

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

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 13130-1:2004 sisaldab Euroopa standardi EN 13130-1:2004 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 23.09.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 13130-1:2004 consists of the English text of the European standard EN 13130-1:2004.</p> <p>This document is endorsed on 23.09.2004 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p><b>Käsitlusala:</b> This part of this European Standard provides a guide to the selection of the appropriate conditions of contact of food simulants with the test article before the determination of specific migration of those substances subject to a migration limit.</p>	<p><b>Scope:</b> This part of this European Standard provides a guide to the selection of the appropriate conditions of contact of food simulants with the test article before the determination of specific migration of those substances subject to a migration limit.</p>
--	--

ICS 67.250

Võtmesõnad:

ICS 67.250

English version

Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 1: Guide to test methods for the specific migration of substances from plastics to 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 des denrées alimentaires - Substances dans les matières plastiques soumises à des limitations - Partie 1 : Guide des méthodes d'essai pour la migration spécifique dans les denrées alimentaires et les simulants d'aliments de substances contenues dans les matières plastiques, détermination des substances dans les matières plastiques et choix des conditions d'exposition aux simulants d'aliments

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Substanzen in Kunststoffen, die Beschränkungen unterliegen - Teil 1: Anleitung für Testmethoden für die spezifische Migration von Substanzen aus Kunststoffen in Lebensmitteln und Lebensmitteln-Simulantien, Bestimmung der Substanzen in Kunststoffen und Auswahl von Expositionsbedingungen für Lebensmitteln-Simulantien.

This European Standard was approved by CEN on 24 March 2004.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, 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

	page
Foreword.....	6
<b>1</b> <b>Scope</b> .....	<b>9</b>
<b>2</b> <b>Normative references</b> .....	<b>9</b>
<b>3</b> <b>Terms and definitions</b> .....	<b>9</b>
<b>4</b> <b>General</b> .....	<b>12</b>
4.1 <b>Summary</b> .....	<b>12</b>
4.2 <b>Precautions in handling and testing</b> .....	<b>12</b>
4.3 <b>Analysis of a substance in a food simulant - migration test</b> .....	<b>12</b>
4.4 <b>Analysis of substance in a foodstuff</b> .....	<b>13</b>
4.5 <b>Analysis of a substance in a test medium - substitute fat tests</b> .....	<b>13</b>
4.6 <b>Analysis of a substance in a 'volatile' test medium - alternative fat tests</b> .....	<b>13</b>
4.7 <b>Analysis of a substance in a plastics material or article</b> .....	<b>13</b>
4.8 <b>Multi-analyte analyses</b> .....	<b>13</b>
4.9 <b>Multilayer materials and articles</b> .....	<b>13</b>
<b>5</b> <b>Types of test</b> .....	<b>14</b>
5.1 <b>Substitute tests</b> .....	<b>14</b>
5.2 <b>Substitute tests</b> .....	<b>14</b>
5.3 <b>Alternative fat tests</b> .....	<b>14</b>
5.3.1 <b>General</b> .....	<b>14</b>
5.3.2 <b>Alternative tests with volatile media</b> .....	<b>14</b>
5.3.3 <b>Extraction tests</b> .....	<b>14</b>
5.4 <b>Residual content determination</b> .....	<b>15</b>
5.4.1 <b>"QM" test</b> .....	<b>15</b>
5.4.2 <b>"QMA" test</b> .....	<b>15</b>
<b>6</b> <b>Food simulants, test media and reagents</b> .....	<b>15</b>
6.1 <b>Aqueous food simulants</b> .....	<b>15</b>
6.2 <b>Fatty food simulants</b> .....	<b>16</b>
6.3 <b>Test media</b> .....	<b>16</b>
6.3.1 <b>Test media for substitute tests</b> .....	<b>16</b>
6.3.2 <b>Test media for alternative tests</b> .....	<b>16</b>
6.4 <b>Reagents</b> .....	<b>16</b>
<b>7</b> <b>Selection of food simulants</b> .....	<b>17</b>
7.1 <b>General</b> .....	<b>17</b>
7.2 <b>Simulating contact with all food types</b> .....	<b>17</b>
7.3 <b>Simulating contact with specific food types</b> .....	<b>17</b>
7.4 <b>Simulating contact with dry foods and frozen food</b> .....	<b>23</b>
7.5 <b>Testing for fatty contact</b> .....	<b>23</b>
<b>8</b> <b>Migration test, substitute test and alternative test conditions and conditions of residual content determination</b> .....	<b>24</b>
8.1 <b>Test conditions for migration tests</b> .....	<b>24</b>
8.1.1 <b>General</b> .....	<b>24</b>
8.1.2 <b>Introduction</b> .....	<b>24</b>
8.1.3 <b>Contact conditions generally recognized as 'more severe'</b> .....	<b>24</b>
8.1.4 <b>Contact for less than 15 min at temperatures between 70 °C and 100 °C</b> .....	<b>25</b>
8.1.5 <b>Contact in a microwave oven</b> .....	<b>26</b>
8.1.6 <b>Contact conditions causing changes in physical or other properties</b> .....	<b>26</b>
8.1.7 <b>Contact not covered by the conventional condition for migration tests</b> .....	<b>26</b>
8.1.8 <b>Testing at low temperatures</b> .....	<b>26</b>

8.1.9	Testing at high temperature .....	27
8.1.10	Caps, gaskets, stoppers or similar sealing devices and lids .....	27
8.1.11	Tubing, taps, valves, filters .....	27
8.2	Test conditions for substitute fat tests .....	27
8.3	Test conditions for alternative fat tests .....	28
8.3.1	Alternative fat test with volatile media .....	28
8.3.2	Extraction tests.....	28
9	Apparatus .....	28
9.1	Specimen supports .....	28
9.2	Tubes, glass rods and glass beads .....	28
9.3	Cells .....	29
9.4	Thermostatically controlled ovens or incubators .....	29
10	Samples and sample geometry.....	29
10.1	Samples .....	29
10.2	Surface-to-volume ratio .....	30
10.3	Single surface versus double surface testing (by total immersion) .....	30
10.4	Single surface testing using a cell type A Mark 2.....	31
10.5	Single surface testing using a pouch.....	31
10.6	Single surface testing using a reverse pouch.....	31
10.7	Single surface testing by filling .....	32
10.8	Articles intended for repeated use .....	32
10.9	Caps, closures and other sealing devices.....	32
10.10	Large containers.....	33
10.11	Tubing, taps, valves and filters.....	33
10.12	Fibres and cloths.....	33
10.13	Articles of irregular shape .....	33
11	Sampling.....	33
11.1	Sampling of test articles .....	33
11.2	Sampling of foodstuffs .....	34
12	Precision.....	34
13	Expression of results .....	34
13.1	General - specific migration test results.....	34
13.1.1	Introduction.....	34
13.1.2	For unknown surface-to-volume ratios.....	34
13.1.3	For known surface-to-volume ratios and tested under these conditions .....	35
13.1.4	For known surface-to-volume ratios and not tested under these conditions.....	35
13.1.5	Conversion recalculation.....	35
13.2	Reduction factors with the fat simulant.....	35
13.3	Calculation of QA for compliance with QMA .....	36
13.4	Validity of results.....	37
13.5	Confirmation of results .....	37
13.6	Group limits .....	37
14	Test reports and statements of compliance .....	38
14.1	Test reports .....	38
15	Exposure by total immersion in a thermostatically controlled oven, incubator or refrigerator .....	38
15.1	Introduction.....	38
15.2	Principle.....	38
15.3	Reagents.....	39
15.3.1	Distilled water or water of equivalent quality (simulant A) .....	39
15.3.2	Acetic acid 3 % (w/v) in aqueous solution (simulant B) .....	39
15.3.3	Ethanol 10 % (v/v) in aqueous solution (simulant C).....	39
15.3.4	Alcoholic simulants for liquids or beverages of an alcoholic strength exceeding 10% (v/v).....	39
15.3.5	Olive oil, simulant D as specified in clause 8.....	39
15.3.6	Dewaxed sunflower oil for determinations at low temperatures.....	39
15.3.7	Test media for substitute tests .....	39
15.4	Apparatus .....	39

15.5	Preparation of test specimens .....	40
15.5.1	Number of test specimens .....	40
15.5.2	Thin films and sheet materials .....	40
15.5.3	Containers and other articles .....	40
15.5.4	Articles of irregular shape .....	40
15.5.5	General.....	41
15.6	Procedure .....	41
16	Exposure by total immersion at reflux temperatures .....	41
16.1	Introduction .....	41
16.2	Principle.....	41
16.3	Reagents.....	42
16.4	Apparatus .....	42
16.5	Preparation of test specimens .....	42
16.6	Procedure .....	42
17	Single-side exposure in a cell in a thermostatically controlled oven, incubator or refrigerator.....	42
17.1	Introduction .....	42
17.2	Principle.....	42
17.3	Reagents.....	43
17.4	Apparatus .....	43
17.5	Preparation of the test specimens .....	43
17.5.1	Number of test specimens.....	43
17.5.2	Cutting test specimens .....	43
17.6	Procedure .....	43
18	Single-side exposure with a pouch in a thermostatically controlled oven, incubator or refrigerator.....	44
18.1	Introduction .....	44
18.2	Principle.....	44
18.3	Reagents.....	45
18.4	Apparatus .....	45
18.5	Preparation of test specimens .....	45
18.5.1	Number of test specimens.....	45
18.5.2	Cutting and preparation of specimens.....	45
18.6	Procedure .....	46
19	Single-side exposure by article fill in a thermostatically controlled oven, incubator or refrigerator.....	46
19.1	Introduction .....	46
19.2	Principle.....	46
19.3	Reagents.....	47
19.4	Apparatus .....	47
19.5	Preparation of the test specimens .....	47
19.5.1	Number of test specimens.....	47
19.5.2	Articles with a capacity of less than 500 ml or more than 10 l .....	47
19.6	Procedure .....	47
Annex A (normative)	Criteria for classification of non-volatility.....	49
A.1	Volatile substances .....	49
A.2	Criteria for conventional classification of non-volatility .....	49
Annex B (normative)	Characteristics of fatty food simulants and test media.....	50
	Characteristics of rectified olive oil, reference simulant D .....	50
	Composition of the mixture of synthetic triglycerides, simulant D.....	50
	Characteristics of sunflower oil, simulant D.....	51
	Characteristics of corn oil, simulant D.....	51
	Characteristics of modified polyphenylene oxide (MPPO).....	51
Annex C (normative)	Tolerances on contact times and contact temperatures applicable to all parts of this standard .....	52
Annex D (informative)	Supports and cells .....	54

**Annex E (informative) Relationship of this European Standard with Council Directive 89/109/EEC  
and Commission Directive 2002/72/EC and associated Directives..... 63**

**Bibliography..... 65**

This document is a preview generated by EVS

## Foreword

This document (EN 13130-1:2004) has been prepared by Technical Committee CEN/TC 194 "Utensils in contact with food", the secretariat of which is held by BSI.

This document was prepared by Subcommittee SC1 of TC 194 to provide guidance in the preparation of samples for testing in a series of test methods contained in other parts of this standard.

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 November 2004, and conflicting national standards shall be withdrawn at the latest by November 2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

Informative annex E details the relationship of this standard with the European Union Directives.

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 a test or tests described in this standard.

Further parts of EN 13130, under the general title *Materials and articles in contact with foodstuffs - Plastics substances subject to limitation*, have been prepared, and others are in preparation, concerned with the determination of specific migration from plastics materials into foodstuffs and food simulants and the determination of specific monomers and additives in plastics. The other parts of EN 13130 are as follows.

Part 2: *Determination of terephthalic acid in food simulants*

Part 3: *Determination of acrylonitrile in food and food simulants*

Part 4: *Determination of 1,3-butadiene in plastics*

Part 5: *Determination of vinylidene chloride in food simulants*

Part 6: *Determination of vinylidene chloride in plastics*

Part 7: *Determination of monoethylene glycol and diethylene glycol in food simulants*

Part 8: *Determination of isocyanates in plastics*

Part 9: *Determination of acetic acid, vinyl ester in food simulants*

Part 10: *Determination of acrylamide in food simulants*

Part 11: *Determination of 11-aminoundecanoic acid in food simulants*

Part 12: *Determination of 1,3-benzenedimethanamine in food simulants*

Part 13: *Determination of 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A) in food simulants*

Part 14: *Determination of 3,3-bis(3-methyl-4-hydroxyphenyl)-2-indoline in food simulants*

Part 15: *Determination of 1,3-butadiene in food simulants*

Part 16: *Determination of caprolactam and caprolactam salt in food simulants*

Part 17: *Determination of carbonyl chloride in plastics*

Part 18: *Determination of 1,2-dihydroxybenzene, 1,3-dihydroxybenzene, 1,4-dihydroxybenzene, 4,4'-dihydroxybenzophenone and 4,4'-dihydroxybiphenyl in food simulants*

Part 19: *Determination of dimethylaminoethanol in food simulants*

Part 20: *Determination of epichlorohydrin in plastics*

Part 21: *Determination of ethylenediamine and hexamethylenediamine in food simulants*

Part 22: *Determination of ethylene oxide and propylene oxide in plastics*

Part 23: *Determination of formaldehyde and hexamethylenetetramine in food simulants*

Part 24: *Determination of maleic acid and maleic anhydride in food simulants*

Part 25: *Determination of 4-methyl-pentene in food simulants*

Part 26: *Determination of 1-octene and tetrahydrofuran in food simulants*

Part 27: *Determination of 2,4,6-triamino-1,3,5-triazine in food simulants*

Part 28: *Determination of 1,1,1-trimethylpropane in food simulants*

Parts 2 to 8 are European Standards.

Parts 9 to 28 are Technical Specifications, prepared within the Standards, Measurement and Testing project, MAT1-CT92-0006, "Development of Methods of Analysis for Monomers" <sup>1)</sup>.

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

---

<sup>1)</sup> Franz R. and Rijk.R; Development of methods of analysis for monomers and other starting substances with SML and/or QM limits in Directives 2002/72/EC and 92/39/EEC. European Commission, BCR information: Chemical analysis, EU report 17610 EN, ECSC-EC-EAEC. Brussels - Luxembourg 1997.

## Introduction

EN 13130-1 is intended to give guidance on the selection of the most appropriate type of test, test conditions and test method for a given application of a plastics material or article and is intended to be read in its entirety before testing protocols are finalized.

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 ISO/IEC 17025, EN 45002 and EN 45003. It is recommended that laboratories using this standard validate their procedures by taking part in a proficiency scheme. 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 of contact of food simulants with the test article before the determination of specific migration of those substances subject to a migration limit.

**NOTE** According to Directive 2002/72/EC[2] the determination of the migration of specified components in foodstuffs instead of the use of simulants is permitted. However, in that situation there is no need to give guidance on the test conditions of time and temperature as contact conditions shall be equal to conditions applied in real.

Also general guidance is given for the determination of the amount of the substance in the final plastics material or article.

## 2 Normative references

This European Standard incorporates by dated or 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 or 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 10088-1; *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; *Laboratory glassware – One-mark pipettes.*

ISO 4788; *Laboratory glassware – Graduated measuring cylinders.*

ISO 5725 (all parts); *Accuracy (trueness and precision) of measurement methods and results.*

## 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. Silicones and other macromolecular compounds should also be regarded as plastics. Other substances or matter can be added to such compounds.

### 3.2

#### **final material/article**

material or 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