

The “Declaration of Compliance” for food contact materials and articles

according to the German Commodity Ordinance

1. Introduction

In the commerce with materials and articles in contact with food, it is common practice and partly prescribed by the German Commodity Ordinance (Bedarfsgegenstände-verordnung) to issue certificates confirming the suitability and compliance with the relevant food law.

Since 1997, there is a specific legal regulation for plastic materials and articles intended to come into contact with food, namely to provide in writing information about the compliance with specific migration limits and purity requirements based on current legislation as well as to provide information about the producer or importer ("Declarations of Compliance"). With the implementation of European legislation into the German Commodity Ordinance in 2008, there were significant changes regarding the contents of the declarations.

This paper shall inform all participants in the food chain on the relevant regulations, contribute to a legally complying application and provide information on form and content of legally binding declarations of compliance. Within the scope of the Ordinance, plastic food contact materials have a special status regarding the requirements to be fulfilled for such a declaration of compliance. This is why this paper will focus on such materials and articles. This information is mainly addressed at the producers of plastic food contact materials and their customers.

The German Federation of Food Law and Food Science (BLL) has harmonized this information with other 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)

German Federation of Food Law and Food Science (BLL)
Claire-Waldoff-Str. 7, 10117 Berlin **www.bll.de**
Contact: Dr. Sieglinde Stähle

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2. Relevant regulations regarding the declaration of compliance

The general and fundamental requirements for materials and articles intended to come into contact with food (food contact materials) are laid down in the framework Regulation (EC) No 1935/2004¹. In general, all food contact materials must comply with general requirements, i.e. they have to be produced following the principles of Good Manufacturing Practice thus excluding the occurrence of a health hazard or any other unacceptable change in the composition of the food during its intended use.

According to Article 16 of this Regulation, declarations of compliance are compulsory if "specific measures" require that materials and articles be accompanied by a written declaration stating that they comply with the rules applicable to them. Specific measures in the sense of the framework Regulation (EC) No 1935/2004, i.e. specific rules and specifications on the characteristics of individual materials, are in place for food contact materials made from ceramic, regenerated celluloses and plastic. The specific measures - due to their legal form as EU Regulation - are to be implemented into national Commodity Ordinances². Supplementary, the European Regulation on the restriction of use of certain epoxy derivatives³ is also applicable.

Within the scope of the 15. amendment of the German Commodity Ordinance (of 30 April 2008) as result of the implementation of the Commission Directive 2007/19/EC (amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food)⁴ the definition of "plastic food contact materials" as well as the scope of duties included in the declaration of compliance have been expanded. According to the latest wording, **food contact materials made from plastic** may only be placed on the market when accompanied by a **written declaration in German language**. This declaration shall be issued by the **manufacturer or the party responsible for the first placing on the market** and shall include all **information stipulated in Annex 12 of the German Commodity Ordinance**. Added to this, **relevant documents** must be made available to the national competent authorities at their request to demonstrate the compliance of the food contact materials with the legal requirements.

¹ 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 (see also information on the application of the Regulation (EC) No 1935/2004 on the website of the BLL)

² 15th amendment of the German Commodity Ordinance of 30 April 2008, [Official Gazette Part I No 17 of 13 May 2008]

³ 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

⁴ Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC 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

The documentation shall contain **the conditions and results of testing, calculations, other analysis**, and evidence on the safety or reasoning demonstrating compliance.

Food contact materials made from **regenerated cellulose film** and **ceramic materials** must be accompanied by a general written declaration of compliance, Annex 12 is not compulsory for these materials. Excluded from the compulsory presentation of a written declaration is the placing on the market in retail businesses.

The wording of § 10 as well as Annex 12 including the “information in the written declaration according to § 10, (1)” are included in **Enclosure 1**.

The 15. amendment of the Ordinance is effective as per 14 May 2008; however, plastic food contact materials may be produced and imported until 30 April 2009, according to the stipulation of the legislation applicable until 13 May 2008, and placed on the market even beyond this date. Within the **transition period ending 30 April 2009**, the declaration of compliance can be revised according to § 10(1) in connection with Annex 12; after this date it must comply with the new legislation.

3. The Declaration of Compliance for food contact materials made from plastics

3.1 Current issues

3.1.1 What are plastic food contact materials?

Plastic food contact materials are materials and articles intended to come into contact with food, including

- a) materials and articles as well as parts thereof made exclusively from plastic material,
- b) materials and articles made from plastic material consisting of two or more layers of which at least one is made exclusively from plastic material and that are kept together with adhesive or in any other manner (multi-layered (composite) materials and articles made from plastics),
- c) plastic layers or coatings serving as sealing material for lids which are composed of two or more layers of different types of material.

Plastic material is defined as

“an organic, macromolecular compound produced by polymerization, polycondensation, polyaddition or any other comparable process from low-molecular molecules or by chemical modification of natural macromolecules; other substances or preparations may be added to this macromolecular compound.

However, the following are **not considered to be plastic material**:

- a) regenerated cellulose film,
- b) elastomers, natural or synthetic rubber,
- c) paper and cardboard even if these are modified by added plastic materials,
- d) coatings made from paraffin wax, including synthetic paraffin wax and micro-crystalline wax as well as their blend or blends with plastic material,
- e) ion exchange resins,
- f) silicones.”

The specifications for plastic materials do not apply for the production of

1. surface coatings with liquid, powdered or dispersed resins and polymers, in particular lacquers and paints,
2. epoxy resins,
3. adhesive and primers as well as for
4. printing inks.”

A functional barrier made from plastic material is

“a barrier consisting of one or more layers of plastics that ensures the compliance of the food contact materials in its finished state with the requirements of this Ordinance and with Article 3 of the Regulation (EC) No 1935/2004 [...]”

[according to § 2 (3), (3a) and (3b) as well as § 4 (2) last sentence of the German Commodity Ordinance].

**EXAMPLES:
Plastic food contact materials**

- Materials intended to be used for food packaging: Plastic films, multi-layer films and film bags, composite films;
- Primary packagings 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, containers, pipelines, water hoses, mobile water supply units coming into contact with the food and being 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;
- Edible wrappings (on plastic base);
- Sealings and inserts in closures made from metal or other materials (e. g. vacuum lids for glasses, crown caps, screw caps for bottles).

**EXAMPLES:
Articles made from plastic that are not considered to be food contact materials and articles**

- Secondary packagings, 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 made of plastics, 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.

3.1.2 Are Declarations of Compliance requested for the raw materials used in the production of plastic materials?

In general, plastic materials are made from preliminary products (compounds and granulates, additives, colorants). The production and procurement of these raw materials is legally not subjected to a declaration of compliance in the meaning of Annex 12, because they are not included in the scope of the German Commodity Ordinance.

For issuing a factually and legally conforming declaration as well for the internal documentation within the scope of the so called supporting documents, the manufacturer of a plastic food contact material needs relevant information from his suppliers. This applies in particular to the use of substances with limitations (e. g. substances with specific migration limits) and to the approval and suitability documents of the individual additives and components.

The following list may assist in phrasing a respective “**food contact confirmation**” for preliminary products:

Instructions for information provided in a written confirmation of the food contact suitability of preliminary products in the manufacture of plastic materials

1. Name and address of the manufacturer;
2. Date of issue or version of the declaration;
3. Product name/function;
4. Confirmation that the composition of the product complies with the requirements laid down in the Directive 2002/72/EC relating to plastic materials in the relevant version or the applicable requirements of the framework regulation (EC) No 1935/2004;
5. Information about substances that were used and for which legal limits or specifications exist in order to enable the downstream processor or the party responsible for the first placing on the market to adhere to these limitations (e. g. regarding specific migration limits or dual-use substances);
6. The written declaration shall be directly related to the product it refers to and shall be renewed in case significant modifications of the production process will cause migration or if newer scientific findings are present.

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

The specifications of the German Commodity Ordinance do **not** apply to the production of printing inks, lacquers and adhesives used in the manufacture of food contact materials and articles. The obligation to issue a declaration of compliance does also **not** apply to the placing of such substances on the market. If used as intended, these products, usually made of several substances (preparations), may become part of a plastic food contact material or article (e. g. printed or glued plastic food package), even if these will not come into food contact during the later proper use of a plastic food contact material or article and are used away from the food.

The manufacturer of the finished food contact material or article must issue a declaration of compliance according to Annex 12 of the German Commodity Ordinance. Consequently, he must rely on relevant information provided by the supplier of the printing ink, lacquer or adhesive in order to be able to present appropriate, legally conforming and comprehensive information in the declaration of compliance. This applies in particular to the information on the use of substances subjected to certain limitations (specific migration limits for example).

The European Printing Ink Association EuPIA has compiled an exemplary "Description on the composition" of printing inks and lacquers and recommends the following:

Information provided with the "Description on the composition of printing inks and lacquers used in the production of food packaging materials"

1. Name and address of the manufacturer;
2. Date of issue;
3. Product name/code;
4. Confirmation on the compliance with the EuPIA guidelines⁵ and the EuPIA GMP;
5. Confirmation that the intended use "food packaging" was taken into consideration during the formulation of the inks;
6. Information on the substances used that are subject to limitations according to Directive 2002/72 (EC);
7. Information on dual use additives contained.

The German Adhesive Association has compiled an information leaflet on the issue "Food contact status of adhesives/raw materials"⁶. Based on the information provided in the briefing note, the manufacturers of the finished food contact materials or articles will be enabled to meet the obligation of issuing a declaration of compliance.

Information format "Food contact status of adhesives/raw materials used in the production of food packagings"

1. Name and address of the manufacturer;
2. Date of issue;
3. Name of the adhesive;
4. Information on the substances used that are subject to limitations according to Directive 2002/72 (EC) and/or according to relevant national regulations;
5. If needed, verification of the safe use of the product provided by a specialist laboratory or institute.

⁵ Source: www.eupia.org

⁶ Source: www.klebstoffe.com

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

With the new regulations, the contents of the declarations of compliance have been substantiated but the identification of issuing and receiving parties has not been changed. In principle, the **manufacturer** of the food contact material or article has the legal obligation to issue and pass on the declaration of compliance, e. g. the manufacturer of a plastic film packaging which is delivered to a food manufacturers to be used as food packaging material, i. e. the one who is responsible for the first placing of the product on the market. In practice, this results in sometimes highly complex situations 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 down-stream process the food contact material or article is modified (e. g. printer) and again placed on the market, the down-stream operator must issue own declarations of compliance based on the manufacturer's declaration. If the printer and possible other down-stream processors are acting on behalf of the manufacturer, the later 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.

In case of **imports** of food contact materials and articles, the importer is deemed to be legally equal to the manufacturer and thus the first placer on the market and with that responsible for the declaration of compliance. A food producer or retailer has the duties of an importer if he imports food contact materials and articles that are subject to obligatory declarations of compliance.

There are also case where a **food manufacturer** produces the food contact materials or articles to be used as packaging entirely or in parts immediately before or during the packaging process by himself (e. g. deep-drawing of plastic cups from film, blowing of PET bottles). In this case it is required that the food manufacturer as producer of the food contact material or article possesses the required information on suitability and legality needed for the declaration of compliance and that he keeps the respective records.

Retail

Complex situations may arise for food retailer⁷ selling food contact materials and articles made from plastic materials, e. g. disposable dinnerware, household films. According to the wording of the German Commodity Ordinance, **no** declaration of compliance is required for *“placing on the market in retail businesses”*.

Spirit and purpose of the regulation is aimed at the passing on of necessary information along the value added chain. The information of the (final) consumer is not done via declaration of compliance rather but via special labeling elements that have to be applied to certain food contact materials and articles (*“symbol glass-fork, for food contact”*). With these symbols the manufacturer indicates to the final consumer the legality, compliance and suitability.

If a manufacturer supplies the relevant product to the retail business without intermediary trade stages, then he is the first placer on the market and 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 levels, they have to be accompanied by the declaration of compliance up to the retail level (also distributors, wholesalers).

There are situations in practice where commercial users of food contact materials and articles buy their products at retailers and then use them in activities sometimes requiring 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 depending on receiving a specific declaration of compliance from the retail business. It might be appropriate to pass on the declaration to the user via internet.

For certain activities, a retail business may be deemed to be legally 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 brands, 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.

⁷ "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 centres and wholesale outlets [Regulation (EC) No 178/2002 Art. 3 (7)]

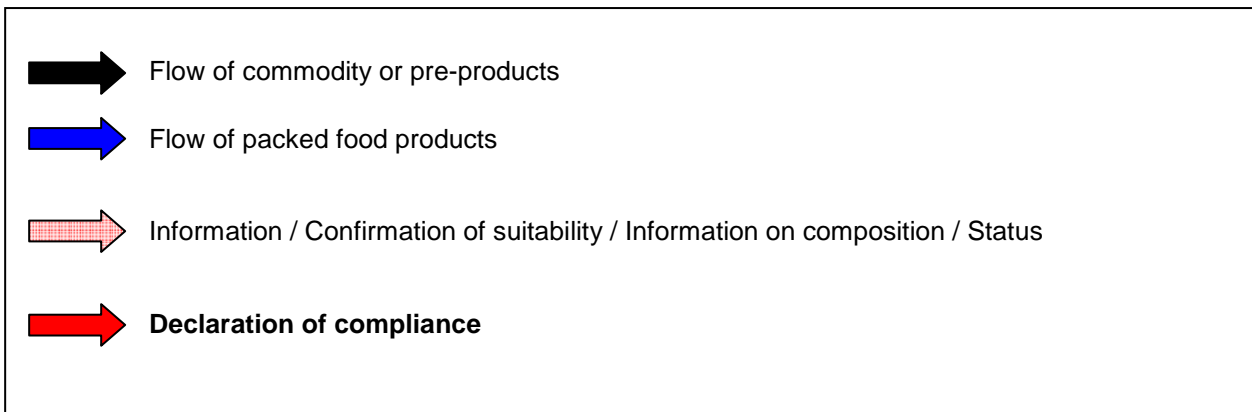
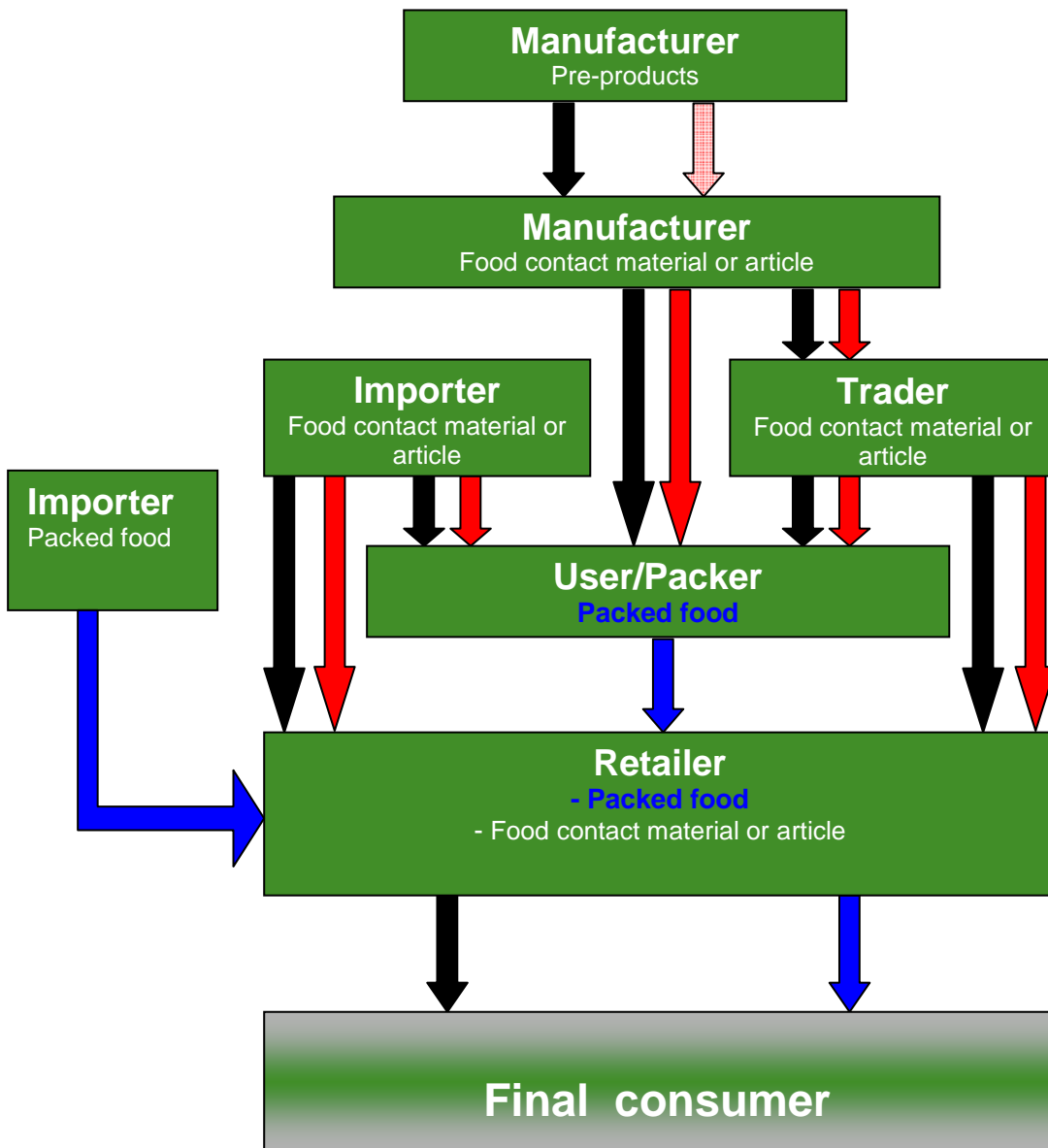


Fig. 1: Issuer and recipient in the chain

3.1.5 Must the food packaging company pass on the declaration of compliance?

For the food manufacturer, procuring and using a food contact material or article made from plastic material 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 placer on the market of the packaging material along with the packaging material.

It corresponds to the spirit and purpose of the regulation that this declaration verifies the food law compliance and provides key information on the possible use of e. g. the packaging materials to users and monitoring authorities alike. If the packaging material is used as intended and if the final product, i. e. a packed food product, is passed on within the chain, it is no longer required to also pass on the declaration of compliance with the packed product. This applies to the transfer of packed food product to other processors but also to the different trading levels (wholesaler/retailers). The reasons for this are among other due to the limiting stipulation in the regulation (“*does not apply to the placing on the market in retail businesses*”) and to the fact that with the packaging process the materials have been used as intended and thus the actual food contact material or article is not longer on the market. In case of importing packed food, no declaration of compliance is required because this act is not the placing on the market of a food contact material or article.

3.1.6 What is a declaration of compliance and what are other suitable documents?

When passing on the declaration of compliance, it is distinguished between the actual document “*Declaration of Compliance*” according to Annex VII of the Directive 2007/19/EC and other “*suitable documents*”, also often termed as “supporting documents” for the competent authorities according to § 10 (1) of the German Commodity Ordinance.

The **declaration of compliance** is a confirmation for the down-stream user of the food contact material or article described that the relevant rules have been met. The declaration of compliance accompanies the food contact material or article from the production or importer either as paper document or as part of the shipping documents or by electronic means. According to the requirements of the legislator, it “*has to be issued new in case significant modifications in the production process will cause migration or if newer scientific findings are present.*”

The individual elements included in a declaration of compliance are stated in Annex 12 of the German Commodity Ordinance and will be explained in detail in section 4.

The declaration of compliance shall be distinguished from the other **records or supporting documents**. These records and documents may include test results, calculations, evidence on the safety or reasoning demonstrating compliance records. The supporting documents will remain with the manufacturer and are not part of the declaration of compliance that has to be passed on. They substantiate the manufacturer’s compliance and shall document legal compliance to competent authorities upon request.

In this context please also refer to the obligations laid down in the European regulation on good manufacturing practice for materials and articles intended to come into contact with food⁸. The obligation to maintain a documentation regarding “manufacturing operations” within the scope of the quality control system includes to “*establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article*”. In this respect, the GMP or QC documentation in the company is the basis for the compilation of the declaration of compliance.

⁸ 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

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
<ul style="list-style-type: none"> - 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

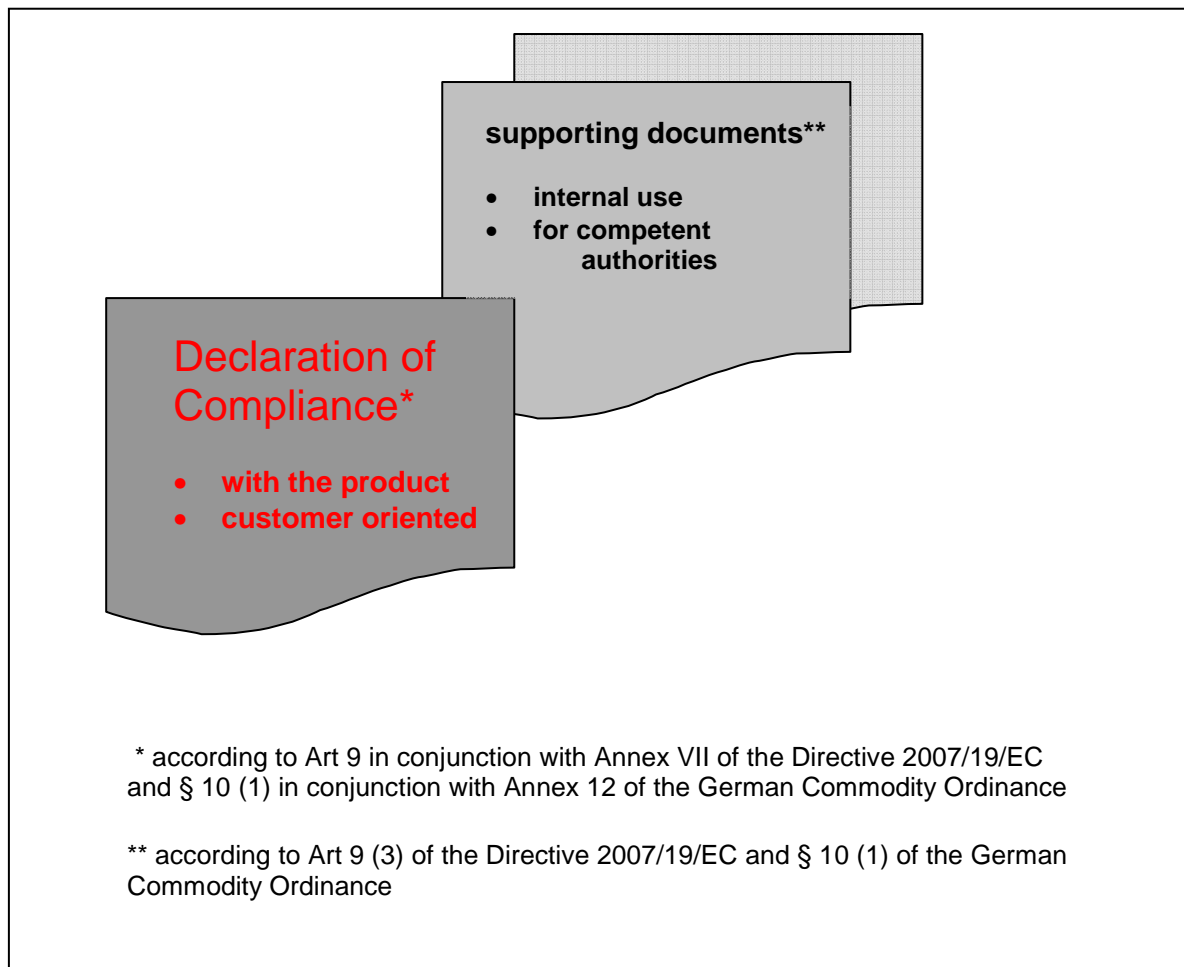


Figure 2: Declaration of compliance and supporting documents

3.1.7 Suitable ways of communication

Paper or electronic documents are considered to be the most common means of communication and documentation, except if otherwise stipulated. 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.

In case the same recipient is supplied repeatedly with an unmodified product, it is not required to send a declaration of compliance along with the food contact material or article each time. It is possible to deposit valid declarations of compliance at 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 match the declaration and the respective products without any doubt.

The German Commodity Ordinance 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 case of significant process modifications with effect on migration, or amendments of the Ordinance or if new scientific findings are available.

Within the relationship between customer and supplier, it is in principle possible to limit the validity of the declaration of compliance (e. g. to two or three years) resulting in a frequent renewal of the document and possible validation of the information provided.

According to the legislator, the declaration of compliance shall be provided in German language. This request is not always easy to fulfill because the English language is used in international trade relationships and market structures. However, at least the translation of key information is recommended.

3.1.8 Obligatory tests and due diligence of the down-stream user

In principle, the declaration of compliance provided by the manufacturer of a food contact material or articles does not release the down-stream user from the exercise of due diligence. The food manufacturer/packer using e. g. a packaging material for his food product is the responsible placer on the market for this packed product and has thus to ensure the legality of the actual application. For example, for the specific application he has to guarantee the compliance with the relevant migration limits until the expiration of the best-before date and he has to verify this on a random base, if necessary, or have it tested in agreement with the supplier.

The declaration of compliance is a basis founded on trust in the presumption of legality but it does not cover all imaginable applications. The down-stream 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 in general is 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 is not possible.

Within the scope of the declaration of compliance, the issuing manufacturer can clarify which applications (goods to be packed and food contact conditions) are covered by the declaration based on the tests performed. A guideline on the selection of test conditions to be applied is given in the Directives 85/572/EEC⁹ and 82/711/EEC¹⁰. Added to that, it shall be pointed out that in case of a deviating application the user has to verify the suitability himself (see also Enclosure 2, EXAMPLES).

⁹ Council Directive 85/572/EEC 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

¹⁰ Council Directive 82/711/EEC 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

3.2 Information requested within the scope of the declaration of compliance

In the following the individual information requirements are discussed which are obligatory according to the wording in **Annex 12** of the German Commodity Ordinance and thus describe the minimum requirements of a declaration of compliance.

- *“2. Type of the food contact material or article made from plastic material”*

The food contact material or article shall be described as detailed as possible (e. g. printed/colored), including material or specification numbers if issued.

- *“3. Declaration of compliance”*

The stipulation in Annex 12 refers directly to the relevant legal regulations (German Commodity Ordinance and EU framework Regulation No 1935/2004). The confirmation of compliance can be kept brief and shall be substantiated by the confirmation of compliance of the overall migration limit.

- *“5. Information on substances used that are subject to limitations and/or specifications”*

Only such substances (additives/monomers) as components of the material have to be stated that are subject to SML or QM restrictions. Substances without restrictions must not be stated. The objective is to provide sufficient information for the down-stream user so that all limiting values can be met in all subsequent processing operations.

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

- Option a) No substances are used that are subject to SML or QM values.
- Option b) Substances subject to SML or QM values are used and named, the compliance of the limits is confirmed for the stated types of food and conditions of application. 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. In special non-disclosure situations it is possible to disclose the specific information about individual substances to third parties (e. g. test laboratories) which then confirm the compliance of the limits for the respective application to the customer.

- *“6. Information on dual-use substances”*

Substances approved as additive for plastic materials and as food additive (so called dual-use substances) have to be stated separately in the declaration of compliance due to the legally limited use in food. The objective is to compulsory give the down-stream user the necessary information on the migration to be expected (*“test results or theoretical calculations on the specific migration”*) so that food-related regulations (Regulation on permitted use of additives) are not infringed in specific situations.

- *“7. Specifications on use”*

The information provided here can be rather comprehensive. The objective is to assist the user in terms of specific suitability of the food contact material or article as much as possible. For food packaging materials, the specification of the food to be packed in combination with information on shelf life and storage conditions would be the ideal case; a specification for the manufacturer of the packaging material as basis for the compilation and statements provided in the declaration of compliance is the method of choice.

The declaration of compliance must contain suitability statements derived from the standardized groups of goods to be packed, in particular regarding

- “a) Type(s) of food”* e. g. physical condition - pH - corresponding or tested stimulants
- “b) length and temperature of the food contact”* e. g. information on suitability for microwave heating, pasteurization, freezing
- “c) Ratio between contact area and volume on which the determination of compliance is based”*

The comparison of the specific application conditions of packaging materials or food contact materials or articles with the correlating test conditions implies a communication between manufacturer and user in the ideal case (e.g. specifications). 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 (Directives 82/711/EEC and 85/572/EEC and their amendments) accordingly (see also **figure 4**).

Alternatively, the maximum application conditions as tested by the manufacturer can be stated. e. g. olive oil, longest possible contact time, highest possible contact temperature for which the overall migration is not exceeded. The user can take these conditions to decide the scope of suitability for this packaging material. Films are two-dimensional packaging materials, therefore, a surface-volume ratio of 6 is taken as basis for the tests.

- “8. *Functional barrier*”

In case of using a *functional barrier*, the compliance with specific prohibited uses according to § 4 (5) as well as migration § 8 (1a) has to be confirmed within the scope of the declaration of compliance.

Finally, within the scope of Annex 12 it is requested that the declaration of compliance must be identifiable (“*directly assigned*”) and valid for an unlimited period but still up-to-date (“*to be renewed in case of significant modifications or new scientific findings*”). These are important instructions by the legislator for the control of documents that are to be implemented into practice by respective document and material numbers and a validity entry, if necessary.

The above description as well as the **standard of a declaration of compliance** (see figure 3) correspond to the legally requested scope. Supplemental information, specifications and agreements within the scope of the declaration of compliance and referring to the respective relationship between customer and supplier are possible. 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.

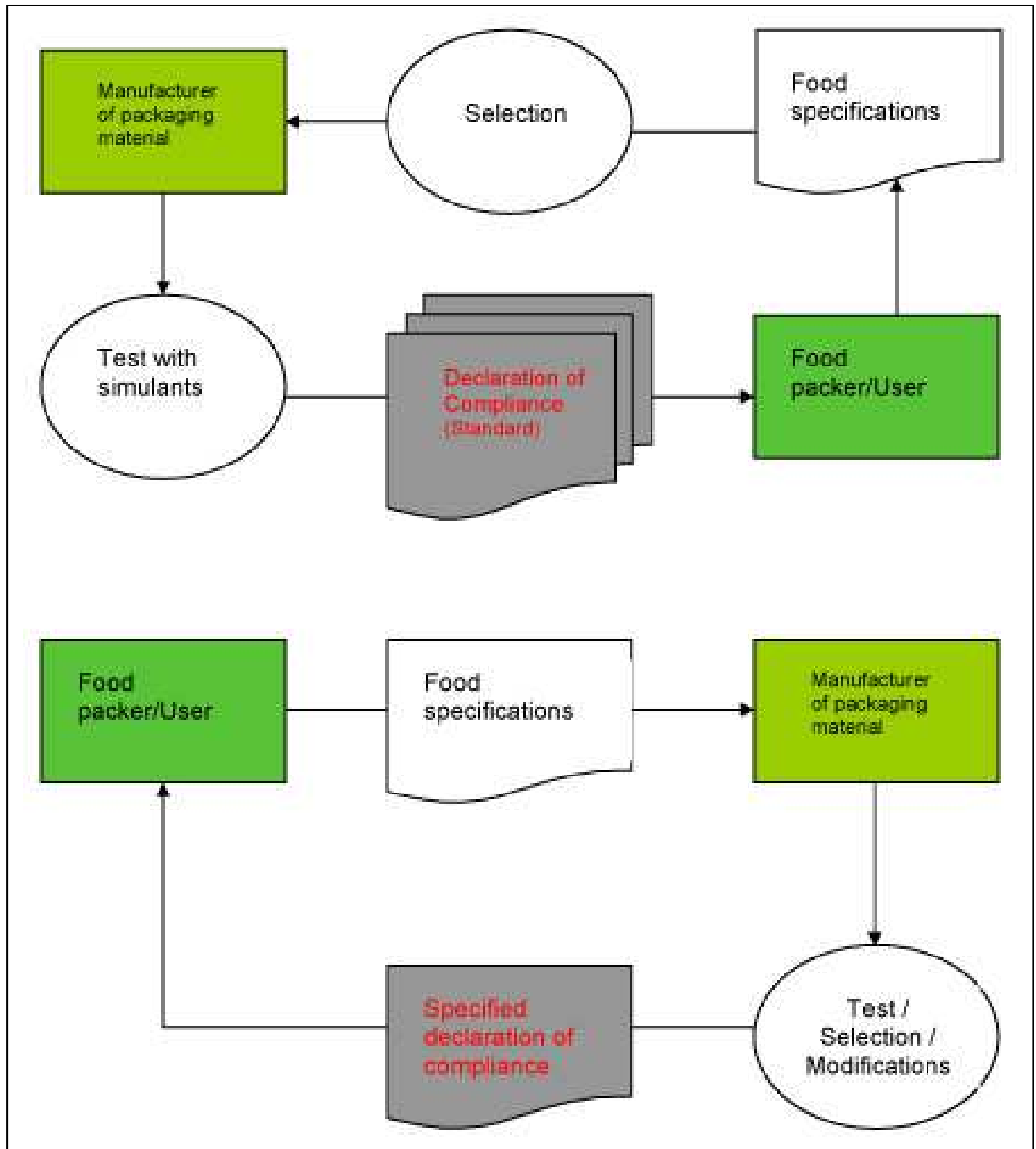


Fig. 4: Flow of communication within the chain
 a) Development of a specific packaging material
 b) Design of a specific packaging application

4. **Declarations for food contact materials and articles made from regenerated cellulose film and ceramic as well as materials and articles containing epoxy derivatives**

For food contact materials and articles made from regenerated cellulose film and ceramic, the German Commodity Ordinance requires written declarations on legal compliance. However, the declarations are not bound to Annex 12 with regard to form and scope. The Ordinance contains detailed descriptions of the declarations for the different material groups (plastic, regenerated cellulose, ceramic). This is due to the different community law stipulations.

When placing food contact materials and articles made from **regenerated cellulose film** on the market, they must be accompanied by a no further specified certificate in German language that contains a confirmation of compliance according to Regulation (EC) No 1935/2004.

The same applies to food contact materials and articles made from **ceramic**; when placed on the market, the products must be accompanied by a written declaration in German language certifying their legality. Additionally, the following information must be provided for food contact materials made from ceramic:

- 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 keep further documents (supporting documents) for this group of materials to prove the compliance with the specific regulations on ceramic materials and articles within the scope of the German Commodity Ordinance to the monitoring authorities. These documents must at least state the results of the analyses conducted, the test conditions as well as name and address of the laboratory performing the analyses.

All food contact materials and articles, including coatings and lacquers, containing **epoxy derivatives** (BADGE, NOGE) must be accompanied "*on all trade levels, except retail*" by written declarations confirming legal compliance with the limitations laid down in the EU Regulation³. At their request, sufficient documentation as evidence of compliance shall be made available to the competent authorities, the declarations are not further specified.

5. Declarations/certificates for other food contact materials and articles (stainless steel, glass, paper)

For other materials except plastic, regenerated cellulose and ceramic there are no specific regulations in place. The general stipulations on design and properties of such products and their application according to Regulation (EC) No 1935/2004 (requisite of inertness) are applicable. The business placing the product on the market, i. e. the food manufacturer or retailer, is responsible in each case for the compliance with these requirements.

Manufacturer or supplier of the food contact materials and articles may agree on a specification and formulate a general or specific "declaration" on a voluntary base. Manufacturers of food contact materials and articles may also provide unilateral declarations on suitability to be used with food and legality without direct reference to a certain application; however, this is legally not required.

Voluntary international standards aimed at food businesses such as IFS 5, ISO 22000 or BRC exceed the relevant legal regulations in terms of the requested evidence of legality. These standards request to some degree "compliance" declarations, certificates, test results and risk analyses for all types of packaging, processing and non-food materials. It is left to the discretion of the individual business to comply with these standards and to follow these additional requirements voluntarily. 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 bilaterally by explanations provided by standard setters (see among other IFS Food Version 5, Compendium of Doctrine) or within the scope of the audit situation.

6. Obligations of information and disclosure

The manufacturers and suppliers of plastic food contact materials and articles are obliged to provide further individual information to monitoring authorities or down-stream processors; however, these cannot be described in detail here.

A limited scope of duties for down-stream processor may also arise from the REACH Regulation¹¹ as well as from the application of the Directive 94/62/EC on packaging and packaging waste¹² which stipulate the general requirements regarding composition, reuse and recycling of packagings. For example, for packagings made from plastic (only limited to food contact packagings) confirmation shall be presented to the user stating that the products comply with the Directive's requirements and that sum of concentration levels of lead, cadmium, mercury and hexavalent chromium does not exceed 100 ppm. This confirmation as well as possibly other certificates not related to the food law could be appropriately summarized in the declaration of compliance according to the German Commodity Ordinance and controlled accordingly.

¹¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

¹² European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste

Enclosure 1

§ 10 in conjunction with Annex 12 of the German Commodity Ordinance

§ 10 Labeling, obligation to produce supporting documents

(1) Plastic food contact materials and articles, under consideration of sentence 5, shall only be placed on the market on a commercial base if accompanied by a written declaration in German language according to the stipulation in sentence 2. The declaration must be issued by the manufacturer or the party responsible for the first placing on the market and must include all information stipulated in Annex 12 of the German Commodity Ordinance. The manufacturer or the party responsible for the first placing on the market shall make available relevant documents to the respective authorities upon request that prove the compliance of the food contact materials with this Ordinance. That documentation shall contain the results obtained and the conditions of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance. Sentence 1 shall not apply to the placing on the market in retail businesses.

(1a) Food contact materials and articles made from regenerated cellulose film shall only be placed on the market on a commercial base if accompanied by a written declaration in German language confirming the compliance with this Ordinance and the Regulation (EC) No 1935/2004. Sentence 1 does not apply to the placing on the market in retail businesses and for food contact materials and articles made from regenerated cellulose film that should obviously be used for the production, treatment, marketing or consumption of food.

(2) Section 1a sentence 1 applies correspondingly to food contact materials and articles made from ceramic materials.

(3) The food contact materials and articles listed in Annex 9 shall only be sold to consumers on a commercial base if the information listed in column 3 is applied permanently, clearly visible, easy to read and in German language at the positions listed in column 4.

(4) The one who places the food contact materials and articles on the market has to label the information according to Article 15 (1) (a and b) of the Regulation (EC) No 1935/2004 in German language.

Annex 12

Information provided in the written declaration according to § 10 (1)

1. *Name and address of the manufacturer or the one responsible for the first placing on the market who produces or imports the plastic food contact material or article;*
2. *Type of the food contact material or article made from plastic material;*
3. *Date of issue of the declaration;*
4. *Confirmation that the plastic food contact material or article complies with the regulations in this Ordinance and with 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 in their relevant version;*
5. *Information about substances that were used and which are limited or specified in this Ordinance in order to enable the downstream processor or the party responsible for the first placing on the market to adhere to these limitations;*
6. *Information on substances whose use in food is subject to limitations obtained from test values or theoretical calculation on specific migration values as well as on purity criteria according to the German Regulation on the Use of Additives of 29 January 1998 (BGI I S. 230, 269 in German language), if applicable, both in their relevant versions;*
7. *Specifications on the use of plastic food contact materials or articles, in particular*
 - a) *Type(s) of food that shall come into contact with the material or article;*
 - b) *Duration and temperature of treatment and storage while in contact with the food;*
 - c) *Ratio of the area of the food contact material to the volume used to determine the compliance of the plastic food contact material or article;*
 - d) *If a functional barrier made from plastic material according to § 2 (3)(b) is used, an additional confirmation is required stating that the food contact material complies with the requirements laid down in § 4 (5) and § 8 (1)(a).*

The written declaration must be directly related to the plastic food contact material or article it refers to and must be renewed in case significant modifications in the production process will cause migration or if newer scientific findings are present.

Enclosure 2

EXAMPLE

Company

Address

.....

.....

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

Hereby we confirm that our product

Plastic sample film X

complies with the legal regulations laid down in the German Commodity Ordinance (or the respective stipulations laid down in the European Regulations on Plastic materials) as well as Regulation (EC) No 1935/2004, both in their relevant versions.

When used as specified, the overall migration as well as the specific migration do not exceed the legal limits. The test was performed according to the Directive 82/711/EEC and 85/572/EEC.

The materials and raw materials used comply with the German Commodity Ordinance (or the respective stipulations laid down in the European Regulation 2002/72/EC ff.).

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

Name of substance	Limits
<p><i>2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride), CAS No: 038103-06-9, Ref. No 13530</i></p>	<p><i>SML = 0,05 mg/kg</i></p>

Specification of the intended use or limitations:

- Type(s) of food intended to come into contact with the material:

Fruits, vegetables, dry food

- Type(s) of food NOT intended to come into contact with the material:

Fat-containing food

- Duration and temperature of treatment and storage while in contact with the food;

10 days, 40 °C, tested

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

6

Because a functional barrier made from plastic is used in the above mentioned product, we confirm the compliance with the special stipulations of the German Commodity Ordinance (corresponds to Regulation (EC) No 2002/72, Article 7a (2), (3), (4)).

Traceability of the product is ensured according to Regulation (EC) No 01935/2004 via the *number of the roll in conjunction with the date of production.*

This declaration is valid for the product delivered by us as specified above. The Directives 82/711/EEC and 85/572/EEC provide a guideline for the selection of test conditions to be used for various food products. According to that and under consideration of the food contact conditions stated, the product complies with the stipulations of these Directives regarding the packaging of food products to be packed. The user shall verify himself that the product is suitable for the intended food to be packed beyond the stipulations of the Directives.

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

Place/date

Signature

Expires 3 years after date of issue