SLOVENSKI STANDARD
SIST EN 1186-1:2002

01-september-2002

Nadomeġļa:
SIST ENV 1186-1:1997

Materiali in predmeti v stiku z živili - Polimerni materiali - 1. del: Vodilo za izbiro pogojev in preskusnih metod za celotno migracijo

Materials and articles in contact with foodstuffs - Plastics - Part 1: Guide to the selection of conditions and test methods for overall migration

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 1: Leitfaden für die Auswahl der Prüfbedingungen und Prüfverfahren für die Gesamtmigration

Matériaux et objets en contact avec les denrées alimentaires - Matiere plastique - Partie 1: Guide pour le choix des conditions et des méthodes d'essai en matiere de migration globale

Ta slovenski standard je istoveten z: **EN 1186-1:2002**

ICS:

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

SIST EN 1186-1:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1186-1

April 2002

ICS 67.250

Supersedes ENV 1186-1:1994

English version

Materials and articles in contact with foodstuffs - Plastics - Part 1: Guide to the selection of conditions and test methods for overall migration

Matériaux et objets en contact avec les denrées alimentaires - Matière plastique - Partie 1: Guide pour le choix des conditions et des méthodes d'essai en matière de migration globale

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 1: Leitfaden für die Auswahl der Prüfbedingungen und Prüfverfahren für die Gesamtmigration

This European Standard was approved by CEN on 5 January 2002.

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

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

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

Contents

Foreword

This document EN 1186-1:2002 has been prepared by Technical Committee CEN/TC 194 'Utensils in contact with food', the secretariat of which is held by BSI.

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

This document supersedes ENV 1186-1:1994.

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

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

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

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

The titles of other parts of this European Standard are as follows:

EN 1186 Materials and articles in contact with foodstuffs - Plastics —:

Part 2	Test methods for overall migration into olive oil by total immersion
Part 3	Test methods for overall migration into aqueous food simulants by total immersion
Part 4	Test methods for overall migration into olive oil by cell
Part 5	Test methods for overall migration into aqueous food simulants by cell
Part 6	Test methods for overall migration into olive oil using a pouch
Part 7	Test methods for overall migration into aqueous food simulants using a pouch
Part 8	Test methods for overall migration into olive oil by article filling
Part 9	Test methods for overall migration into aqueous food simulants by article filling
Part 10	Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs)
Part 11	Test methods for overall migration into mixtures of ^{14}C-labelled synthetic triglycerides
Part 12	Test methods for overall migration at low temperatures
Part 13	Test methods for overall migration at high temperatures
Part 14	Test method for substitute tests for overall migration into iso-octane and 95 % aqueous ethanol

Part 15	Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and/or 95 % ethanol

Annexes A and B form normative parts of this standard. Annex C is for information only

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

Introduction

No single test method has been devised which can be used to determine overall migration, at all temperatures, in all food simulants. Indeed, owing to the practical difficulties inherent in testing with involatile extractants such as fats and the multitude of applications in which plastics articles come into contact with food, there are many methods and permitted variations to methods in this standard.

EN 1186-1 is intended to give advice on the selection of the most appropriate type of test, test conditions and test method for a given application of a plastics article and is intended to be read in its entirety before testing protocols are finalized. For most plastics articles methods in EN 1186-2 to EN 1186-9 are suitable, according to the form in which the article is tested. Subsequent Parts of this standard are intended to be used in conjunction with the methods in EN 1186-2 to EN 1186-9 for more difficult samples and at other temperatures.

The general criteria for the operation and assessment of testing laboratories as well as the general criteria for laboratory accreditation bodies are set out in EN 45001, EN 45002 and EN 45003. It is recommended that laboratories using this standard validate their procedures by testing certified reference samples and by taking part in a proficiency scheme. Reference plastics samples with well characterized values for overall migration into the fatty food simulant olive oil have been prepared as part of a programme sponsored by the Standards, Measurement & Testing Programme of the European Commission, DG XII. Suitable proficiency schemes are operated in Germany and in the United Kingdom, for example the German Assessment Scheme for Food Testing (GAFT) and the Food Analysis Performance Assessment Scheme (FAPAS) conducted by the Central Science Laboratory of the Ministry of Agriculture, Fisheries and Food.

1 Scope

This Part of this European Standard provides a guide to the selection of the appropriate conditions and test methods for the determination of overall migration into food simulants and test media from plastics which are intended to come into contact with foodstuffs.

2 Normative references

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

EN 1186:2002, *Materials and articles in contact with foodstuffs – Plastics.*

ENV 1186-10, *Materials and articles in contact with foodstuffs – Plastics - Part 10: Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs).*

ENV 1186-13, *Materials and articles in contact with foodstuffs – Plastics - Part 13: Test methods for overall migration at high temperatures.*

ENV 1186-14, *Materials and articles in contact with foodstuffs – Plastics - Part 14: Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95 % ethanol.*

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1
plastics
organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any similar process from molecules with a lower molecular weight or by chemical alteration of natural molecules. Other substances or matter may be added to such compounds

3.2
final article
article in its ready-for-use state or as sold

3.3
sample
material or article under investigation

3.4
test specimen
portion of the sample on which a test is performed

3.5
test piece
portion of the test specimen

3.6
conventional oven
oven where the air within the oven is heated and this heat is then transferred to the food through the plastic as opposed to a microwave oven where the food itself is heated directly by microwave irradiation

3.7
food simulant
medium intended to simulate a foodstuff (see clause 3 and clause 4)

3.8
migration test
test for the determination of overall migration using food simulants under conventional test conditions

3.9
substitute test
test carried out which uses test media under conventional substitute test conditions when the use of migration tests is not feasible

3.10
test media
substances used in "substitute tests", iso-octane, 95 % ethanol in aqueous solution and modified polyphenylene oxide

3.11
alternative test
tests, with volatile media, that may be used instead of migration tests with fatty food simulants

3.12
extraction tests
tests in which media having strong extraction under very severe test conditions are used

3.13
overall migration, global migration
mass of material transferred to the food simulant or test media as determined by the relevant test method

3.14
reduction factor
numbers, 2 to 5, which may be applied to the result of the migration tests relevant to certain types of fatty foodstuffs and which is conventionally used to take account of the greater extractive capacity of the simulant for such foodstuffs

3.15
pouch
receptacle of known dimensions manufactured from film to be tested, which when filled with food simulant exposes the food contact side of the film to the food simulant or test medium

3.16
reverse pouch
pouch which is fabricated such that the surface intended to come into contact with foodstuffs is the outer surface. All of its sides are sealed to prevent the inner surfaces coming into contact with the food simulant. The reverse pouch is intended to be totally immersed in food simulant or test medium

3.17
cell
device in which a film to be tested can be mounted which, when assembled and filled with food simulant, exposes the food contact side of the film to the food simulant or test medium

3.18
repeatability value '*r*'
value below which the absolute difference between two single test results obtained under repeatability conditions may be expected to lie with a probability of 95 %

3.19
reproducibility value '*R*'
value below which the absolute difference between two single test results obtained under reproducibility conditions may be expected to lie with a probability of 95 %

3.20
repeatability conditions
conditions where mutually independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time

3.21
reproducibility conditions
conditions where test results are obtained with the same method on identical material in different laboratories with different operators using different equipment

4 Types of test

4.1 Migration tests

"Migration" tests for the determination of overall migration are carried out using the "food simulants" and "conventional migration test conditions", see 5.1, 5.2 and Table 1.

4.2 Substitute tests

If the migration test using fatty food simulants is not feasible, for technical reasons connected with the test method, "substitute tests" which use test media under the conventional substitute test conditions may be appropriate. The substitute tests involve the use of all of the substitute test media, 95 % ethanol in aqueous solution, iso-octane and modified polyphenylene oxide under the test conditions corresponding to the test conditions for simulant D, see Table 4. A new test specimen is used for each test. The reduction factors, 2 to 5, are applicable to these substitute tests, see clause 6. To ascertain compliance with the overall migration limit the highest value obtained using all of the test media is selected.

4.3 Alternative tests

4.3.1 "Alternative tests" with volatile media

The results of alternative tests, using volatile test media such as iso-octane and 95 % ethanol in aqueous solution or other volatile solvents or mixtures of solvents may be used to demonstrate compliance with the legislative limit, provided that:

a) the result obtained in a comparison test shows that the value is equal to or greater than those obtained in the migration test with a fatty food simulant;

b) the migration in the alternative test does not exceed the overall migration limit, after application of appropriate reduction factors.

If either or both conditions are not fulfilled, then the migration tests (4.1) have to be performed.

4.3.2 Extraction tests

Other tests are permitted which use other test media having very strong extractive power under severe test conditions, if it is generally recognized, on the basis of scientific evidence, that the results obtained using these extraction tests are equal to or higher than those obtained with simulant D.

4.4 Criteria for the use of substitute tests

The use of substitute tests is justified, when the migration test carried out with each of the possible simulants D is found to be inapplicable due to technical reasons connected with the migration test, e.g. interferences, incomplete extraction of oil, absence of stability of the mass of the plastics, excessive absorption of fatty food simulant, reaction of components with the fat.

5 Food simulants, test media and reagents

5.1 Aqueous food simulants

The aqueous food simulants shall be of the following quality:

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

- 3 % acetic acid (w/v) in aqueous solution, simulant B;

  For the purposes of this standard this means a solution prepared by diluting 30 g of acetic acid with distilled water to a volume of 1 l;

- 10 % ethanol (v/v) in aqueous solution, simulant C.

For liquids or beverages with an ethanol content greater than 10 % (v/v) the test is carried out with aqueous solutions of ethanol of a similar strength.

Each of the above food simulants shall give a non-volatile residue of less than 5 mg/l, when evaporated to dryness and dried to constant mass at 105 °C to 110 °C.

5.2 Fatty food simulants

The fatty food simulants are as follows:

- rectified olive oil, "reference simulant D".

This "reference simulant D" may be replaced by a synthetic mixture of triglycerides or sunflower oil or corn oil with standardized specifications. These are known as "other fatty food simulants" and called "simulant D".

For the characteristics of olive oil, a synthetic mixture of triglycerides, sunflower oil and corn oil, see annex A.

NOTE When these fatty food simulants are used to simulate some classes of food, reduction factors can be used, see 6.2 and Table 2.

5.3 Test media

5.3.1 Test media for substitute tests

The test media to be used in substitute tests are iso-octane, 95 % ethanol in aqueous solution and a modified polyphenylene oxide (MPPO). The characteristics of modified polyphenylene oxide are to be found in annex A.

5.3.2 Test media for alternative tests

These are volatile media such as iso-octane and 95 % ethanol in aqueous solution or other volatile solvents or mixtures of solvents.

5.4 Reagents

Unless otherwise required, reagents shall be of analytical quality.

NOTE Specifications for solid reagents, used as such in discrete quantities, may not address suitability for use in methods of analysis in this standard. Solid reagents meight not be homogeneous with respect to contaminants not addressed by specifications, therefore it may be necessary to demonstrate that such reagents are suitable for use.

6 Selection of food simulants

NOTE Commission Directive 85/572/EEC [6] specifies the use of 15 % ethanol (v/v) in aqueous solution as simulant C. This has been superseded by Commission Directive 97/48/EC [5] the second amendment to Council Directive 82/711/EEC [3] that specifies 10 % ethanol (v/v) in aqueous solution.

6.1 Simulating contact with all food types

Where a plastics article is intended for use in contact with all types of food it shall be tested with 3 % acetic acid (w/v) in aqueous solution, simulant B, 10 % ethanol (v/v) in aqueous solution, simulant C and a fatty food simulant, simulant D, without reduction factors. If when using any of the other fatty food simulants, see 5.2, the migration limit is exceeded, for the judgement of non compliance with the overall migration limit a confirmation of the result by using olive oil is obligatory, when technically feasible. If this confirmation is not technically feasible and the migration from the material or article exceeds the limit it shall be deemed not in compliance with the overall migration limit.

6.2 Simulating contact with specific food types

Provision for materials and articles intended to come into contact with specific food types has been made in the following situations:

a) when the material or article is already in contact with a known foodstuff;

b) when the material or article is accompanied, by a specific indication stating with which food types it may or may not be used, for example "only for aqueous foods";

c) when the material or article is accompanied by a specific indication stating with which foodstuff(s) or group(s) of foodstuffs they may or may not be used. This indication shall be expressed:

1) at the marketing stage other than retail stage, by using the " reference number" or "description of foodstuffs";

2) at the retail stage using an indication which shall refer to only a few foods or groups of food, preferably with examples which are easy to understand.

In situation b) the simulants to be used in the overall migration tests are specified in Table 1.

Table 1 — Food simulants to be selected for testing food contact materials in special case

Contact foods	Simulant
Only aqueous foods	Simulant A
Only acidic foods	Simulant B
Only alcoholic foods	Simulant C
Only fatty foods	Simulant D
All aqueous and acidic foods	Simulant B
All alcoholic and aqueous foods	Simulant C
All alcoholic and acidic foods	Simulants C and B
All fatty and aqueous foods	Simulants D and A
All fatty and acidic foods	Simulants D and B
All fatty and alcoholic and aqueous foods	Simulants D and C
All fatty foods and alcoholic and acidic foods	Simulants D, C and B

In situation a) and c) the tests are carried out using the food simulants mentioned in Table 2.

In Table 2 for each foodstuff or group of foodstuffs, only the simulant(s) indicated by an 'X' is (are) to be used, using for each simulant, a new sample of the materials and subject concerned. Where no 'X' appears, no migration test is required for the heading or subheading concerned.

When 'X' is followed by an oblique stroke and a figure, the result of the migration tests should be divided by the number indicated. In the case of certain types of fatty foodstuffs, this figure, known as the 'reduction factor, is conventionally used to take account of the greater extractive capacity of the simulant for such foodstuffs.

Where a letter 'a' is shown in brackets after the 'X' only one of the two simulants given should be used:

- if the pH value is higher than 4,5, simulant A should be used;

- if the pH value is 4,5, or less, simulant B should be used.

Where a foodstuff is listed under both a specific heading and a general heading, only the simulant(s) indicated under the specific heading is (are) to be used.

Where the foodstuff(s) or group(s) of foodstuffs are not included in the Table 2, select the item from the table of food simulants to be selected for testing food contact materials in special cases, which corresponds most closely to the foodstuff(s) or group of foodstuff(s) under examination.

Table 2 — List of simulants to be used in the migration test with a particular foodstuff or group of foodstuffs

Reference number[1]	Description of foodstuffs	Simulants to be used			
		A	B	C	D
01	**Beverages**				
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5 % vol.:				
	Waters, ciders, fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and others	X(a)	X(a)		
01.02	Alcoholic beverages of an alcoholic strength equal to or exceeding 5 % vol.:				
	Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5 % vol.:				
	Wines, spirits and liqueurs		X(*)	X(**)	
01.03	Miscellaneous: undenatured ethyl alcohol		X(*)	X(**)	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**				
02.01	Starches				
02.02	Cereals, unprocessed, puffed in flakes, (including popcorn, corn flakes and the like)				
02.03	Cereal flour and meal				
02.04	Macaroni, spaghetti and similar products				
02.05	Pastry, biscuits, cakes, and, other bakers' wares, dry:				
	A. With fatty substances on the surface				X/5
	B. Other				
02.06	Pastry, cakes, and, other bakers' wares, fresh:				
	A. With fatty substances on the surface				X/5
	B. Other	X			
03	**Chocolate, sugar and products thereof Confectionery products**				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products:				
	A. In solid form:				
	I. With fatty substances on the surface				X/5
	II. Other				

(*) This test shall be carried out only in cases where the pH is 4,5 or less.
(**) This test may be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10 % vol. with aqueous solutions of ethanol of a similar strength.

[1] The source of the reference number is Commission Directive 85/572/EEC[6]

Table 2 (continued)

Reference number	Description of foodstuffs	Simulants to be used			
		A	B	C	D
03.02 *(continued)*	B. In paste form: I. With fatty substances on the surface II. Moist	 X			 X/3
03.03	Sugar and sugar products A. In solid form B. Honey and the like C. Molasses and sugar syrups	 X X			
04	**Fruit, vegetables and products thereof**				
04.01	Whole fruit, fresh or chilled				
04.02	Processed fruit: A. Dried or dehydrated fruit, whole or in the form of flour or powder B. Fruit in the form of chunks, purée or paste C. Fruit preserves (jams and similar products - whole fruit or chunks or in the form of flour or powder, preserved in a liquid medium): I. In an aqueous medium II. In an oily medium III. In an alcoholic medium (≥ 5 % vol.)	 X(a) X(a) X(a)	 X(a) X(a) X(*)	 X	 X
04.03	Nuts, (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and other): A. Shelled, dried B. Shelled and roasted				 X/5(**)
04.04	C. In paste or cream form	X			X/3(**)
04.05	Whole vegetables, fresh or chilled Processed vegetables: A. Dried, or dehydrated vegetables whole or in the form of flour or powder B. Vegetables, cut, in the form of purées C. Preserved vegetables; I. In an aqueous medium II. In an oily medium III. In an alcoholic medium (≥ 5 % vol.)	 X(a) X(a) X(a)	 X(a) X(a) X(a) X(*)	 X	 X
05	**Fats and oils**				
05.01	Animals and vegetable fats and oil, whether natural or treated (including cocoa butter, lard, resolidified butter)				X
05.02	Margarine, butter and other fats and oils made from water emulsions in oils				X/2

(*) This test is to be used only where the pH is 4,5 or less.
(**) If it can be determined by means of an appropriate test that there is no 'fatty contact' with the plastics, the test with simulant D may be dispensed with.