BRITISH STANDARD

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Materials and articles in contact with foodstuffs — Plastics —

Part 7: Test methods for overall migration into aqueous food simulants using a pouch

The European Standard EN 1186-7:2002 has the status of a British Standard

ICS 67.250

National foreword

This British Standard is the official English language version of EN 1186-7:2002. It supersedes DD ENV 1186-7:1994 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CW/47, Materials in contact with food, to Subcommittee CW/47/1, Migration from plastics, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

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This British Standard, having been prepared under the direction of the Consumer Products and Services Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 21 May 2002

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Materials and articles in contact with foodstuffs - Plastics - Part 7: Test methods for overall migration into aqueous food simulants using a pouch

Matériaux et objets en contact avec les denrées alimentaires - Matière plastique - Partie 7: Méthodes d'essai pour la migration globale dans les liquides simulateurs aqueux à l'aide d'un sachet

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 7: Prüfverfahren der Gesamtmigration in wässrige Prüflebensmittel mit einem Beutel

This European Standard was approved by CEN on 4 January 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

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Contents

Foreword

This Document EN 1186-7:2002 has been prepared by Technical Committee CEN/TC 194 "Utensils in contact with food", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2002, and conflicting national standards shall be withdrawn at the latest by October 2002.

This document supersedes ENV 1186-7:1994.

This European Standard is one of a series of methods of test for plastics materials and articles in contact with foodstuffs.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EC Directive(s), see informative annex ZA, which is an integral part of this document.

At the time of preparation and publication of this standard the European Union legislation relating to plastics materials and articles intended to come into contact with foodstuffs is incomplete. Further Directives and amendments to existing Directives are expected which could change the legislative requirements which this standard supports. It is therefore strongly recommended that users of this standard refer to the latest relevant published Directive(s) before commencement of any of the test or tests described in this standard.

EN 1186-7:2002 should be read in conjunction with EN 1186-1:2002.

Further Parts of this standard have been prepared, and others are in preparation, concerned with the determination of overall migration from plastics materials into food simulants.

Their titles are as follows:

EN 1186 - Materials and articles in contact with foodstuffs - Plastics –

Part 1	Guide to the selection of conditions and test methods for overall migration
Part 2	Test methods for overall migration into olive oil by total immersion
Part 3	Test methods for overall migration into aqueous food simulants by total immersion
Part 4	Test methods for overall migration into olive oil by cell
Part 5	Test methods for overall migration into aqueous food simulants by cell
Part 6	Test methods for overall migration into olive oil using a pouch
Part 8	Test methods for overall migration into olive oil by article filling
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Part 10	Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs)
Part 11	Test methods for overall migration into mixtures of ^{14}C-labelled synthetic triglyceride
Part 12	Test methods for overall migration at low temperatures

Part 13	Test methods for overall migration at high temperatures
Part 14	Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95 % ethanol
Part 15	Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and/or 95 % ethanol

Annexes A and B are informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This Part of this European Standard specifies test methods for the determination of the overall migration into aqueous based food simulants from plastics which are intended to come into contact with foodstuffs, by forming the plastics film or sheet into standard pouches and filling with a selected food simulant at test temperatures up to and including 70 °C for selected test times.

This method is most suitable for plastics in the form of films and sheets which are sealable by heat or pressure. The test is particularly applicable to those materials consisting of more than one layer, which are tested with the food simulant in contact only with the surface which is intended to be in contact with the foodstuffs.

A standard pouch is a pouch with the dimensions as described in 6.3.

NOTE Pouches of dimensions other than 10 cm $\times$ 10 cm can be used for testing. These pouches should be prepared where possible so that the total surface area exposed is not less than 1 dm².

2 Normative references

This European Standard incorporates by dated and undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to and revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 1186-1:2002, *Materials and articles in contact with food – Plastics – Part 1: Guide to the selection of conditions and test methods for overall migration*.

ISO 648, *Laboratory glassware - One mark pipettes*.

ISO 4788, *Laboratory glassware - Graduated measuring cylinders.*

3 Principle

The overall migration of non-volatile substances from a sample of the plastics is determined as the mass of non-volatile residue after evaporation of the food simulant, see clauses 4, 5 and 5 of EN 1186-1:2002.

Test specimens in the form of pouches are filled with the aqueous food simulant for the exposure time at temperatures up to and including 70 °C. At the end of the test period, the food simulant is removed from each test specimen. The food simulant from each test specimen is evaporated to dryness, the mass of the non-volatile residue is determined and expressed as milligrams per square decimetre of surface area of test specimen.

NOTE In some circumstances the procedure described in this standard can be used for exposure at temperatures above 70 °C.

Overall migration is reported as the mean of three determinations on separate test specimens.

4 Reagents

NOTE For details of the preparation and purity of these reagents see clause 4 of EN 1186-1:2002.

4.1 Distilled water or water of equivalent quality (simulant A)

4.2 Acetic acid 3 % (w/v) in aqueous solution (simulant B)

4.3 Ethanol 10 % (v/v) in aqueous solution (simulant C)

4.4 Alcoholic simulants for liquids or beverages of an alcoholic strength exceeding 10 % (v/v).

NOTE In the case of materials and articles intended to come into contact with liquids or beverages of an alcoholic strength exceeding 10 % (v/v), the test can be carried out with aqueous solutions of ethanol of a similar strength.

5 Apparatus

5.1 Cutting slab, clean smooth glass, metal or plastics slab of suitable area to prepare test specimens, 250 mm × 250 mm is suitable.

5.2 Tweezers, stainless steel, blunt nosed.

5.3 Cutting implement, scalpel, scissors or sharp knife or other suitable device.

5.4 Rule, graduated in mm, and with an accuracy of 0,1 mm.

5.5 Metal template (120 mm ± 1 mm) × (120 mm ± 1 mm) (square).

5.6 Analytical balance capable of determining a change in mass of 0,1 mg.

5.7 Pouch holder, the example shown in Figure A.1 has been shown to be suitable, constructed from aluminium or other suitable material or an equivalent holder, plus clips to secure corners of pouches.

5.8 Pipettes, complying with the minimum requirements of ISO 648, 50 ml and 100 ml.

5.9 Glass tubes, ground neck, and stoppers, for retaining the food simulant. Tubes with an internal diameter of approximately 35 mm and length in the range of 100 mm to 200 mm, excluding the ground neck, (see 7.2 of EN 1186-1:2002) have been found to be satisfactory.

5.10 Thermostatically controlled oven or incubator or refrigerator capable of maintaining the set temperature within the tolerances specified in Table B.2 of EN 1186-1:2002.

5.11 Dishes, stainless steel, nickel, platinum, platinum alloy, gold 50 mm to 90 mm diameter and maximum mass 100 g, for evaporation of food simulants and weighing of residues. Glass, glass ceramic or ceramic dishes may be used provided that the surface characteristics are such that the masses of the dishes after evaporation of any specified food simulants followed by conditioning in the desiccator used achieves a constancy of ± 0,5 mg. Stainless steel and nickel dishes are suitable only for distilled water and ethanol solutions. Glass, glass ceramic, glazed ceramic, platinum, platinum alloy or gold dishes are suitable for all three simulants.

5.12 Steam bath, hot plate, distillation apparatus or rotary evaporator for evaporation of food simulant at the end of test period.

5.13 Desiccator with anhydrous calcium chloride or self indicating silica gel.

5.14 Heat or pressure sealing device, for use in forming pouches.

5.15 Measuring cylinders, 100 ml, complying with the minimum requirements of ISO 4788.

6 Preparation of test specimens

6.1 General

It is essential that test specimens are clean and free from surface contamination (many plastics can readily attract dust due to static charges). Before preparing test specimens, remove any surface contamination from the sample by gently wiping it with a lint-free cloth, or by brushing with a soft brush. Under no circumstances wash the sample

with water or solvent. If it is specified in the instructions for use of the article that it should be washed or cleaned before use see 8.1 of EN 1186-1:2002. Minimize handling of the samples and where necessary, wear cotton gloves.

6.2 Number of test specimens

Three test specimens are required.

6.3 Cutting and preparation of specimens

Lay the sample on the cutting slab (5.1) with the surface to be in contact with the food simulant uppermost and cut the test specimens using the 120 mm $\times$ 120 mm template (5.5).

Place pairs of the test pieces together with the surfaces to be in contact with the food simulant facing. Using the heat or pressure sealer (5.14), join to form pouches with four seals parallel to all four edges, 10 mm from the edge. Measure the distances between the inner edges of the seals to the nearest 1 mm and calculate the total surface area of the test specimen which will be exposed to the food simulant, to the nearest 0,01 dm^2. This shall be approximately 2 dm^2. Using the cutting implement (5.3), remove excess film from the sealed area (to reduce area of film not directly exposed to food simulant whilst leaving enough to withstand the test conditions without leaking.

Measure and record the surface area of the pouch which will be in contact with the simulant and the total external area of the pouch after trimming excess material.

Mark each pouch for identification. Cut off one corner of the pouch to leave a hole sufficiently large to insert a 100 ml pipette.

7 Procedure

7.1 Exposure to food simulant

Take three glass tubes (5.9), for the simulant for filling the pouches and a further two to provide the blanks, measure by measuring cylinder 100 ml $\pm$ 2 ml of the food simulant into each tube. Insert a thermometer or thermocouple, if applicable, see NOTE 3, in one of the tubes and stopper the tubes.

Place the five tubes and the pouch holder in the thermostatically controlled oven or incubator or refrigerator, set at the test temperature and leave until the test temperature has been attained.

Remove the pouch holder from the thermostatically controlled oven or incubator or refrigerator and place between the spacers the test specimen pouches.

Remove the three of the tubes containing the 100 ml of food simulant from the thermostatically controlled oven or incubator or refrigerator and into the three test specimens pouches pipette sufficient food simulant to just fill the pouch. This shall be about 100 ml, but for thick/semi-rigid materials the quantity will be less. Remove the thermometer or thermocouple from the tube and insert, if applicable, see NOTE 3, in one of the filled pouches. Secure the open corner of each pouch with a clip.

NOTE After filling, the corner of the pouch can be closed by heat sealing.

If all the simulant is not used to fill the pouch, retain the tube and residual contents. Measure and record the volume of the residual food simulant. This part of the operation should be carried out in the minimum time to prevent undue heat loss.

Replace the pouch holder, containing the test specimen pouches, in the thermostatically controlled oven or incubator or refrigerator, set at the test temperature. Observe the temperature and leave the pouches and blank tubes for the selected period of time after the temperature of the simulant has reached a temperature within the permitted tolerance for the test temperature, see Tables B.1 and B.2 of EN 1186-1:2002 for permitted tolerances on test times and temperature.

NOTE 1 Annex B of EN 1186-1:2002 includes tolerances on a wide range of contact times and contact temperatures. All of these contact times and contact temperatures are not necessarily relevant to this Part of the standard.

Take the pouch holder and the tubes containing the blank food simulant from the thermostatically controlled oven or incubator or refrigerator.

Examine the pouches for leaks, if at least 90 % of original volume of simulant is not recovered, the test is invalid and shall be repeated using fresh pouches.

NOTE 2 For plastics that lose simulant during the test period due to permeation through the plastic see 9.11 of EN 1186-1:2002.

NOTE 3 For exposure times 24 h or more it is acceptable to monitor the temperature of the air bath of the thermostatically controlled oven or incubator or refrigerator or refrigerator, instead of the temperature of the simulant.

7.2 Determination of migrating substances

7.2.1 Preparation of dishes

Take five dishes (5.11), marked for identification, place the dishes in an oven maintained at 105 °C to 110 °C, for a period of 30 min ± 5 min, to dry.

Remove the dishes from the oven, place in a desiccator (5.13) and allow to cool to ambient temperature. Weigh and record the individual masses of each dish.

Replace the dishes in the oven and repeat the cycle of heating, cooling and weighing until individual consecutive masses differ by no more than 0,5 mg, record their final masses.

7.2.2 Evaporation method

Take the pouches and the two tubes containing the simulant and pour 40 ml to 50 ml from each into separate dishes. By means of a steam bath, hot plate or other form of heating (5.12) evaporate to a low volume, taking care to avoid loss, in particular by sputtering or overheating of the residue.

NOTE 1 The evaporation of acetic acid and ethanol should be carried out in a fume cupboard.

When most of the simulant has evaporated, pour the remaining simulant from each of the pouches and tubes into the respective dishes and continue the evaporation. Wash out each pouch and each tube with two lots of 10 ml ± 1 ml of unused simulant and pour these washings into the respective dishes. Continue the evaporation.

NOTE 2 A stream of nitrogen can be used to facilitate evaporation.

When the simulant has almost completely evaporated, place the dish in an oven maintained at 105 °C to 110 °C, for a period of 30 min ± 5 min, to complete the evaporation and dry the residue.

Remove the dishes from the oven, place in a desiccator (5.13) and allow to cool to ambient temperature. Weigh and record the individual masses of a dish and residue.

Replace the dishes in the oven and repeat the cycle of heating, cooling and weighing until individual consecutive masses differ by not more than 0,5 mg.

Determine the mass of the residue by subtracting the original stable mass of the dish from the stable mass of the dish and residue.

7.2.3 Distillation method

Transfer the simulants to individual round bottom flasks (250 ml are suitable). Wash out each pouch and the blank tubes, twice with 10 ml ± 1 ml of unused simulant, add these rinses and residual simulant from the retained tube to the respective flasks. Place the flasks in an electric heating mantle and connect to a side arm distillation

arrangement or rotary evaporator. Distil off the simulants until approximately 30 ml to 50 ml remains in each flask. Transfer the remaining simulant in each flask to individual evaporating dishes (5.11). Rinse each flask with 10 ml ± 1 ml of the simulant and add the rinses to the appropriate dishes. Continue the evaporation of the simulant by means of a steam bath, hot plate or other form of heating, proceeding as in 7.2.2.

NOTE The evaporation of acetic acid and ethanol should be carried out in a fume cupboard.

8 Expression of results

8.1 Method of calculation

Express the overall migration as milligrams of residue per square decimetre of the surface of the sample which is intended to come into contact with foodstuff, calculated for each test specimen using the following formula:

$$M = \frac{(m_a - m_b) \times 1000}{S}$$

where;

M is the overall migration into the simulant, in milligrams per square decimetre of the surface area of sample intended to come into contact with the foodstuff;

m_a is the mass of the residue from the test specimen after evaporation of the simulant which had filled the pouch, in grams;

m_b is the mass of residue from the blank simulant of equal volume to that which filled the pouch, in grams;

S is the surface area of the test specimen in contact with the food simulant, in square decimetres.

Calculate the result for each test specimen to the nearest 0,1 mg/dm² and the mean of the individual test results, to the nearest 0,1 mg/dm².

See 11.3 of EN 1186-1:2002 for the directions to determine whether the results are valid.

8.2 Precision

See annex B.

9 Test report

The test report shall include the following (see clause 11 of EN 1186-1:2002):

a) reference to this European Standard and to the Part used for the test procedure;

b) all information necessary for complete identification of the sample such as chemical type, supplier, trade mark, grade, batch number, thicknesses;

c) conditions of time and temperature of exposure to simulants;

d) departures from the specified procedure, and reasons for these;

e) individual test results, and the mean of these, expressed as milligrams of residue per square decimetre of sample;

f) relevant comments on the test results, including the area of the pouch in contact with the simulant, the total external area of the pouch after trimming excess material and the volume of simulant filled into each pouch.

Annex A
(informative)

Example of a pouch holder

Dimensions in millimetres

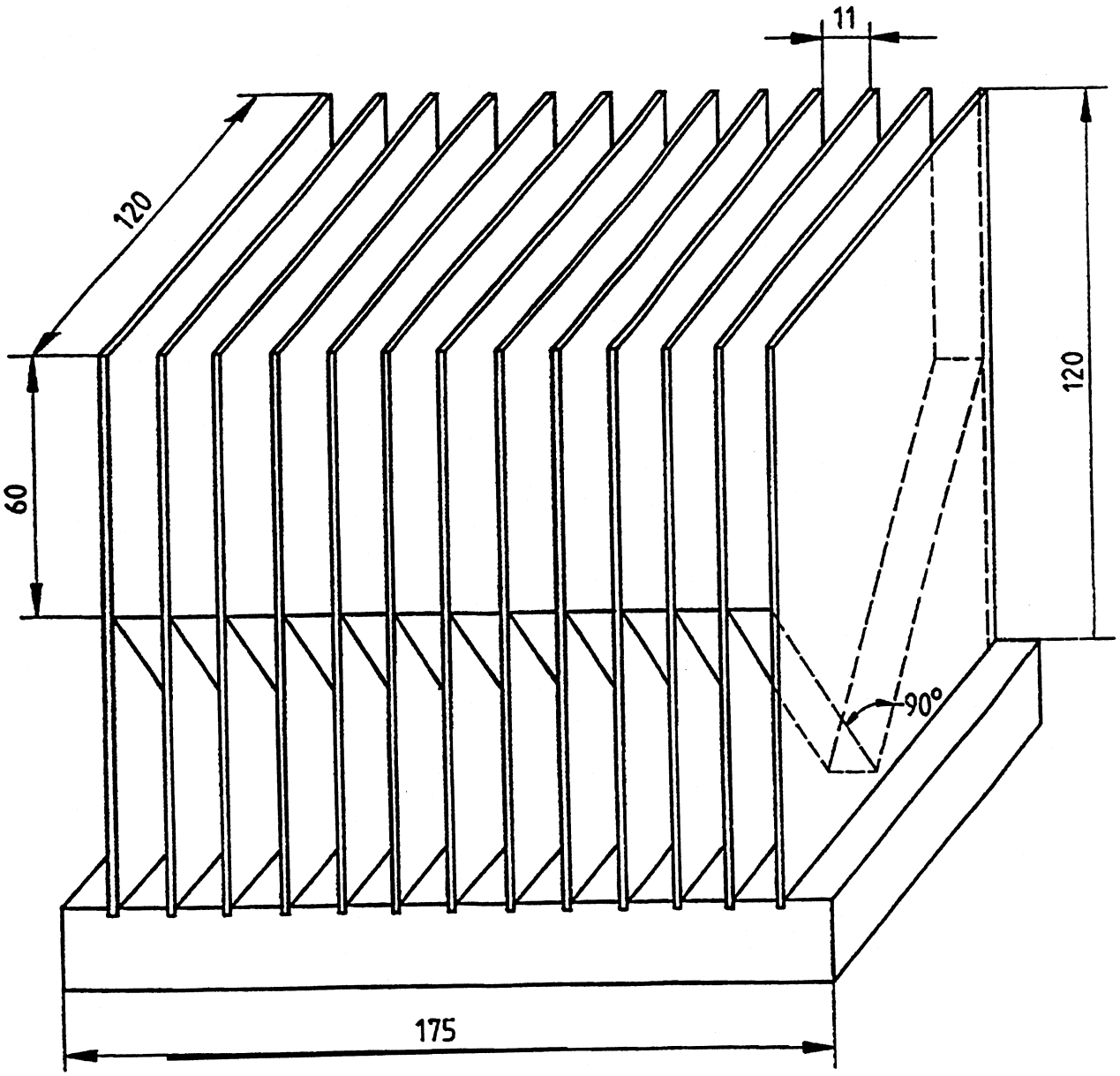

Figure A.1 — Pouch holder

Annex B
(informative)

Precision data

The precision data were determined for a polyamide sample under the test conditions of total immersion for 24 h at 40 °C with simulants A, B and C.

As such they are intended to be indicative of the results to be expected using the other methods, for which the precision data are at present unavailable.

NOTE It is anticipated that more complete precision data, for all of the methods will be incorporated in a future revision of EN 1186-1.

The precision data for simulant A were determined from the BSI/DTI trial conducted in 1991 (Pira Report No.SP91/2- January 1992) involving 13 laboratories and one sample.

The precision data for simulant B were determined from the BSI/DTI trial conducted in 1991 (Pira Report No.SP91/2- January 1992) involving 10 laboratories and one sample.

The precision data for simulant C were determined from the BSI/DTI trial conducted in 1991 (Pira Report No.SP91/2- January 1992) involving 13 laboratories and one sample.

Table B.1 — Precision data

Level	Repeatability (*r)*	Reproducibility *(R*)
Simulant A 6,9 mg/dm²	1,3 mg/dm²	2,6 mg/dm²
Simulant B 10,7 mg/dm²	1,1 mg/dm²	2,3 mg/dm²
Simulant C 11,9 mg/dm²	1,1 mg/dm²	2,9 mg/dm²

The difference between two single results found on identical test material by one operator using the same apparatus within the shortest feasible time interval will exceed the repeatability value *r* on average not more than once in 20 cases in the normal and correct operation of the method.

Single results on identical test material reported by two laboratories will differ by more than the reproducibility value *R* on average not more than once in 20 cases in the normal and correct operation of the method.

Annex ZA
(informative)

Relationship of this European Standard with Council Directive 89/109/EEC and Commission Directive 90/128/EEC and associated Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association (EFTA).

NOTE Other requirements and other EU Directives may be applicable to products falling within the scope of this standard.

The clauses of this standard are likely to support Directives 89/109/EEC [1], 90/128/EEC [2], 82/711/EEC [3] and its amendments 93/8/EEC [4] and 97/48/EC [5], and 85/572/EEC [6].

Compliance with this standard provides one means of conforming to the overall migration requirements of the Directive concerned and associated EFTA regulations.

European Commission Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs, [2], specifies in article 2.

> Plastics materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of materials or articles (overall migration limit). However this limit shall be 60 milligrams of constituents released per kilogram of foodstuff in the following cases :
>
> > a) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 ml and not more than 10 l;
> >
> > b) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;
> >
> > c) caps, gaskets, stoppers or similar devices for sealing.

European Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs [3], and the subsequent amendments (Directives 93/8/EEC [4] and 97/48/EC [5]), recognizes that there are difficulties in the determination of the migration in food products and allows use of food simulants with conventional test conditions, which reproduce, as far as possible, the migration phenomena which may occur with contact between the article and foodstuffs. There are four food simulants:

- simulant A, distilled water or water of equivalent quality;
- simulant B, 3% acetic acid (w/v) in aqueous solution;
- simulant C, 10% ethanol (v/v) in aqueous solution;
- simulant D, rectified olive oil, or other fatty food simulants.

European Directive 82/711/EEC and the subsequent amendments also contain the conventional test conditions (time and temperature) for migration tests with food simulants. European Commission Directive 97/48/EC, the second amendment to European Council Directive 82/711/EEC, also contains test media and conventional test conditions for 'substitute tests'. Substitute tests may be performed in place of migration tests with simulant D, if it has been shown that for technical reasons connected with the method of analysis it is not feasible to obtain a valid test result in a migration test with simulant D.

European Council Directive 85/572/EEC laying down the list of simulants to be used for testing of constituents of

plastics materials and articles intended to come into contact with foodstuffs [6] has a Table in the Annex which contains a non-exhaustive list of foodstuffs and which identify the simulants to be used in migration tests on those plastic materials and articles intended to come into contact with a particular foodstuff or group of foodstuffs.

This standard contains the test methods for the measurement of overall migration from plastics materials to food simulants, or test media, using conventional contact test conditions of time and temperature, to determine compliance with the legislative overall migration limit specified in article 2 of European Commission Directive 90/128/EEC.

These test methods may also be used for the verification of compliance with the specific migration limits provided for in paragraph 1 of Commission Directive 90/128/EEC, if it can be established that compliance with the overall migration limit laid down in Article 2 of Commission Directive 90/128/EEC implies that the specific migration limits are not exceeded.

Commission Directive also specifies that the migration tests using rectified olive oil or substitutes shall not be carried out to check compliance with the overall migration limit in cases were there is conclusive proof that the specified analytical method is inadequate from the technical standpoint.

In any such case, substances exempt from specific migration limits or other restrictions in the list provided in Annex II of Commission Directive 90/128/EEC, a generic specific migration limit of 60 mg/kg or 10 mg/dm², according to the case, is applied. However, Commission Directive 90/128/EEC requires that the sum of all specific migrations determined shall not exceed the overall migration limit.

Bibliography

[1] Commission of the European Communities, Council Directive of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuff (89/109/EEC), Official Journal of the European Communities, 11 February 1989, no. L 40, p 38.

[2] Commission of the European Communities, Commission Directive of 23 February 1990 relating to plastics materials and articles intended to come into contact with foodstuffs (90/128/EEC), Official Journal of the European Communities, 13 December 1990, no. L 349, p 26. Corrigendum of the previous publication, Official Journal of the European Communities, 21 March 1990, no. L 75. p 19.

[3] Commission of the European Communities, Council Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (82/711/EEC), Official Journal of the European Communities, 23 October 1982, no. L 297, p 26.

[4] Commission of the European Communities, Commission Directive of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (93/8/EEC), Official Journal of the European Communities, 14 April 1993, no. L 90, p 22.

[5] Commission of the European Communities, Commission Directive of 97/48/EC of 29 July 1997 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs, Official Journal of the European Communities, 12 August 1997, no. L 222, p 10.

[6] Commission of the European Communities, Council Directive of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastics materials and articles intended to come into contact with foodstuffs (85/572/EEC), Official Journal of the European Communities, 31 December 1985, no. L 372, p 14.

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