business operator issuing the declaration of compliance;
2. the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;
3. the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;
4. the date of the declaration;
5. confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) No 1935/2004;
6. adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;
7. adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance

with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;

8. specifications on the use of the material or article, such as:
- i) type or types of food which is intended to come into contact with the material or article;
  - (ii) time and temperature of treatment and storage in contact with the food;
  - (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;
9. when a functional barrier is used in a multi-layer material or article,
- the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

**(Nationale) Bedarfsgegenständeverordnung (German Consumer Goods Ordinance)**  
(in der Fassung vom 23. Dezember 1997; zuletzt geändert am 13.12.2011)

**§ 10 Kennzeichnung, Nachweispflichten**

**(1a)** Lebensmittelbedarfsgegenstände aus Zellglasfolie dürfen gewerbsmäßig nur in den Verkehr gebracht werden, wenn ihnen eine schriftliche Erklärung in deutscher Sprache beigelegt ist, in der bescheinigt wird, dass sie den Anforderungen dieser Verordnung und der Verordnung (EG) Nr. 1935/2004 entsprechen. Satz 1 gilt nicht für das Inverkehrbringen im Einzelhandel und für Lebensmittelbedarfsgegenstände aus Zellglasfolie, die offensichtlich für das Herstellen, Behandeln, Inverkehrbringen oder den Verzehr von Lebensmitteln verwendet werden sollen.

**(2)** Bei Lebensmittelbedarfsgegenständen aus Keramik, die noch nicht mit Lebensmitteln in Berührung gekommen sind, gilt Absatz 1a Satz 1 entsprechend. Die Erklärung muss vom Hersteller oder, sofern dieser nicht in der Europäischen Union ansässig ist, dem in der Europäischen Union ansässigen Einführer ausgestellt sein und folgende zusätzliche Angaben enthalten

1. Name und Anschrift des Herstellers und, sofern dieser nicht in der Europäischen Union ansässig ist, auch des Einführers,
2. Identität des Lebensmittelbedarfsgegenstandes aus Keramik,
3. Datum der Erstellung der Erklärung.

Darüber hinaus müssen der Hersteller oder der Einführer für Zwecke der Überwachung Nachweise darüber vorhalten, ob der Lebensmittelbedarfsgegenstand die in Anlage 6 Nummer 2 festgelegten Höchstmengen einhält. Diese Nachweise müssen mindestens die Ergebnisse der durchgeführten Analysen, die Testbedingungen sowie Name und Anschrift des Laboratoriums, das die Analyse durchgeführt hat, enthalten

**(2a)** Die in Artikel 1 Absatz 2 in Verbindung mit Absatz 3 der Verordnung (EG) Nr. 1895/2005 genannten Materialien und Gegenstände, die BADGE oder seine Derivate enthalten, dürfen gewerbsmäßig nur in den Verkehr gebracht werden, wenn ihnen eine schriftliche Erklärung in deutscher Sprache beigelegt ist, in der bescheinigt wird, dass sie den Anforderungen der Verordnung (EG) Nr. 1895/2005 und der Verordnung (EG) Nr. 1935/2004 entsprechen. Satz 1 gilt nicht für das Inverkehrbringen im Einzelhandel.

**(3)** Die in Anlage 9 aufgeführten Bedarfsgegenstände dürfen gewerbsmäßig an Verbraucherinnen oder Verbraucher nur abgegeben werden, wenn die in Spalte 3 aufgeführten Angaben an den in Spalte 4 vorgesehenen Stellen unverwischbar, deutlich sichtbar, leicht lesbar und in deutscher Sprache angebracht sind.

**(4)** Wer Bedarfsgegenstände in Verkehr bringt, hat die Angaben nach Artikel 15 Abs. 1 Buchstabe a und b der Verordnung (EG) Nr. 1935/2004 in deutscher Sprache anzubringen.

**John Doe Company, importer**

Address

**Declaration of compliance**

We hereby confirm that our product

**Composite film**

**Material number: xy 01.02.; PET-met/PE (12/80 µm) 300 mm, printed**

complies with the legal regulations laid down in the European Plastic Regulation (EU) No 10/2011 as well as in Regulation (EC) No 1935/2004, both as amended.

When used as specified, the overall migration as well as the specific migration do not exceed the legal limits. The testing was performed according to Regulation (EU) No 10/2011 (Annex V).

The materials and raw materials used comply with Plastic Regulation (EU) No 10/2011; the following substances subject to limitations and/or specification have been used in the above mentioned product:

Name of substance	SML
<i>Terephthalic acid, terephthalic acid dichloride, group 28 PM/Ref.No. 24910, 24940</i>	7.5 mg/kg SML(T)
<i>Ethylene glycol (diethylene glycol, stearic acid with ethylene glycol); group 2 PM/Ref. No 53650, 16990, 47680, 89440</i>	30 mg/kg SML(T)

Note on dual use substances:

*The PE used may contain substances that are also approved for use as food additives:*

- E 321: 2,6-Di-tert-butyl-p-kresol (BHT), PM/Ref.No. 46640

- E 551: Silicon dioxide, PM/Ref.No. 86241

*Due to the overall migration limit (60ppm), it seems very unlikely that a food additive used as a plastic additive will compromise the compliance with the regulatory threshold for this additive in the food product. In case an additive is used in a quantity approaching the maximum level in food, we will discuss this situation with the producers of the raw material.*

**Specification of the intended use or restrictions:**

- Type or types of food or processes for which the material is suitable:

*Dry food*

- Type or types of food or processes for which the material is **not** suitable:

*Not suitable for hot filling/in-pack sterilization*

- Test conditions: *Simulant D (rectified olive oil)/10 days at 40 °C or isooctane 2 days at 20 °C*

- Ratio of food contact surface area to volume used to determine the compliance of the material or article:

- *Surface to volume ratio = 6 dm<sup>2</sup>/kg food*

Because a functional barrier made from plastic is used in the above mentioned product, we confirm the compliance with the special stipulations set out in Regulation (EU) No 10/2011.

Formulation and production of the printing inks we use are employed in accordance with the "EuPIA Guideline on Printing Inks applied to the Non-food Contact Surface of Food Packaging Materials and Articles".

Traceability of the product is ensured according to Regulation (EC) No 1935/2007 via the *number of the roll* in conjunction with the *date of production*.

*This declaration is valid for the product we delivered and its use as specified above. The verification of compliance was performed based on the above rules; according to which the product complies with the legal requirements subject to adherence to the stated conditions for contact with food. In case of deviations from the intended use, the user is responsible for verifying compliance and suitability.*

Place/date/signature

Validity: 2 years after date of issue

**John Doe Company, manufacturer**

Address

**Declaration of compliance**

We hereby confirm that our product

**plastic cup**

Material number: AB 03.04.

complies with the legal regulations laid down in the European Plastic Regulation (EU) No 10/2011 as well as in Regulation (EC) No 1935/2004, both as amended.

When used as specified, the overall migration as well as the specific migration do not exceed the legal limits. The testing was performed according to Regulation (EU) No 10/2011 (Annex V).

The materials and raw materials used comply with Plastic Regulation (EU) No 10/2011.

The following substances subject to limitations and/or specification are used in the above mentioned product:

Name of substance	Restriction
2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride) CAS No: 038103-06-9, Ref. No. 13530	SML = 0.05 mg/kg

Note on dual use substances:

Substances also approved as food additives do not migrate or are contained in marginal quantities only so that they do not display any technological effect in case of migration.

**Specification of the intended use or restrictions:**

- Type or types of food or processes for which the material is suitable:  
*aqueous media, up to pH 6  
microwaveable*
- Type or types of food or processes for which the material is **not** suitable:  
*food containing fat or oil*
- Test conditions: *Simulant B or C (3% HAc and 20% ethanol)/at pH >4.5 simulant C only*
- 
- Ratio of food contact surface area to volume used to determine the compliance of the material or article: *Surface to volume ratio = 6 dm<sup>2</sup>/kg food*

A functional barrier made from plastic is not used in the above mentioned product.

Traceability of the product is ensured according to Regulation (EC) No 01935/2007 via the *number of the roll* in conjunction with the *date of production*.

*This declaration is valid for the product as described and delivered by us. **The verification of compliance was performed based on the rules set out in Regulation (EU) No 10/2011; according to which the product complies with the legal requirements subject to adherence to the stated conditions for the contact with food. In case of deviating food contact conditions, it is up to the user to verify the suitability.***

*In particular it is emphasized that in the case of printed material, no contact is allowed between the printing ink and the food product.*

Place/date/signature

Validity: until revocation and renewal