DRAFT FOR DEVELOPMENT

DD CEN/TS
13130-27:2005

Materials and articles in contact with foodstuffs — Plastics substances subject to limitation —

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

ICS 67.250

BSI
British Standards

National foreword

This Draft for Development is the official English language version of CEN/TS 13130-27:2005.

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 the method was not evaluated using recognized ring trial procedures. As a consequence there are no reproducibility data for the method. 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 3-year life. Notification of the start of the review period will be made in an announcement in the appropriate issue of *Update Standards*.

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 Technical Specification or to withdraw it. Comments should be sent in writing to the Secretary of BSI Subcommittee CW/47/1 Migration from plastics, at British Standards House, 389 Chiswick High Road, London W4 4AL, giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Summary of pages

This document comprises a front cover, an inside front cover, the CEN/TS title page, pages 2 to 14, an inside back cover and a back cover.

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Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 27: Determination of 2,4,6-triamino-1,3,5-triazine in food simulants

Matériaux et objets en contact avec les denrées alimentaires - Substances dans les matières plastiques soumises à des limitations - Partie 27 : Détermination de la 2,4,6-triamino-1,3,5-triazine dans les simulants d'aliments

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Substanzen in Kunststoffen, die Beschränkungen unterliegen - Teil 27: Bestimmung von 2,4,6-Triamino-1,3,5-Triazin in Prüflebensmitteln

This Technical Specification (CEN/TS) was approved by CEN on 16 December 2004 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 promptly at national level in an appropriate form. 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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Contents

Foreword

This document (CEN/TS 13130-27:2005) has been prepared by Technical Committee CEN/TC 194 “Utensils in contact with food”, the secretariat of which is held by BSI.

This part of EN 13130 has been prepared within the Standards, Measurement and Testing project, MAT1-CT92-0006, “*Development of Methods of Analysis for Monomers*” and has been prepared by Subcommittee (SC 1) of TC 194 "Utensils in contact with food" as one of a series of test methods for plastics materials and articles in contact with foodstuffs.

This standard is intended to support Directives 2002/72/EC [1], 89/109/EEC [2], 82/711/EEC [3] and its amendments 93/8/EEC [4] and 97/48/EC [5], and 85/572/EEC [6].

At the time of preparation and publication of this part of EN 13130 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.

This part of EN 13130 should be read in conjunction with EN 13130-1.

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 parts of EN 13130 are as follows.

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*

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-trimethylolpropane in food simulants*

Parts 1 to 8 are European Standards. Parts 9 to 28 are Technical Specifications.

WARNING All chemicals are hazardous to health to a greater or lesser extent. It is beyond the scope of this Technical Specification to give instructions for the safe handling of all chemicals, that meet, in full, the legal obligations in all countries in which this Technical Specification may be followed. Therefore, specific warnings are not given and users of this Technical Specification should ensure that they meet all the necessary safety requirements in their own country.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this CEN Technical Specification: 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.

Introduction

2,4,6-triamino-1,3,5-triazine, ($C_3H_6N_6$), PM/Ref. No 25420, is a monomer used in the manufacture of certain plastics materials and articles intended to come into contact with foodstuffs. Other frequently used names for 2,4,6-triamino-1,3,5-triazine are melamine and 2,4,6-triamino-s-triazine. After manufacture residual 2,4,6-triamino-1,3,5-triazine can remain in the finished product and may migrate into foodstuffs coming into contact with that product.

The method has been pre-validated by a collaborative trial with two laboratories.

1 Scope

This document, part of EN 13130, specifies an analytical procedure for the determination of 2,4,6-triamino-1,3,5-triazine in food simulants distilled water, 3 % (w/v) acetic acid aqueous solution, 15% (v/v) ethanol aqueous solution and rectified olive oil. The level of 2,4,6-triamino-1,3,5-triazine monomer determined is expressed as milligrams per kilogram food simulant. The method is appropriate for the quantitative determination of 2,4,6-triamino-1,3,5-triazine in approximate analyte concentration range of 2 mg/kg to 60 mg/kg food simulant.

NOTE The method should also be applicable to other aqueous food simulants as well as to the other fatty food simulants e.g. sunflower oil, corn oil or a mixture of synthetic triglycerides.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 13130-1:2004, *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..*

3 Principle

The level of 2,4,6-triamino-1,3,5-triazine in food simulants is determined by high performance liquid chromatography (HPLC) using UV detection at 230 nm. The aqueous food simulants are analyzed directly by HPLC. The olive oil test samples are extracted with water/isopropanol and the resultant solutions analyzed by HPLC. Quantification is achieved by means of external standard calibration using relevant food simulant samples fortified with known amounts of 2,4,6-triamino-1,3,5-triazine.

Confirmation of 2,4,6-triamino-1,3,5-triazine is carried out by diode array detection and peak ratio measurement at various wavelengths.

4 Reagents

NOTE All reagents should be of recognized analytical quality unless otherwise stated.

4.1 Analyte

2,4,6-triamino-1,3,5-triazine, ($C_3H_6N_6$), purity > 99 %.

4.2 Chemicals

4.2.1 Acetonitrile, HPLC grade.

4.2.2 Isopropanol

4.2.3 Iso-octane

4.2.4 Water deionized, HPLC quality,

4.2.5 Sodium dihydrogen phosphate monohydrate

4.2.6 Sodium hydroxide

4.3 Solutions

4.3.1 Stock solution of 2,4,6-triamino-1,3,5-triazine in water (1 mg/ml)

Weigh to the nearest 0,1 mg approximately 50 mg of 2,4,6-triamino-1,3,5-triazine (4.1) in a 50 ml volumetric flask and add 40 ml water (4.2.4). Place the flask for 15 min to 30 min in an ultrasonic water-bath at 70 °C to dissolve the 2,4,6-triamino-1,3,5-triazine. Cool the solution to room temperature and fill the volumetric flask up to the mark with water (4.2.4).

Calculate the actual concentration in milligrams of 2,4,6-triamino-1,3,5-triazine per millilitre of solution.

Repeat the procedure to obtain a second stock solution.

Store the solution in a well closed container in dark for a maximum period of 3 months at any temperature between - 20 °C and + 20 °C.

2,4,6-triamino-1,3,5-triazine is only slightly soluble in water, therefore assure that all 2,4,6-triamino-1,3,5-triazine is dissolved. Preparation of more concentrated stock solutions is not feasible.

4.3.2 Diluted standard solutions of 2,4,6-triamino-1,3,5-triazine in aqueous food simulants (0,1 mg/ml)

Pipette 5 ml of the stock solution (4.3.1) into a 50 ml volumetric flask. Make up to the mark with the appropriate food simulant.

Calculate the actual concentration in milligrams of 2,4,6-triamino-1,3,5-triazine per millilitre of solution.

Repeat the procedure using the second standard stock solution to obtain a second set of diluted standard solutions.

4.3.3 Standard solution of 2,4,6-triamino-1,3,5-triazine in isopropanol/water

Pipette, into a series of 25 ml volumetric flasks, 0 ml, 0,5 ml, 1 ml, 2 ml, 4 ml and 8 ml of the stock solution (4.3.1). Add 12,5 ml isopropanol (4.2.2) and make up to the mark with water (4.2.4).

The standard solutions thus obtained contain 0 μg/ml, 20 μg/ml, 40 μg/ml, 80 μg/ml, 160 μg/ml, and 320 μg 2,4,6-triamino-1,3,5-triazine per millilitre.

Calculate the actual concentrations in micrograms of 2,4,6-triamino-1,3,5-triazine per millilitre of solution.

Repeat the procedure using the second standard stock solution to obtain a second series of standard solutions.

4.3.4 10 % Sodium hydroxide solution

Weigh 10 g sodium hydroxide (4.2.6) and dissolve in 100 ml water (4.2.4).

4.3.5 5 mM phosphate buffer pH 6,5

Weigh 690 mg of sodium dihydrogen phosphate monohydrate (4.2.5) and dissolve in approximately 900 ml of water (4.2.4). Adjust to pH (6,5 ± 0,2) by adding small portions of 10 % sodium hydroxide (4.3.4). Make up to 1 litre with water (4.2.4).

4.3.6 Mobile phase for HPLC analysis

Prepare a mixture of 75 % acetonitrile (4.2.1) and 25 % 5 mM phosphate buffer pH (6,5 ± 0,2) (4.3.5).

NOTE Degassing the mobile phase may be necessary with some HPLC equipment..

4.3.7 10 % isopropanol in water (v/v)

Pipette 10 ml isopropanol (4.2.2) into a 100 ml volumetric flask and make up to the mark with water (4.2.4).

5 Apparatus

NOTE An instrument or item of apparatus is listed only where it is special or made to a particular specification, the usual laboratory glassware and equipment being assumed to be available.

5.1 High performance liquid chromatograph, preferably with an automatic injector or 20 µl injection loop, and a variable UV detector, set to 230 nm, connected to a strip chart recorder or integrator.

5.2 HPLC column, capable of producing a symmetric peak of 2,4,6-triamino-1,3,5-triazine, and capable to separate 2,4,6-triamino-1,3,5-triazine from peaks originating from simulants and/or solvents used.

Appropriate operating conditions shall be established for the specific equipment used for the determination.

NOTE 1 The column and parameters established for the column found to be suitable are as follows:

Column:	Stainless steel 200 mm x 4,6 mm, filled with amino coated irregular silica gel 60 Å, particle size 5 μm
Column temperature:	Ambient
Eluent (43.6):	75 % acetonitrile (3.2.1) 25 % 5 mM phosphate buffer pH 6.5 (4.3.5)
Flow rate:	1 ml/min
Injection volume:	20 μl
Detection:	UV
Wavelength:	230 nm

NOTE 2 In the literature several other types of columns are described. However, only the amino coated silica gel was found to produced symmetric peaks with a suitable retention time for 2,4,6-triamino-1,3,5-triazine. The column is used in the straight phase mode, so a higher percentage of acetonitrile will increase retention time.

5.3 Ultrasonic bath with heater

6 Samples

6.1 Preparation of test samples

6.1.1 General

Laboratory samples of the food simulant to be analyzed shall be obtained as described in EN 13130-1. Samples shall be kept refrigerated with the exclusion of light. Analyte-free samples of relevant food simulants of the same type as those to be analyzed shall also be prepared for calibration purposes.

6.1.2 Aqueous food simulants

Transfer approximately 1 ml of food simulant obtained from the migration experiment into a vial suitable for HPLC injections.

6.1.3 Olive oil

Weigh 5 g ± 0,1 g of olive oil, obtained from the migration experiment, into a 25 ml conical flask. Add 5 ml of iso-octane (4.2.3) and mix. Add, by volumetric pipette, 5,0 ml of isopropanol/water 10 % (4.3.7). Place the tube for 30 min in an ultrasonic bath at 70 °C. Allow the phases to separate for approximately 30 min. Retract, by means of a syringe, approximately 2 ml of the aqueous (lower) layer and filter the solution through a 0,2 μm disposable HPLC filter, to retain any oil, into a vial suitable for HPLC injections.

6.2 Blank sample preparation

Treat simulants which have not been in contact with packaging material in the same way as described in 6.1.

6.3 Calibration sample preparation

6.3.1 Calibration curves for aqueous food simulant

Pipette, into a series of 20 ml volumetric flasks, 0 ml, 1 ml, 2 ml, 4 ml, 8 ml and 12 ml of the diluted standard solution (4.3.2).

Fill the volumetric flasks up to the mark with the appropriate analyte free food simulant and mix thoroughly. The solutions thus obtained contain approximately 0 μg/ml, 5 μg/ml, 10 μg/ml, 20 μg/ml, 40 μg/ml and 60 μg of 2,4,6-triamino-1,3,5-triazine per millilitre of simulant.

Repeat the procedure with the second set of standard solutions.

6.3.2 Calibration curves in olive oil

Weigh, into a series of 25 ml conical flasks, 5,0 g ± 0,1 g of analyte free olive oil. Add by pipette, 1 ml of each of the standard solutions in isopropanol/water (4.3.3) and mix. The solutions thus obtained contain approximately 0 μg/g, 4 μg/g, 8 μg/g, 16 μg/g, 32 μg/g and 64 μg of 2,4,6-triamino-1,3,5-triazine per gram of olive oil. Add 5 ml isooctane (4.2.3) and 4,0 ml of water (4.2.4). Place the mixture for 30 min in an ultrasonic bath at 70 °C. Allow the phases to separate for 30 min. Retract, by means of a syringe, approximately 2 ml of the aqueous (lower) layer and filter the solution through a 0,2 μm disposable HPLC filter, to retain any oil, into a vial suitable for HPLC injections.

Repeat the procedure with the second set of standard solutions.

7 Procedure

7.1 HPLC analysis

Analyze the test samples, blanks and calibration samples prepared in 6.1 to 6.3 as they are without any further sample treatment. Identify the 2,4,6-triamino-1,3,5-triazine peak on the basis of the retention time and measure the peak area.

Examine the baseline stability and response linearity of the detector before starting measurements.

Maintain the same operating conditions throughout the measurement of all samples and calibration solutions.

Inject each solution at least in duplicate.

NOTE The detector should be able to detect at least 60 ng on column of 2,4,6-triamino-1,3,5-triazine at a signal to noise ratio of 3:1.

Under the conditions given in 5.2 the retention time obtained for 2,4,6-triamino-1,3,5-triazine was approximately 6 min.

7.2 Calibration

Inject each of the working standard solutions as prepared in 6.3.1 and 6.3.2, in duplicate, into the HPLC column under the conditions given in 5.2. Measure the peak area of 2,4,6-triamino-1,3,5-triazine. Plot the peak area against the concentration of 2,4,6-triamino-1,3,5-triazine in the calibration samples in milligrams per kilogram of food simulant.

NOTE Commission Directive 2002/72/EC [1] states that the specific gravity of all simulants should conventionally be assumed to be ‘1’. Milligrams of substance released per litre of simulant will thus correspond numerically to milligrams of substance released per kilogram of simulant and, taking into account of the provisions laid down in Directive 82/711//EEC [3], to milligrams of substance released per kilogram of foodstuff.

The calibration curves shall be rectilinear and the correlation coefficient shall be 0,996 or better.

The two sets of calibrant solutions made from independently prepared stock solutions shall be cross-checked by generating two calibration curves which on the basis of peak ratio measurement shall agree to within ± 5 % of one another.

7.3 Evaluation of data

NOTE The following calculations assume that for all measurements exactly the same mass or volume of water, 3 % w/v aqueous acetic acid, 15 % v/v aqueous ethanol or olive oil has been used.

Following the method described no interference have been detected.

8 Expression of results

8.1 Calculation of analyte level

8.1.1 Graphical determination

Calculate the average of peak area values obtained from the test samples in accordance with 7.1 and read the 2,4,6-triamino-1,3,5-triazine concentration of the test samples from the calibration graph (7.2).

8.1.2 Calculation from the regression parameters

If the regression line equation is:

$$y = (a \times x) + b$$

where

y is the peak area of 2,4,6-triamino-1,3,5-triazine;

a is the slope of the regression line;

x is the concentration of 2,4,6-triamino-1,3,5-triazine in the food simulant in milligrams per kilogram;

b is the intercept of the regression line.

then the concentration of 2,4,6-triamino-1,3,5-triazine in the food stimulant is given by:

$$C_{Mel,fs} = \frac{y - b}{a}$$

where

$C_{Mel,fs}$ is the concentration of 2,4,6-triamino-1,3,5-triazine in the food simulant in milligrams per kilogram.

Both procedures yield directly the 2,4,6-triamino-1,3,5-triazine concentration in the food simulant in milligrams per kilogram.

The method applying calculation from the regression parameters is the preferred method.

8.2 Calculation of the specific 2,4,6-triamino-1,3,5-triazine migration

Depending on the fill volume of the test material and on the surface area/food simulant ratio, the concentration in the laboratory sample as determined according to 8.1 may need mathematical transformation to calculate the specific migration value to be compared with the specific migration limit (SML). For guidance see EN 13130-1:2004, Clause 13.

8.3 Precision

8.3.1 Validation

This method was pre-evaluated by a collaborative trial with two laboratories using the four official EU food simulants to establish the precision data at the restriction criterion. Also, migration tests were performed with samples containing 2,4,6-triamino-1,3,5-triazine as monomer in contact for 10 d at 40 °C with 3 % w/v aqueous acetic acid and olive oil.

8.3.2 Repeatability

Evaluation of the within-laboratory precision experiment results according to ISO 5725, at a concentration of 30 mg 2,4,6-triamino-1,3,5-triazine/kg food simulant yielded the following performance characteristics at the 95 % probability level (lab1/lab2):

Repeatability r = 2,5/0,9 mg 2,4,6-triamino-1,3,5-triazine per kilogram water;

r = 1,4/1,2 mg 2,4,6-triamino-1,3,5-triazine per kilogram 3 % acetic acid;

r = 2,4/4,5 mg 2,4,6-triamino-1,3,5-triazine per kilogram 15 % ethanol ;

r = 1,7/4,6 mg 2,4,6-triamino-1,3,5-triazine per kilogram olive oil.

8.3.3 Detection limit

The within-laboratory detection limits (WDL), based on the calibration curve method according to DIN 32645, were found to be in the range of 0,6 mg/kg to 1,6 mg/kg food simulant, depending on the type of food simulant. Thus the method is capable of quantitative detection of 2,4,6-triamino-1,3,5-triazine at a minimum level of 1,6 mg/kg food simulant.

9 Confirmation

9.1 Requirement for confirmation

If the specific migration of 2,4,6-triamino-1,3,5-triazine into the food simulant, calculated in accordance with the procedure given in EN 13130-1 from the analyte level calculated according to 8.2 exceeds a restriction, i.e. a specific migration limit of 30 mg/kg, the result of the determination shall be confirmed by the method described in 9.2.

The confirmation is qualitative in the sense that it should demonstrate the correct identity of the measured analyte and the absence of interferences. For the purposes of quantification the result as calculated according to 8.2 shall be taken as the true value.

9.2 Confirmation by diode array detection

By use of diode array detection, record the spectral profiles over the range of 190 nm to 300 nm at the front, apex and tail of the peak with the retention time of 2,4,6-triamino-1,3,5-triazine. 2,4,6-triamino-1,3,5-triazine can be identified as having an absorbance peak maximum at 205 nm. The absorbance ratio 205:230:260 nm shall be established for standards and samples at concentrations as close as possible to each other. Ratios for samples shall agree to within ± 10 % of ratios for the standards.

If the peak is pure, overlaid spectral profiles of the front, apex and tail of the peak shall be identical. Therefore, if the three profiles are normalized, they shall superimpose on top of each other.

NOTE Typical ratios of the absorbance at 205 : 230 : 260 nm were found to be 100 : 9,5 : 0.

10 Test report

The test report shall include at least the following, where applicable:

a) identification of the sample;

b) name of the laboratory;

c) name of responsible analyst;

d) date of report;

e) date of analysis;

f) analyte;

g) a reference to this method;

h) sample details, such as:

   1) type of food/food simulant/material/article;

   2) origin and denotation of the sample;

   3) date and method of obtaining the laboratory sample;

   4) storage conditions;

i) results expressed in milligrams of 2,4,6-triamino-1,3,5-triazine per kilogram of food simulant. Results shall be reported as the average value from two or more determinations satisfying the repeatability criterion of 8.3.2;

j) details of confirmation procedure, if any;

k) reasons for modifications introduced into the test method, if any.

Bibliography

[1] Commission of the European Communities, Commission Directive of 23 February 1990 relating to plastics materials and articles intended to come into contact with foodstuffs (2002/72/EC), Official Journal of the European Communities, 13 December 1990, no. L349, p26. Corrigendum of the previous publication, Official Journal of the European Communities, 21 March 1990, no. 75. p19.

[2] Commission of the European Communities, 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 foodstuff (89/109/EEC), Official Journal of the European Communities, 11 February 1989, no. L 40, p 38.

[3] Commission of the European Communities, Council Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (82/711/EEC), Official Journal of the European Communities, 23 October 1982, no. L 297, p 26.

[4] Commission of the European Communities, Commission Directive of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (93/8/EEC), Official Journal of the European Communities, 14 April 1993, no. L 90, p 22.

[5] Commission of the European Communities, Commission Directive of 97/48/EC of 29 July 1997 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs, Official Journal of the European Communities, 12 August 1997, no. L 222, p 10.

[6] Commission of the European Communities, Council Directive of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastics materials and articles intended to come into contact with foodstuffs (85/572/EEC), Official Journal of the European Communities, 31 December 1985, no. L372, p14.

[7] ISO 5725, *Accuracy (trueness and precision) of measurement methods and result.*

[8] DIN 32645, *Chemical analysis; decision limit; detection limit and determination limit; estimation in case of repeatability; terms, methods, evaluation.*

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