

Materials and articles in contact with foodstuffs — Plastics

Part 1. Guide to the selection of conditions and test methods for overall migration

UDC 663/664 : 678-4 : 620.1

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National foreword

This Draft for Development has been prepared under the direction of the Consumer and Contract Goods Standards Policy Committee and is the English language version of European Prestandard ENV 1186-1 : 1994 *Materials and articles in contact with foodstuffs — Plastics — Part 1: Guide to the selection of conditions and test methods for overall migration*, published by the European Committee for Standardization (CEN).

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 more experience of the methods described is required. 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 three-year life. The commencement of the review period will be notified by an announcement in *BSI News*.

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 prestandard or to withdraw it. Comments should be sent in writing to the Secretary of BSI Technical Committee CCM/47 at BSI, 389 Chiswick High Road, London W4 4AL giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

CAUTION. Attention is drawn to the Health and Safety at Work etc. Act 1974, and the need for ensuring that the method specified in this Draft for Development is carried out with suitable precautions.

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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 des
Prüfbedingungen und Prüfverfahren für die
Gesamtmigration

This European Prestandard (ENV) was approved by CEN on 1993-03-09 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 (EN).

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.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

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 methods of test 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 overall migration from plastics materials into food simulants.

Their titles are as follows:

ENV 1186-2	<i>Test methods for overall migration into olive oil by total immersion</i>
ENV 1186-3	<i>Test methods for overall migration into aqueous simulants by total immersion</i>
ENV 1186-4	<i>Test methods for overall migration into olive oil by cell</i>
ENV 1186-5	<i>Test methods for overall migration into aqueous food simulants by cell</i>
ENV 1186-6	<i>Test methods for overall migration into olive oil using a pouch</i>
ENV 1186-7	<i>Test methods for overall migration into aqueous simulants using a pouch</i>
ENV 1186-8	<i>Test methods for overall migration into olive oil by article filling</i>
ENV 1186-9	<i>Test methods for overall migration into aqueous food simulants by article filling</i>
ENV 1186-10	<i>Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs)</i>

Further Parts in preparation are as follows:

ENV 1186-11	<i>Test methods for overall migration into mixtures of ¹⁴C-labelled synthetic triglyceride</i>
ENV 1186-12	<i>Test methods for overall migration at low temperatures</i>
ENV 1186-13	<i>Test methods for overall migration at high temperatures</i>

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

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

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0 Introduction

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

Attention is drawn to Article 2 of the 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 foodstuffs (89/109/EEC) (C.2).

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 prestandard.

ENV 1186-1 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. For most plastics articles methods in ENV 1186-2 to ENV 1186-10 are suitable, according to the form in which the article is tested. Subsequent Parts of this prestandard are intended to be used in conjunction with the methods in ENV 1186-2 to ENV 1186-10 for more difficult samples and at other temperatures.

1 Scope

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

2 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:

2.1 **final article:** article in its ready-for-use state or as sold.

2.2 **sample:** material or article under investigation.

2.3 **test specimen:** portion of the sample on which a test is performed.

2.4 **test piece:** portion of the test specimen.

2.5 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.

2.6 food simulant: medium intended to simulate a foodstuff (see clause 4).

2.7 overall migration; global migration: mass of material transferred to the food simulant as determined by the relevant test method.

2.8 standard pouch: pouch of fixed dimensions which when filled with food simulant exposes a surface area of 2 dm² of plastic to the food simulant.

2.9 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.

3 Conditions of test

3.1 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 Council Directive 82/711/EEC (C.3). This Directive specifies the test times and temperatures to be chosen according to conditions of contact in actual use. These are detailed in table A.1 for conditions of use up to 121° C. The Council Directive stated that where temperatures in use are above 121° C the test conditions should be in accordance with national laws.

NOTE: Since the approval of this Part by Subcommittee 1 of TC194 Council Directive 82/711/EEC has been amended by Commission Directive 93/9/EEC (C.4). This Directive includes amendment to the test conditions and temperatures to be chosen according to conditions of contact in actual use. The amended conditions are detailed in table A.2.

3.2 Testing where temperatures and times of use are known

Where the conditions of use, in terms of temperature(s) and time(s) of exposure, of the final article are known, it may be tested according to the test conditions specified in table A.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 clause 2 of the Annex of 82/711/EEC.

3.3 Testing where temperatures and times of use are not known

Many articles may be used at a variety of temperatures and for varying times, or their conditions of use may not be known. Where the plastics material or article may in actual use be employed under any conditions of contact time or temperature, only the 10 day tests at 40 °C and the 2 h tests at 70 °C are

to be carried out with new specimens, these being conventionally regarded as the most stringent, according to clause 4 in Chapter II in the Annex of EC Directive 82/711/EEC. If the fat simulant is used, only the 10 day tests at 40 °C is to be carried out (see table A.1). This is considered to be sufficient testing to demonstrate compliance for use at all temperatures up to 121° C.

3.4 Testing at low temperatures

Testing with fats at 5 °C may 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 overall migration does not exceed the limit when tested at 10° C this indicates that it would not have exceeded the limit at 5 °C (see table A.1).

Alternatively a sunflower oil, which is free of components which solidify at the temperature of test (i.e. a "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, although 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.

The method of test for the determination of overall migration, at low temperatures (5 °C and 20 °C) is to be given in ENV 1186-12¹⁾.

3.5 Testing at high temperatures

When the test conditions for simulating exposure at temperatures above 121 °C have been agreed in a European Community Directive the methods for the determination at these temperatures will be incorporated in ENV 1186-13¹⁾.

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

In many cases lids and closures may be expected to come into contact with foodstuffs and should be tested under similar conditions to the rest of the container. However in some high temperature applications the lid may only be exposed to water vapour and this condensed vapour may be returned to the bulk of the foodstuff (see 6.9).

3.7 Tubing, taps, valves, filters

Defining the time of exposure may be difficult for articles such as tubing, taps, valves, filters etc. as they may be in contact with flowing foodstuff. However, this exposure may be considered to be repeated brief contact for the purposes of migration testing. Such articles may be tested by repeated total immersion or by repeated filling, tubing may be stoppered with an inert stopper.

1) In preparation.

4 Food simulants and reagents

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 (C.5). This is reproduced in table A.3.

4.1 Aqueous food simulants

The aqueous food simulants should be of the following quality:

- simulant A, distilled water or of equivalent quality;
- simulant B, acetic acid in aqueous solution. Council 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, ethanol 15 % (v/v) in aqueous solution.

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

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

4.2 Fat simulants

The fat simulants are as follows:

- simulant D, rectified olive oil.

Also included in table A.3 are the characteristics of the 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 shall 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.

4.3 Simulating dry foods

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

4.4 Simulating all food types

Where a plastics article is intended for use in contact with all types of food it should be tested with all 3 aqueous simulants and the fat simulant without reduction factors.

4.5 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 prestandard. Solid reagents may not be homogenous with respect to contaminants not addressed by specifications, therefore it may be necessary to demonstrate that such reagents are suitable for use.

5 Apparatus

5.1 Specimen supports

In the methods for determining overall migration by total immersion, cruciform specimen supports, see figure B.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 B.2. This type of support when loaded with the specimens is exposed to the simulants in 100 ml beakers. The beaker is then covered with a watch glass. When using this support the ratio of 1 dm² of food contact area to 100 ml of simulant should be maintained where possible.

5.2 Tubes, glass rods and glass beads

In several of the methods for determining overall migration 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 the 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.

5.3 Cells

In the methods described in this European Prestandard, the availability of the standard cell, type A as shown in figure B.3, has been assumed. However alternative cells may be satisfactory if they produce results which, within experimental error, are equivalent to those produced with type A. These 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 non-volatile 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 B and type C; these are shown in figures B.4 and B.5 respectively.