

Explanatory notes on the declaration of conformity with the food laws for food packaging with sample (meat and meat products)

For plastic packaging materials with direct food contact, a current declaration of conformity from the manufacturer must be available, in which it is legally declared that the product fulfils the requirements of the relevant EC/EU directives.

1 Contents of the conformity declaration according to Reg. (EC) No. 10/2011

The conformity declaration in accordance with **Reg. (EC) No. 10/2011** (including amendment regulation **Reg. (EC) No.1282/2011**) must contain the following information in line **with Annex IV:**

- Identity and address of the company issuing the conformity declaration
- Identity and address of the company which manufactures or imports the plastic materials or objects, or products from intermediate stages of their manufacture, or substances intended for the manufacture of these materials and objects
- Identity of the materials, objects, products from intermediate manufacturing stages or the substances intended for the manufacture of these materials and objects
- Date of the declaration
- Confirmation that materials or objects made of plastic, products made from the intermediate stages of manufacture and the substances themselves comply with the requirements of Regulation **(EC) No. 10/2011** and **Regulation (EC) No. 1935/2004**
- Sufficient information on the substances used or their degradation products for which Annexes I and II or **Regulation (EC) No. 10/2011** contain restrictions and/or specifications to ensure that downstream companies can also ensure compliance with the restrictions
- Sufficient information on substances with restricted use in in foods, acquired from test data or theoretical calculations of their specific migration values and, if necessary, of purity criteria in accordance with the **directives 2008/60/EC, 95/45/EC and 2008/84/EC**, so that the user of these materials or objects can comply with the relevant EU regulations or, in the absence thereof, with the national regulations applicable to foodstuffs
- Specifications on the use of the material or object, e.g.:
 - Type or types of foods which are to come into contact with it
 - Duration and temperature of treatment and storage once contact has been made with the foodstuff
 - Ratio of the surface that comes in contact with the food to the volume on the basis of which the conformity of the material or object was established
- If a functional barrier is used in a multi-layer material or object, confirmation that the material or object complies with the provisions of Article 13, Paragraphs 2,3, and 4 or Article 14, Paragraphs 2 and 3 of **Reg.(EC) No. 10/2011**.

2 Samples

2.1 General

We confirm to the company XXX, address (street, house number, postcode, town) that the delivered plastic films are suitable for use as food packaging.

Our products comply with the requirements of the following legal regulations (including all supplements in each instance and in the version valid at the time this declaration was made):

- Regulation **(EC) No. 1935/2004**
- **Regulation (EC) No. 10/2011** (including amendment **regulation (EC) 1282/2011**)
- German Food and Feed Code (LFGB) of 01 Sep. 2005
- German Commodities Ordinance of 23 Dec. 1997
- other: ...

We only make changes to the composition after consultation with and written authorisation from the customer, the prerequisite for which is the issue of an updated conformity declaration.

We closely follow the new release of the relevant laws and notify buyers of any essential amendments of laws and standards which are of significance for the manufacture and use of the product.

Table 1: Description of Use

Foodstuff	Treatment, with food contact		Storage, with food contact		Ratio of contact surface to filling quantity [dm ² /kg]
	[°C] max	[min] max	[°C]	[h] / [d]	
Meat products (watery, fatty, sour, smoked)	95	1	23	120 days	14.3 dm ² /kg (ratio: largest packaging surface to smallest filling quantity)

2.2 Migration and residue levels

Tests of the migration and residue levels are repeated at regular intervals to ensure that the limit values are complied with at all times. Measurements are made in accordance with **Directive 82/711/EEC** (including amendment **regulations 93/8/EC and 97/48/EC**) and **Directive 85/ 572/EEC** (including amendment **regulation 2007/19/EC and Reg. (EC) 10/2011**).

Table 2: Test Conditions for Migration Tests Based on Utilisation

Simulant	Test Conditions* (Time/Temperature)
3 % acetic acid (W/V)	10 days/ 40 °C
Fat (rectified olive oil/ test fat HB 307)	10 days/ 40 °C
Alternative test in line with EC Directive 97/48 (Empirical significance confirmed by reference measurement with fat simulant) Isooctane	

Simulant	Test Conditions* (Time/Temperature)
Ethanol (95%)	2 days/ 20 °C 10 days/ 40 °C

Total Migration (TM)

The limit value of 60 mg/kg of food or simulant solvent or 10 mg/dm² surface with containers with a filling quantity of less than 500 ml or more than 10 litres or plates, films and other non-fillable objects is complied with under the test conditions listed in 2.2.

Specific migration limits (SML) and maximum residue levels (QM) and (QMA)

The SML and/or QM or QMA values prescribed by Reg. (EC) No. 10/2011 (including the amendments listed in 2.2) are complied with under the test conditions listed in 2.2.

The following substances are involved here:

Substance	PM/ Ref No.	SML/ QM/ QMA [mg/kg]
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Ingredients with restricted use in foods ("dual use additives")

The following substances are involved here (please list):

Substance	PM/ Ref No.	Limit Value [mg/kg]
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2.3 Adhesives

Not applicable

The adhesives used comply with the recommendation of the German Federal Institute for Risk Assessment (BfR) and/or FDA regulations (FDA 21 CFR), each in the currently valid version.

Migration of primary aromatic amines (PAA)

Not applicable

The limit value for the migration of primary aromatic amines in line with the official collection of test procedures according to **Art. 64 LFGB Method L.00.006** of the **German Food, Commodities and Feed Code** (not detectable) is complied with on delivery. Migration is in accordance with **DIN EN 13130- 1 Chapter 18** using the bag method with a bag contact surface of 2 dm² and a filling quantity of 100 ml. Migration is carried out at 70 °C over two hours with 3 % acetic acid as the food simulant.

If the detection limit is exceeded using this method, this is proof that the specific limit value for primary aromatic amines as defined by **Directive 2002/72/EC** (including the amendments mentioned under Item 2) has been complied with.

2.4 Printing

- Not applicable

The printing inks are suitable and authorised for printing on food packagings as defined by the valid regulations mentioned above. The raw materials have been carefully selected in this regard. The printing method excludes direct contact between printing inks and foods.

The comments contained in the "Pamphlet on printing inks for food packagings" issued by the Association of Printing Ink Manufacturers and the "Exclusion list for printing inks and related products" issued by the European Council of Paint, Printing Ink and Artists' Colour Industry (CEPE) in their currently valid versions have been complied with.

Additional information for UV printing/lamination systems

- Not applicable

Ingredient substances, monomers and residues of photoinitiators (e.g. ITX isopropyl thioxanthone) or benzene which were not subsequently toxicologically evaluated as harmless cannot be detected in the printing ink film. The corresponding test results are available. The tests are repeated at regular intervals to ensure that the provisions of Framework Regulation 1935/ 2004 and the LFGB are complied with at all times.

Varnishings/coatings (direct contact with food possible)

- Not applicable

The varnishings/coatings used comply with European Council Resolution AP (2004) 1 and/or FDA regulations (FDA 21 CFR)

2.5 Hygiene

A hygiene, cleaning and pest control concept which can be audited when necessary has been implemented. Packaging materials are manufactured under conditions of good hygiene practice, in particular to identify potential hazards, estimate the related risks and establish a system to control recognised dangers (chemical, physical and microbiological risks in line with HACCP) when using with foods.

- Hygiene certification in accordance with _____ is on hand.

Microbiology

The material is free of pathogenic bacteria, other germs and mould fungus (<50 CFU/100 cm²).

Heavy metals

The provisions of Directive 94/62/EC, including the amendment regulations (2004/12/EC and 2005/20/EC), regarding heavy metals are complied with.

Powders

Powders are not used.