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Materiali in predmeti v stiku z ģivili - Snovi v polimernih materialih, katerih koncentracija je omejena - 1. del: Vodilo za preskusne metode za specifi no migracijo snovi iz polimernih materialov v ģivila in njihove modelne raztopine ter dolo anje evanje snovi v polimernih materialih in izbiranje pogojev izpostavljanja modelnim raztopinam za ģivila

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

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

Matériaux et objets en contact avec des denrées alimentaires - Substances dans les matieres plastiques soumises a 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 matieres plastiques, détermination des substances dans les matieres plastiques et choix des conditions d'exposition aux simulants d'aliments

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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

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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.

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Contents

page

Foreword 6

1 Scope 9

2 Normative references 9

3 Terms and definitions 9

4 General 12
4.1 Summary 12
4.2 Precautions in handling and testing 12
4.3 Analysis of a substance in a food simulant - migration test 12
4.4 Analysis of substance in a foodstuff 13
4.5 Analysis of a substance in a test medium - substitute fat tests 13
4.6 Analysis of a substance in a 'volatile' test medium - alternative fat tests 13
4.7 Analysis of a substance in a plastics material or article 13
4.8 Multi-analyte analyses 13
4.9 Multilayer materials and articles 13

5 Types of test 14
5.1 Substitute tests 14
5.2 Substitute tests 14
5.3 Alternative fat tests 14
5.3.1 General 14
5.3.2 Alternative tests with volatile media 14
5.3.3 Extraction tests 14
5.4 Residual content determination 15
5.4.1 "QM" test 15
5.4.2 "QMA" test 15

6 Food simulants, test media and reagents 15
6.1 Aqueous food simulants 15
6.2 Fatty food simulants 16
6.3 Test media 16
6.3.1 Test media for substitute tests 16
6.3.2 Test media for alternative tests 16
6.4 Reagents 16

7 Selection of food simulants 17
7.1 General 17
7.2 Simulating contact with all food types 17
7.3 Simulating contact with specific food types 17
7.4 Simulating contact with dry foods and frozen food 23
7.5 Testing for fatty contact 23

8 Migration test, substitute test and alternative test conditions and conditions of residual content determination 24
8.1 Test conditions for migration tests 24
8.1.1 General 24
8.1.2 Introduction 24
8.1.3 Contact conditions generally recognized as 'more severe' 24
8.1.4 Contact for less than 15 min at temperatures between 70 °C and 100 °C 25
8.1.5 Contact in a microwave oven 26
8.1.6 Contact conditions causing changes in physical or other properties 26
8.1.7 Contact not covered by the conventional condition for migration tests 26
8.1.8 Testing at low temperatures 26

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**

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-trimethylopropane 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*" [1)] .

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.

[1)] 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

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 plastics 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 4 to 7)

3.8
specific migration
mass of the substance transferred to the simulant as determined in the test method

3.9
residual content
mass of the substance present in the final material or article

3.10
specific migration limit (SML)
maximum permitted level of a named substance migrating from the final material or article into food or food simulants

3.11
SML(T)
maximum permitted level of a named substance migrating from the final material or article into food or food simulants expressed as total of moiety or substance(s) indicated

3.12
compositional limit (Qm)
maximum permitted amount of the "residual" monomer, additive or substance in the material or article

3.13
Qm(T)
maximum permitted amount of the "residual" monomer, additive or substance in the material or article expressed as total of moiety or substance(s) indicated

3.14
quantity per surface area (QMA)
maximum permitted amount of residual monomer, additive or substance in the material or article expressed as mg/6dm^2

3.15
reduction factor
numbers, 2 to 5, which can 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

3.16
migration test
test for the determination of specific migration of substance, using food simulant under conventional test conditions

3.17
substitute fat test
test carried out which uses test media under conventional substitute test conditions when the use of a migration test into fatty food simulant(s) is not feasible

3.18
test media
substances used in "substitute tests", iso-octane, 95 % ethanol in aqueous solution and modified polyphenylene oxide (MPPO)

3.19
alternative fat test
tests, with suitable, usually, volatile media, that can be used instead of migration tests with fatty food simulants

3.20
'volatile' test media
volatile substances used in alternative fat tests

3.21
extraction tests
tests in which media having strong extraction properties under very severe test conditions, are used

3.22
dissolution test
tests in which the sample is dissolved to liberate the substance from the plastics test specimen

3.23
pouch
receptacle of known dimensions manufactured from plastics film/sheet to be tested, which when filled with food simulant or test medium exposes the food contact side of the film/sheet to the food simulant or test medium

3.24
reverse pouch
pouch which is fabricated such that the plastics surface intended to come into contact with foodstuff is the outer surface. All of its edges are sealed to prevent the inner surfaces coming into contact with the food simulant or test medium during the test period. The reverse pouch is intended to be totally immersed in the food simulant or test medium

3.25
cell
device in which a plastics film to be tested can be mounted which when assembled and filled with food simulant or test medium, exposes the food contact side of the film to the food simulant or test medium

3.26
repeatability value 'r'
value below which the absolute difference between two single test results obtained under repeatability conditions can be expected to lie with a probability of 95 %, as described in ISO 5725

3.27
reproducibility value 'R'
value below which the absolute difference between two single test results obtained under reproducibility conditions can be expected to lie with a probability of 95%, as described in ISO 5725

3.28
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

3.29
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 General

4.1 Summary

When determining the specific migration of substances from plastics materials and articles into foodstuffs, food simulants or test media, the test procedure is carried out in two stages. The first stage is the exposure of the plastics material or article to the foodstuff, food simulant or test medium under conditions of use or simulated conditions of use. The second stage is the determination of the migrant in the foodstuff, food simulant or test medium. This part of this standard comprises advice and instructions on the procedures to be followed, where appropriate, in preparing the plastics sample for exposure, the selection of conditions of exposure to food simulants or test media and the calculation of migration levels when the analysis of the migrating substance is complete.

In addition, guidance is given in the preparation of plastics test specimens for the determination of the residual content of a substance or group of substances.

Procedures for sampling plastics materials and articles and foodstuffs for analysis are described in clause 11.

Methods for the chemical analysis of the individual substances or groups of substances in foodstuffs, food simulants and test media, and as residues in plastics materials and articles, are given in other parts of this standard.

4.2 Precautions in handling and testing

Many substances which are the subject of testing are volatile substances which migrate spontaneously from plastics. When testing a plastics material or article containing a volatile substance, careful consideration needs to be given to possible loss of the substance by volatilization after sampling and during testing. Loss of volatiles after sampling and before testing, can be minimized by low temperature storage or hermetic sealing with limited void volume (see clause 11).

In many applications of plastics materials and articles under actual conditions of use, it is possible that volatile substances will not migrate exclusively into the foodstuff but be lost to the surrounding atmosphere.

Considerations are given to the classification of substances on the basis of volatility in annex A.

Cutting or any mechanical treatment of the sample to prepare test specimens or test pieces, for testing with foodstuffs, food simulants or test media, can have an irreversible effect on the composition and/or morphology of the edges of the sample. As a result, with tests performed with test pieces totally immersed in the foodstuff or food simulant the obtained migration value might not be a true reflection of the real migration under actual conditions of use. Plastics sensitive to this phenomenon are acrylonitrile/butadiene/styrene terpolymers (ABS), polystyrene and other styrene co-polymers. With these plastics types, cut edges shall preferably not be in contact with the foodstuff, food simulant or test medium. Care shall also be taken to avoid mechanical damage to surfaces of these types of plastics.

4.3 Analysis of a substance in a food simulant - migration test

Where a plastics material or article 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 foodstuff precludes the use of simple analytical methods. For these reasons migration testing with conventional food simulants is permissible.

In general, the methods described in other parts of this standard 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 standard is intended to give advice on the selection of the most appropriate test conditions and test method for a given application of a plastics material or article and shall be read in its entirety before testing protocols are started.

4.4 Analysis of substance in a foodstuff

In some cases it could be necessary to carry out the analysis for a migrant in an actual foodstuff. This is particularly so for enforcement authorities where a sample of the plastics material or article which has not been in contact with the foodstuff is not available. Testing in actual foodstuff could also be appropriate when the testing in food simulants under the conventional conditions, taking into account reduction factors is known to produce invalid results.

For some analytical procedures, for example headspace gas chromatography analyses of volatile substances, analyses in a wide variety of foodstuffs can be possible. When the analysis is carried out in an actual foodstuff particular care needs be taken to ensure the validity of the test result, since the performance characteristics of the method are unlikely to have been established for the foodstuff. Where a particular procedure has also been found to be suitable for determinations in foodstuffs, this will be indicated in the part of this standard relevant to that particular substance.

4.5 Analysis of a substance in a test medium - substitute fat tests

Where the determination of a specified substance in a fatty food simulant is not feasible, for technical reasons connected with the method of analysis, then a substitute fat test using a test medium (iso-octane, 95% ethanol or modified polyphenylene oxide) can be used. Validity of the test result needs to be verified, since the performance characteristics of the test method might not have been established for the particular test medium.

4.6 Analysis of a substance in a 'volatile' test medium - alternative fat tests

Alternative fat tests using 'volatile' test media can be used to demonstrate compliance with the relevant specific migration limit. The alternative fat test conditions and the 'volatile' test medium shall be selected with great care as the migration into the 'volatile' test medium shall be equivalent to or higher then the migration into the fatty food simulant. Validity of the test result needs to be verified, since the performance characteristics of the method are unlikely to have been established for the particular 'volatile' test medium used.

4.7 Analysis of a substance in a plastics material or article

For those plastics substances which are subject to compositional limits, expressed as maximum quantity of substance, in milligrams, present per kilogram of plastics (mg/kg) - QM, or as maximum quantity of substance, in milligrams, present per 6 square decimetres of surface area of plastics (mg/6 dm^2), an analysis is carried out on the plastics material and article prior to contact with any foodstuff.

4.8 Multi-analyte analyses

Some plastics materials and articles contain several substances subject to specific migration limitations and/or compositional limitations. For the determination of the migration of more than one substance, one test simulant, test medium or one sample of foodstuff derived from a single exposure of the plastics to the food simulant, test medium or a single sample of foodstuff, can be prepared for the analyses. The test simulant, test medium or sample of foodstuff shall be divided to allow each substance to be individually determined, using the appropriate individual analytical test methods. If one of the substances is designated a 'volatile' substance, then the procedures for exposure to simulants, test media and sampling, have to be those applicable to volatile substances. Where the analyses are for substances in the plastics material or article, a suitable sample shall be appropriately divided for the analyses of the individual substances.

4.9 Multilayer materials and articles

There are many plastics constructions in food contact applications where the food contact surface is chemically different from the other layers. For a substance with a compositional limit (QM, mg/kg), the limit can apply only to the layer containing the substance. The concentration in the particular layer is calculated from the analytical measurement of the substance in the multilayer material, if the thickness and density of the layer is known or can be measured.