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English version

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

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln
– Polymerebeschichtungen auf Substraten aus Metall –
Leitfaden zur Auswahl der Bedingungen und Prüfverfahren
zur Bestimmung der Gesamtmigration

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

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

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

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Foreword

This document (CEN/TS 14235:2002) has been prepared by CEN/TC 194 "Utensils in contact with food", the secretariat of which is held by BSI.

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

In this Technical Specification the annexes A, B and C are normative.

This Technical Specification includes a Bibliography.

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

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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 polymeric coatings on metal substrates come into contact with food, there are many methods and permitted variations to methods in this Technical Specification.

This Technical Specification 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 polymeric coating on a metal substrate and is intended to be read in its entirety before testing protocols are finalized. A test method for overall migration into aqueous simulants by article filling from polymeric coatings on food and beverage cans and non-stick coatings is given in clause 12. For many polymeric coated articles methods in EN 1186-2 to EN 1186-9 are suitable, according to the form in which the article is tested.

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 Technical Specification validate their procedures by testing certified reference samples and 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.

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1 Scope

This Technical Specification gives guidelines for the selection of the appropriate conditions and test methods for the determination of overall migration into food simulants and test media from polymeric coatings on metal substrates which are intended to come into contact with foodstuffs and a test method for overall migration into aqueous simulants by article filling from polymeric coatings on food and beverage cans and non-stick coatings.

NOTE Polymeric coatings on metal substrates are not yet included in the scope of any European Union Directive. This Technical Specification has been prepared to assist in the development of such a Directive.

2 Normative references

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

EN 1186-2, *Materials and articles in contact with foodstuffs - Plastics - Part 2: Test methods for overall migration into olive oil by total immersion.*

EN 1186-3, *Materials and articles in contact with foodstuffs - Plastics - Part 3: Test methods for overall migration into aqueous food simulants by total immersion.*

EN 1186-4, *Materials and articles in contact with foodstuffs - Plastics - Part 4: Test methods for overall migration into olive oil by cell.*

EN 1186-5, *Materials and articles in contact with foodstuffs - Plastics - Part 5: Test methods for overall migration into aqueous food simulants by cell.*

EN 1186-6, *Materials and articles in contact with foodstuffs - Plastics - Part 6: Test methods for overall migration into olive oil using a pouch*

EN 1186-7, *Materials and articles in contact with foodstuffs - Plastics - Part 7: Test methods for overall migration into aqueous food simulants using a pouch.*

EN 1186-8; *Materials and articles in contact with foodstuffs - Plastics - Part 8: Test methods for overall migration into olive oil by article filling.*

EN 1186-12, *Materials and articles in contact with foodstuffs - Plastics - Part 12: Test methods for overall migration at low temperatures.*

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

ISO 648 *Laboratory glassware - One-mark pipettes*

3 Terms and definitions

For the purposes of this Technical Specification the following terms and definitions apply.

3.1 polymeric coating

organic material applied in the form of a continuous film on a substrate in such a way as to form a protective layer and/or a functional barrier between food and substrate. They may be applied to the substrate in the form of solution, dispersions, powders, or solvent free preparations.

NOTE This may be different to the definition which is expected to be included in Commission Directive 90/128/EEC when its scope is extended to include polymeric coatings

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 final article 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 clauses 3 and 4)

3.8**migration test**

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

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3.9**substitute test**

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

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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

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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**inert substrate**

material (e.g. silver, platinum, stainless steel, tantalum) which is non-reactive in the food simulant and which can simulate the intended metal substrate when coated with the test material. It is necessary that the inert substrate does not interfere with the overall migration from the coating under the applied test conditions

3.18**pressure retort or autoclave**

pressure vessel (complying with appropriate pressure vessel regulations) in which hermetically sealed containers (e.g. metal plastics, glass) may be safely heated in a controlled manner, typically up to 122 °C and above, and which has suitable controlled cooling facilities

3.19**cell**

device in which a film or flat sheet 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

3.20**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 %

3.21**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%.

3.22**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

3.23**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 4.1, 4.2 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 5. 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:

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- 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.

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If either or both conditions are not fulfilled, then the migration tests (3.1) 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 weight of the polymeric coating, 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 Technical Specification this means a solution prepared by diluting 30 g of acetic acid with distilled water to a volume of 1 l;

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

For liquids or beverages with an ethanol content greater than a volume fraction of 10 % 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 weight at 105 °C to 110 °C.

For overall migration testing of a coating material which is applied to substrates which are not resistant to acid, 3 % acetic acid is an unsuitable simulant because of the interfering corrosion products. 10 % aqueous ethanol should be used instead, since intensive studies have demonstrated that they provide sufficient information to evaluate coating materials for the overall migration properties even under the condition of contact with acidic food.

Only in certain cases would it appear necessary to use 3 % acetic acid as simulant, e.g. for samples containing inorganic constituents and testing specific migration of certain additive such as pigments, siccatives, amines and similar. In these cases the finished product can be tested with acetic acid only if the corrosion products do not interfere with the determination of the particular specific migrant. Otherwise it is recommended either to apply the coating on to an inert substrate prior to testing, or to test the unsupported film in the case of laminated metal.

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 may be used, see 5.3 and Table 2.

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When determining the overall migration from materials and articles the mixtures of fatty acid triglycerides conventionally chosen to simulate fatty food have a number of shortcomings, as follows:

- they are not a single chemical compound and composition can vary even within the permitted specification. The naturally occurring unsaturated fatty acid triglycerides can change upon storage. This allows the possibility of inconsistent results;
- they cannot be evaporated to dryness without decomposition and therefore direct determination of the overall migration by weighing the residue after evaporation is not feasible. An inherently less accurate and more time consuming indirect determination is required;
- they are absorbed by the polymeric coating under test to a varying extent. If the absorption is excessive, this leads to gross inaccuracies in the determination. If the olive oil is not readily extractable errors also can occur. Errors can also occur if the different components of the fatty acid triglyceride are absorbed and extracted from the polymeric coating to a varying degree. Furthermore, substances present in the polymeric coating can interfere with the gas chromatographic determination of olive oil as described in EN 1186-2, EN 1186-4, EN 1186-6 and EN 1186-8;
- fatty acid triglycerides pose safety hazards when used at high temperatures both from the possibility of fire and the dangers of handling hot liquids;
- testing of thin layer coatings, such as used as protective coatings in cans, collapsible tubes and similar articles, does not give reliable results. The overall migration which could be expected under worst case conditions is of about the same order of magnitude as the accuracy of the method (3 mg/dm²). The olive oil procedure is difficult to apply to cans with double seamed or heat sealed ends, and it cannot be applied to finished articles of greater dimension or weight.

For these reasons alternatives are desirable which should, as far as possible, avoid the deficiencies arising with triglycerides while still giving levels of migration comparable with, but not less than, that obtained with fatty acid triglycerides. Alternative fatty food simulants when compared with fatty food or existing fatty food simulants should

possess the following characteristics:

- they should penetrate polymeric coating to the same extent;
- they should be as good a solvent for ingredients of polymeric coatings;
- they should be single substances or clearly defined mixtures.

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 Technical Specification. Solid reagents may 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.

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6 Selection of food simulants

6.1 General

NOTE Commission Directive 85/572/EEC [6] specifies the use of a volume fraction of 15 % ethanol 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 a volume fraction of 10 % ethanol in aqueous solution.

6.2 Simulating contact with all food types

Where a polymeric coating on a metal article is intended for use in contact with all types of food it shall be tested with a volume fraction of 3 % acetic acid in aqueous solution, simulant B, a volume fraction of 10 % ethanol in aqueous solution, simulant C and a fatty food simulant, simulant D, without reduction factors, except when the coating material is applied to a substrate which is not resistant to acid then testing with a volume fraction of 3 % acetic acid is not required, see 4.1.

If, when using any of the other fatty food simulants, see 4.2, 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.

6.3 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

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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, see 5.4 on dry foods and frozen foods.

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.

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