DRAFT FOR DEVELOPMENT

DD CEN/TS 14234:2002

Materials and articles in contact with foodstuffs — Polymeric coatings on paper and board — Guide to the selection of conditions and test methods for overall migration

ICS 67.250

British Standards

National foreword

This Draft for Development is the English language version of CEN/TS 14234:2002.

This publication is not to be regarded as a British Standard.

It is being issued in the Draft for Development series of publications and is of a provisional nature because of the need to develop a method of test dealing with the coatings of materials and articles in contact with food, in order to satisfy the proposed European legislation. It should be applied on this provisional basis, so that information and experience of its practical application may be obtained.

Comments arising from the use of this Draft for Development are requested so that UK experience can be reported to the European organization responsible for its conversion to a European standard. A review of this publication will be initiated 2 years after its publication by the European organization so that a decision can be taken on its status at the end of its 3-year life. Notification of the start of the review period will be made in an announcement in the appropriate issue of *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into a European standard, to extend the life of the Technical Specification or to withdraw it. Comments should be sent in writing to the Secretary of BSI Subcommittee CW/47/1, Migration from plastics, 389 Chiswick High Road, London W4 4AL, giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

A list of organizations represented on this committee 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 Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

This Draft for Development was published under the authority of the Standards Policy and Strategy Committee on 30 January 2003

Summary of pages

This document comprises a front cover, an inside front cover, the CEN/TS title page, pages 2 to 26, an inside back cover and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

ISBN 0 580 41152 4

TECHNICAL SPECIFICATION
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

CEN/TS 14234

October 2002

ICS 67.250

English version

Materials and articles in contact with foodstuffs — Polymeric coatings on paper and board — Guide to the selection of conditions and test methods for overall migration

Matériaux et objets en contact avec les denrées alimentaires – Revêtements polymères sur papier et carton – Guide pour le choix des conditions et des méthodes d'essai en matière de migration globale

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Polymere Beschichtungen auf Papier und Pappe – Leitfaden für die Auswahl von Prüfbedingungen und Prüfverfahren für die Gesamtmigration

This Technical Specification (CEN/TS) was approved by CEN on 28 July 2002 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. CEN/TS 14234:2002 E

Contents

Foreword

This document (CEN/TS 14234:2002) has been prepared by Technical Committee CEN/TC 194, "Utensils in contact with food", the secretariat of which is held by BSI.

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 EU Directive(s).

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

In this standard the Annex A is normative and Annex B is informative.

Guidance for migration testing of polymeric coatings on cellulosic substrates (paper and board) is given in the informative annex B.

At the time of preparation and publication of this Technical Specification the European Union legislation relating to resinous and polymeric coatings on paper and board has not been formulated.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: 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 Technical Specification specifies test methods for 'alternative tests' and 'substitute tests' performed with volatile test media, iso-octane and a volume fraction of 95 % aqueous ethanol, for the determination of overall migration from polymeric coatings on paper and board intended to come into contact with fatty foodstuffs.

NOTE 1 It also includes guidance for the application of Council Directive 82/711/EEC [1], as last amended by Commission Directives 93/8/EC and 97/48/EC [2] [3] as regards the determination of the specific and overall migration into fatty food simulants (fat test) and includes a glossary to clarify the terminology used, see annex B.

NOTE 2 The iso-octane and a volume fraction of 95 % aqueous ethanol volatile test media used in these test methods are those specified for 'substitute tests' in Council Directive 82/711/EEC and its subsequent amendments. In addition to the use of iso-octane and 95 % v/v aqueous ethanol as test media for 'substitute tests', Council Directive 82/711/EEC and its subsequent amendments specifies the use of modified polyphenylene oxide as a test medium for use at temperatures of 100 °C and above. A test method for overall migration from polymeric coatings intended to come into contact with fatty foodstuffs using modified polyphenylene oxide (MPPO) is in preparation.

NOTE 3 These test methods can also be used for the 'alternative tests' described in Council Directive 82/711/EEC and its subsequent amendments, when the chosen volatile test media are iso-octane and a volume fraction of 95 % aqueous ethanol, see ENV 1186-1.

A suggested test scheme is given in Figure A.1. If the test result obtained by the total immersion method, described in clause 4 of this Technical Specification, exceeds the allowed overall migration limit the single-sided migration test using a cell, see clause 5, if technically feasible; may be used. If it is not possible to use the single sided cell method, e.g. because of pinholes, use adsorption by modified polyphenylene oxide, (MPPO).

Iso-octane is used as a test medium for test samples coated with non polar food contact layers, such as polyolefins. For test samples coated with polar food contact polymers such as polyamide and polyethylene terephthalate, a volume fraction of 95 % aqueous ethanol is used. For polystyrenes, plasticised polyvinyl chloride and other polymers where the identification or polarity of the polymer is not clear, two parallel tests shall be conducted using both of the proposed test media and taking the higher value obtained as the relevant result.

NOTE 4 The nature of the food contact layer determines the selection of the test medium(a).

NOTE 5 The overall migration limit for materials and articles of an all polymeric construction is specified in Commission Directive 90/128/EEC [4] and the conditions of test in Council Directive 82/711/EEC [1] and its subsequent amendments, [2],[3]. There is an expectation that the scope of this directive will be extended to cover polymeric coatings on paper and board.

The 'substitute tests' described in this Technical Specification are by total immersion, see clause 4 and in a migration cell, see clause 5.

NOTE 6 The test conditions are those described in Council Directive 82/711/EEC [1] and its subsequent amendments, [2],[3].

The 'alternative test' methods described here specifies a rapid extraction test with a 'more severe' test character, for the assessment of the overall migration into fatty food simulants. The method differs from the substitute test methods only in the combination of test time and test temperature. The method is based on the determination of the extraction of migrateable substances from polymeric coated paper or board,_which are intended to come into contact with foodstuffs, by total immersion in non-polar, iso-octane, and/or polar, ethanol, solvents depending on the polarity of the polymeric coating. According to the results obtained by this method, see [5],[6],[7],[8],[9] and taking physio-chemical considerations into account, the obtained extraction efficiency has, generally, been found to be equivalent to or higher than overall migration results obtained using fat simulant D,under the test conditions, 10 days at 40 °C, 2 h at 70 °C, 1 h at 100 °C, 30 min at 121 °C and 30 min at 130 °C.

NOTE 7 This method is not applicable to test materials intended for applications over 130 °C. Test materials intended for applications over 70 °C have to be checked for their physical suitability at the intended time and temperature of use.

The test method should be applied to polymer coated packagings where the polymer layer is less than 300 µm in thickness. However, if this extraction test is applied to materials with coatings with higher thickness than 300 µm and the result does not exceed any allowed overall migration limit then the method is considered to be suitable for those materials.

In those cases where the rapid extraction test by total immersion, yields total extraction values that exceed the overall migration limit or may be technically unsuitable a cell test method using the same time and temperature conditions is applicable. This cell test method should primarily only be applied to packagings with a physical barrier layer (for instance of aluminium or other material to prevent penetrative loss of test medium) and which have a thinner food contact layer than 300 µm. This test method can not be applied if the polymeric coating is shown to have pinholes.

2 Normative references

This Technical Specification 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 Technical Specification only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

ENV 1186-1:1994	Materials and articles in contact with foodstuffs – Plastics - 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 Test conditions

3.1 ´Substitute test´ methods

For substitute tests, the conditions of test will be determined by the conditions of use, see clauses 4, 5 and 6 of ENV 1186-1:1994.

3.2 ´Alternative test’ methods

For alternative tests, the test medium (a) and test conditions are to be selected according to the nature of the polymeric coating as given by Table 1.

Table 1 — Use of test media and test conditions for alternative tests

Polymer type of food contact layer	Test medium to be applied	Test conditions to be applied
Polyolefins and copolymers	iso-octane	24 h at 40 °C
Polyamides	95 % ethanol	24 h at 40 °C
Polystyrene	iso-octane and 95 % ethanol	24 h at 40 °C
Polyethylene terephthalate	95 % ethanol	24 h at 50 °C
Polyvinyl chloride (plasticised)	iso-octane and 95 % ethanol	24 h at 40 °C
Polyvinyl chloride (rigid)	95 % ethanol	24 h at 50 °C
In case of doubt or unknown	iso-octane and 95 % ethanol	24 h at 50 °C

4 Total immersion method

4.1 Principle

The migrateable substances extracted from a sample of the polymer coated paper or board is determined as the mass of non-volatile residue after evaporation of the solvent following immersion.

Test specimens of at least 1 dm² (single side considered) are immersed in the test medium for set periods of time and at set temperatures and then removed. The test medium is evaporated to dryness, the mass of the non-volatile residue is determined and expressed as milligrams per square decimetre of surface area of the test specimen.

4.2 Apparatus

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

4.2.2 Tweezers, stainless steel, blunt nosed.

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

4.2.4 Metal template, 100 mm ± 0,2 mm x 100 mm ± 0,2 mm (square).

4.2.5 Rule, graduated in mm, and readable to the nearest 0,1 mm.

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

4.2.7 Extraction containers; glass weighing jars with ground joints, tall form, of a capacity of approximately 60 ml.

4.2.8 Thermostatically controlled oven or incubator capable of maintaining a temperature within the range of + 40 °C to + 50 °C and meeting temperature tolerance values within those specified for the test temperature, see annex B of ENV 1186-1: 1994.

WARNING The interior/sample space of the oven or incubator should not have any exposed heating elements, to minimise safety hazards arising from any loss of flammable test media during the test period.

4.2.9 Dishes, stainless steel, nickel, platinum, platinum alloy or gold, 50 mm to 90 mm diameter and maximum weight 100 g, for evaporation of solvents and weighing of residues. Glass, glass ceramic, ceramic or aluminium dishes may be used provided that the surface characteristics are such that the weights of the dishes after evaporation of any specified solvent followed by conditioning in the desiccator used achieves a constancy of 0,5 mg.

4.2.10 Steam bath, hot plate, distillation apparatus or rotary evaporator.

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

4.2.12 Measuring cylinder, of a capacity of 50 ml, complying with the minimum requirements of ISO 4788.

4.3 Reagents

4.3.1 Iso-octane, (2,2,4-trimethyl pentane), a volume fraction of 98,5 % purity or greater, CAS No. 540-84-1[1])

4.3.2 Ethanol [a volume fraction of 95 % in aqueous solution], a volume fraction of 96 % purity or greater,

WARNING Both iso-octane and ethanol are volatile flammable solvents. Take care to ensure that the test specimens are well stoppered, closed and covered to prevent solvent volatilising into the interior of the oven, incubator or refrigerator and generating an explosive mixture. Care should be taken at all times when handling these solvents to prevent contact with sources of ignition

---

[1]) The source of this is the Chemical Abstracts published by the American Chemical Society

4.4 Preparation of test specimens

4.4.1 General

It is essential that test specimens are clean and free from surface contamination (many polymeric coatings 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 ENV 1186-1: 1994. Minimize handling of the samples and where necessary, wear cotton gloves.

To ensure that test pieces are well separated and that the surfaces are freely exposed to the extractant during the period of the test, insert a piece of fine stainless steel gauze between the cut test pieces.

4.4.2 Number of test specimens

Three replicate test specimens are required.

4.4.3 Cutting and preparation of specimen

Lay the sample on the cutting slab (4.2.1) and cut the test specimens of 1 dm² (see 8.3 of ENV 1186-1:1994), using the 100 mm x 100 mm template (4.2.4). Check, using the rule (4.2.5), that the dimensions of the specimen are within the specified tolerance (1mm). Fold the test specimens into a fan-like shape or cut into strips approximately 2 cm wide and 5 cm long. Place in the extraction containers (4.2.7).

4.5 Procedure

4.5.1 Exposure to solvent

Take three extraction containers or jars (4.2.7), measure by measuring cylinder (4.2.12) 50 ml of the solvent into each of these jars and immerse the test specimens in the solvent. Ensure that the test specimens are totally immersed in the solvent. If the evaporation method is to be used (4.5.2.2) measure into a further two jars by measuring cylinder the same amount of solvent, plus 10 ml ± 2 ml, to provide blanks. If the distillation method (4.5.2.3) is to be used measure into those further two jars by measuring cylinder the same amount of solvent in contact with the test specimens to provide blanks. Stopper the jars. Mark the jars for identification. Mark the liquid level on the outside of each jar with a suitable marker.

The extraction conditions are to be selected from table 1 (clause 3.1) according to the nature of the polymeric coating of the samples, or according to clauses 4, 5 and 6 of ENV 1186-1: 1994.

Place the five jars in the thermostatically controlled oven or incubator (4.2.8), set at the test temperature and observe the temperature, leave the jars for the set test period after the air bath of the thermostatically controlled oven or incubator has reached the set temperature and taking the permitted time and temperature tolerances into account, see annex B of ENV 1186-1: 1994. Take the jars from the oven or incubator and allow them to cool down to room temperature. Check the level of solvent in each. If this has fallen to more than 5 mm below the mark, or has exposed any part of the test pieces, repeat the test using fresh samples. If the level of solvent in a jar is less than 5 mm below the mark, remove the test specimen from the jar, and allow the solvent adhering to the test specimen and support to drain back into the tube. Recover at least 90 % of the original volume of solvent or repeat the test.

WARNING Both iso-octane and ethanol are volatile flammable solvents. Take care to avoid any loss of solvent into the interior of the thermostatted device. Place the jars, if possible, in a drip container serving as a possible solvent reservoir in case of leakage. Do not allow the temperature to exceed 60 °C.

4.5.2 Determination of extracted substances

4.5.2.1 Preparation of dishes

Take five dishes (4.2.9), 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 (4.2.11) 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 not more than 0,5 mg. Record their final masses.

4.5.2.2 Evaporation method

For each jar containing the solvent, pour 20 ml to 25 ml into a prepared dish. By means of a steam bath, hot plate or other form of heating evaporate to a low volume (4.2.10), taking care to avoid loss, in particular, by sputtering or overheating of the residues.

NOTE 1 The evaporation should be carried out in a fume cupboard.

When most of the solvent has evaporated, pour the remaining solvent from each of the jars into the respective dishes and continue the evaporation. Wash out each of the tubes which had contained test specimens with two lots of 5 ml ± 1 ml of fresh solvent 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 solvent 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 (4.2.11) 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 mass of the dish from the final mass of the dish and residue.

4.5.3 Distillation method

For each jar, transfer the contents to a round bottom flask (250 ml is suitable). Rinse each jar twice, including the blank jars, with 20 ml ± 2 ml of fresh solvent, add these rinses to the respective flasks. Place the flasks in an electric heating mantle and connect to a side arm distillation arrangement or use a rotary evaporator. Distil off the solvent until approximately 15 ml to 25 ml remains in the flask. Transfer the remaining solvents to an evaporating dish. Rinse the flask with 10 ml ± 1 ml of fresh solvent and add the rinses to the appropriate dishes. Continue the evaporation of the solvent by means of a steam bath, hot plate or other form of heating, proceeding as in 4.5.2.2.

NOTE The evaporation should be carried out in a fume cupboard.

Continue with clauses 6 and 7.

5 Cell method

5.1 Principle

The total migrateable substances extracted from a sample of the polymeric coating is determined as the mass of non-volatile residue after evaporation of the solvent following immersion.

One surface of the test specimen of at least 1 dm^2 (single side considered) is exposed in a cell to the extraction solvent for set periods of time and at set temperatures and then removed. The extraction solvent is evaporated to dryness, the mass of the non-volatile residue is determined and expressed as milligrams per square decimetre of surface area of the test specimen. The measured value is compared to the EC-official overall migration limit and taking the analytical tolerance of this method (± 1mg/dm^2) into account.

5.2 Apparatus

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

5.2.2 Tweezers, stainless steel, blunt nosed.

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

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

5.2.5 Cell, type B (as shown in Figure C.3 of ENV 1186-1: 1994), either the aluminium (anodized) cells or the cells with the stainless steel (316 grade) lids and rings, are suitable for the extraction solvents.

5.2.6 Glass tubes, ground neck, and stoppers, for retaining the food simulant.

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

5.2.8 Thermostatically controlled oven or incubator capable of maintaining the test temperature and meeting temperature tolerance values within those specified for the test temperature, see annex B of ENV 1186-1: 1994.

WARNING The interior/sample space of the oven or incubator should not have any exposed heating elements, to minimize safety hazards arising from any loss of flammable test media during the test period.

5.2.9 Dishes, stainless steel, nickel, platinum, platinum alloy, gold 50 mm to 90 mm diameter and maximum weight 100 g, for evaporation of solvents and weighing of residues. Glass, glass ceramic, ceramic or aluminium dishes may be used provided that the surface characteristics are such that the weights of the dishes after evaporation of any specified solvent followed by conditioning in the desiccator used achieves a constancy of 0,5 mg.

5.2.10 Steam bath, hot plate, distillation apparatus or rotary evaporator.

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

5.2.12 Measuring cylinder, of a capacity of 50 ml, complying with the minimum requirements of ISO 4788.

5.3 Reagents

5.3.1 Iso-octane, (2,2,4-trimethyl pentane), a volume fraction of 98,5 % purity or greater, CAS No. 540-84-1¹)

5.3.2 Ethanol, a volume fraction of 96 % purity or greater, a volume fraction of 95 % in aqueous solution.

WARNING Both iso-octane and ethanol are volatile flammable solvents. Take care to ensure that the test specimens are well stoppered, closed and covered to prevent solvent volatilising into the interior of the oven, incubator or refrigerator and generating an explosive mixture. Care should be taken at all times when handling these solvents to prevent contact with sources of ignition.

---

1) The source of this is the Chemical Abstracts published by the American Chemical Society

5.4 Preparation of test specimens

5.4.1 General

It is essential that test specimens are clean and free from surface contamination (many polymeric coatings 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 ENV 1186-1: 1994. Minimize handling of the samples and where necessary, wear cotton gloves.

5.4.2 Number of test specimens

Three replicate test specimen are required.

5.4.3 Cutting test specimens

Lay the sample on the cutting slab (5.2.1) with the surface to be in contact with the food simulant uppermost. Take the ring from the cell (5.2.5) and place on the surface of the sample. Cut out the test specimen by cutting round the outer edge of the ring, using the cutting implement (5.2.3).

5.5 Procedure

5.5.1 Exposure to solvent

Take three cells (5.2.5), mark these for identification purposes. Dismantle and place on the base of each cell one test specimens. Reassemble the cells, ensuring that the clamping screw wheel is well tightened down.

Measure by measuring cylinder an appropriate amount of the solvent into each cell through the filler hole and replace the filler plug. The ratio between the area in square decimetres exposed to the amount of food simulant in millilitres should be a maximum 1/50. If the evaporation method is to be used (5.5.2.2) measure into two tubes (5.2.6) by measuring cylinder the same amount of solvent, plus 10 ml ± 2 ml, to provide blanks. If the distillation method (5.5.2.3) is to be used measure into those two tubes by measuring cylinder the same amount of solvent in contact with the test specimens to provide blanks. Stopper the tubes. Mark the tubes for identification. Mark the liquid level on the outside of each tube with a suitable marker.

The extraction conditions are to be selected from table 1 (3.1) according to the nature of the polymeric coating of the samples, or according to clauses 4, 5 and 6 of ENV 1186-1: 1994.

Place the three cells and the two tubes in the thermostatically controlled oven or incubator (5.2.8), set at the test temperature and observe the temperature. Leave the cells and tubes for the set test period after the air bath of the thermostatically controlled oven or incubator has reached the set temperature and taking the permitted time and temperature tolerances into account (see annex B of ENV 1186-1: 1994). Take the cells and the two tubes containing the blank simulants from the thermostatically controlled oven or incubator and let the cell temperature allow to come down to room temperature. Transfer by a 50 ml or 100 ml pipette (5.2.7) the simulant from each of the three cells into three tubes, check the level of simulant in each. Recover at least 90 % of the original volume of solvent or repeat the test. Rinse each cell twice with 20 ml ± 2 ml of simulant, add these rinses to the respective tubes.

WARNING Both iso-octane and ethanol are volatile flammable solvents. Take care to avoid any loss of solvent into the interior of the thermostatted device. Place the cells and tubes, if possible, in a drip container serving as a possible solvent reservoir in case of leakage. Do not allow the temperature to exceed 60 °C.

5.5.2 Determination of extracted substances

5.5.2.1 Preparation of dishes

Take five dishes (5.2.9), 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 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 not more than 0,5 mg, record their final masses.

5.5.2.2 Evaporation method

Take the tubes containing the solvent and pour 20 ml to 25 ml from each into separate dishes. By means of a steam bath, hot plate or other form of heating (5.2.10) evaporate to a low volume, taking care to avoid loss, in particular, by sputtering or overheating of the residues.

NOTE 1 The evaporation should be carried out in a fume cupboard.

When most of the solvent has evaporated, pour the remaining solvent from each of the tubes into the respective dishes and continue the evaporation. Wash out each of the tubes which had contained test specimens with two lots of 5 ml ± 1 ml of unused solvent 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 solvent 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 (5.2.11) 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 mass of the dish from the stable mass of the dish and residue.

5.5.2.3 Distillation method

Transfer the solvents to individual round bottom flasks (250 ml are suitable). Rinse each tube twice, including the blank tubes, with 20 m ± 2 ml of fresh solvent, add these rinses 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 solvents until approximately 15 ml to 25 ml remains in the flask. Transfer the remaining solvents to an evaporating dish. Rinse the flask with 10 ml ± 1 ml of fresh solvent and add the rinses to the appropriate dishes. Continue the evaporation of the solvent by means of a steam bath, hot plate or other form of heating, proceeding as in 5.5.2.2.

NOTE The evaporation should be carried out in a fume cupboard.

6 Expression of results

6.1 Method of calculation

Express the extracted mass 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 equation:

$$m = \frac{(m_a - m_b)}{S} \tag{1}$$

where

m is the total mass extracted into the test medium, in milligrams per square decimetre of surface area of sample intended to come into contact with foodstuffs;

m_a is the mass of the residue from the test specimen after evaporation of the test medium in which it had been immersed, in milligrams;

5.4 Preparation of test specimens

5.4.1 General

It is essential that test specimens are clean and free from surface contamination (many polymeric coatings 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 ENV 1186-1: 1994. Minimize handling of the samples and where necessary, wear cotton gloves.

5.4.2 Number of test specimens

Three replicate test specimen are required.

5.4.3 Cutting test specimens

Lay the sample on the cutting slab (5.2.1) with the surface to be in contact with the food simulant uppermost. Take the ring from the cell (5.2.5) and place on the surface of the sample. Cut out the test specimen by cutting round the outer edge of the ring, using the cutting implement (5.2.3).

5.5 Procedure

5.5.1 Exposure to solvent

Take three cells (5.2.5), mark these for identification purposes. Dismantle and place on the base of each cell one test specimens. Reassemble the cells, ensuring that the clamping screw wheel is well tightened down.

Measure by measuring cylinder an appropriate amount of the solvent into each cell through the filler hole and replace the filler plug. The ratio between the area in square decimetres exposed to the amount of food simulant in millilitres should be a maximum 1/50. If the evaporation method is to be used (5.5.2.2) measure into two tubes (5.2.6) by measuring cylinder the same amount of solvent, plus 10 ml ± 2 ml, to provide blanks. If the distillation method (5.5.2.3) is to be used measure into those two tubes by measuring cylinder the same amount of solvent in contact with the test specimens to provide blanks. Stopper the tubes. Mark the tubes for identification. Mark the liquid level on the outside of each tube with a suitable marker.

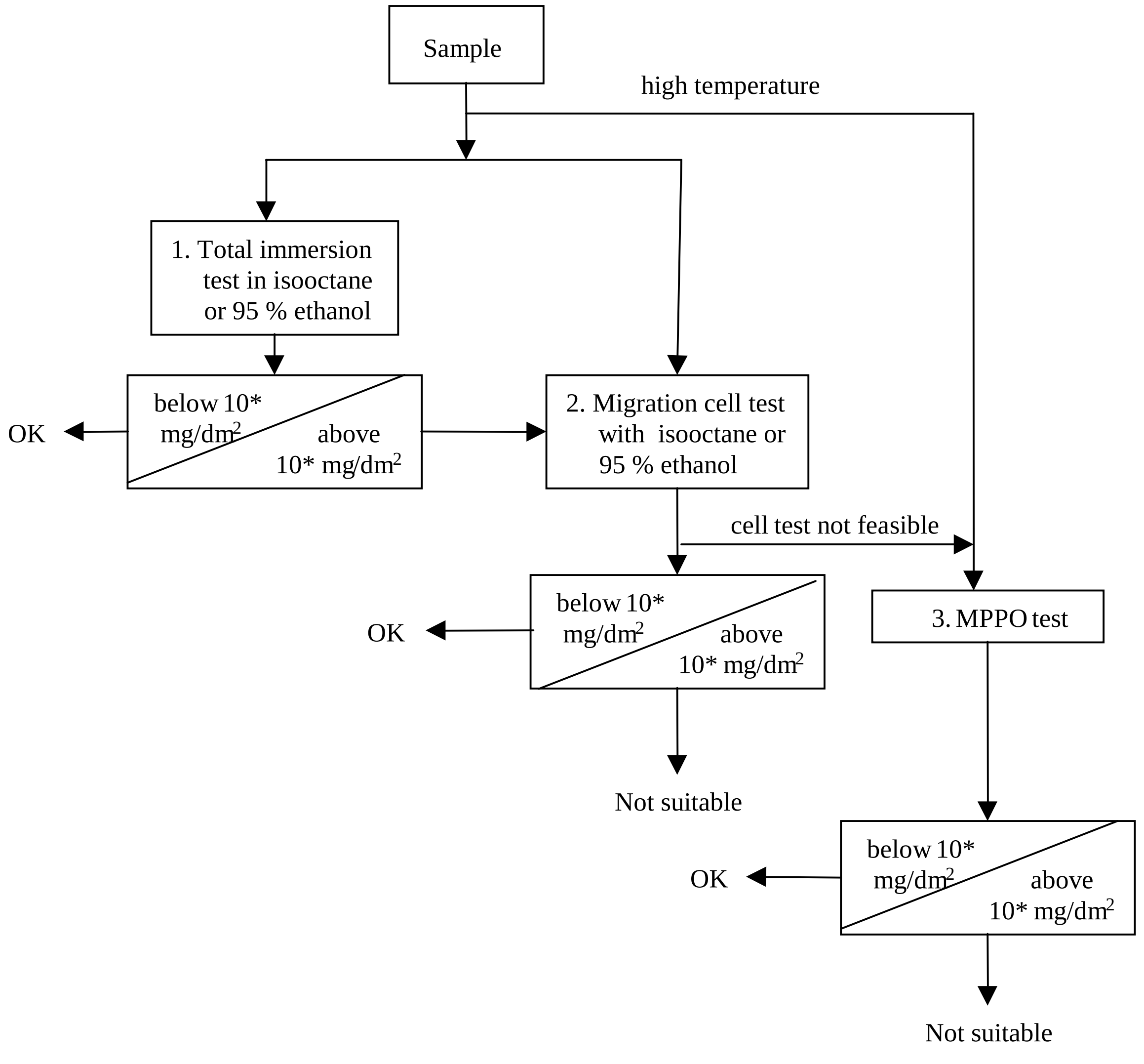
The extraction conditions are to be selected from table 1 (3.1) according to the nature of the polymeric coating of the samples, or according to clauses 4, 5 and 6 of ENV 1186-1: 1994.

Place the three cells and the two tubes in the thermostatically controlled oven or incubator (5.2.8), set at the test temperature and observe the temperature. Leave the cells and tubes for the set test period after the air bath of the thermostatically controlled oven or incubator has reached the set temperature and taking the permitted time and temperature tolerances into account (see annex B of ENV 1186-1: 1994). Take the cells and the two tubes containing the blank simulants from the thermostatically controlled oven or incubator and let the cell temperature allow to come down to room temperature. Transfer by a 50 ml or 100 ml pipette (5.2.7) the simulant from each of the three cells into three tubes, check the level of simulant in each. Recover at least 90 % of the original volume of solvent or repeat the test. Rinse each cell twice with 20 ml ± 2 ml of simulant, add these rinses to the respective tubes.

WARNING Both iso-octane and ethanol are volatile flammable solvents. Take care to avoid any loss of solvent into the interior of the thermostatted device. Place the cells and tubes, if possible, in a drip container serving as a possible solvent reservoir in case of leakage. Do not allow the temperature to exceed 60 °C.

Annex A
(normative)

Proposed test scheme for papers with polymeric coatings intended for fatty food contact



***** Reduction factors according to 85/572/EEC should be applied

Figure A.1 — Proposed test scheme for papers with polymeric coatings intended for fatty food contact. (Applies to both ´substitute Tests´ and ´alternative Tests´)

Annex B
(informative)

Guidance for migration testing of polymeric coatings on cellulosic substrates (paper and board)

Introduction

The European Commission intends to extend the scope of the Commission Directive 90/128/EEC [4] relating to plastic materials and articles intended to come into contact with foodstuffs to polymeric coatings on paper and board. The aim of this document is to give guidance for the application of Council Directive 82/711/EEC [1], as amended by Commission Directives 94/8/EC and 97/48/EC [2], [3] as regards the determination of the specific and overall migration into fatty food simulants. A glossary of terms and definitions is also included to clarify the terminology used.

B.1 Glossary of terms relating to polymeric or plastics layers on paper and board

B.1.1 Scope and field of application

This glossary deals with terms used in the manufacture of polymeric or plastics layers and their application to paper and board.

The following terms and definitions are used in the converting and packaging industries in respect of multi-layer materials.

B.1.2 Basic materials

B.1.2.1
polymer
macromolecular compound obtained by polymerisation (polyaddition, polycondensation or any other similar process) of monomers and other starting substances or by fermentation with bacteria from other starting substances

B.1.2.2
monomer and other starting substance
substance used in the manufacture of a macromolecule, which constitutes the repeating unit of a polymer chain or of a polymer network of any substance used for the manufacture of a plastics for food contact or used to modify existing natural or synthetic macromolecular substances

B.1.2.3
plastics
polymer or mixture of polymers to which additives may have been added and which is used, as such, for the manufacture of finished materials and articles. Or as defined in Commission Directive 90/128 /EEC [4] the organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules

B.1.2.4
additive
substance which is incorporated into plastics to achieve a technical effect in the finished product or used to provide a suitable medium in which polymerization occurs

B.1.2.5
prepolymer
reactive polymer with few repeating units, which has been prepared for use as a monomer or starting substance.

NOTE Usually there are approximately 2 to 20 repeating units

B.1.2.6
paper
Generic term for a range of materials in the form of a coherent sheet or web, excluding sheets or laps of pulp commonly understood for paper making or dissolving purposes and non-woven products, made by deposition, of vegetable, mineral, animal or synthetic fibres, or their mixtures, from a fluid suspension onto a suitable forming device, with or without the addition of other substances

NOTE They may be coated, impregnated or otherwise converted, during or after their manufacture, without necessarily losing their identity as paper. In conventional paper making processes, the fluid medium is water; new developments, however, include the use of air and other fluids.

B.1.2.7
board
generic term applied to certain types of paper frequently characterized by their relatively high rigidity

NOTE 1 In the generic sense the name "paper" can be used to describe both paper and board as defined.

NOTE 2 For some purposes, materials of a grammage of less than 225 g/m² are considered to be paper, are generally referred to as "paper".

B.1.2.8
binder
Material that holds the pigment particles, in a pigment coating, together and fixes them to the surface of the paper or board

B.1.2.9
dispersion
Mixture of particles distributed in a vehicle. The particles can be in the form of hard aggregates or be flocculated, or both conditions could exist together

B.1.2.10
emulsion
Mixture of two mutually insoluble liquids in which one liquid is finely dispersed as droplets in the other

B.1.2.11
paraffin wax
Mixtures of high-boiling hydrocarbons derived from petroleum, solid at room temperature with a melting range from approximately 40 °C to 60 ^{o}C

B.1.2.12
layer
continuous thickness of a material covering the surface of a substrate, forming a multi-component structure

B.1.3 Processes

B.1.3.1 coating
process by which one, or more, continuous layers of a material, in fluid or molten form, is applied to the surface of an existing material

B.1.3.2
solvent coating
process by which a solution or dispersion of a polymeric material and additives, in an appropriate volatile solvent, is applied in one or more steps onto the moving web of the substrate. The film is formed by evaporation of the solvent

NOTE This process is also known under the name of lacquering or lacquer coating.

B.1.3.3
dispersion or emulsion coating
process by which an aqueous dispersion or emulsion and additives is applied in one or more steps onto the moving web of the substrate. The film is formed by evaporation of water

NOTE Wax is a common additive.

B.1.3.4
solvent free coating
process by which monomers or prepolymers in liquid form, with or without reaction agents, is applied onto the moving web of the substrate. The polymer is formed by a chemical reaction (curing) initiated by catalysis, radiation (ultraviolet or infra red radiation, heat), electron beam, high frequency, water, steam or high temperature

B.1.3.5
extrusion or co-extrusion coating
process by which a molten polymeric material is forced (extruded) through a die positioned immediately above the nip between a supporting roll and chill roll and drawn down into this nip, where the molten film comes in contact with the moving web of the substrate. The polymer is solidified by cooling in the nip and remains tightly bonded to the substrate. When two or more polymeric materials are melted in two or more separate machines (extruders) and the melts are forced through one single die the process is called co-extrusion coating

B.1.3.6
hot melt coating
process by which a molten mixture of waxes, polymers or other film forming materials is applied by means of rollers or dies onto the moving web of the substrate, where it is solidified by cooling and remains tightly bonded to the substrate

NOTE Hot melt coated paper or board does not come within the scope of Commission Directive 90/128/EEC [4] and its subsequent amendments.

B.1.3.7
paraffin or wax coating
process by which a molten paraffin or wax is applied by rollers or curtain onto the moving web of the substrate, where it is solidified by cooling.

NOTE Paraffin or wax coated paper or board does not come within the scope of Directive 90/128/EEC or its subsequent amendments.

B.1.3.8
pigment coating
process by which a layer of mineral or artificial pigments, together with binders and other additives, is applied in the form of a slurry (coating slip) onto the moving web of the substrate

NOTE 1 This process is commonly used during paper or board production and is usually described as 'paper coating'.

NOTE 2 This type of coated paper or board does not come within the scope of Commission Directive 90/128/EEC [4] or its subsequent amendments and therefore is not seen as a polymeric coated material.

B.1.3.9
laminating
process by which two or more layers are joined together by a layer with an adhesive function to form a multi-layer structure

NOTE 1 In the case of paper and board the adhesive layer can be, for example, a dispersion or solvent based or a solvent free adhesive, an extruded polymer, a hot melt, a wax, or a paraffin.

NOTE 2 In some countries the laminating process is called lining, when a surface layer of paper, plastics film, metal foil or any other material is pasted with an adhesive onto one or both sides of paper or board.

B.1.3.10
impregnation
process by which a moving web of an absorptive substrate is immersed in a liquid, which penetrates into the substrate. This can either be molten wax or paraffins or a dispersion of waxes, paraffins or polymeric materials

NOTE Film forming does not usually occur. Impregnated paper and board does not come within the scope of Commission Directive 90/128/EEC [4] or its subsequent amendments.

B.1.4 Products

B.1.4.1
coated product
two or more layers of different materials produced by means of a coating process as mentioned in B.1.3.1 to B.1.3.8.

B.1.4.2
coated paper or board
coated product (B.1.4.1) in which at least one layer is paper or board. (see NOTE in B.1.3.8)

B.1.4.3
laminated product, laminate
two or more layers of similar or different materials combined by means of a laminating process (B.1.3.9)

B.1.4.4
laminated paper, laminated board
laminated product (B.1.4.3) in which at least one layer is paper or board.

B.1.4.5
impregnated product
substrate permeated with a liquid by impregnation (B.1.3.10)

B.1.4.6
impregnated paper or board
impregnated product (B.1.4.5) in which the impregnated layer is paper or board (see NOTE B.1.3.8).

B.1.5 Others

B.1.5.1
perforation
Holes in the polymeric layer made by boring, piercing or stamping

NOTE Although these combinations come within the scope of the Commission Directive 90/128/EEC [4]and its subsequent amendments, testing with liquid simulants according the rules laid down in Council Directive 82/711/EEC [1] is not possible.

B.1.5.2
pinholes
Unintentional small holes in the polymeric layer occurring during the coating process

NOTE The presence of pinholes can sometimes make migration testing with liquid simulants impossible.

B.2 Specific migration into fatty food simulants

For the specific migration into fatty food simulants Council Directive 82/711/EEC [1], as last amended by Commission Directives 94/8/EC and 97/48/EC {2], [3], applies.

B.3 Overall migration into fatty food simulants

B.3.1 Problems related to the determination of the overall migration into fatty food simulants

Many investigators have reported problems with overall migration testing of plastics coated paper and board with fatty food simulants [10], [11], [12], [13].

The problems described are:

- unreliable results , with a very high spread exceeding the analytical tolerance and negative values;
- the test is technically impossible due to the penetration of olive oil through pinholes in the polymeric layer, cell leakages, problems with conditioning to constant weight.

The technical problems are mainly caused by the water content of paper and board and the hygroscopic behaviour of these materials. Often equilibrium moisture content can only reached after a long period of drying or is never reached. The hygroscopic properties of paper and board can also give weighing problems because of rapid uptake of moisture present in the air.

B.3.2 Use of the "substitute tests" and "alternative tests"

As provided by Commission Directive 97/48/EC[3] in this specific case the fat test may be replaced by the substitute fat tests in accordance with the rules provided by Chapter III. In principle this Chapter allows the use of the substitute media, isooctane and 95 % ethanol and, at temperatures $\geq$ 100 °C modified polyphenylene oxide. Moreover the same Directive permits the use of "alternative tests" under the conditions mentioned in Chapter IV.

In order to simplify the application of the substitute and alternative tests CEN/TC 194/SC 1/WG 6 has carried out a research programme on the feasibility of these tests, see clause B.5. This study has shown:

a) the use of iso-octane in single side contact is recommended for polyolefin coatings, e.g. polyethylene and polypropylene;

b) the use of ethanol 95 % is recommended for some coatings, e.g. polyesters and polyamides [14],[15];

c) the use of modified polyphenylene oxide is recommended at higher temperatures or in cases where a single side test with solvents is impossible because of excessive penetration of the solvent through pinholes;

d) the test using iso-octane at 1 d at 40 °C in total immersion condition is considered the more severe test condition of Table IV of Commission Directive 97/48/EC. Therefore it may be used, in first instance, to establish the compliance of the material or article, provided that the test results do not exceed the migration limits. In cases where the limits are exceeded this test has to be performed in single side contact condition.

A guide to the selection of conditions and test methods for the test of overall migration from polymeric coatings on cellulosic substrates (paper and board) is given in clause B.5.

B.4 Research on “Substitute” and “Alternative” Tests

A research programme on the feasibility of different test methods was initiated by CEN/TC194/SC1/WG6. In this research five representative material structures were tested for extraction and migration with substitute simulants iso-octane, 95 % ethanol and modified polyphenylene oxid at different test conditions and the results were compared with conventional overall migration into olive oil.

The conclusions of this study were that

- the determination of the overall migration into olive oil from polymeric coatings on paper and board may be impossible in some cases, 3 out of 5 in this study, due to technical difficulties and/or unreliable results;
- the test condition of 1 d at 40 °C was found to be more severe than 2 d at 20 °C for both solvents iso-octane and 95 % ethanol;
- total immersion was confirmed as a more severe test than exposure in single side contact;
- in those cases where the olive oil test was technically feasible as a reference, single side test procedure with iso-octane, 95 % ethanol and modified polyphenylene oxide provided results which were equal to or greater than those found with olive oil;
- 95 % ethanol was found to be inappropriate for some materials as follows:
  a) when tested by total immersion which led to an extensive extraction of substances of the paper and board. This is a situation that does not occur under worst foreseeable conditions of use where such an extensive penetration of foodstuffs is prevented by the functional polymeric barrier covering the paper and board;
  b) when tested by single side contact, for certain types of polymeric coatings (from polymer dispersions soluble in ethanol), because the polymeric layer was physically affected (dissolved), causing penetration of the solvent and extraction of substances of the paper and board layer underneath to an extent which does not occur under worst foreseeable conditions of use of these materials.

The final conclusion is that for determining overall migration from polymeric coatings on paper and board substitute tests should be used instead of olive oil under test conditions laid down in Chapter III, Table 4 (Conventional conditions for substitute tests) of Commission Directive 97/48/EC [3]. Use of iso-octane as fatty food simulant in single side contact is recommended for polyolefin coatings, e.g. polyethylene and polypropylene. For some coatings, e.g. polyesters and polyamides, 95 % ethanol is recommended [14],[15].

Modified polyphenylene oxide can be used in a verification test at higher temperatures or in cases where a single side test with solvents is impossible because of excessive penetration of the solvent through pinholes.

Since extraction by total immersion into iso-octane 1 day at 40 °C was clearly found to be an even more severe test condition than to 2 days at 20 °C it will also be permissible - in accordance with Chapter IV of Commission Directive 97/48/EC [3] - to use these conditions. This cheap and simple test procedure may be applied as a first approach in testing overall migration and may also be applied where single side testing with solvents is linked to technical problems like cell leakages or pinholes. Provided that the test results do not exceed the migration limits overall migration shall be regarded as being in compliance. In cases where overall migration limits are exceeded in the extraction test by total immersion, a substitute test in single side contact has to be performed to verify compliance.

B.5 Proposed guide to the selection of conditions and test methods for the test of overall migration from polymeric coatings on cellulosic substrates (paper and board) intended for contact with fatty food

B.5.1 Examine the sample and determine the type of coating. For the definition of different types of coatings see clause B.1.

B.5.2 As shown in Figure B.1, the sample is first tested by total immersion according to ENV 1186-14 “Test methods for substitute tests” clause 3. The test time and temperature is chosen according to Commission Directive 97/48/EC [3].

NOTE 1 The type of coating determines the choice of solvent, see. the European Commission’s Note for Guidance [2])

---

[2]) See the latest version of the document on the European Commission website (http://cpf.jrc.it/webpack/)

NOTE 2 The test according to step 1 may be omitted and the test started at step no 2.

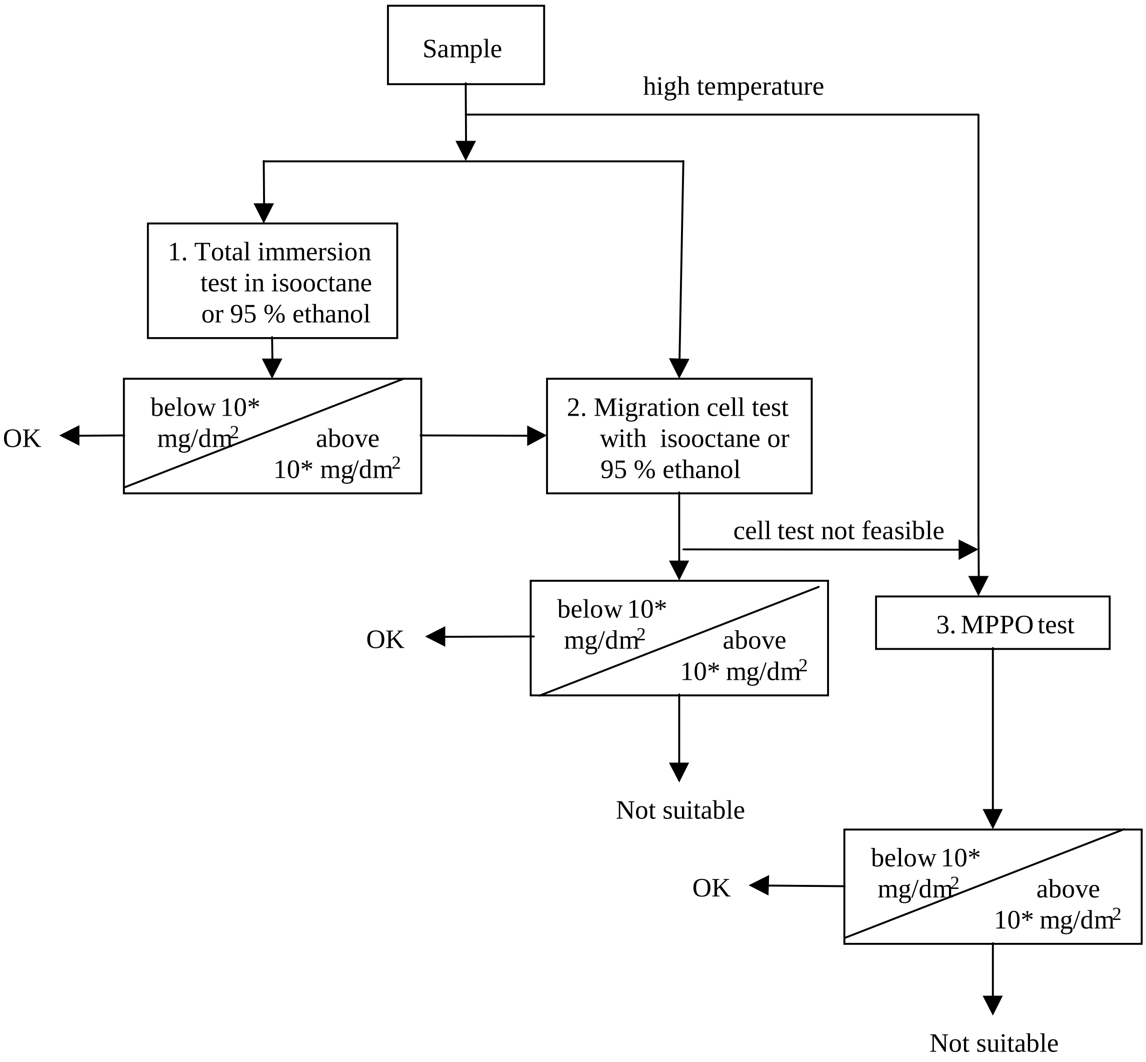
NOTE 3 If the coating is damaged by the solvent (dissolved or partly dissolved) the test should start at step 3 below.

B.5.3 If the test result from step 1 is above 10 mg/dm^2, the sample is tested in migration cell according to ENV 1186-14:1999 “Test methods for substitute tests”. The test time and temperature is chosen according to Commission Directive 97/48/EC [3].

B.5.4 If the test according to step 2 above is not possible to perform, the sample may be tested according to ENV 1186-13 B “Test method for overall migration at high temperatures”, but using a lower temperature. Test time and temperature is chosen according to Commission Directive 97/48/EC [3] (hot fill applications).

B.5.5 For samples intended for use at high temperatures (e.g. microwave susceptors) the test shall be started directly at step No. 3. Test time and temperature is in this case chosen according to directive 97/48/EC.

B.5.6 The “alternative tests” defined as in Commission Directive 97/48/EC [3] may be used as an alternative to this test scheme, e.g. ENV 1186-15 “Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and/or 95 % ethanol”.



***** Reduction factors according to Council Directive 85/572/EEC should be applied.

Figure B.1 — Proposed test scheme for papers with polymeric coatings intended for fatty food contact

Annex ZA
(informative)

Relationship of this Technical Specification with Council Directive 89/109/EEC and associated EU Directive(s)

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

WARNING Other requirements and other EU Directives may be applicable to products falling within the scope of this Technical Specification.

All materials and articles intended to come into contact with foodstuffs have to comply with Council Directive 89/109/EEC on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs.

This Directive lays down requirements for all materials intended for food contact applications, not only plastics. Council Directive 89/109/EEC [16] states that "materials and articles shall be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which can:

- endanger human health;
- bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

The Directive includes a list of groups of materials and articles to be covered by specific Directives. These include plastics, varnishes and coatings, and paper and paperboard.

Commission Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs, [4] has been published and implemented by Member States. However, the scope of this Directive does not yet cover plastics coatings on non plastics substrates, such as paper and board. It is expected that the scope of Commission Directive 90/128/EEC will be extended to include plastics coatings on non plastics substrates and this Technical Specification has been prepared in support of the possible provisions of that extended scope in advance of the extension.

There is an expectation that polymeric coatings on non plastics substrates will be subject to an overall migration limit similar to that specified for materials and articles of an all plastics construction, which is as follows:

European Commission Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs, [4], 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 [1], and the subsequent amendments (Directives 93/8/EEC [2] and 97/48/EC [3]), 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', provision for alternative tests and more severe 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.

In the case of polymeric coatings on paper and board the use of fatty food simulants is not feasible for technical reasons so the substitute test media isooctane and 95 % ethanol are used.

Testing with aqueous foods can be carried out according to the procedures for single surface testing of plastics as described in ENV 1186.

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 [17] 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 plastics materials and articles intended to come into contact with a particular foodstuff or group of foodstuffs.

Bibliography

[1] 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.

[2] 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.

[3] Commission of the European Communities, Commission Directive 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

[4] 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. L349, p26. Corrigendum of the previous publication, Official Journal of the European Communities, 21 March 1990, No. L 75. p19.

[5] Berghammer, A., Bücherl, T., Malter, C. and Pröckl M.: "Schnellextraktionsverfahren zur Bestimmung der potentiell migrierfähigen Substanzen aus flexiblen Verpackungen und beschichteten und/oder lackierten Metallen.", Verpackungs-Rdsch. 45, p 41-45 (1994).

[6] Baner, A.L., Franz, R. and Piringer, O.: "Alternative methods for the determination and evaluation of migration potential from polymeric food contact materials.", Deutsche Lebensm.-Rdsch. 90 (5), p 137-143 and 90 (6) p 181-185 (1994).

[7] Baner, A.L., Franz, R. and Piringer O.: "Alternative fatty food simulants for polymer migration testing: experimental confirmation.", J. Polymer Engineering 15 (1-2), p 161-180, (1995/6).

[8] Van Battum, D.: “Alternative Fatty-Food Simulants - A Fact-Finding Exercise“, EU Commission Research Report N33, Revision 1, February 1996.

[9] Cooper, I., Goodson, A. and Tice, P.A.: “PVC Thermoformed containers for food packaging: establishment of a rapid extraction test for overall migration limit compliance testing“, Packaging Technology and Science 10, p 169-175, (1997).

[10] H. Hainje, Results inventory of problems related to testing polymeric coatings on cellulosic substrates. CEN/TC194/SC1/WG6 Document N 11, August 1995

[11] D. van Battum, Alternative fatty food simulants, a fact finding exercise. October 1994, revised February 1996 (EU Commission RESEARCH N 33)

[12] R. Franz, Research programme of CEN/TC194/SC1/WG6/TG2 on "The feasibility of alternative approaches to overall migration testing of coated cellulosic substrates for food contact". Final Report November 1997

[13] M. Björklund Jansson, Alternative methods for the evaluation of migration from plastic coated paperboard to fatty food simulants. Lecture held on a workshop at JRC, Ispra, October 1997

[14] prENV 1186 –15:1999.

[15] Practical Guide, CS/PM/2604 Rev 2, March 1997

[16] 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.

[17] 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.

[18] EN 13676 Polymer coated paper and board intended for food contact – Detection of pinholes

BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: +44 (0)20 8996 9000. Fax: +44 (0)20 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: +44 (0)20 8996 9001. Fax: +44 (0)20 8996 7001. Email: orders@bsi-global.com. Standards are also available from the BSI website at http://www.bsi-global.com.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre. Tel: +44 (0)20 8996 7111. Fax: +44 (0)20 8996 7048. Email: info@bsi-global.com.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: +44 (0)20 8996 7002. Fax: +44 (0)20 8996 7001. Email: membership@bsi-global.com.

Information regarding online access to British Standards via British Standards Online can be found at http://www.bsi-global.com/bsonline.

Further information about BSI is available on the BSI website at http://www.bsi-global.com.

Copyright

BSI
389 Chiswick High Road
London
W4 4AL