BRITISH STANDARD

BS EN
1186-9:2002

Materials and articles in contact with foodstuffs — Plastics —

Part 9: Test methods for overall migration into aqueous food simulants by article filling

The European Standard EN 1186-9:2002 has the status of a British Standard

ICS 67.250

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National foreword

This British Standard is the official English language version of EN 1186-9:2002. It supersedes DD ENV 1186-9:1994 which is withdrawn.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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EUROPEAN STANDARD

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EN 1186-9

April 2002

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English version

Materials and articles in contact with foodstuffs - Plastics - Part 9: Test methods for overall migration into aqueous food simulants by article filling

Matériaux et objets en contact avec les denrées alimentaires - Matière plastique - Partie 9: Méthodes d'essai pour la migration globale dans les liquides simulateurs aqueux par remplissage

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 9: Prüfverfahren für die Gesamtmigration in wässrige Prüflebensmittel durch Füllen des Gegenstandes

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

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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Contents

page

Foreword 3

1 **Scope** 5

2 **Normative references** 5

3 **Principle** 5

4 **Reagents** 5

5 **Apparatus** 6

6 **Preparation of test specimens** 6

7 **Procedure** 7

8 **Expression of results** 9

9 **Test report** 11

Annex A (informative) **Precision data** 12

Annex ZA (informative) **Relationship of this European Standard with Council Directive 89/109/EEC and Commission Directive 90/128/EEC and associated Directives** 13

Bibliography 15

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Foreword

This document EN 1186-9:2002 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 1186-9:1994.

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 1186-9 should be read in conjunction with EN 1186-1.

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	Test methods for overall migration into olive oil using a pouch
Part 7	Test methods for overall migration into aqueous food simulants using a pouch
Part 8	Test methods for overall migration into olive oil by article filling
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

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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

Annex A is 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.

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1 Scope

This Part of this European Standard specifies test methods for the determination of the overall migration from one surface only of plastics articles in the form of containers, which are intended to come into contact with foodstuffs, into aqueous based food simulants, by filling articles 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 containers and articles that can be filled.

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.*

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 simulants following filling the test specimen.

The selection of the conditions of test and the food simulant(s) will be determined by the conditions of use as specified in clauses 4, 5 and 6 of EN 1186-1:2002 ([3] and [6]).

Test specimens are filled with the food simulant for the exposure time at temperatures above up to and including 70 °C. At the end of the test period each test specimen is emptied. 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 exposed to the food simulant.

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

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.

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5 Apparatus

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

5.2 Lint-free cloth or soft brush.

5.3 Beaker, 2 l.

5.4 Glass beads, 2 mm to 3 mm diameter.

5.5 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.

5.6 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.

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

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

5.9 Beakers, 250 ml.

5.10 Pipette, 200 ml, complying with the minimum requirements of ISO 648.

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

6.2.1 Volume of articles

Determine and record the volume of food simulant required to fill an article to its nominal foodstuff volume. If the nominal volume of foodstuff to fill the article is not known, determine the surface area that will be in contact with the food simulant when filled to 5 mm from the top of the test specimen.

6.2.2 Articles with a nominal volume of more than 200 ml

Five articles are required to provide five test specimens. These test specimens are utilized as follows:

a) three test specimens for the migration test;

b) two test specimens for the determination of surface area.

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6.2.3 Articles with a nominal volume of less than 200 ml

The number of articles required to provide a test specimen is dependent on their volume. A test specimen shall be made up of sufficient articles to contain a minimum of 200 ml of the food simulant.

Five test specimens are required. These test specimens are utilized as follows:

a) three test specimens for the migration test;

b) two test specimens for the determination of surface area.

Record the number of articles used to provide the test specimen.

6.3 Surface area of test specimen exposed to food simulant

Determine and record the surface area of the test specimen which is intended to come into contact with its nominal volume of foodstuff. If the nominal volume of foodstuff to fill the article is not known, determine the surface area which will be in contact with the food simulant when filled to 5 mm from the top of the test specimen.

NOTE 1 For some articles it is recognized that it is impractical to measure the surface area intended to come into contact with foodstuff. For such articles the overall migration is measured as milligrams of substance released per kilogram of food simulant.

NOTE 2 In the case of articles with a volume of less than 200 ml this will be the surface area of one article multiplied by the number of articles used to provide a test specimen.

6.4 Articles with a capacity of not less than 500 ml and not more than 10 l

It is not necessary to determine the volume of these articles since the migration is expressed in mg/kg of food simulant.

7 Procedure

7.1 Exposure to food simulant

Mark each test specimen for identification, and where more than one article has been used for a test specimen, also mark individually.

Place, in a beaker, a sufficient volume of the food simulant to fill the three test specimens to the nominal volume, if known, or to 5 mm from the top and to provide two 200 ml blanks. Insert a thermometer or thermocouple, if applicable see NOTE 3, in the simulant. Place the beaker in the thermostatically controlled oven or incubator or refrigerator set at the test temperature and leave until the simulant has attained the test temperature.

Remove the beaker containing the food simulant from the thermostatically controlled oven or incubator or refrigerator. Fill the three test specimens with simulant to the nominal volume of the article or to 0,5 cm from the top. If the container has a specified nominal volume of contents see 8.2 of EN 1186-1:2002. Insert the thermometer or thermocouple in one of the test specimens containing simulant, if applicable see NOTE 3. Cover the test specimens and the remaining simulant with an inert material to prevent evaporation. This part of the operation should be carried out in the minimum time to prevent undue heat loss from the simulant.

Place the test specimens and food simulant in the thermostatically controlled oven or incubator or refrigerator set at the test temperature. Observe the temperature and leave the test specimens and food simulant for the selected period of time after the temperature of the simulant has reached a temperature within the permitted tolerance for temperature, see Tables B.1 and B.2 of EN 1186-1:2002 for permitted tolerances on test times and temperature.

NOTE 1 Where the surface of simulant is large, a check should be made to ensure that excessive loss of simulant by evaporation does not occur.

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NOTE 2 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 test specimens and food simulant from the thermostatically controlled oven or incubator or refrigerator.

NOTE 3 For exposure times of 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 (5.6) 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 (5.8) 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 masses.

7.2.2 Evaporation method

Take the test specimens and measure from each, by pipette, 200 ml of the simulant into separate 250 ml beakers, ensuring that the simulant is mixed.

Measure aliquots of 200 ml of the food simulant from the beaker which had been in the thermostatically controlled oven or incubator or refrigerator with the test specimens into two more beakers to provide blanks.

Pour 40 ml to 50 ml from each into separate dishes (5.6). By means of a steam bath, hot plate or other form of heating (5.7) evaporate to a low volume, taking care to avoid loss, in particular, by sputtering or overheating of the residues.

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 into the respective dishes. Wash out each of the beakers with two lots of 10 ml ± 1 ml of the unused simulant and pour these washings into the respective dishes. Continue the evaporation.

NOTE 2 A stream of nitrogen may 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 (5.8) and allow to cool to ambient temperature. Weigh and record the individual masses of each 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). Rinse each article with two lots of 10 ml ± 1 ml of unused simulant, add these rinses to the respective flasks. Measure into individual round bottom flasks two portions of the food simulant equal in volume to the food simulant that has been in contact with the test

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specimen plus the rinses to provide blanks. 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 simulants to individual evaporating dishes (5.6). Rinse each flask with two lots of 10 ml ± 1 ml of fresh 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 Methods of calculation

8.1.1 General

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 foodstuffs calculated for each test specimen using the following formula:

$$M = \frac{(m_a - m_b) \times 1000}{S} \qquad (1)$$

where

M is the overall migration into the simulant, in milligrams per square decimetre of surface area of sample;

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

m_b is the mass of residue from the blank simulant equal to the volume which had filled the test specimen, in grams;

S is the surface area of the test specimen which was in contact with the simulant during the exposure in square decimetres.

Calculate the result for each test specimen to the nearest 0,1 mg/dm^2 and the mean of the individual test results, to the nearest 0,1 mg/dm^2.

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

However, the overall migration shall be expressed in milligrams lost per kilogram of foodstuff in the following cases, see reference Commission Directive 90/128/EEC [2]:

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.

The overall migration shall be calculated for each test specimen using the following formula:

$$ML = \frac{(m_a - m_b) \times 1000}{V} \qquad (2)$$

where

ML is the overall migration into the simulant, in milligrams per kilogram of food simulant;

m_a is the mass of the residue from the test specimen after evaporation of the simulant which had filled

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the article, in grams;

m_b is the mass of residue from the blank simulant equal to the volume which had filled the test specimen, in grams;

V is the volume of simulant which had filled the test specimen in litres.

NOTE The specific gravities are by convention assumed to be 1. Therefore 1 litre of simulant is numerically the same as 1 kilogram.

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

See 12.3 of EN 1186-1:2002, for the directions to determine whether the results are valid.

8.1.2 Articles with a volume of more than 200 ml but less than 500 ml; or of a volume greater than 10 l

$$M = \frac{(m_a - m_b) \times 1000 \times v}{S \times 200} \quad (3)$$

where

M is the overall migration into the simulant, in milligrams per square decimetre of surface area of sample;

m_a is the mass of the residue from the test specimen after evaporation of 200 ml of the simulant which had filled the article, in grams;

m_b is the mass of residue from the food simulant only, in grams;

v is the volume of the food simulant which had filled the article, in millilitres.

S is the surface area of the test specimen which was in contact with the simulant during exposure.

Calculate the result for each test specimen to the nearest 0,1 mg/dm^2 and the mean of the individual test results, to the nearest 0,1 mg/dm^2.

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

8.1.3 Articles with a volume of not less than 500 ml and not more than 10 l

$$ML = \frac{(m_a - m_b) \times 1000}{0,2} \quad (4)$$

that is:

$$ML = 5000 \times (m_a - m_b) \quad (5)$$

where

ML is the overall migration into the simulant, in milligrams per kilogram of food simulant;

m_a is the mass of the residue from the test specimen after evaporation of 200 ml of the simulant, in grams;

m_b is the mass of residue from the 200 ml of blank simulant, in grams;

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

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

8.1.4 Articles with a volume of less than 200 ml

$$M = \frac{(m_a - m_b) \times 1000}{s \times N} \qquad (6)$$

where

M is the overall migration into the simulant, in milligrams per square decimetre of surface area of sample;

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

m_b is the mass of residue from the blank simulant equal to the volume which had filled the test specimen, in grams;

s is the surface area of one test article in square decimetres;

N is the number of articles exposed to the simulant.

Calculate the result for each test specimen to the nearest 0,1 mg/dm^2 and the mean of the individual test results, to the nearest 0,1 mg/dm^2.

See 8.3 of EN 1186-1:2002 for the directions to determine whether the results are valid.

8.2 Precision

See annex A.

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 or as milligrams per kilogram of food simulant as appropriate;

f) relevant comments on the test results.

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Annex A
(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 A.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.

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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.

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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.

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[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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