PET-Films

Quality assurance
External Quality Audit

Table of contents

Quality and Test Regulations for polyester films (PET films)
for use in sensitive applications

Quality and Test Regulations for polyester films (PET films) for use in sensitive applications

1 Scope

These quality assurance specifications are for the manufacture of films made of polyester for packaging material for the food industry and contact with medicine and medicinal products. To achieve a high standard of quality manufacture will be carried out adhering to the Quality and Test Regulations.

The films for packaging material in the food industry are made of original raw materials (polyester and/ or copolyester) or equal quality recycled materials or the latter will be added. Recycled materials may only origin from food regulation conforming plastics of known composition manufactured in accordance with the positive lists of the EU Directive 2002/72/EG[1]. Appendix 1 contains the applicable limitations for food packaging containing recycled materials. The manufacture of packaging materials for medicine and medicinal product exclusively uses original raw materials.

2 Correlated Regulations

The following correlated regulations - in their most current edition - apply in the sections referring to the Scope of these Quality and Test Regulations. In as far as regulations have been dealt with in EU directives or are regulated by CEN standards, the national laws and standards have to be applied. In the case of additives and pigments the German BgW recommendations or alternatively comparable positive lists of EU member state regulations will apply.

2.1 EU directives, CEN standards, other European regulations:

- Framework Directive 89 / 109/ EWG
- Commission Directive on Plastics Recommendations 2002 / 72 / EG,
- Migration Directive 82 / 711 / EWG,
- Directive about Simulant Solvents 85 / 572 / EWG,
- CEN standard DIN EN 1186, Raw materials and stuffs in contact with food (Global migration from plastics).
- Regulations of the European Pharmacopoeia (VI 2.2.1, Containers and seals) and related monographies.

2.2 German acts, decrees and regulations

- Decree about Objects of Use dated 14.4.1992
- Official collection of inquiry procedures as per section § 35 of the German Food Code (LMBG)
- BgW recommendation XVII, polyterephthalic acid diol ester, latest issue
- BgW recommendation IX, Colouring substances to colour plastics and other polymers for objects of use, latest issue
- BgW: Report of the plastics commission of the BgW about the use of plastic products for multi-use applications and of plastic recycled materials for the manufacture of food related objects of use. Bundesgesundhbl. (German Federal Health Publication) 2/95, S. 73

  (BgW: Federal Institute for Health Related Consumer Protection and Veterinary Medicine, Berlin; since November 2002: Bundesinstitut für Risikobewertung (BfR) Federal Institute for Risk Analysis).

3 Quality and Test Regulations

3.1 PET films for contact with foodstuffs

3.1.1 Raw materials

All raw materials have to conform to specifications determined with the supplier. which also includes the statuary requirements and regulations for the corresponding application of the finished product.

Only raw materials and recycled materials with a known content and food code approved substances.

With the aid of a suitable quality assurance system (minimum requirements are a HACCP concept or further national regulations like the BRC Packaging Standard (BRC/IOP) or regulations, required by the market) in each stage of the production chain, and the traceability of the raw materials has to be warranted (in accordance with the 1. amendment of the directive 89/109/EWG) including the identification of original substances of the polymer production.

3.1.2 Global migration

The threshold value of 10 mg/dm^2 determined in directive 2002/72/EG and the object of use decree for global migration under test conditions, has to be adhered to and to be used in correspondence with the intended application as per directive 82/711/EWG and 85/572/EWG, and / or the official collection of inquiry procedures as per section § 35 of the German Food Code (LMBG), methods B.80.30.1 (EG) -3 (EG). The test has to be carried out in accordance with the European standard (CEN) DIN EN 1186.

3.1.3 Specific migration (SML), maximum concentration (Qm)

If for one of the selected monomers has a specific migration limit stated in directive 2002/72/EG and / or in the Decree about Objects of Use, this limit has to be adhered to within the conditions as per section 3.1.2. If there is a CEB standard for the measurement of a specific migration, test should be carried out in accordance to this standard. If there is a specified quantity limit (QM) for a monomer, this limit has to be adhered to.

[1] This is a new version/summary of the "Directive about Plastics"

3.1.4 Organoleptics

Raw materials made of recycled materials have to be tested in a sensory test. With accordance to article 2 of the Framework Directive 89/109/EWG no sensory changes in the raw materials made of recycled materials should be detectable. A sensory test comprises evaluation of look, smell and taste.

3.1.5 Challenge-Test, mycotoxins and endotoxins

Additional investigations are required for raw materials that received a mix of recycled materials. These plastics require the submission of test results gained in a challenge test and test results for mycotoxins and endotoxins have to be submitted. The test methods applied have to correspond with the current state of technical and analytical know-how.

3.1.6 Additives

All additives used have to correspond with major government regulations on the basis of BgVV recommendations or alternatively the positive lists of other EU member states. If additives have already been dealt with by the EU within the framework of directive 2002/72/EG and / or the Decree about Objects of Use, these specifications have to be adhered to. If an additive has a migration or quantity limit stated in directive 2002/72/EG and / or in the Decree about Objects of Use, the determined conditions as per section 3.1.3 have to be adhered to.

3.1.7 Pigments

The pigments used have to correspond with the purity requirements of the BgVV recommendation IX, Colouring for the colouring of plastics and other polymers for objects of use and the European Council resolution AP 89-1.

3.1.8 Hygiene

The films have to be manufactured in such a way that a contamination by micro-organism and production residue can be excluded if possible.

3.2 PET films for contact with medicine and medicinal products

3.2.1 Raw materials

All raw materials have to conform to specifications determined with the supplier. which also includes the statuary requirements and regulations for the corresponding application of the finished product.

Only original raw materials without any added recycled materials should be used, the original raw materials have to comply with European Pharmacopoeia (VI 2.2.1, container and seals) regulations and corresponding monographies and / or statuary food regulations.

With the aid of a suitable quality assurance system (minimum requirements are a HACCP concept or further national regulations like the BRC Packaging Standard (BRC/IOP) or regulations, required by the market) in each stage of the production chain, and the traceability of the raw materials has to be warranted (in accordance with the 1. amendment of the directive 89/109/EWG) including the identification of original substances of the polymer production.

3.2.2 Global migration

The threshold value of 10 mg/dm^2 determined in directive 2002/72/EG and the object of use decree for global migration under test conditions, has to be adhered to and to be used in correspondence with the intended application as per directive 82/711/EWG and 85/572/EWG, and / or the official collection of inquiry procedures as per section § 35 of the German Food Code (LMBG), methods B.80.30.1 (EG) -3 (EG). The test has to be carried out in accordance with the European standard (CEN) DIN EN 1186.

3.2.3 Specific migration (SML), maximum concentration (Qm)

If for one of the selected monomers has a specific migration limit stated in directive 2002/72/EG and / or in the Decree about Objects of Use, this limit has to be adhered to within the conditions as per section 3.1.2. If there is a CEB standard for the measurement of a specific migration, test should be carried out in accordance to this standard. If there is a specified quantity limit (QM) for a monomer, this limit has to be adhered to.

3.2.4 Additives

All additives used have to correspond with major government regulations on the basis of BgVV recommendations or alternatively the positive lists of other EU member states. If additives have already been dealt with by the EU within the framework of directive 2002/72/EG and / or the Decree about Objects of Use, these specifications have to be adhered to. If an additive has a migration or quantity limit stated in directive 2002/72/EG and / or in the Decree about Objects of Use, the determined conditions as per section 3.1.3 have to be adhered to.

3.2.5 Pigments

The pigments used have to correspond with the purity requirements of the BgVV recommendation IX, Colouring agents for the colouring of plastics and other polymers for objects of use and the European Council resolution AP 89-1.

3.2.6 Hygiene

The manufacture of films has to be carried out in accordance with criteria determined in audits with the customer and should comply with the regulations for packaging for medicine and medicinal products.

3.3 Technical data

The technical data is valid for PET films for contact with food (3.1) and also for contact with medicine and medicinal products (3.2).

3.3.1 Film Thickness (Test as per DIN 53 370)

For the individual values the following tolerance range applies referring to the nominal thickness from 100 µm: ± 5 %

3.3.2 Change of measurements after warm storage (Test as per DIN 53377)

The storage of samples will be done in a warming box at 80° C for 10 Min. The following changes in measurements, referring to the mean value, may not be exceeded:

MD* < - 5 % for thicknesses of 100-300 µm, < - 3 % for thicknesses * 300 µm

TD** < - 5 % for thicknesses of 100-300 µm, < - 3 % for thicknesses * 300 µm

3.3.3 Tensile strength (Test as per DIN EN ISO 527-3/1B/50)

The following values have to be adhered to:

- MD* > 40 MPa,
- TD** > 40 mPa.

3.3.4 Elongation at break (Test as per DIN EN ISO 527-3/1B/50)

The following values have to be adhered to:

- MD* > 3 %,
- TD** > 3 %.

4 Monitoring

4.1 General

The Süddeutsche Kunststoff-Zentrum (SKZ) as the accredited test institute has received the order to carry out the test as per sections 3.1.1 - 3.1.6 and 3.2.1 - 3.2.4 of these Quality and Test Regulations and arrange the external auditing of its own tests.

Film samples will be taken from the finished product of the mark of quality user's operation.

4.2 Monitoring by the mark of quality user / Quality-Management (QM)

4.2.1 Production

The mark of quality user will constantly monitor the orderly production of his goods

The results of his monitoring have to be recorded, evaluated by the mark of quality user and upon request have to be submitted to an external auditor. The records of these tests and corresponding samples have to be stored by the mark of quality user for at least four years.

4.2.2 Raw materials and auxiliary substances

The monitoring proof for raw materials and auxiliary substances is completed by the inspection of the factory records by an external auditor.

4.2.3 Film test

Film tests are carried out as per the stipulations of sections 3.1.2-3.1.8, 3.2.2-3.2.6 and 3.3.1-3.3.4.

4.3 External monitoring / External-Qializy-Audit (EQA)

4.3.1 First test

The first test is a condition for the award and use of the quality mark and is to determine, whether the machinery and personnel arrangements do comply with the requirements of these Quality and Test Regulations and are suitable for constant normal production and self-monitoring and that the films marked with the quality mark PET-Film External Quality Audit do comply with the before mentioned regulations.

4.3.2 Monitoring inspection

Inspections have to be carried out twice a year without any prior notification and within a reasonable time lag. The test includes taking polyester films out of the production of the quality mark user and inspecting the self-monitoring results.

4.3.3 Repeat inspection

If a monitoring inspection was not passed the inspection has to be repeated.

5 Marking

5.1 Polyester films that comply with the quality and test conditions, may me marked with the in the following illustrated quality mark.

5.2 The quality mark PET Film External Quality Audit can be supplemented by manufacturer data or the company's logo or by a identification number and / or character of the quality mark user.

5.3 The marking of the quality assured polyester films has to be complete and durable.

6 Changes and final stipulations

These Quality and Test Regulations can be subject to changes or further development in line with technical developments and certain customer specifications.

* machine direction
** across to machine direction

Appendix 1

Matrix of the raw materials for PET films for food packaging

		Direct contact	Indirect contact			
			Food with container	Food with container	multilayer	separating layer
			edible	inedible	Co-extrusion compound film	not made of plastic
dry food		**V**	**V**	**R**	**R**	**R**
moist food	**fatty**	**V**	**V**	**V**	**V**	**V**
moist food	**watery**	**V**	**V**	**V**	**V**	**V**
Water		**V**	**V**	**V**	**V**	**V**

V = Virgin PET with certificate
R = recycled material in accordance with PET quality guideline