SLOVENSKI STANDARD
SIST ENV 13130-1:2000

01-april-2000

Materiali in predmeti v stiku z ġivili - Snovi v plastiļ nih masah, katerih koncentracija je omejena - 1. del: Vodilo za preskusne metode za specifiļ no migracijo snovi iz plastiļ nih mas v ġivila in njihove modelne raztopine ter doloļ evanje snovi v plastiļ nih masah in izbiranje pogojev izpostavljanja modelnim raztopinam za ġivila

Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 1: Guide to the test methods for the specific migration of substances from plastics into foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Substanzen in Kunststoffen, die Grenzwerten unterliegen - Teil 1: Leitfaden für die Auswahl der Prüfverfahren für die spezifische Migration von Substanzen aus Kunststoffen in Lebensmitteln und Prüflebensmittel, die Bestimmung von Substanzen in Kunststoffen und die Auswahl der Kontaktbedingungen für Prüflebensmittel

Matériaux et objets en contact avec les denrées alimentaires - Matieres plastiques soumises a des limitations - Partie 1: Guide des méthodes d'essai pour la migration spécifique dans les denrées alimentaires et les simulants de susbstances contenues dans les matieres plastiques, pour la détermination des substances dans les matieres plastiques et pour le choix des conditions d'exposition aux simulants alimentaires

Ta slovenski standard je istoveten z: ENV 13130-1:1999

ICS:

67.250	Materiali in predmeti v stiku z živili	Materials and articles in contact with foodstuffs

SIST ENV 13130-1:2000 en

EUROPEAN PRESTANDARD
PRÉNORME EUROPÉENNE
EUROPÄISCHE VORNORM

ENV 13130-1

March 1999

ICS 67.250

English version

Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 1: Guide to the test methods for the specific migration of substances from plastics into foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants

Matériaux et objets en contact avec les denrées alimentaires - Matières plastiques soumises à des limitations - Partie 1: Guide des méthodes d'essai pour la migration spécifique dans les denrées alimentaires et les simulants de substances contenues dans les matières plastiques, pour la détermination des substances dans les matières plastiques et pour le choix des conditions d'exposition aux simulants alimentaires

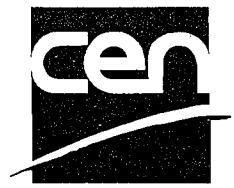
Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Substanzen in Kunststoffen, die Grenzwerten unterliegen - Teil 1: Leitfaden für die Auswahl der Prüfverfahren für die spezifische Migration von Substanzen aus Kunststoffen in Lebensmittel und Prüflebensmittel, die Bestimmung von Substanzen in Kunststoffen und die Auswahl der Kontaktbedingungen für Prüflebensmittel

This European Prestandard (ENV) was approved by CEN on 18 February 1999 as a prospective standard for provisional application.

The period of validity of this ENV 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 ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV 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, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. ENV 13130-1:1999 E

Contents

Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 194 "Utensils in contact with food", the secretariat of which is held by BSI.

This Part of this European Prestandard has been prepared by a Subcommittee (SC1) of TC194 "Utensils in contact with food" as one of a series of test methods for plastics materials and articles in contact with foodstuffs.

Further Parts of this prestandard have been prepared, and others are in preparation, concerned with the determination of specific migration from plastics materials into foodstuffs and food simulants and with the determination of specific monomers and additives in plastics.

Their titles are as follows:

ENV 13130-2 Determination of terephthalic acid in food simulants

ENV 13130-3 Determination of acrylonitrile in food and food simulants

ENV 13130-4 Determination of 1,3-butadiene in plastics

ENV 13130-5 Determination of vinylidene chloride in food simulants

ENV 13130-6 Determination of vinylidene chloride in plastics

ENV 13130-7 Determination of ethylene glycol and diethylene glycol in food simulants

ENV 13130-8 Determination of isocyanates in plastics

Method development for other monomers subject to limitation is being co-ordinated by the Measurement and Testing Programme of DG XII (formerly BCR).

Annexes A, B and C to this prestandard are normative where applicable.

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

1 Scope

This Part of this European Prestandard provides a guide to the selection of the appropriate conditions and test methods for the determination of specific migration of those substances subject to a limit upon their migration into food and food simulants from plastics which are intended to come into contact with foodstuffs and the determination of substances in plastics.

This prestandard is concerned with the testing required by the Commission Directive of 23 February 1990 relating to plastics materials and articles intended to come into contact with foodstuffs (90/128/EEC) (D.1).

Attention is drawn to Article 2 of the Council Directive of 21 December 1988 on the approximation the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (89/109/EEC) (D.2).

2 Normative references

This European Prestandard 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 Prestandard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 10088-1:1995	Stainless steels - Part 1: List of stainless steels
EN ISO 8442-2:1997	Materials and articles in contact with foodstuffs - Cutlery and table holloware - Part 2: Requirements for stainless steel and silver-plated cutlery (ISO 8442-2:1997)
ISO 648:1977	Laboratory glassware - One mark pipettes
ISO 4788:1980	Laboratory glassware - Graduated measuring cylinders

3 Definitions

NOTE: For the purposes of this prestandard plastics are as described in Commission Directive 90/128/EEC Article 1 paragraph 3.

For the purposes of this prestandard, the following definitions apply:

3.1 final article: Article in its ready-for-use state or as sold.

3.2 sample: Material which is under investigation.

3.3 test specimen: Portion of the sample on which a test is performed.

3.4 test piece: Portion of the test specimen.

3.5 conventional oven: Oven where the air within the oven is heated and this heat is then transferred to the food through the plastics as opposed to a microwave oven where the food itself is heated directly by microwave irradiation.

3.6 food simulant: Medium intended to simulate foods, see clause 7.

3.7 specific migration: Mass of the substance transferred to the simulant as measured in the test method.

3.8 standard pouch: Pouch of known dimensions which when filled with food simulant exposes an area of 2 dm^2 of the food contact side of the plastics to the food simulant.

3.9 reverse pouch: Pouch which is fabricated such that the surface intended to come into contact with foodstuffs is the outer surface.

NOTE: All of its sides are sealed to prevent the inner surfaces coming into contact with the food simulant and it is intended to be totally immersed in food simulant.

3.10 specific migration limit (SML): Maximum level of a named substance migrating from the final article into food or food simulants as permitted by Commission Directive 90/128/EEC (D.1) and its subsequent amendments.

3.11 SML(T): Maximum level of a named substance migrating from the final article into food or food simulants as permitted by Commission Directive 90/128/EEC (D.1) and its subsequent amendments, expressed as total of moiety or substance(s) indicated.

3.12 compositional limit (Qm): Maximum level of the "residual" monomer or substance in the material or article as permitted by Commission Directive 90/128/EEC and its subsequent amendments.

3.13 Qm(T): Maximum level of the "residual" monomer or substance in the material or article as permitted by Commission Directive 90/128/EEC and its amendments, expressed as total of moiety or substance(s) indicated.

3.14 standard cell: Cell of known dimensions which when filled with food simulant exposes a known surface area of the food contact surface of the plastics to the food simulant.

4 General

4.1 Summary

This Part of this prestandard is intended to give advice on the selection of the most appropriate test conditions for a given application of a plastics article and should be read in its entirety before testing protocols are finalized.

When determining the specific migration of substances from plastics into foodstuffs or food simulants the test procedure is carried out in two stages. The first stage is the exposure of the plastics to the foodstuffs or food simulants under conditions of use or simulated conditions of use. The second stage is the determination of the migrant in the foodstuff or food simulant. This Part of this prestandard comprises advice and instructions on the procedures to be followed, where appropriate, in preparing the sample for exposure, the selection of conditions of exposure to food simulants and the calculation of migration levels when the chemical analysis is complete. Methods for the chemical analysis of the individual substances or groups of substances in food or food simulants and in plastics are given in other Parts of this prestandard.

4.2 Precautions in handling and testing

Many substances are volatile substances which migrate spontaneously from plastics. When plastics containing volatile substances subject to a specific limitation are sampled or tested, careful consideration needs to be given to possible loss of the substance by volatilization. Loss of volatiles could be minimized by low temperature storage or hermetic sealing.

In many applications of plastics, under actual conditions of use, it is possible that volatile substances will not migrate exclusively into the food but could be lost to the surrounding atmosphere. Considerations are given to the classification of substances on the basis of volatility in annex A.

4.3 Analysis in food simulants

Where a plastics is intended to be used in contact with a wide variety of foodstuffs it could be impracticable to test with all possible foodstuffs. Frequently the presence of interfering substances in the food precludes the use of simple analytical methods in actual foodstuffs. For these reasons migration testing with conventional food simulants is authorized in the EC Directives.

In general, the methods described in other Parts of this prestandard have been devised for use with the conventional food simulants. When the analysis is in the liquids chosen by convention to simulate foodstuffs, this Part of this prestandard is intended to give advice on the selection of the most appropriate test conditions and test method for a given application of a plastics article and should be read in its entirety before testing protocols are finalized.

4.4 Analysis in food

In some cases it could be necessary to carry out the analysis for a migrant in actual foodstuffs. This is particularly so for enforcement authorities where a sample of the plastics which has not been in contact with food is not available. Testing in actual real foods could also be appropriate when the testing in food simulants under the conventional conditions, taking into account reduction factors of Directive 85/572/EEC (D.5), is known usually to be too severe.

For some analytical procedures, for example head space gas chromatography analysis of volatile substances, analysis in a wide variety of foodstuffs could be possible. When the analysis is carried out in actual foodstuffs particular care needs be taken to ensure the validity of the results (see 11.3) since the performance characteristics of the method are unlikely to have been established for actual foods. Where a particular procedure has also been found to be suitable in actual foodstuffs this will be indicated in the Part of this prestandard relevant to that particular substance.

4.5 Analysis of materials and articles

Some substances listed in the directives are subject to a compositional limit (Qm). In these instances the methods given in the subsequent Parts of this prestandard require direct analysis of materials and articles prior to contact with foodstuffs or food simulants. The procedure for sampling materials and articles for analysis is described in clause 10.

4.6 Multi-analyte analysis

Some plastics contain several substances subject to specific migration limitation and/or compositional limitation. In the case of determination of migrants, frequently one test solution or one sample of foodstuff derived from a single exposure of the plastics to food simulant or foodstuff could contain several substances and subsequently needs to be divided to allow each substance to be determined. In the case of compositional limits when the plastics article is subsampled these could be divided for the analysis of individual substances. If one substance is designated as a volatile substance then the procedures for exposure to simulants and sampling have to be those applicable to volatile substances.

4.7 Multi-layer materials

There are many plastics constructions in food contact applications where the food contact surface is different chemically from the other layers. The current Commission Directive 90/128/EEC requires that when all layers are plastics all components shall comply with the Directive. If there is a compositional limit (Qm) then this applies to the article as a whole. This is the only practical means of testing the final article. Where a specific migration limit (SML) applies, it is essential that the test is carried out with only the food contact surface in contact with the food simulant so that permeation of monomers through the food contact surface is simulated in the test conditions in a similar manner to that which occurs under actual conditions of use.

5 Test conditions

5.1 General

The basic rules necessary for testing the migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs are laid down in EC Directive 82/711/EEC (D.3) as amended by EC Directive 93/8/EEC (D.4). Directive 93/8/EEC specifies the test times and temperatures to be chosen according to conditions of contact in actual use. These are detailed in table B.1.

5.2 Testing where temperatures and times of use are known

Where the conditions of use, that is temperatures and times of exposure of the final article, are known the final article may be tested according to the test conditions specified in table B.1. If the final article is known to be subjected to a combination of conditions of use a combination of test conditions has to be employed as indicated in Chapter II Paragraph 3 of the Annex of 93/8/EEC (D.4).

5.3 Testing where temperatures and times of use are not known

Many articles could be used at a variety of temperatures and for varying times, or their conditions of use are not known. Where the plastics material or article could in actual use be employed under any condition of time, but be employed at any temperature up to and including 70 °C and is labelled accordingly, only the 10 day test at 40 °C is required, see paragraph 4 in Chapter II in the Annex of EC Directive 93/8/EEC (D.4).

Where the plastics material or article could in actual use be employed under any condition of time, but be employed at a temperature above 70 °C and is not labelled, tests shall be carried out with simulants 3 % w/v aqueous acetic acid and 15 % v/v aqueous ethanol at reflux or 100 °C for 2 h, if possible, and also with olive oil for 2 h at 175 °C, see paragraph 4 in Chapter II in Annex of EC Directive 93/8/EEC (D.4).

Where labelling or instructions are given to indicate conditions of use expected in real use, times and temperatures from the table in Chapter II in Annex of the amendment of EC Directive 82/711/EEC should be used.

If a plastics material or article is, in actual use, employed for periods less than 15 min at temperatures between 70 °C and 100 °C and is labelled accordingly only the 2 h test at 70 °C and the 10 day test at 40 °C shall be carried out.

5.4 Testing at low temperatures

Testing with fats at 5 °C could lead to unreliable results if the fat partially solidifies or, in the case of the synthetic triglyceride mixture, totally solidifies. However, with olive oil and sunflower oil the test is usually without this problem at 10° C. If the specific migration does not exceed the limit when tested at 10 °C ± 1 °C this indicates that it would have passed at 5 °C. However solidification should not affect the result.

Alternatively a sunflower oil, which is free of components which solidify at the temperature of test (i.e. a so-called "dewaxed" oil), may be used.

Testing by total immersion or in a standard cell or in an equivalent cell or in a standard pouch is practicable at low temperatures. However if a cell or pouch is used for the fat simulant, where a visual check on solidification is difficult, a dewaxed simulant should be used.

5.5 Caps, gaskets, stoppers or similar sealing devices and lids

In many cases lids and closures could be expected to come into contact with foodstuffs and should be tested under similar conditions to the rest of the container. In some high temperature applications the lid is only exposed to aqueous vapours and this condensed vapour is returned to the bulk of the foodstuff and, therefore, the testing should be carried out with the aqueous food simulants.

5.6 Tubing, taps, valves, filters

Defining the time of exposure can be difficult for articles such as tubing, taps, valves, filters etc. as they can be in contact with flowing foodstuff. However, this exposure can be considered to be repeated brief contact. For most articles the migration test should be carried out three times on a single sample, each test period being of 0,5 h. When the contact is more than 30 min, longer periods according to the actual conditions should be used. See 9.8 for further guidance on

repeat testing. Such articles may be tested by repeated total immersion or by repeated filling and tubing may be stoppered with an inert stopper.

6 Sampling of foodstuffs

Where a plastics material or article has been in contact with foodstuff it is not practicable to test with food simulants and therefore, compliance can only be demonstrated by analysis of the foodstuff. Care has to be taken in sampling to avoid loss of volatile substances and also to ensure that portions taken for analysis are representative of the foodstuff as a whole.

Wherever possible the entire contents of the article should be homogenized under cooled conditions (for example liquid nitrogen) and portions of the homogenized material taken for subsequent analysis.

7 Food simulants

7.1 General

The food simulants to be used in migration tests with a particular foodstuff or groups of foodstuffs are laid down in the annex of EC Directive 85/572/EEC (D.5). This is reproduced in table B.2.

7.2 Aqueous food simulants

The aqueous food simulants should be of the quality indicated below:

- simulant A, distilled water or water of equivalent quality;

- simulant B, acetic acid in aqueous solution. Commission Directive 85/572/EEC specifies the use of 3 % w/v aqueous acetic acid. For the purposes of this prestandard this means a solution prepared by diluting 30 g of acetic acid with distilled water to a volume of 1 l;

- simulant C, 15% ethanol (v/v) in aqueous solution.

- Additional alcoholic simulants for liquids or beverages with an ethanol content greater than 15% (v/v). Council Directive 85/572/EEC (D.5) specifies that this test may be carried out with aqueous solutions of ethanol of a similar strength.

7.3 Fat simulants

The fat simulant is as follows:

- simulant D, rectified olive oil.

Included in table B.2 are the characteristics of rectified olive oil and of sunflower oil, and the composition of the mixture of synthetic triglycerides. If for technical reasons connected with the method of analysis it is necessary to use different simulants, olive oil has to be replaced by a mixture of synthetic triglycerides or sunflower oil.

When these fatty food simulants are used to simulate some classes of food, reduction factors may be used as specified in EC Directive 85/572/EEC (D.5).

7.4 Simulating dry foods

According to EC Directive 85/572/EEC (D.5) plastics intended to come into contact with dry food, such as cereals and dried eggs, need not be tested for specific migration.

7.5 Simulating all food types

Where a plastics article is intended for use in contact with all types of food, it shall be tested with 3 % w/v aqueous acetic acid and 15 % v/v aqueous ethanol and the fat simulant without reduction factors. The first amendment to Council Directive 82/711/EEC states that water may be omitted for general case testing. The Directive further provides that when testing to simulate conditions of use at temperatures between 100 °C and 130 °C, 15 % aqueous ethanol is only used at reflux temperatures and for contact conditions of temperatures of 130 °C and above the aqueous simulants are used at 100 °C or reflux.

7.6 Actual foodstuffs

Where the tests are to be carried out with the actual foodstuff intended to come into contact with the plastics material or article, then paragraph 3 of Annex I of Commission Directive 90/128/EEC specifies that the sample has to be placed in contact with the foodstuff in a manner representing the most adverse foreseeable contact conditions in actual use.

8 Apparatus

8.1 General

For volatile substances the testing procedure described intends to reduce the loss of volatiles as far as possible. For non-volatiles a similar approach can be used but the system need not be sealed.

8.2 Specimen supports

In the procedures for exposing plastics to food simulants by total immersion cruciform specimen supports, see figure C.1, have been specified, but other supports may be used providing they are capable of holding and keeping the test pieces apart and at the same time ensuring complete contact with the simulant.

An example of a type of support that has been used successfully, particularly for thick and very thin samples which are wound around the support, is shown in figure C.2.

8.3 Glass rods and glass beads

In several of the procedures for the exposure of plastics to food simulants by total immersion the samples are tested at a fixed ratio of surface area of test specimen to food simulant volume. In order to ensure that all parts of the test specimen are in contact with the food simulant, glass tubes of the appropriate diameter should be used. The dimensions of suitable tubes are specified in the individual methods. However, minor adjustments to the level of the surface in the tubes may be made by adding glass rods or glass beads sufficient to ensure complete immersion of all of the surface of the test specimen. Again the dimensions of suitable glass rods and glass beads are specified in the individual methods.

8.4 Cells

In the procedures described in this Part the availability of the standard Mark 2 cell, type A as shown in figure C.3, has been assumed. However the alternative cells shown in annex C produce results which, within experimental error, are similar. Alternative cells should be of such design to give satisfactory performance, particularly freedom from leakage, with all four food simulants to prevent contamination of the food simulant with analytes under examination and other interfering substances, and with minimum area of the test specimen not in direct contact with the food simulant. Examples of other cells that are available are type A Mark 1, type B and the type C; these are shown in figures C.4, C.5 and C.6 respectively. Type A Mark 1, type B and type C may not be suitable for the determination of volatile substances.

8.5 Thermostatically controlled ovens, incubators or refrigerators

Experience has shown that close temperature control is essential to obtain repeatable results. Therefore care has to be exercised in selecting ovens, incubators or refrigerators to ensure that the temperature control is that specified in the methods throughout the volume of air encompassing the sample tubes, cells or pouches.

9 Samples and sample geometry

9.1 Samples

The samples taken for testing should be the final article, that is in its ready-for-use state. In some cases this could be impracticable and Commission Directive 90/128/EEC allows specimens to be taken from the material or article or where appropriate, specimens representative of this material or article may be used.

When samples are taken all of the data required for sample characterisation should be recorded (see clause 12).

An example is where an article is filled with food at the time it is formed. In this case the test may be carried out on a test article prepared especially for testing purposes. This article has to be as representative as possible of the article in actual use.

A further example is where the sample to be tested is of inhomogeneous construction, is too large to be tested by filling and no flat surfaces can be cut from the sample for testing in the standard cell. In this case the test may be carried out on a test article prepared especially for testing purposes. This article has to be as representative as possible of the article in actual use.

Where samples are taken at random from a production batch this should be indicated when reporting the result. The samples shall be representative of normal production material.
Similarly if the sample was not a random sample, that is it was selected according to some other parameter, e.g. thickness variation, this should also be reported.

Samples can be inhomogeneous, e.g. varying in crystallinity or in molecular orientation, or of irregular shape or thickness, e.g. sections cut from bottles, trays, work surfaces, cutlery etc., or so small that several samples are required to constitute a test specimen. Replicate samples as similar as possible to each other and proportionally representing the sample article shall be tested and the sampling details shall be included in the final report.

Samples shall appear to be clean and free from surface contamination; dust may be removed by wiping the sample with a lint-free cloth or brushing with a soft brush.

Some final articles have instruction to the user that they should be cleaned or treated with oils or other solvents before use. In these cases the samples should be tested after the cleaning process.

9.2 Surface-to-volume ratio

Where the surface-to-volume ratio to be used in contact with food is known this shall be used in the migration testing. An example of this is where a bottle or other container is intended to contain a specified volume of contents even if this does not completely fill the article. In this case the article should be tested with the specified volume of simulant.

Where the surface-to-volume ratio to be used in contact with foodstuff is not known conventional conditions shall be used, i.e. 0,6 dm² of total surface area (counting only one surface in total immersion testing) shall be in contact with 100 ml of foodstuff or food simulant. In Commission Directive 90/128/EEC the surface-to-volume ratio, conventionally, 6 dm² of surface in contact with 1 kg of food and the limits are set in the Directive upon this assumption.
In order to obtain a more favourable concentration of analyte for analysis it could be necessary to vary the surface to volume ratio in the test conditions. Valid results can only be achieved if the migration values obtained, expressed in milligrams per square decimetre, are the same for both the surface-to-volume ratios. This may not be so if there are solubility limitations. Experience has shown that for fatty food simulants the surface-to-volume ratio can be reduced to a maximum ratio of 1 dm²/20 ml and for 15 % v/v aqueous ethanol the maximum ratio is 1 dm²/50 ml to provide increased sensitivity. For 3 % w/v aqueous acetic acid and water no reduction of the surface to volume ratio is advisable.

9.3 Single surface versus double surface testing (by total immersion)

Commission Directive 90/128/EEC (D.1) requires that the test shall be performed in such a way that only those parts of the sample intended to come into contact with foodstuffs in actual use will be in contact with the foodstuff or simulant. However, it shall be permissible to demonstrate compliance with migration limits by the use of a more severe test.

In the total immersion test both the surface which is intended to come into contact with the foodstuff and the outside surface are in contact with the food simulant. No allowance is made for this in the calculation of migration per unit of surface area. It is therefore a more severe test than testing in a pouch or in a cell or by filling.

However, for symmetrical samples only, it could be possible to demonstrate that including both surfaces in the calculation could be valid. This is when it has been shown that the value for specific migration obtained in the total immersion test including both surfaces in the calculation is, allowing for analytical tolerance, the same as that obtained by single surface testing. Conventionally, if the thickness exceeds 0,5 mm, the whole of the surface area is taken into account in determining the migration value.

Samples with cut edges could give higher results than those without. In use the plastics would not normally have cut edges in contact with the foodstuff. Conventionally, in calculating the specific migration result as milligrams of the migrant per square decimetre, the area of the cut edges may be taken into account only if the thickness exceeds 2 mm.

Testing samples with the test specimens prepared by cutting sections from the plastics and totally immersing in the food simulant, is a more severe test.

The surface-to-volume ratio in the total immersion test is conventionally 6 dm^2 of food contact area to 1000 ml of food simulant.

The procedure for exposure by total immersion is given in this Part of the prestandard.

9.4 Single surface testing using a standard Mark 2 cell

Where single surface testing is the preferred procedure, particularly important for multi-layer articles, this may be carried out in a standard Mark 2 cell or in an equivalent cell. For samples that can be obtained in flat form, e.g. film, foil or sheet, testing in the standard cell has the advantage of readily reproducible sample geometry. The standard cell is described in this Part of the prestandard.

Many other cell designs have been proposed for migration testing. Some of these are unsatisfactory as they are prone to leakage of simulant and analyte, which gives rise to inconsistent results.

Other cells which will be evaluated are referred to in 8.4.

The surface-to-volume ratio in the standard Mark 2 cell is conventionally 6 dm^2 of food contact area to 1000 ml of food simulant.

When using a cell, particular care has to be exercised to minimize loss of volatiles and this may be checked using a simulant "spiked" with the analyte at a known concentration.

The procedure for the exposure in a standard Mark 2 cell is given in this Part of the prestandard.

9.5 Single surface testing using a pouch

For flat articles which have sufficient seal strength to form durable pouches testing in a pouch could be preferred as this does not require specialized apparatus and allows more efficient use of oven space. The standard pouch has precise dimensions specified.

The surface-to-volume ratio in the standard pouch is conventionally 2 dm^2 of food contact area to 100 ml of food simulant. If the analyte is determined in milligrams per millilitre, then this may be recalculated for the conventional surface-to-volume ratio of 6 dm^2 to 1 kg (l) of food or food simulant by multiplying by the factor of 300, the result is then in milligrams per kilogram (litre).

The procedure for exposure in a standard pouch is given in this Part of the prestandard.

9.6 Single surface testing using a reverse pouch

As an alternative to using a standard pouch, a reverse pouch may be used. In this case the surface intended to come into contact with the foodstuff is the outer surface and the pouch is exposed to the food simulant by total immersion.

The use of a reverse pouch offers advantages over the standard pouch. Since standard pouches are filled with simulant the sealed edges have to be capable of bearing the weight of that simulant, if they do not the seals give way and the pouches are prone to leakage. With the reverse pouch the seals do not have to withstand the pressure of the simulant and consequently are less likely to leak and the sealed area can be reduced. The use of a reverse pouch permits a more accurate determination of the area exposed to food simulant. However it is possible that simulant can leak into the reverse pouch thus increasing the area exposed to simulant. A way of checking if leaks have occurred is to seal into the reverse pouch a piece of filter paper which is of similar dimensions to the pouch. If the pouch leaks the paper will absorb the simulant and this will be visible. Any pouch that leaks should be discarded and the test repeated.

A further advantage of reverse pouches is that the surface-to-volume ratio can, if required, be adjusted to coincide with that to be used in contact with the foodstuff.

Where the surface-to-volume ratio to be used in contact with food is not known the conventional conditions shall be used, i.e. 6 dm^2 of surface in contact with 1000 ml.