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Guidelines on testing conditions for articles in contact with foodstuffs.

(with a focus on kitchenware)

A CRL-NRL-FCM Publication
1st Edition [2009]

Community Reference Laboratory
Food Contact Materials

EU Network of National Reference Laboratories
Food Contact Materials

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On behalf of the CRL-NRL-FCM

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The mission of the IHCP is to provide scientific support to the development and implementation of EU policies related to health and consumer protection.

The IHCP carries out research to improve the understanding of potential health risks posed by chemical, physical and biological agents from various sources to which consumers are exposed.

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Executive summary

Comparability of results is an important feature of the measurements carried out for official controls purposes. The Community Reference Laboratory (CRL) and National Reference Laboratories (NRLs) for Food Contact Materials (FCM) have recognised that technical specifications (exposure test conditions) are not always described in sufficient detail in standards or legislative documents. In such cases differences in interpretation have resulted in gaps of harmonisation in how official controls are practically performed.

The aim of these guidelines is to ensure that all NRLs can have the same interpretation of test conditions for specific materials and articles and consequently to give the same advice to National Authorities, Food Inspection services and private compliance laboratories for the practical implementation of official controls for FCM.

These guidelines contain practical information that define the parameters that should be used to perform either an overall or a specific migration test according to the nature of the materials and articles to be tested, with a focus on kitchenware. Existing legislation for plastics states that migration test conditions should be selected according to the worst foreseeable conditions of use of the material or article to be tested. The focus on kitchenware was chosen because these articles are typically placed in contact with food in the home and thus the challenge is to define worst foreseeable conditions of use.

These guidelines are intended as a dynamic document and they will evolve and expand into further editions. This is the first edition. These guidelines have been endorsed by the European Union official Network of National Reference Laboratories and approved by the EU Commission competent service DG SANCO.

This work also highlights an important deliverable for the Network of NRLs. In particular, the members of the task force “test conditions” that have dedicated time and effort to provide input into the development of these guidelines. They are gratefully acknowledged here for their contribution: NRL-BE (Fabien Bolle, Tina n’Goy), NRL-DE (Oliver Kappenstein), NRL-DK (Jens Petersen), NRL-ES (Juana Bustos), NRL-FR1 (Patrick Sauvegrain), NRL-EL (Timokleia Togkalidou), NRL-IT (Maria Rosaria Milana), NRL-NL (Durk Schakel, Dita Kalsbeek-van Wijk), NRL-PL (Kazimiera Cwiek-Ludwicka), NRL-SI (Viviana Golja), NRL-UK (Emma Bradley). Special thanks are extended to Emma Bradley for her contribution to the editing of the document.

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1 CONTEXT

As part of comparability of the data which ensures free safe trade in the European Union (EU), the Community Reference Laboratory (CRL) and National Reference Laboratories (NRLs) for Food Contact Materials (FCM) under Regulation EC No 882/2004 have a duty to exemplify a unified position on sampling and test conditions when these are not explicitly established or detailed in existing Directives/Regulations, and without prejudice to those. For plastic food contact materials the time/temperature conditions are specified in Directive 82/711/EEC, as amended. Test conditions are selected based on the worst foreseeable use of the material or article. For kitchen articles, kitchenware and cookware, i.e. articles placed in contact with food in the home, Rapid Alerts have sometimes shown differences in enforcement protocols. Therefore the definition of the worst foreseeable test conditions must be agreed to ensure harmonisation of official controls.

2 SCOPE AND OBJECTIVE

The objective of these guidelines was to develop unified reference consensus guidelines for NRLs describing test conditions for food contact articles such as kitchenware. They aim to address sampling, treatment of the test specimen(s), exposure testing (e.g. time/temperature, simulant etc) and interpretation of results. They contain information defining the parameters of an overall or specific migration test according to the nature of the materials and articles in contact with food, and according to the worst foreseeable conditions of use.

These guidelines are intended as a dynamic document and therefore will evolve and expand into further editions to cover more aspects. This is the first edition.

3 QUALITY CONTROL AND UPDATES

These guidelines will be reviewed at regular intervals. The CRL-NRL Network for FCM is charged with this review and the undertaking of any necessary updates.

Peer –review process

- Drafting: CRL for the CRL-NRL Network with contributions and under advice of a dedicated task force of NRLs.
- Verifying and Consensus; NRL Network
- Approval and Endorsement: European Commission, DG SANCO E3

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Quality control box

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4 ABBREVIATIONS

Abbreviations	Explanation
CEN	European Committee for Standardisation
CoE	Council of Europe
CRL	Community Reference Laboratory
DG	General Directorate
DL	Detection Limit
DRF	D Reduction Factor
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FCM	Food Contact Materials
FRF	Fat Reduction Factor
GMP	Good Manufacturing Practice
MS	Member States
NRL	National Reference Laboratory
OM	Overall Migration
QM	Maximum permitted quantity of the substance in mg/kg of the finished material or article
QMA	Maximum permitted quantity of the substance mg per 6 dm2 of the surface of the finished material or article in contact with food
RASFF	Rapid Alert System for Food and Feed
SANCO	Health and Consumer Directorate-General
SML	Specific Migration Limit
v/v	Volume per volume
w/v	Weight per volume

5 GENERAL CONSIDERATIONS

This chapter is intended as a short summary of the legislation in the EU, it does not substitute any of the official documents and is given for informative purposes only and for the continuity of the present guidelines.

At the time of preparation and publication of these guidelines the EU legislation relating to materials and articles intended to come into contact with foodstuffs is incomplete. Therefore it is recommended that users of these guidelines refer to the latest relevant published Directive(s)/Regulations for an up-to-date view of legislation in the field of FCMs.

5.1 Introduction

The potential for the constituents of a food contact material or article to be transferred into a particular food matrix must be taken into account when developing adequate

analytical protocols. This extent to which a substance migrates depends on the nature of the migrant (the chemical), the nature of the material(s) from which it can be released, and the nature of the food with which it comes into contact. Taking plastic FCMs as an example, the EU Plastics Directive contains a positive list of monomers and additives permitted for use in the manufacture of plastic for food contact. Specific migration limits have been assigned to some of these substances following their toxicological assessment. Testing for compliance with these specific migration limits can be achieved in several ways. The food itself can be tested. The food contact material or article can be tested before it is used to ensure that it does not contain residues that can migrate at levels that could cause problems. Finally, uniquely for food contact materials, the food contact material or article can be tested for its suitability before use by employing food simulants that are intended to mimic the migration properties of different categories of foods. There are five simulants described in the legislation for plastics: distilled water or water of equivalent quality (simulant A), 3% acetic acid (w/v) in aqueous solution (simulant B), 10% ethanol (v/v) in aqueous solution (simulant C), rectified olive oil (simulant D) and 50% ethanol (v/v) in aqueous solution (simulant D for dairy products). These simulants mimic under worst case conditions aqueous foods, acidic foods, alcoholic foods and fatty foods. Olive oil can be replaced by other equivalent non-volatile fatty food simulants (e.g. sunflower oil) or by volatile test media in cases where it is not technologically possible to carry out the determination of the migration into olive oil. The correspondence between foodstuffs and the required simulant can be found in Directive 85/572/EEC, as amended. As well as specifying which simulants should be used with which foodstuffs the plastics legislation (Directive 82/711/EEC, as amended), also provides guidance as to which exposure conditions (time / temperature) should be used to conduct migration tests with food simulants. The mode of contact between the material and the simulant also aims to correspond to the worst case scenario. A material that comes in contact with the food by both faces (e.g. cling film) will be tested by total immersion, in which the material is immersed in the simulant. A material that contacts by single face will be tested using a metallic cell holding that exposes only one side of the material to the simulant, or by a pouch if the material can be sealed, or for rigid containers by article filling. CEN standard methods describe how the migration tests should be performed (http://www.cen.eu/cenorm/)

The Regulation on official food and feed controls (EC) No 882/2004 establishes a hierarchy of methods which should be used in compliance testing, as follows:

1. “Community methods”: methods laid down in the legislation

For the field of FCMs Community methods exist for ceramics and vinyl chloride.

2. Internationally recognised methods: European Committee for Standardisation (CEN) http://www.cen.eu/cenorm/standards_drafts/index.asp

These methods are deemed generally reliable, collaboratively tested and should be used in case of dispute. Method standardisation takes in place in ”technical committees” where for example:

- CEN TC 194 is for plastics materials and articles in contact with foodstuffs, http://www.cen.eu/CENORM/BusinessDomains/TechnicalCommitteesWorkshops/CENTechnicalCommittees/TCStruc.asp?param=6175&title=CEN%2FTC+194

leading to several working group and series of standards, such as:

  - EN 1186 Overall migration plastics
  - EN 13130 Specific migration plastics

- TS 14235 polymeric coatings… and others

- CEN TC 172 is for paper and board for the cellulosic material analysis. http://www.cen.eu/CENORM/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/TCStruc.asp?param=6153&title=CEN%2FTC+172
- CEN TC 261 is for packaging material analysis. http://www.cen.eu/CENORM/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/TCStruc.asp?param=6242&title=CEN%2FTC+261
- CEN TC 132 Aluminium and aluminium alloys (steel: BNAC 43-00) http://www.cen.eu/CENORM/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/TCStruc.asp?param=6114&title=CEN%2FTC+132
- CEN TC 252 is for child care articles http://www.cen.eu/CENORM/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/TCStruc.asp?param=6233&title=CEN%2FTC+252

3. There are also ISO norms related to tableware:

ISO TC 186 (tableware articles) http://www.iso.org/iso/fr/iso_catalogue.htm

Finally, some standards were set up to help agri-businesses to set up provisions of hygiene control whose scope includes packaging materials (see ISO TC 34). http://www.iso.org/iso/fr/iso_catalogue.htm

4. Other technical specifications can also be found at the level of:

- Council of Europe (CoE) Resolutions
- National legislations or recommendations

5.2 General principles

The legislation in the EU on materials and articles intended to come into contact with foods ("food contact materials" or FCM) is composed of:

- Community measures e.g. Regulations and Directives adopted at EU level and
- National laws.

The Community measures establish common rules applicable to all 27 EU Member States (MS), while the national legislations set out provisions which are, in principle, valid only in the MS which issued them. These national laws may differ from each other. National legislation can only be issued in those areas which are not covered by Community law.

Community rules such as Directives or Regulations are being adopted at European level to harmonise the national provisions and to replace them.

During the preparation of the proposals the European Food Safety Authority (EFSA) is consulted on the aspects related to health protection and the European professional and consumer organisations on the content of the measures. Member States have to agree with a qualified majority to Community measures.

5.3 EU legislation of Food Contact Materials

The adopted measures can be divided into three categories:

General Measures such as Framework Regulation and GMP Regulation relating to all materials and articles;

Specific Material Measures relating to groups of materials and articles. Four such measures exist; plastics, recycled plastics, regenerated cellulose films and ceramics;

Specific Substance Measures relating on individual or groups of substances e.g. certain epoxy-derivatives (BADGE, BFDGE and NOGE) in coatings.

Consolidated versions of the Directives are usually made available at the Commission website EURLEX (http://eur-lex.europa.eu/). They collate (=consolidate) into one text the original measure and the amendments indicating the changes that have been introduced.

Figure 1 gives an overview of the Community measures adopted (up to March 2008) and in the SANCO website.

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

5.3.1 General Measures

5.3.1.1 Framework Regulation (EC) No 1935/2004

The text of the web-site of DG SANCO is reported here.

The Framework Regulation (EC) 1935/2004 (L338/4) states that food contact materials shall be safe. They shall not transfer their components into the food in quantities that could endanger human health, change the composition of the food in an unacceptable way or deteriorate the taste and odour of foodstuffs.
The Regulation also includes the following provisions :

- If an article is intended for food contact it shall be labelled for food contact or bear the symbol with a glass and fork. In cases where the intention for food contact is obvious by the nature of the article e.g. knife, fork, wine glass, this labelling is not obligatory.
- Labelling, advertising and presentation of food contact materials shall not mislead the consumer.

The Regulation establishes 17 groups of materials and articles which may be covered by specific measures.

- active and intelligent materials and articles
- adhesives
- ceramics
- cork
- rubbers
- glass
- ion-exchange resins
- metals and alloys
- paper and board
- plastics
- printing inks
- regenerated cellulose
- silicones
- textiles
- varnishes and coatings
- waxes
- wood

Up to now specific measures exist for ceramics, regenerated cellulose and plastics.
On active and intelligent packaging the Regulation includes definitions and it specifies that these materials and articles may induce changes in the foodstuff, only, if the food then still complies with the Community provisions applicable to food such as those on food additives. These materials and articles shall especially not be used to mask spoilage of the food and shall not mislead the consumer.
The Regulation lays down the procedure to be followed for authorisation of substances to be used in food contact materials and articles including the evaluations of the European Food Safety Authority, and the opinion of the Standing Committee on the Food Chain and Animal Health (SCFCAH).
From 26 October 2006 food contact materials and articles should be traceable throughout the production chain.
The Regulation entered into force 3 December 2004 and replaced the Framework Directive 89/109/EEC and Directive 80/590/EEC.

Source: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/framework_en.htm

These texts establish measures for their technical implementation with regards to for example composition. The Framework Regulation also allows for the application of national measures in the absence of specific directives (e.g. paper & board, pigments and colouring agents). Article 6 states:

"In the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty"

The Framework Regulation establishes the general principles and provisions applicable to all FCMs such as:

The definition of the scope;

- The obligation to manufacture the FCM following the 'good manufacturing practice'(GMP);
- The prevention of an "unsafe" migration of the constituents of the materials or articles (safety clause);
- The prevention of any unacceptable contamination of the foods even if this contamination does not imply health problems (inertness clause);
- The prevention of any deterioration in the organoleptic characteristics of foods i.e. taste, odour or texture of the foods;
- Information, through an appropriate labelling ("for food contact") or a symbol 

to the consumer or food industry of the suitability of the materials and articles to come in contact with food (labelling clause);

- The obligation for the business operators to trace FCM i.e. to identify the businesses from which, and to which, the FCM are supplied (traceability clause);
- The obligation for the MS to check the conformity of FCM to the related laws (control clause).
- The establishment of a Community Reference Laboratory for food contact materials

There are also general rules that are applicable to active and intelligent packaging (materials or articles which are intended to maintain or improve or monitor the condition of the food).

Finally the Regulation establishes rules to be applied when specific and individual measures are adopted:

- The delegation of power to the European Commission to adopt specific measures for materials and articles listed in Annex I of the Framework Regulation;
- The criteria and procedures to be followed in drafting specific and individual measures;
- The procedures for the authorisation of substances and materials;
- The obligation to consult EFSA if the specific measure deals with aspects having an impact on the consumer health;
- The safeguard measures to be taken in certain dangerous situations;
- The public access to the technical dossier made available by the business operator when required for the authorisation of a substance;

- The right of the business operator to require a certain confidentiality on the management by EC or EFSA of certain data the disclosure of which may significantly harm its competitive position;
- The obligation to have a declaration of compliance for materials and articles covered by specific legislation.

5.3.1.2 GMP REGULATION (EC) No 2023/2006

Link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R2023:EN:NOT

The obligation to apply the rules of GMP is included in general terms in the Framework Regulation. To ensure a harmonised application of GMP throughout the EU and throughout the different business sectors the basic principles of good manufacturing practice are detailed in GMP Regulation (EC) No 2023/2006. These requirements, applicable as from 1 August 2008, have to be applied at all stages of production of FCM and in all sectors. The stages of production of starting substances and raw materials are excluded even if the business operators shall describe their products in the declaration of compliance.

As an example, for the plastics production chain the GMP requirements start with the plastic manufacturer, followed by the converter including the printing process of the packaging up to the production of the final article. All aspects of the GMP need to be adequately documented and the documentation should be available to control authorities. Imports from third countries should also apply adequate GMP systems in their production. For two materials GMP requirements have been further detailed i.e. for printing inks and for recycled plastics.

5.3.2 Specific material measures

Measures on specific materials deal with the groups of FCM mentioned in Annex I of the Framework Regulation. Until now only four groups of materials have been regulated by specific EU measures plastics, recycled plastics, ceramics and regenerated cellulose films.

5.3.2.1 Plastics

They are mainly regulated by three measures:

- Directive 2002/72/EC, as amended, which set out the main provisions and
- Directives 82/711/EEC, as amended, and 85/572/EEC, as amended, which set out the basic rules for checking the compliance with the quantitative restrictions and specifications given in Directive 2002/72/EC.

Links:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0072:20070420:EN:PDF

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1982L0711:19970901:EN:PDF

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1985L0572:20070420:EN:PDF

Their main provisions are related to:

- The overall migration limit (OML), which has the same value for all plastics i.e. 60 mg/kg or 10 mg/dm^2;

- The positive lists of monomers and additives (for additives as from 1.1.2010), which lists all the substances that are authorised for use in food contact plastics and, then, prevents the use of monomers and additives not listed;
- The quantitative restrictions or specifications applicable to the substance(s) (e.g. SML, SML(T), QM, QM(T) and QMA);
- The functional barrier (FB), which is a layer permitting the use of non-authorised substances in the layer(s) not in direct contact with the food provided (a) their migration in food or food simulant does not exceed 0.01 mg/kg (of food/food simulant) and (b) the substances are not classified in the EU as proven or suspect "carcinogenic" "mutagenic" or "toxic to reproduction";
- Certain more restrictive provisions for young children;
- The rules on the choice of food simulants in relation to food in contact and the conditions of contact (duration and temperatures) in the migration testing.

The field of application is quite limited as it applies only to plastic mono and all-plastic multi-layer materials. It applies to bio-based polymers and biodegradable polymers. However multi-layers containing materials other than plastics are excluded from the scope.

5.3.2.2 Ceramics

They are regulated by Directive 84/500/EEC and 2005/31/EC which set out the provisions to regulate ceramics and establishes details related to the declaration of compliance and the method.

Links:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1984L0500:20050520:EN:PDF

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:110:0036:0039:EN:PDF

The Directive sets out migration limits for lead and cadmium, which depend on use and form of the articles. It specifies the requirement of the declaration of compliance as well as the supporting documentation to be made available to the national competent authorities on request. This documentation must contain the results of the analysis carried out, the test conditions and the name and the address of the laboratory that performed the testing. For other heavy metals the safety clause of the Framework Regulation applies. Some MS (e.g. Austria, Netherlands and Norway) have national restrictions for other heavy metals and Denmark and Germany have separate limits for migration from the mouth rim of cups and beakers.

5.3.2.3 Regenerated Cellulose films (RCF)

Directive 2007/42/EC on RCF establishes:

- A list of authorised substances (positive list)
- Restrictions on the composition of the material.

Link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:172:0071:0082:EN:PDF

The restrictions in the positive list are usually expressed as residual content in the film because migration testing with pure cellophane film into liquid simulant is in general not feasible due to the absorption of water by the film. Only for mono-ethylene glycol (MEG) and di-ethylene glycol (DEG), which under certain circumstances can be transferred in unacceptable high quantities, have migration limits been set.

For RCF covered by a plastic coating the Directive specifies that the coating has to comply with the rules of the plastics Directive and the whole material with the migration limits set out in the plastics Directive.

5.3.2.4 Recycled plastics

The Regulation (EC) No. 2008/282 which applies to mechanical recycling of plastics, foresees the authorisation of the recycling process at Community level based on the safety evaluation of the recycling process performed by EFSA. Critical points in the recycling process are the sourcing of the material that is being recycled as well as the capacity of the process to reduce contamination. Only those plastics that respect the compositional requirements of the plastics Directive can be used as source material for mechanical recycling. As the recycling processes are unique based on the technology applied, individual authorisation dedicated to the applicant will be issued. All recycling processes shall be accompanied by an adequate quality assurance system which should be audited by Member States. Recycled plastic as well as the materials and articles containing recycled plastics need to be accompanied by a declaration of compliance. The Regulation also covers recycled plastics from third countries. These can only be used if the recycling process is authorised. Requests for authorisation have to be addressed to a Member State's contact point. Premises in Third Countries that use the authorised recycling processes have to be notified to the Commission.

Link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:086:0009:0018:EN:PDF

5.3.3 Specific substance measures

Measures on specific substances refer to single substances or groups of substances used in the manufacture of FCM or their reaction or degradation products. In Figure 1 these specific measures are mentioned.

5.3.3.1 Nitrosamines in rubber teats and soothers

Rubber teats and soothers may release carcinogenic or suspected carcinogenic nitrosamines as reaction or degradation products from accelerators and stabilisers used in the rubber. Directive 93/11/EEC establishes that nitrosamines and nitrosatable substances - substances which can be transformed into nitrosamines in the stomach - shall not be released from the rubber teats and soothers in detectable quantities. Methods for the analysis are proposed with the detection limit set to 0.01 mg/kg rubber for nitrosamines and 0.1 mg/kg rubber for nitrosatable substances.

Link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0011:EN:HTML

5.3.3.2 Certain epoxy-derivatives (BADGE, BFDGE and NOGE)

The Regulation (EC) No 1895/2005 restricts the use of certain epoxy-derivatives (BADGE, BFDGE and NOGE) in materials and articles in contact with foods. These substances were suspected to be carcinogenic and some of them were not authorised in some applications.

The main rules in the Regulation are:

- Establishment of an SML for BADGE (9 mg/kg) and certain of its derivatives (1 mg/kg)
- Ban of BFDGE and NOGE as from 1 January 2005.

Link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:302:0028:0032:EN:PDF

5.3.3.3 Vinyl Chloride Monomer (VCM)

Council Directive 78/142/EEC regulates the residual content of VCM in the finished

material or article with a limit of 1mg/kg. Furthermore, VCM should not be detectable in foodstuffs. Commission Directives 80/766/EEC and 81/432/EEC give methods of analysis for VCM in the finished product and in foodstuffs.

Links:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31978L0142:EN:NOT

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31980L0766:EN:NOT

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31981L0432:EN:NOT

5.4 Other legal or recommended provisions in the EU

When exporting into the EU, it is necessary to take into consideration the numerous national legislations or recommendations for the non-harmonised materials. In the EC DG SANCO website additional laws existing at national level are indicated (http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_nat_laws_en.pdf)

In the absence of national legal texts, often the MS refer to laws in other MS. In the absence of national law the MS may also recommended to the stakeholders to follow as much as possible the Resolutions and Technical Documents of the CoE.

The following hierarchy of compliance can be set up

1. EU legislation; If not in place for certain materials =>

2. National legislation; If not in place for certain materials =>

3. Recommendations such as CoE resolutions, US FDA rules

5.5 Other EC bodies involved in FCM control

Other EC Directorates or agency and European organisations deal with FCM. Some of them are shortly described below.

5.5.1 Community reference laboratory (CRL)

The CRL is hosted at the European Joint Research Centre which is part of the EC. In the context of the EU strategy aimed at improving food safety and establishing the single market for food and FCM, the CRL together with a network of National Reference Laboratories has been set up which deal with major scientific and technical issues. Scientifically sound and uniform testing is an element of fundamental importance for the application of the necessary control and adequate analytical methodologies. The tasks of CRL are:

- Provide national reference laboratories with details of any relevant analytical methods, including reference methods for the detection and quantification of substances released from FCM;
- Organise comparative testing for harmonised application of the cited analytical methods by the national reference laboratories,
- Conduct training courses for the benefit of staff from national reference laboratories and experts from developing countries;

- Provide scientific and technical assistance to the Commission, especially in collaborating with laboratories responsible for analysing feed and food in third countries.

Link: http://crl-fcm.jrc.ec.europa.eu/

5.5.2 Food and Veterinary Office (FVO)

The FVO is a directorate of DG SANCO which is responsible for monitoring official controls in Member States of EU legislation on the food chain including food contact materials. The FVO also performs inspections of official control systems in Third Countries exporting into the EU. The FVO performs this function by verifying, mainly through inspections, the effectiveness of national control systems for enforcing Community legislation in these fields. The mission of the FVO is:

- To carry out on-the-spot inspections to evaluate the food safety control systems operated by national authorities in Member States and also in Third Countries exporting, or wishing to export, to the EU;
- To report its findings and conclusions, and to make recommendations;
- To follow up the action taken by national authorities in response to its reports.

Link: http://ec.europa.eu/food/fvo/index_en.cfm

5.6 Other European organisations

5.6.1 Council of Europe (CoE)

CoE is a European international institution which was created before the EU. It should be distinguished from EU and it is independent from it. It includes 48 European countries while the EU includes 27 Member States. The CoE limits its activity to all materials not covered by an ongoing or planned measure at EU level. CoE adopts Resolutions, Guidelines and Technical Documents (TD) on FCM. These documents are not binding texts unless the CoE countries transpose them partially or totally into national law. Numerous Resolutions, Guidelines and TD regarding various types of materials such as paper, inks, coatings, rubber, and metals have been adopted. Some have been recently transposed into national legislation of some EU countries. All CoE adopted texts are reported in the CoE website.

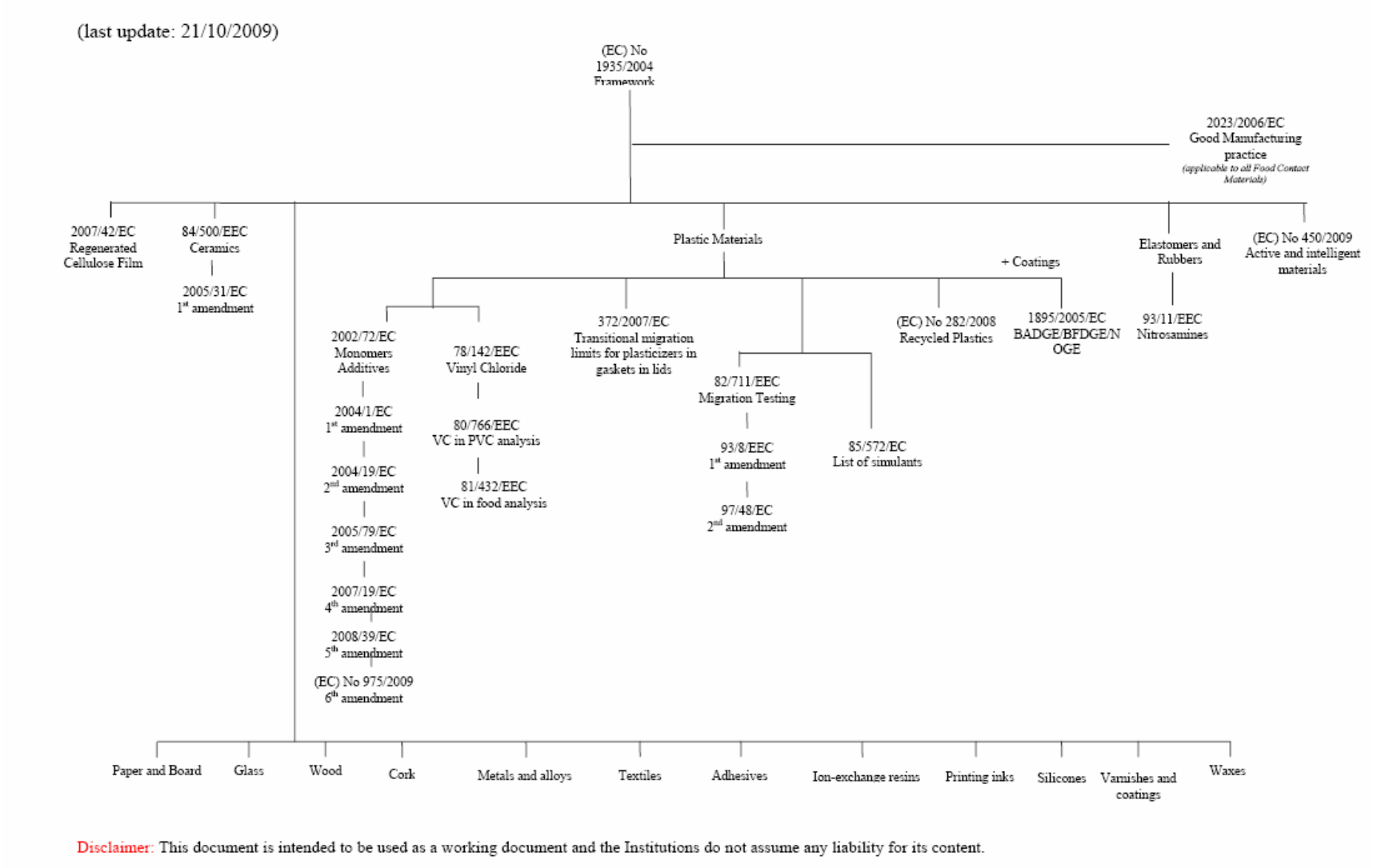
Link: http://www.coe.int/T/E/Social_Cohesion/soc-sp/Public_Health/Food_contact/

5.6.2 European Committee for Standardisation (CEN)

CEN produces harmonised EN standards to facilitate the exchange of goods and services within Europe by eliminating barriers to trade. It devotes considerable efforts to the development and validation of test methods. CEN established several validated method of analysis for the determination of overall and specific migration limits. All of the methods adopted by CEN are given on the website.

Link: http://www.cen.eu/catweb/67.250.htm

Figure 1:Overview of Community Legislation (update to 26.10.2009),
source http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm**, document** EU and National Laws**, page 4**



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6 NON-SPECIFIC EXPERIMENTAL MIGRATION TESTING

6.1 Introduction

Different experimental methodologies, mainly for plastics, have been developed to test migration within the frame of the European Committee for Standardisation (CEN: http://www.cen.eu/cenorm/homepage.htm). These methods are validated and constitute CEN standards. Methods for the determination of overall migration correspond to the CEN standard EN 1186 series whereas those for specific migration correspond to the CEN standard EN 13130 series. The method descriptions give details relating to the performance of migration experiments and the analytical procedures (apparatus, reagents, samples etc.). Other methods which have not been fully validated have been issued as CEN Technical Specifications. Another source of analytical methods is the Community Reference Laboratory for Food Contact Materials (CRL-FCM) website http://crl-fcm.jrc.ec.europa.eu/

WARNING: the methods on the CRL website are for informative purposes only. They do not in many cases constitute validated methods, but rather many come from methods provided by petitioners for the authorisation of new substances or the re-evaluation of existing substances which can be made available by JRC to the public domain under reg. 1935/2004.

6.2 Plastics

6.2.1 Food simulants

Simulants intended to mimic the migration from plastics into foods were introduced in the early-1980's (Directive 82/711/EEC, as amended). These are shown in Table 1. When a material or article may be used with a range of food types simulants are selected from those given in Table 2.

Link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31982L0711:EN:NOT

Food type	Food simulant	Abbreviation
Aqueous food (pH > 4.5)	Distilled water	Simulant A
Acidic foods (pH ≤ 4.5)	Acetic acid 3% in water (w/v)	Simulant B
Alcoholic foods	Ethanol 10% in water (v/v) Ethanol X% adjust % for foods with >10%	Simulant C
Fatty foods	Rectified olive oil or other fatty food simulants	Simulant D
Dry foods	none	None
Milk products	Ethanol 50% in water (v/v)	

Table 1: Food type and food simulants

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
Dairy foods	See above

Table 2: Food simulants to be selected for testing food contact materials in special cases

6.2.2 Correspondence foods - simulants

The rules for using simulants to mimic migration into foods are described in Directive 85/572/EEC, as amended. This Directive defines which food simulant should be used to mimic a specific foodstuff. Because olive oil (simulant D) is a severe medium compared with most fatty foods, a reduction factor ranging from 2-5 may be applied depending on the food. For example chocolate has been assigned a reduction factor of 5, which means that the value obtained for the overall migration into simulant D must be divided by 5 before checking it against the limit. The reduction factors are defined in Directive 85/572/EEC.

Link:http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1985L0572:20070420:EN:PDF

6.2.3 Time- temperature conditions

As mentioned above Directive 82/711/EEC, as amended, establishes that the level of migration can be determined in food simulants. These tests should be performed under standardised conditions of time, temperature and contact which correspond to the worst foreseeable contact with food and to any labelling information describing the maximum temperature of use. Therefore, if the final plastic material or article is intended for a food contact application covered by a combination of two or more times and temperatures taken from the table, the migration test should subject the sample successively to all the applicable worst foreseeable conditions. The standardised conditions of time and temperature are given in Directive 82/711/EEC, as amended, and are reproduced here in Table 3.

Conditions of worst foreseeable use	Test conditions
Contact time	Test time
T ≤ 5 min	See conditions
5 minutes < t ≤ 0.5 hours	0.5 hours
0.5 hour < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 4 hours	4 hours
4 hours < t ≤ 24 hours	24 hours
T > 24 hours	10 days
Contact temperature	
t ≤ 5°C	5°C
5°C < t ≤ 20°C	20°C
20°C < t ≤ 40°C	40°C
40°C < t ≤ 70°C	70°C
70°C < t ≤ 100°C	100°C or reflux
100°C < t ≤ 121°C	121°C (*)
121°C < t ≤ 130°C	130°C (*)
130°C < t ≤ 150°C	150°C (*)
t >150°C	175°C (*)

Table 3: Conventional conditions for migration tests with food simulants

(*)This temperature shall be used only for simulant D. For simulants A, B or C the test may be replaced by a test at 100 °C or at reflux temperature for a duration of four times the time selected according to the general rules of paragraph 1.

Link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31982L0711:EN:NOT

If the use of the fatty food simulants (e.g. olive oil) is not feasible for technical reasons connected with the method of analysis then other test media can be used (isooctane, 95% ethanol or modified polyphenylene oxide (MPPO)). The time and temperature conditions which should be used in these cases, corresponding to the test conditions for simulant D, are given in Table 4.

Test conditions with simulant D	Test conditions with isooctane	Test conditions with ethanol 95%	Test conditions with MPPO (*)
10 days at 5 °C	0.5 day at 5 °C	10 days at 5 °C	---
10 days at 20 °C	1 day at 20 °C	10 days at 20 °C	---
10 days at 40 °C	2 days at 40 °C	10 days at 40 °C	---
2.0 hours at 70 °C	0.5 hour at 40 °C	2.0 hours at 60 °C	---
0.5 hour at 100 °C	0.5 hour at 60 °C (**)	2.5 hour at 60 °C	0.5 hour at 100 °C
1.0 hour at 100 °C	1.0 hour at 60 °C (**)	3.0 hour at 60 °C (**)	1.0 hour at 100 °C
2.0 hours at 100 °C	1.5 hours at 60 °C (**)	3.5 hours at 60 °C (**)	2.0 hours at 100 °C
0.5 hour at 121 °C	1.5 hours at 60 °C (**)	3.5 hours at 60 °C (**)	0.5 hour at 121 °C
1.0 hour at 121 °C	2.0 hours at 60 °C (**)	4.0 hours at 60 °C (**)	1.0 hour at 121 °C
2.0 hours at 121 °C	2.5 hours at 60 °C (**)	4.5 hours at 60 °C (**)	2.0 hours at 121 °C
0.5 hour at 130 °C	2.0 hours at 60 °C (**)	4.0 hours at 60 °C (**)	0.5 hour at 130 °C
1.0 hour at 130 °C	2.5 hours at 60 °C (**)	4.5 hours at 60 °C (**)	1.0 hour at 130 °C
2.0 hours at 150 °C	3.0 hours at 60 °C (**)	5.0 hours at 60 °C (**)	2.0 hours at 150 °C
2.0 hours at 150 °C	4.0 hours at 60 °C (**)	6.0 hours at 60 °C (**)	3.0 hours at 175 °C

Table 4: Conventional conditions for substitute tests

(*) MPPO: modified polyphenylene oxide

(**) The volatile tests are used up to a maximum temperature of 60°C. A precondition of using the substitute tests is that the material or article will withstand the test conditions that would otherwise be used with simulant D. Immerse a test specimen in olive oil under the appropriate conditions. If the physical properties are changed (e.g. melting, deformation) then the material is considered unsuitable for use at that temperature. If the physical properties are not changed, then proceed with the substitute tests using new specimens.

6.2.4 Cases where CEN guidelines provide a practical interpretation of the test conditions

As described above migration tests conditions should always correspond to the more severe (worst foreseeable) conditions of contact between the plastic material or article and the foodstuff and to any labelling information on the maximum temperature for use. Specific examples, provided in CEN guidelines (EN 1186 Part 1 and EN 13130 Part 1), are given below.

6.2.4.1 Articles subjected to a combination of two or more times and temperatures

The migration test should be carried out by subjecting the sample successively to all of the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

6.2.4.2 Microwave versus conventional oven heating

For materials and articles intended for use in microwave ovens, migration testing may be carried out in either a conventional oven or a microwave oven provided the appropriate time and temperature conditions are selected. A method for the determination of the temperature of plastic materials and articles at the plastic/food interface exists (EN 14233:2002).

6.2.4.3 Any condition of time and temperature

Many articles may be used at a variety of temperatures and for varying times, or their conditions of use may not be known, and no labelling may be present. Under these circumstances depending on food type(s)the test conditions are:

- 4 hours at 100°C or for 4 hours at reflux temperature for simulants A, B, and/or C
- and/or 2 hours at 175°C for simulant D.

6.2.4.4 Room temperature or below for an unspecified period

For materials and articles intended for use at room temperature or below for an unspecified period of time the test conditions are 10 days at 40°C.

6.2.4.5 Contact for less than 15 minutes at temperatures between 70°C and 100°C

If the material or article is used under conditions that are similar to hot fill (i.e. less than 15 minutes at temperatures between 70 and 100°C) or these conditions are indicated by labelling, the test conditions are:

- 2 hours at 70°C.
- However, if the material or article is also intended to be used for storage at room temperature then test conditions of 10 days at 40°C should be used (these are conventionally the most severe).

6.2.4.6 Contact conditions causing changes in physical or other properties

If the contact conditions chosen for the test cause physical or other changes in the sample (which do not occur under the worst foreseeable use of the material or article), then the migration tests should be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

6.2.4.7 Contact not covered by the conventional condition migration tests

In some cases, conventional conditions may not reflect the actual food contact application, for example:

- contact at temperatures greater than 175°C or
- contact times of less than 5 minutes.

In these cases other contact conditions may be used which are more appropriate to the case under examination, provided that the selected conditions represent the worst foreseeable conditions of contact.

6.2.4.8 Testing at low temperatures

Testing with olive oil at low temperatures may result in partial crystallization and solidification of the fat. In such cases a more unsaturated oil such as sunflower oil may be used. CEN provides a standard method for testing at low temperature (5°C and 20°C) in EN 1186-12.

6.2.4.9 Testing at high temperature

Test conditions at temperatures > 121°C may not always be reproducible. This is due to variation in the time taken to reach the test temperature with olive oil and other fatty food simulants. In CEN standard EN 1186 Part 13A a method is described for determining overall migration by total immersion using an aluminium block with a consistent thermal capacity to test at such temperatures.

6.2.4.10 Repeat use testing (repeated testing on the same article)

EN 1186 and EN 13130 Part 1 state that "it is accepted that when a material or article is intended to come into repeated contact with foodstuffs, the migration tests are carried out three times on the same test sample, using a fresh sample of the food simulant on each occasion. The compliance of the material is then checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of migration does not increase in the second and third tests and if the migration limit is not exceeded on the first test, no further test is necessary".

6.2.5 Testing type

Migration tests may be performed in four ways: using a migration test cell, by preparation of a pouch, by total immersion and by article filling. According to the form and the dimensions of the material or article to be tested, one of these methods is chosen. Figure 1 illustrates the various modes of testing.

6.2.5.1 Testing by total immersion

With this method samples are cut out in order to obtain specimens of 1 dm^2 which are immersed in the simulant. With an immersion test, both faces of the sample are in contact with the simulant.

6.2.5.2 Single sided testing using a migration cell

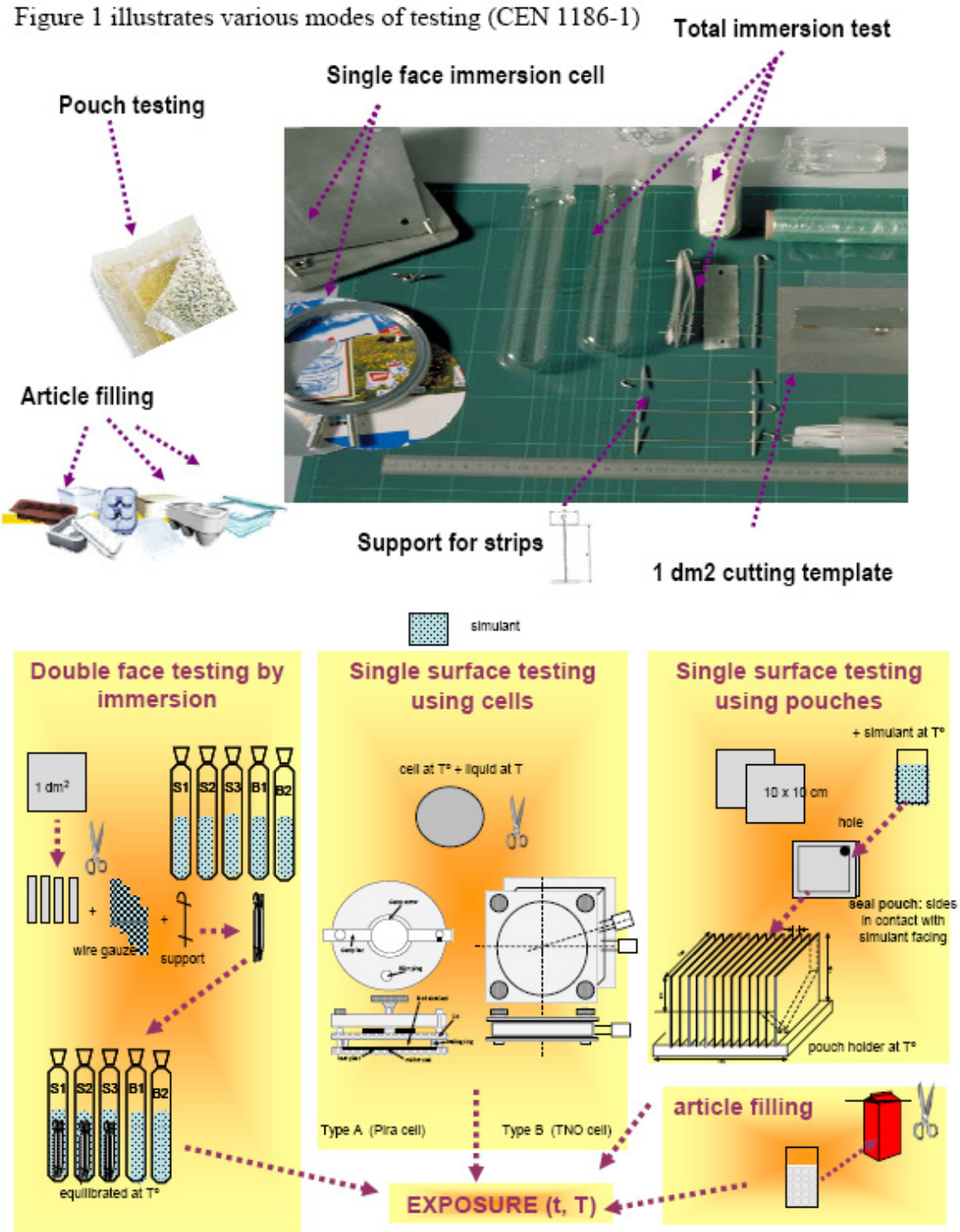
When testing uses a cell only one surface of the material is in contact with the simulant. This is particularly important for multi-layer materials.

6.2.5.3 Single sided testing using a pouch

For flat articles which have sufficient seal strength to form durable pouches, single sided testing in a pouch may be preferred as this does not require specialised apparatus and allows more efficient use of oven space. Like a migration cell only one surface is in contact with the food simulant. The surface to volume ratio in a pouch is conventionally 2 dm^2 of material to 100 ml of food simulant.

6.2.5.4 Single sided testing by filling

For articles in container form it is usually most convenient to test them by filling with the food simulant. For very large containers testing by filling may not be practicable and it may be necessary to fabricate smaller test specimens representing the article to be tested.



6.2.6 Overall migration testing

The overall migration limit has been assigned to ensure that materials do not transfer large quantities of substances which, even if they are not unsafe, could bring about an unacceptable change in the composition of the food.

The overall migration limit is 10 mg/dm^2 or 60 mg/kg. The analytical error in the determination of the overall migration is 2 mg/dm^2 or 12 mg/kg for the aqueous food

simulants (A, B and C. It has been assumed to be applicable as well for the simulant 50% ethanol for dairy products), and 3 mg/dm^2 or 20 mg/kg for the fatty food simulant (D). These methods are described in detail in official CEN or ISO methods (Table 5).

6.2.6.1 Scope of testing

The definition in the Directive does not specify the ranges of substances that should be included in the calculation of the overall migration. However, the CEN standard methods for overall migration methods do not determine the mass of any volatile substances that migrate. Therefore volatile substances are not included in the calculation of the overall migration value.

6.2.6.2 Tests for overall migration plastics: series EN-1186

EN 1186-1 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 plastics article and is intended to be read in its entirety before testing. For most plastic articles methods in EN 1186-2 to EN 1186-9 are suitable, according to the form in which the article is tested. Subsequent Parts of this standard are intended to be used in conjunction with the methods in EN 1186-2 to EN 1186-9 for more difficult samples and for other exposure temperatures. The methods are listed in Table 5. Figures 2 and 3 illustrate the standardised approaches that are used to determine overall migration.

Reference	Title
Plastics	Materials and articles in contact with foodstuffs – Plastics -
EN 1186-1:2002	Part 1: Guide to the selection of conditions and test methods for overall migration
EN 1186-2:2002	Part 2: Test methods for overall migration into olive oil by total immersion
EN 1186-3:2002	Part 3: Test methods for overall migration into aqueous food simulants by total immersion
EN 1186-4:2002	Part 4: Test methods for overall migration into olive oil by cell
EN 1186-5:2002	Part 5: Test methods for overall migration into aqueous food simulants by cell
EN 1186-6:2002	Part 6: Test methods for overall migration into olive oil using a pouch
EN 1186-7:2002	Part 7: Test methods for overall migration into aqueous food simulants using a pouch
EN 1186-8:2002	Part 8: Test methods for overall migration into olive oil by article filling
EN 1186-9:2002	Part 9: Test methods for overall migration into aqueous food simulants by article filling
EN 1186-10:2002	Part 10: Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs)
EN 1186-11:2002	Part 11: Test methods for overall migration into mixtures of C-labelled synthetic triglycerides
EN 1186-12:2002	Part 12: Test methods for overall migration at low temperatures
EN 1186-13:2002	Part 13: Test methods for overall migration at high temperatures
EN 1186-14:2002	Part 14: Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95 % ethanol
EN 1186-15:2002	Part 15: Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and/or 95 % ethanol

Table 5: CEN standards related to overall migration in plastics

Figure 2 represents the principle for overall migration in aqueous simulants.

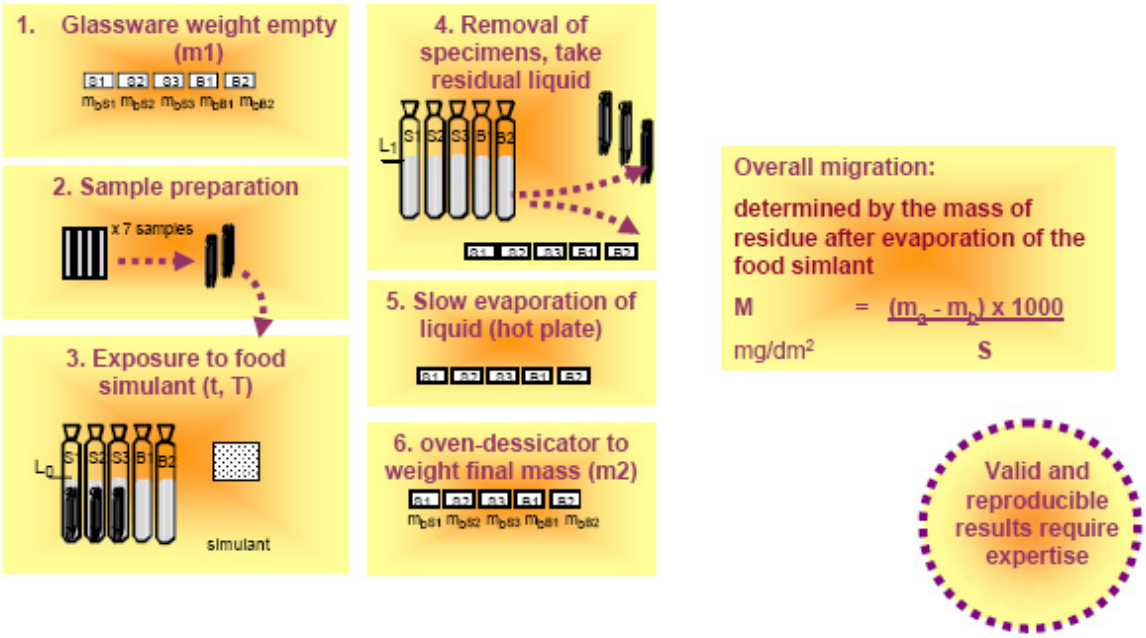
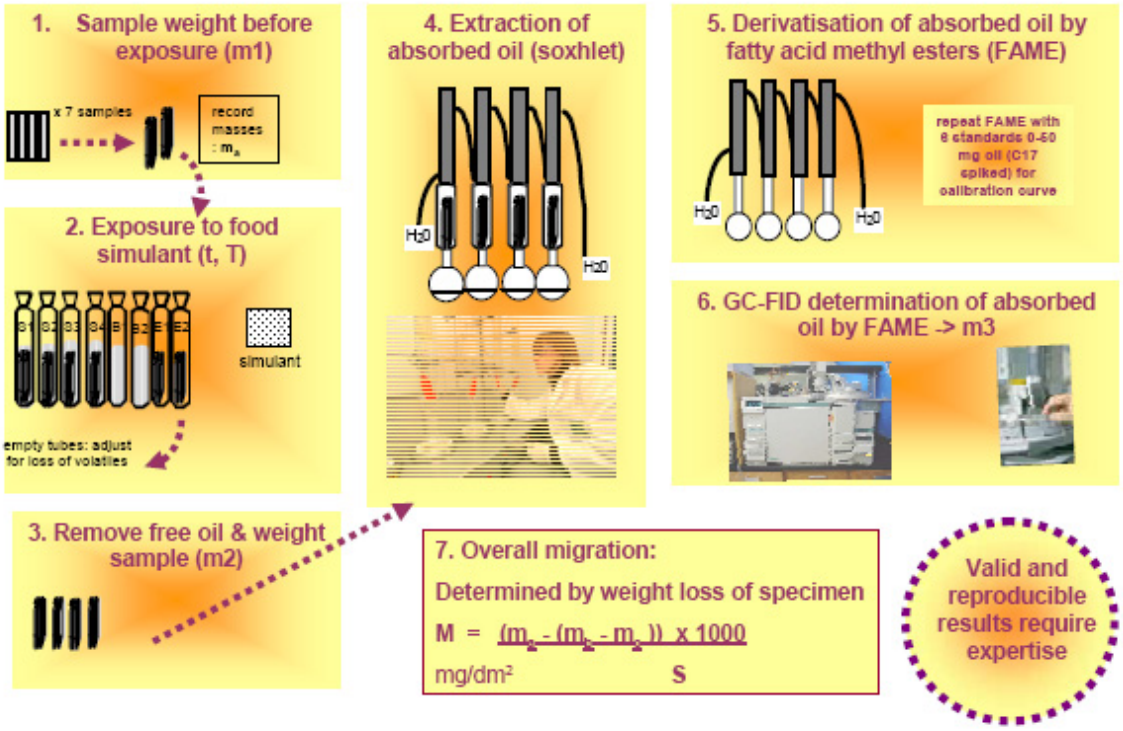


Figure 3 represents the principle for overall migration in fatty simulants.



6.2.7 Testing for fatty contact (EN 14481:2003)

(taken from standard EN14481:2003)

"The simulants have been specified according to the type of food the plastic is intended to contact in actual or foreseeable use. Fatty food simulants, simulant D, are used for testing plastics intended to contact fatty foods. For certain specified food types, testing with simulant D may be dispensed with if it can be demonstrated, by means of an appropriate test, that there is no 'fatty contact' between the plastic and the food with which it comes into contact.
The principle of the method is that food, of a similar nature to that which will contact the plastic in actual use, is placed in contact with a polyethylene test film into which has been incorporated a fat-soluble fluorescent dye. After exposure to the film, the dye is extracted from the food and the quantity transferred from the film is determined by high performance liquid chromatography with fluorescence detection. The degree of transfer indicates whether the food has made fatty contact with the plastic or not and hence determines whether the plastic shall be tested with simulant D or not.
The method described is suitable for direct use for a wide variety of foods. For some foods, it could be necessary to modify the method in order to obtain results which are representative of the food/plastic contact which occurs in actual use. Examples of such foods include crisps and snack foods where the food/plastic contact area in actual use can be small and irregular. In this instance it could be necessary to use a larger food/plastic contact area for the test. In situations where in actual use the food can consist of different surfaces and only one surface is to contact the food, it could be necessary to modify the method. Suitable modifications may involve altering the food so that only the surface that will contact the plastic in use is used for the test. "

6.3 General migration methods for materials other than plastics

For more recent updates the CEN website should be checked:

Link: http://www.cen.eu/cenorm/standards_drafts/index.asp

In the absence of harmonised legislation, it also recommended to verify the existence on national legislation for direction.

At the time of this publication the following methods have been published.

6.3.1 Paper and board

Standard	Title
Paper & board	Paper and board intended to come into contact with foodstuffs -
EN 1104:2005	Determination of the transfer of antimicrobial constituents
EN 1230-1:2001	Sensory analysis - Part 1: Odour
EN 1230-2:2001	Sensory analysis - Part 2: Off-flavour (taint)
EN 13676:2001	Polymer coated paper and board intended for food contact - Detection of pinholes
EN 14338:2003	Conditions for determination of migration from paper and board using modified polyphenylene oxide (MPPO) as a simulant
EN 20187:1993	Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples (ISO 187:1990)
EN 645:1993	Preparation of a cold water extract
EN 646:2006	Determination of colour fastness of dyed paper and board
EN 647:1993	Preparation of a hot water extract
EN 648:2006	Determination of the fastness of fluorescent whitened paper and board
EN 920:2000	Determination of dry matter content in an aqueous extract

Table 6: Examples of CEN standard tests for paper and boards

6.3.2 Other materials

Standard	Title
Other	(Materials and articles in contact with foodstuffs)
CEN/TS 14234:2002	Polymeric coatings on paper and board- Guide to the selection of conditions and test methods for overall migration
CEN/TS 14235:2002	Polymeric coatings on metal substrates - Guide to the selection of conditions and test methods for overall migration
CEN/TS 14577:2003	Plastics - Polymeric additives - Test method for the determination of the mass fraction of a polymeric additive that lies below 1000 Daltons
EN 14481:2003	Test methods for the determination of fatty contact
EN 14233:2002	Determination of temperature of plastics materials and articles at the plastics/food interface during microwave and conventional oven heating in order to select the appropriate temperature for migration testing

Table 7: Examples of CEN standards and CEN technical specifications

6.3.3 Cookware and tableware

Standard reference	Title
Cookware	Cookware - Domestic cookware for use on top of a stove, cooker or hob
CEN/TS 12983-2:2005	Part 2: Further general and specific requirements for ceramic, glass and glass ceramic cookware
Tableware	Cutlery and table hollowware
EN ISO 8442-1:1997	Part 1: Requirements for cutlery for the preparation of food
EN ISO 8442-2:1997	Part 2: Requirements for gold-plated cutlery
EN ISO 8442-2:1997	Part 2: Requirements for stainless steel and silver-plated cutlery
EN ISO 8442-3:1997	Part 3: Requirements for silver-plated table and decorative hollowware
EN ISO 8442-4:1997	Part 4: Requirements for gold-plated cutlery
EN ISO 8442-5:2004	Part 5: Specification for sharpness and edge retention test of cutlery
EN ISO 8442-6:2000	Part 6: Lightly silver plated table hollowware protected by lacquer
EN ISO 8442-7:2000	Part 7: Specification for table cutlery made of silver, other precious metals and their alloys
EN ISO 8442-8:2000	Part 8: Specification for silver table and decorative hollowware

Table 8: Examples of CEN standard for cookware and tableware

7 ANALYTICAL DETERMINATION OF MIGRANTS

7.1 Introduction

The analytical determination of migrants can take the form of a test determining the specific migration of one or more migrants or determining the quantity of one or more substances in a material.

7.2 Specific migration

Specific migration is the quantification of the amount of a specific component or substance that migrates from the food contact material to the food simulant or food during contact. There are several ways to demonstrate compliance with Specific Migration Limits (SMLs) set in EU food contact legislation.

Following the exposure phase the substance(s) in question must be extracted from

the food simulant or the food, and then identified and quantified using a suitable method of analysis. The analytical approach will be dependent on:

- the volatility of the substance(s)
- the polarity of the substance(s)
- the nature of the food or food simulant (e.g. aqueous or fatty)
- the level of determination (e.g. high or low)
- the functional groups of the substance(s) (considered to define the detection method)

Specific migration limits for some substances are defined as not detectable using a method with a detection limit of 10 µg substances / kg food (or food simulant). Many detection methods can achieve this level, even if some concentration of the sample extract is necessary. It is essential that the method of analysis chosen is capable of separating the analyte of interest from any interfering substances. Table 9 gives a generic classification of which migrants from food contact materials are more adequately analysed by different analytical techniques.

Type of substance	Example	Predominant chromatographic technique
Volatiles (bp< 150C)	Monomers, solvent residues (e.g. styrene)	Headspace, SPME, purge & trap and GC, with mostly FID or MS
Semi-volatiles (bp < 300C)	Plasticisers, glycols, additives, MW < 400-500 Da (e.g. phthalates)	Liquid injection (split, splitless, PTV, on-column etc) and GC with FID or MS
Non-volatiles	Antioxidants, polymeric plasticisers, additives with MW > 400-500 Da (e.g. perfluorotelomers)	LC in majority reverse phase, with diode array, fluorescence or MS detection

Table 9: Example of analytical approaches to determine specific migration

Note: GC: gas chromatography, FID: flame ionization detector, MS: mass detector, PTV: programmable temperature vaporizer, SPME: solid phase micro extraction, bp: boiling points, Da: Daltons, MW: molecular weight

The analytical determination of migrants includes three main steps: extraction, sample clean-up if necessary and determination (mainly by chromatographic techniques). The type of extraction and sample clean-up used depends on how much substance is expected to be present and the characteristics of the substance and the matrix from which it is being extracted. The aim of the clean-up step is to remove any substance(s) from the food that could interfere or obscure the signal of the analytes investigated. Another purpose is to remove major food components such as protein, carbohydrates or fats, which may burden and soil the analytical equipment. The elimination of these compounds helps to maintain sample throughput.

7.3 Content in the material

In some cases, the limits imposed in the legislation are on the maximum quantity of a substance or group of substances permitted in a material (QM, QMA) rather than a migration limit into foods. This may be because the substance is volatile and so migration testing would have large uncertainties and measurement difficulties, or that the substance readily reacts with foodstuffs of food simulants and thus, can not be measured as such upon migration.

The measurement of residual content requires the complete extraction of the target substance from the polymer. This can be achieved by headspace analysis for volatile substances or by dissolving the polymer in a strong effective solvent and reprecipitating the polymer with a solvent that would not result in the substance being incorporated into the precipitate. It is widely accepted that the solvent used should both dissolve the target compound well and also swell or dissolve the polymer matrix. Polymer swelling data are readily available in the literature, but the solubilities of the selected substances in potential extraction solvents are not always available and have sometimes have to be estimated as a function of the analyte and of the extraction solvent. Several combinations of solvent/analyte/polymer have been studied. THF for example has been used to dissolve PVC. Other extraction procedures are Soxhlet or reflux or conditions that are the most severe (as defined in the legislation). The sample preparation usually involves pre-cutting the polymer or materials into small pieces or grinding to facilitate the extraction process.

7.4 Guidance documents

7.4.1 Migration from plastics and from plastics into food simulants.

General information about how to determine specific migration is available in CEN document “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”. CEN has also established methods for the determination of some migrants in food simulants or foods. Table 10 lists the methods prepared in the EN 13130 series of standards. Of the methods in Table 10 the ones for residual content (QM, in plastics, in mg substances per kg materials) are highlighted with an asterix (*). A source of analytical methods covering more than 450 methods can be found on the web site of the Community Reference Laboratory for Food Contact Materials (CRL-FCM) website http://crl-fcm.jrc.ec.europa.eu/

Standard reference	Title
Plastics	**Materials and articles in contact with foodstuffs - Plastics substances subject to limitation -**
EN 13130-1:2004	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
EN 13130-2:2004	Part 2: Determination of terephthalic acid in food simulants
EN 13130-3:2004	Part 3: Determination of acrylonitrile in food and food simulants
EN 13130-4:2004 *	Part 4: Determination of 1,3-butadiene in plastics
EN 13130-5:2004	Part 5: Determination of vinylidene chloride in food simulants
EN 13130-6:2004 *	Part 6: Determination of vinylidene chloride in plastics
EN 13130-7:2004	Part 7: Determination of monoethylene glycol and diethylene glycol in food simulants
EN 13130-8:2004 *	Part 8: Determination of isocyanates in plastics
CEN/TS 13130-9:2005	Part 9: Determination of acetic acid, vinyl ester in food simulants
CEN/TS 13130-10:2005	Part 10: Determination of acrylamide in food simulants
CEN/TS 13130-11:2005	Part 11: Determination of 11-aminoundecanoic acid in food simulants
CEN/TS 13130-12:2005	Part 12: Determination of 1,3-benzenedimethanamine in food simulants
CEN/TS 13130-13:2005	Part 13: Determination of 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A) in food simulants
CEN/TS 13130-14:2005	Part 14: Determination of 3,3-bis(3-methyl-4-hydroxyphenyl)-2-indoline in food simulants
CEN/TS 13130-15:2005	Part 15: Determination of 1,3-butadiene in food simulants
CEN/TS 13130-16:2005	Part 16: Determination of caprolactam and caprolactam salt in food simulants
CEN/TS 13130-17:2005 *	Part 17: Determination of carbonyl chloride in plastics

Standard reference	Title
Plastics	**Materials and articles in contact with foodstuffs - Plastics substances subject to limitation -**
CEN/TS 13130-18:2005	Part 18: Determination of 1,2-dihydroxybenzene, 1,3-dihydroxybenzene, 1,4-dihydroxybenzene, 4,4'-dihydroxybenzophenone and 4,4'dihydroxybiphenyl in food simulants
CEN/TS 13130-19:2005	Part 19: Determination of dimethylaminoethanol in food simulants
CEN/TS 13130-20:2005 *	Part 20: Determination of epichlorohydrin in plastics
CEN/TS 13130-21:2005	Part 21: Determination of ethylenediamine and hexamethylenediamine in food simulants
CEN/TS 13130-22:2005 *	Part 22: Determination of ethylene oxide and propylene oxide in plastics
CEN/TS 13130-23:2005	Part 23: Determination of formaldehyde and hexamethylenetetramine in food simulants
CEN/TS 13130-24:2005	Part 24: Determination of maleic acid and maleic anhydride in food simulants
CEN/TS 13130-25:2005	Part 25: Determination of 4-methyl-1-pentene in food simulants
CEN/TS 13130-26:2005	Part 26: Determination of 1-octene and tetrahydrofuran in food simulants
CEN/TS 13130-27:2005	Part 27: Determination of 2,4,6-triamino-1,3,5-triazine in food simulants
CEN/TS 13130-28:2005	Part 28: Determination of 1,1,1-trimethylolpropane in food simulants

Table 10: Examples of CEN standards / technical specifications on specific migration for plastics

7.4.2 Materials other than plastics

Standard reference	Title
Paper and board	**Paper and board**
EN 12497:2005	Determination of mercury in an aqueous extract
EN 12498:2005	Determination of cadmium and lead in an aqueous extract
EN 14719:2005	Determination of the Diisopropylnaphthalene (DIPN) content by solvent extraction
EN 1541:2001	Determination of formaldehyde in an aqueous extract
EN ISO 15318:1999	Determination of 7 specified polychlorinated biphenyls (PCB) (ISO 15318:1999)
EN ISO 15320:2003	Determination of pentachlorophenol in an aqueous extract (ISO 15320:2003)

Table 11: Examples of CEN and ISO standards for substances from paper and board

Standard reference	Title
lacquers	**Materials and articles in contact with foodstuffs - Certain epoxy derivatives subject to limitation**
EN 15136:2006	Determination of BADGE, BFDGE and their hydroxy and chlorinated derivatives in food simulants
EN 15137:2006	Determination of NOGE and its hydroxy and chlorinated derivatives

Table 12: Examples of CEN standard tests for substances from lacquers

Standard reference	Title
Ceramics	Ceramic ware, glass-ceramic ware and glass dinnerware in contact with food
ISO 6486-1:1999	Ware: Release of lead and cadmium — Part 1: Test method
ISO 6486-2: 1999	Ware: Release of lead and cadmium -- Part 2: Permissible limits
ISO 8391-1: 2002	Cookware: Release of lead and cadmium -- Part 1: Method of test
ISO 8391-2 : 2002	Cookware: Release of lead and cadmium -- Part 2: Permissible limits

Table 13: Examples of ISO standard tests for substances from ceramics

Standard reference	Title
Cook /table ware	**Materials and articles in contact with foodstuffs - Silicate surfaces -**
EN 1388-1:1995	Part 1: Determination of the release of lead and cadmium from ceramic ware
EN 1388-2:1995	Part 2: Determination of the release of lead and cadmium from silicate surfaces other than ceramic ware
Glass	**Glass hollowware in contact with food**
ISO 7086-1: 2005	Release of lead and cadmium -- Part 1: Test method
ISO 7086-2: 2005	Release of lead and cadmium -- Part 2: Permissible limits

Enamel	Vitreous and porcelain enamels
ISO 4531-1, 2003,	Release of lead and cadmium from enamelled ware in contact with food -- Part 1: Method of test
ISO 4531-2, 2003,	Release of lead and cadmium from enamelled ware in contact with food -- Part 2: Permissible limits

Table 14: Examples of CEN or ISO standard tests for substances from cookware and tableware, glass, enamel

7.5 Quality assurance in official controls

As with any food analysis, blanks internal standards at best or external at worst must be included, and care must be taken in avoid either loss of target volatile migrants or contamination, which can occur with ubiquitous molecules such as phthalates.

The determination of quantities such as SML, OML, QM and QMA implies various procedural steps e.g. sampling, migration tests with different experimental conditions (OML, SML) or extraction (QM, QMA) as well the usual multi-step analytical determination. Each of these steps is subject to a certain variability and an overall variability will affect the value found by one laboratory (repeatability) or by more than one laboratories (reproducibility). The analytical difficulty, and hence the intrinsic uncertainty of measurements, will vary according to the nature of the limitation in the Directives or Regulations. Rather than expressing variability as “reproducibility” or repeatability” the field of food contact has used the term "Analytical Tolerance" which comprise the variability due to all the above-mentioned procedural steps.

The relevant parts of the CEN Standard EN 13130 give advice and instruction on how to report the results. In addition, a CEN document CEN/TR15356-1:2006 gives information on “Validation and interpretation of analytical methods, migration testing and analytical data for materials and articles in contact with food - Part 1: General considerations “. A specific guidance on practical and state of the art aspects on how to evaluate method performance in the context of food contact materials is also being published by the CRL-NRL-FCM Network. This guide focuses on “Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials”. (Available as a EUR report at the end of 2009).

8 TESTING CONDITIONS FOR ARTICLES OTHER THAN THOSE SPECIFIED IN DIRECTIVES

8.1 General scheme and recommendations

As already mentioned the worst foreseeable conditions by which a consumer may expose an item of kitchenware to a foodstuff are not well defined. The aim of these guidelines is to define test conditions for these applications. The general scheme presented uses a tiered approach.

Where possible the test conditions should be selected from the relevant Directives or Regulations for Food Contact Materials and Articles. These are harmonised at EU level for plastics (Directives 82/711/EEC, as amended,, 85/572/EEC, as amended and 2002/72/EC, as amended. For materials which are not covered under EU

harmonised legislation, guidance given in the National Legislation should be followed.

The simulants to be used and the exposure times and temperatures proposed in these guidelines are based on those given in Directive 82/711/EEC, as amended, and in 85/572/EEC, as amended.

On the basis of the Directives, further reference for technical implementation of test conditions are taken from the CEN ISO standards (series 1186 for OM and 13130 for SM) produced by CEN TC 194. The CEN Technical Committee 194/SC1 has for mandate materials in contact with food and within that, plastics, packaging materials, containers, chemical analysis and testing, determination of content, chemical migration, as well as other food related issues. The standards issued from this TC are the first and foremost applicable to materials and articles in contact with foods.

In the absence of a standard method prepared by TC 194 standards from other sources may be followed. However in all cases standards prepared by TC 194 take precedence.

Further to ISO CEN standards, and in the absence of EU harmonised legislation or descriptive national legislation that could be used to assign test conditions, other recommendations may be used such as Council of Europe if those have provisions in the materials considered.

For kitchenware and articles in general, the technical implementation might generate several interpretations of test conditions which could lead to different conditions used in different laboratories. This is why the present guidelines provide recommendations based on the tiered approached presented above.

8.2 Sampling

Sampling may be performed at the manufacturing plant, at the point of distribution or at the retail outlet.

Food contact articles may be traded in lots of individual articles or sometimes in boxed sets of several articles. The method of sampling may be applied to all the different forms in which the commodities are put on the market.

For certain materials, some individual requirements may exist.

8.2.1 Definitions and general recommendations

8.2.1.1 Sample type

A "lot" means an identifiable quantity of a food contact articles delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings.

A "laboratory sample" means a sample intended for testing in the laboratory.

A “test specimen” portion of the sample on which a test is performed, whereas a “test piece” is a portion of the test specimen. (source CEN 1186 and 13130 part 1).

8.2.1.2 Personnel

Sampling should be performed by an authorised person as designated by the Member State.

8.2.1.3 Material to be sampled

Each lot which is to be examined should be sampled separately. Large lots should be subdivided into sub-lots which should then be sampled separately.

8.2.1.4 Precautions to be taken

In the course of sampling and preparation of the samples, precautions should be taken to ensure the safety of the persons taking the samples.

8.2.1.5 Replicate samples

Replicate samples should be taken for enforcement (primary analysis), dispute (in case of dispute the analysis should be repeated) and confirmation (in case of lack of agreement the analysis should be performed by different laboratory) purposes, unless such a procedure conflicts with Member States' rules as regards the rights of the food business operator.

8.2.1.6 Packaging and transmission of samples

Each sample should be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions should be taken to avoid any change in or damage to the sample, which might arise during transportation or storage.

8.2.1.7 Sealing and labelling of samples

Each sample taken for official use should be sealed at the place of sampling and identified following the rules of the Member State.

A record should be kept of each sample taken, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

8.2.2 Quantity of material to be sampled for laboratory analysis

Analyses on materials and articles intended for contact with foodstuffs should use where possible ISO and EN norms. In particular, the protocols highlighted in series EN1186 and 13130 should be followed. These define sampling procedures such as quantity (dimension, number, surface, volume) of test specimens and samples that should be respected for plastic materials and articles. Care must be taken to always have a sufficient number of samples to be able to reach a conclusion.

Sampling plays a crucial part in the precision of the determination of the levels of contaminants from food contact articles. Such articles are individual objects and the contaminants may be heterogeneously distributed in a lot. It is therefore necessary to fix general criteria with which the sampling method should comply with.

The inspector has as a preliminary duty to get the information from the laboratory on the quantity of the material required to perform the tests. This will depend on how many types of tests are to be conducted, e.g. overall migration only, overall migration and specific migration, and for each how many simulants.

8.2.2.1 Plastics

Using the CEN standards for plastics as a guide then for overall migration four samples should be taken for each of the aqueous simulants and 7 samples for

simulant D.

For specific migration there are no defined requirements, so these guidelines make the recommendation to apply the same principle as adopted in Directive 2004/16/EC on sampling methods and the methods of analysis for the official control of the levels of tin in canned foods

The recommendations given here are as follows:

Sampling at the manufacturing plant/point of distribution

For a lot of greater than 100 pieces -> 5 pieces should be analysed per test i.e. for one simulant for a specific migration test:

> sampling = 5 * 3 = 15 pieces (5 for the initial analysis, 5 for the dispute analysis and 5 for the confirmatory analysis)

For a lot of less than 100 samples -> 3 pieces should be analysed per test, i.e. for one simulant for a specific migration test:

> sampling = 3 * 3 = 9 pieces (3 for the initial analysis, 3 for the dispute analysis and 3 for the confirmatory analysis)

Sampling at the retail outlet

For convenience 1 store is considered a “lot”.

Three pieces should be analysed per test, i.e. for one simulant for a specific migration test:

> sampling = 3 * 3 = 9 pieces (3 for the initial analysis, 3 for the dispute analysis and 3 for the confirmatory analysis)

If this is not possible the sampler should ask the importer to provide other identical lot samples from other retail outlets.

If no additional samples are available the at least 1 sample should be taken (as long as material can be considered homogeneous).

Additional units might be required if there is an intention to also perform compositional analysis.

In case of doubt on whether to and how to sample, seek the advice of the CRL.

8.2.2.2 Ceramics, glass, cement, mortars etc.

For migration of cadmium, chromium, or lead from ceramic food contact materials and articles legislation defines that the sample should be composed of 4 identical individual articles. These articles should be made up of same material, of the same form and size and they should comprise the same decoration and varnish.

8.2.2.3 Others

For other materials, such as paper and board, metals, silicone elastomers, glues and adhesives, inks and pigments the laboratory must use their own expert judgement according to the type of analysis the substances looked for, and following as a guide the recommendations given above.

8.3 Preparation of samples

8.3.1 Codification

Complete traceability from the sample to the test result should be ensured.

8.3.2 Preparation of test specimens

Test specimens can be produced from a sample in a variety of ways, depending on the type of material or article and its use.

8.3.2.1 Use of the article or utensil itself

A food contact article or utensil may be tested as received, i.e. the sample obtained is also the test specimen. Testing may be by immersion or filling. Any part of the article not intended for contact with the foodstuff may be removed prior to testing.

8.3.2.2 Punching

This preparation can be used for the materials or articles are soft and of a shape that allow the test specimen to be punched from the material or article. Materials and homogeneous articles can be cut with a square punch of 100 * 100 mm to generate test specimens for total immersion. Materials and articles that are heterogeneous in nature (e.g. multi layers) can be cut with a circular punch with a diameter equivalent to that of the migration test cell. Punching can be done manually or using a press. Attention should be paid that the edges are not frayed when punching manually.

8.3.2.3 Cutting

The materials or soft articles that cannot be punched can be cut with cutters or scissors. Where possible each test specimen should be made up of a total area of 1 dm^2 of material or article. The analytical tolerance on the measurement is 1 mm.

8.3.2.4 Pouch making

Pouch making can be used for soft materials or articles mono- or multi-layers that are sealable into a dimension of 100 * 100 mm. The pouches are made with a laboratory sealing device after testing the efficacy of the experimental sealing conditions.

8.3.2.5 Sawing

This technique can be used for rigid and homogeneous materials or articles. Where possible each test specimen should be made up of a total area of 1 dm^2 of material or article. The analytical tolerance on the measurement is 1 mm.

8.3.2.6 Workshop cutting

This technique can be used for rigid materials or articles that cannot be sawed or that are heterogeneous. Their cutting should include the following instructions:

- For materials or articles that are heterogeneous, the test specimens should be circular with a diameter equivalent to that of the migration test cell.
- For materials or articles that are homogeneous where possible each test specimen should be made up of a total area of 1 dm^2 of material or article. The analytical tolerance on the measurement is 1 mm.

8.3.2.7 Deposit on inert support

Coatings and varnishes can be deposited on an inert support such as plaques made out of glass of stainless steel of dimensions 25 * 100 mm. Four plaques prepared in this way constitute one test specimen (total area 1 dm^2).

8.3.3 Pre-treatment of test specimens

For plastics samples dust may be removed by wiping the sample with a lint-free cloth or brushing with a soft brush. If articles are labelled with an instruction that they should be cleaned before use then this instruction should be followed before testing.

For ceramics the Directive specifies that the test sample should be washed in a solution containing a household liquid detergent at a temperature of approximately 40°C. It should then be rinsed, allowed to drain and dried.

For other material types the rules for plastics can be followed indicatively.

8.3.4 Surface area of test specimens:

The rules for the surface area for the test specimens are taken from the rules for plastics. They are described in detail in the CEN standards EN-1186 Part 1 and EN 13130 Part 1.

8.3.4.1 Standard surface area

Normally a surface area of 1 dm^2 will be taken to constitute one test specimen. An excerpt of standard EN -1186 Part 1 is reproduced below:

"In the total immersion test, both the surface which is intended to come into contact with the foodstuff and the outside surface are in contact with the food simulant. No allowance is made for this in the calculation of migration per unit of surface area. Although the total surface exposed is 2 dm^2, only 1 dm^2, i.e. the food contact surface, is taken into account in the calculation. It is therefore a more severe test than testing in a pouch or in a cell or by filling. However, if it is possible to demonstrate experimentally that the value obtained in a total immersion test is double that obtained in a single surface test, the value obtained in the total immersion test shall be divided by the total surface area exposed. However, the experimentation can be avoided in the case of materials with a thickness greater than 0.5 mm because it is conventionally agreed, except for plasticized polymers and multi-layer materials where the food contact surfaces are different, that for these materials the calculation shall take into account the total surface exposed. In cases where the overall migration limit is exceeded when testing by total immersion, the test shall be repeated using a method applying single sided contact. "

8.3.4.2 Real surface area

This should be calculated from measured dimensions of the test specimen.

8.3.4.3 Apparent surface area

For alveolar or foamy materials the apparent surface area is taken for the determination of the migration, i.e. if an area of 1 dm^2 is cut from the material or article this is the test specimen surface area.

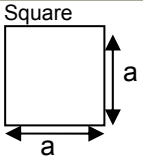
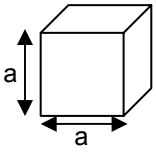
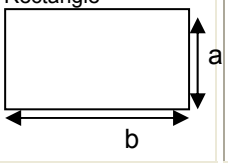
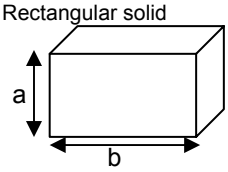
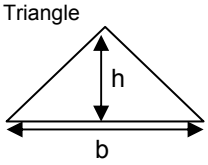
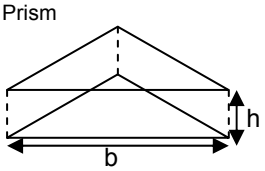
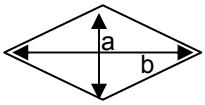
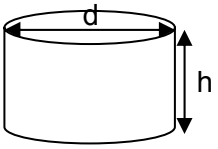
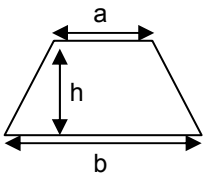
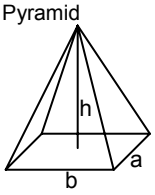
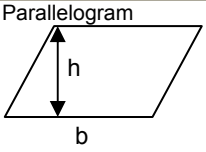
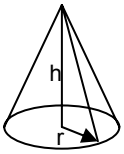
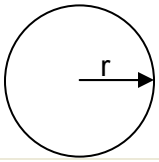
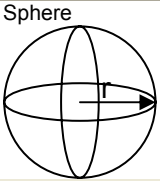
8.3.4.4 Calculation of the surface area

In general, the surface area is the sum of all the areas of all the shapes that make up the food contact surface of the object.

Note: "ab" means "a" multiplied by "b". "a2" means "a squared", which is the same as "a" times "a". Use the same units for all measurements.

(pi = π = 3.141592...)

8.3.4.4.1 Examples

Shape	Surface area formula	Shape	Surface area formula
Square 	Surface = a^2	Cube 	S = $6a^2$ a: length of the side of each edge of the cube
Rectangle 	S = ab	Rectangular solid 	S = = 2ab + 2bc + 2ac = 2(*ab* + *bc* + *ca*) a, b, c: lengths of the 3 sides
Triangle 	S =bh/2	Prism 	S = 2b + Ph *(b is the area of the base P is the perimeter of the base)*
Diamond 	S = (ab) /2	Cylinder 	Lateral surface area S = πdh S = 2 πrh + 2 πr^2 S = areas of top and bottom +area of the side S = 2(Area of top) + (perimeter of top)* height h: height of the cylinder r : radius of the top
Trapezoid 	S = 1/2 [base 1 + base 2] x height S = h(a+b)/2	Pyramid 	S: Add the Area of the base to the sum of the areas of all of the triangular faces. The areas of the triangular faces will have different formulas for different shaped bases. b is the Area of the base
Parallelogram 	S = base x height S = b h	Cone 	Surface = $\pi r^2 + \pi rs$ S = $\pi r^2 + \pi rs$ = $\pi r^2 + \pi r\sqrt{r^2 + h^2}$
Circle 	S = πr^2 r: radius of the circle (distance from the center to any point on the circle)	Sphere 	S = 4 πr^2

8.3.4.4.2 Empirical method to calculate surface areas

Place the articles or item on millimetric piece of paper of sufficient dimension. Wrap the paper around the contour of the item and cut. Calculate the dimension either by counting the area based on millimetric measurements or by weighing the paper and conversion to surface area.

8.3.5 Simulants

As described previously for plastics the simulants and rules for migration testing with simulants are given in Directives 82/711/EEC, as amended, and 85/572/EEC, as amended. For ceramic articles the simulant to be used is defined in the legislation as 4% (v/v) aqueous acetic acid. For other material types for which food simulants have not been defined the rules for plastics have been proposed in these guidelines.

For Plastics:

Where the surface to volume ratio to be used in contact with food is known this ratio should also be used in the migration testing. An example of this is where a container is intended to contain a specified volume of contents even if this does not completely fill the article. In this case the article is tested with the specified volume of simulant. For very large containers testing by filling may not be practicable and it may be necessary to fabricate smaller test specimens representing the article to be tested. When the surface to volume ratio to be used in contact with the food is not known and a material is tested by total immersion the surface to volume ratio is conventionally 1dm² of food contact area to 100 ml of food simulant.

Using a migration test cell the volume to be used should be sufficient to ensure that the whole surface of the test specimen is covered with the simulant. The actual volume will depend on the cell dimensions. As an example the use of cell type A is described in EN 1186-4. The surface to volume ratio in the type A cell is conventionally 2.5 dm² of food contact area to 125 ml of food simulant.

The surface to volume ratio in the pouch is conventionally 2 dm² of food contact area to 100 ml of food simulant.

If the article is a tableware or kitchenware (spatulas, spoons ladles, etc) and can be immersed or is intended to be immersed partially or totally, then immersion should be used as a means for testing the migration. In such cases the volume of simulant should be proportional to the area required to cover the utensil. It should respond to the requirement of covering the utensil entirely including 2 cm of the handle. The area to volume ratio should be recorded.

For ceramic ware:

Directive 2005/31/EC amending Directive 84/500/EEC should be applied. It is also reported in the ISO 6486-1:1999 and other on ceramic ware. It specifies to fill to within 6 mm of overflowing as measured along the sloping side of flatware, or to within 1 mm of the rim as measured vertically for hollowware. The reference surface area may be calculated from the diameter of the article or to cut out and weigh the enclosed area and to determine the area by comparison of the weight with the weight of a rectangular sheet of known area.

8.4 Time-temperature exposure conditions

For materials covered in the EU legislation or where recommendations exist for food contact, those conditions should be used. The conditions given in these guidelines have been defined in accordance with existing EU legislation.

As mentioned previously time and temperature conditions for exposure of plastics to food simulants are given in Directive 82/711/EEC, as amended. The protocols defining the testing methods (for plastics) have been described in CEN standards for overall and specific migration (see previous sections).

For plastic articles where the interpretation of these rules may not be harmonised then more guidance is required. This is provided in these guidelines.

For ceramics, the conditions stipulated in Directive 2005/31/EC amending Directive 84/500/EEC should be applied (22 ± 2°C for a duration of 24 ± 0,5 hours).

For materials for which EU harmonised rules do not exist then specific conditions set in national legislations should be applied.

Where no harmonised rules or national legislation exist these guidelines should be followed.

8.5 Classification and information catalogue on kitchenware

This is a list of food preparation utensils, some of what is known as kitchenware. This is an attempt to classify them by functionality for an easier reading and referencing system.

- Food preparation wear (aprons gloves etc)
- Food preparation utensils (cold use, cold-hot use, hot use)
- Kitchen small appliances
- Food serving (jugs, glasses, trays etc)
- Food serving implements (cutlery, straws etc)

For all articles the following general recommendations are applicable:

- If a label related to the maximum time or temperature conditions exist, then the conditions are those indicated on the label.
- If national legislations specify time or temperature that should be used for the product, those should be used.
- In other cases, the test conditions are established only after evaluating the kind of material used and using expert judgment if required.
- All repeat use articles must be tested three times with fresh simulant each time and the results of the third test considered under the current legislation.
- The experimental design must limit the evaporation occurring during the exposure phase and/or should include a recovery experiment in case there is evaporation. The final volume should be recorded.

Recommendations provided here have been found to be adequate based on potential legal references, expertise, experimental investigation and/or modelling. These conditions can be used as adequately representing worst foreseeable conditions unless it destroys or causes physical modifications of the object. In this case expert judgment of the laboratory must be employed.

8.5.1 Food preparation wear (FPW)

8.5.1.1 FPW_Apron for home use

Illustration	    also bibs 
Definition	An apron is an outer protective garment that covers primarily the front of the body. It may be worn for hygienic reasons as well as in order to protect clothes from wear and tear. Typical materials include plastics, oily cloth.
Sample preparation	Cut test specimen
Test type	Migration test cell or total immersion
Test conditions	Simulant B, simulant D and 50% ethanol 0.5 hours at 40°C - Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that of short term use (< 30 minutes) at ambient temperature, which has a test time of 30 minutes and a test temperature of 40°C as defined in Directive 82/711/EEC, as amended. These conditions apply only for home use and not for aprons used in the food processing or catering industry, where the applicable conditions would be different.

8.5.1.2 FPW_Gloves

Illustration	    
Definition	A glove is a type of garment which covers the hand of a human. Gloves have separate sheaths or openings for each finger and the thumb. Typical materials include nitrile, latex, textiles, plastics etc.
Sample preparation	Turn the glove inside out
Test type	Article fill
Test conditions	Simulant B, simulant D and 50% ethanol 2hours 40 °C - Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that of a use that could last up to 2 hours at ambient temperature, which has a test time of 2 hours and a test temperature of 40°C as defined in Directive 82/711/EEC, as amended. These conditions apply only for home use and not for gloves used in the food processing or catering industry, where the applicable conditions could be extended.

8.5.1.3 FPW_towels- wipes/ napkins/tablecloth/placemats etc

Illustration	    
Definitions	A towel is a piece of absorbent fabric or paper used for drying or wiping. A napkin is a rectangle of cloth or paper used at the table. A placemat is a protective pad (e.g. paper, plastic or cloth) for restaurants and households. A tablecloth is used to cover a table.
Sample preparation	Cut specimen
Test type	Total immersion
Test conditions	2 hours at 40°C - Repeat use conditions For napkins, placemats and tablecloths: Simulant B, simulant D and 50% ethanol For towels: Semi solid simulant made of 40% diatomeous earth, 25% olive oil and 35% water
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale for napkins, placemats and tablecloths is that of use for less than 2 hours at ambient temperature, which has a test time of 2 hours and a test temperature of 40°C as defined in Directive 82/711/EEC, as amended. The test conditions defined for towels are consistent with those specified by the Council of Europe (CoE) for tissues; Method description in Appendix 3 of "Public Health Committee, Committee of experts on materials coming into contact with foods, Policy Statement concerning "tissue paper kitchen towel and napkins". (2007) http://www.coe.int/t/e/social_cohesion/soc%2Dsp/public_health/food_contact/ PS%20E%20TISSUE%20PAPER%20VERSION%201.pdf

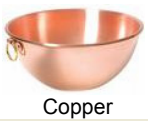
Cheese cloth can be tested in this category; a cheesecloth is a loose woven cotton cloth used in cheese making, such as to press cheese curds; particular case. 10days 40C with EtOH 50%.

8.5.2 Food preparation utensils – cold use (FPU/C)

Illustration	 Pastry spatula/scraper  Pastry brush  pastry bag  Cookie shapes  Rolling pin   Cheese grater  Can opener  Garlic press,  Nut cracker  Lemon zester,  Vegetable peeler  Food scales Etc.
Definitions	Spatula: kitchen utensil with a long handle and a broad flat edge for lifting food Pastry brush: tool used to spread oil or glaze on food. Pastry bag: used to pipe semi-solid foods by pressing them through a narrow opening at one end, for many purposes including cake decoration. Rolling pin: cylindrical food preparation utensil used to shape and flatten dough. Cheese grater: to grate or shred cheese. Cookie shapes: tool to cut out cookie dough in a particular shape. Garlic press: kitchen utensil designed to crush garlic cloves by forcing them through a grid of small holes. Nut cracker: tool to break and remove the shell from nuts. Lemon zester: a kitchen utensil for obtaining zest from lemons and other citrus fruit. Vegetable peeler: metal blade attached to a wooden, metal or plastic handle that is used for peeling certain vegetables. Food scale: weighing instrument that outputs precise weight information for foods or liquids.
Sample preparation	The article should be tested intact. Non-food contact parts can be removed for ease of testing.
Test type	Total immersion
Test conditions	Simulant B and D and 50% ethanol 0.5 hours at 40°C - Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that of short term use (< 30 minutes) at ambient temperature, which has a test time of 30 minutes and a test temperature of 40°C as defined in Directive 82/711/EEC, as amended..

8.5.3 Food preparation utensils – cold or warm use (FPU/C-H)

8.5.3.1 FPU/C-H_Mixing bowl (include measuring cups)

Illustration	 Metal  Glass  Copper  Plastic  Melamine
Definition	A food preparation article to mix ingredients
Sample preparation	The article should be tested intact.
Test type	Article fill
Test conditions	Simulant B and D and 50% ethanol - Repeat use conditions A distinction should be made between room temperature use (e.g. salads) and preparation use that can include hot fill. For use at ambient temperature only 10 days at 40°C For use with hot fill 2 hours 70°C followed by 10 days at 40°C. For cooking or baking the test conditions should conform to those for bake ware and cookware.
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that mixing bowls intended only for use at ambient temperature may be used for long term storage at ambient temperature, which has a test time of 10 days and a test temperature of 40°C as defined in Directive 82/711/EEC, as amended. The rationale for mixing bowls intended hot food use is that the bowl may be filled with a foodstuff at conditions equivalent to hot fill, i.e.2 hours at 70°C as defined in Directive 82/711/EEC, as amended.

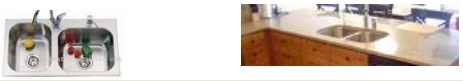
8.5.3.2 FPU/C-H Cooking Spatulas/ladle/slotted spoons/tongs and pasta tongs etc

Illustration	 Nylon Melamine Wood Silicone Metal (aluminium, stainless steel, copper)
Definitions	A spatula is a kitchen utensil with a long handle and a broad flat edge, used both in the preparation of food, as a flipping implement, and in the serving of food. A ladle is a type of spoon used to serve soup or other liquids. Other utensils can be used as preparation or serving implements. Typical material can include nylon, melamine, metal, wood, silicone, metals
Sample preparation	The article should be tested intact. Non-food contact parts can be removed for ease of testing
Test type	Total immersion
Test conditions	Simulant B, simulant D and 50% ethanol - Repeat use conditions The choice of test conditions should be addressed considering the specific use of the utensils. If there is a label test conditions should be selected according to the instructions given. If there is no label test conditions should be: 2 hours at 100°C with simulant B, 2 hours at reflux temperature for 50% ethanol, and 0.5 hours at 175°C with simulant D (a higher temperature may be used if the utensil is labelled as being suitable for contact with foods at higher temperatures)
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale for aqueous simulants is that utensils may be used for up to 30 minutes at temperatures above 100°C. Directive 82/711/EEC, as amended, states that if the exposure temperature is in excess of 100°C the test may be replaced by a test at 100°C or at reflux temperature for a duration of four times the time selected according to the general rules (4 x 30 minutes = exposure time of 2 hours). For simulant D, If the utensil is labelled with a maximum temperature up to 175°C, then it should be tested at that temperature. If the article is labelled that it is suitable for contact with foodstuffs up to a temperature above 175°C other contact conditions may be used. For no label, 175°C is applied. In all cases the exposure time should be 30 minutes.

8.5.3.3 FPU/C-H Cutting Boards

Illustration	
Definition	A cutting board is a durable board used to place material on to be cut. Typical materials include wood, plastics, glass, steel, ceramic, Teflon etc.
Sample preparation	Either the whole article or a cut specimen can be tested.
Test type	Total immersion
Test conditions	Simulant B, simulant D and 50% ethanol 2 hours at 70°C Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that cutting boards are considered for cutting purposes only and not for subsequent storage of foodstuffs. Foods may be in contact with the cutting board for short periods of time (up to 15 minutes) at temperatures between 70 and 100°C. Test conditions given in Directive 82/711/EEC, as amended, which are equivalent to this contact, are 2 hours at 70°C.

8.5.3.4 FPU/C-H Sinks and kitchen countertop or worktop (or bench)

Illustration	
Definitions	A sink or basin is a bowl-shaped fixture that is used for washing hands or food, dishes. Countertop usually refers to a horizontal work surface in kitchens, other food preparation areas. Typical materials include natural stones, stainless steel, or synthetic materials such as resins.
Sample preparation	Either the whole article or a cut specimen can be tested. The manufacturer may be asked to prepare a sample of suitable dimensions for the test.
Test type	Article fill or total immersion
Test conditions	Simulant B, simulant D and 50% ethanol - Repeat use conditions 10 days at 40°C
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that sinks and worktops are intended only for use at ambient temperature may be used for long term storage at ambient temperature, which has a test time of 10 days and a test temperature of 40°C as defined in Directive 82/711/EEC, as amended.

8.5.4 Food preparation utensils –hot or cold use (FPU/H-C)

8.5.4.1 FPU/H-C_Microwave Materials

Illustration	   
Definition	Articles that can be used for food preparation and cooking using a microwave oven
Sample preparation	Either the whole article or a cut specimen can be tested.
Test type	Article fill or total immersion
Test conditions	Simulant B, simulant D and 50% ethanol - Repeat use conditions If the product is labelled with a maximum time and temperature the equivalent test conditions as defined in Directive 82/711/EEC, as amended, should be used. The contact time for aqueous simulants is 2 hours (it assumes a contact temperature is >100°C). The contact time is 30 minutes for simulant D. The temperature of the plastic at the plastic/food interface should be determined according to CEN standard EN 14233:2002. "Determination of temperature of plastics materials and articles at the plastics/food interface during microwave and conventional oven heating in order to select the appropriate temperature for migration testing"
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale for aqueous simulants is that these articles may be used for up to 30 minutes at temperatures above 100°C. Directive 82/711/EEC, as amended, states that if the exposure temperature is in excess of 100°C the test may be replaced by a test at 100°C or at reflux temperature for a duration of four times the time selected according to the general rules. For simulant D, If the article is labelled with a maximum temperature up to 175°C, then it should be tested at that temperature. If the article is labelled that it is suitable for contact with foodstuffs up to a temperature above 175°C other contact conditions may be used. For no label, 175°C is applied. In all cases the exposure time should be 30 minutes.

8.5.4.2 FPU/H-C_Roast strings, sausage casings

Illustration	      
Definitions	Sausage casing is the material that contains and encloses the filling of a sausage. A roast or kitchen string is a string that is used to tie the meat in general for roast and poultry during cooking.
Sample preparation	Cut the material to produce the test specimen =
Test type	Total immersion
Test conditions	Simulant B and simulant D 2 hours at 100°C or reflux temperature for simulant B 2 hours at 175°C for simulant D
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale for aqueous simulants is that can stay in the oven or pot for 30 min. at temperatures above 100°C. The rationale is then the same as for the previous category. For simulant D, 175°C is applied as maximum test temperature conditions in the legislation. For rubber, follow CoE, Policy Statement concerning "rubber intended to come into contact with foodstuffs". (2004) http://www.coe.int/t/e/social_cohesion/soc%2Dsp/public_health/food_contact/COE%27s%20policy%20statements%20food%20contact.asp#TopOfPage

8.5.4.3 FPU/H-C_Coolander/drum sieve/puree masher/ potato masher

Illustration	 
Definitions	A sieve separates wanted from unwanted material using a mesh (also strainer, colander). A potato masher is used to crush soft food
Sample preparation	Either the whole article or a cut specimen can be tested.
Test type	Total immersion
Test conditions	Simulant B and simulant D - Repeat use conditions 2 hours at 70°C
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that foods may be in contact with these articles for short periods of time (up to 15 minutes) at temperatures between 70 and 100°C. Test conditions given in Directive 82/711/EEC, as amended, which are equivalent to this contact, are 2 hours at 70°C.

8.5.5 Food preparation utensils –hot use (FPU/H): Cookware-bakeware

These articles will be addressed in the second edition of the guidelines

8.5.6 Kitchen small appliances (KSA) note: more will be treated in the second edition

8.5.6.1 KSA Coffee Maker

Illustration	
Definition	Kitchen appliance used to brew coffee without having to boil water in a separate container.
Sample preparation	Test the article itself.
Test type	Actual use
Test conditions	Simulant A and Actual use with – 3 cycles, i.e. – Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. As water is the food in contact, the simulant is A. The type of article allows the use of actual use (usually about 30 min between the heating and the keeping hot).

8.5.6.2 KSA Kettle/ teapot

Illustration	
Definition	A kettle is a device used to quickly heat water for hot drinks, such as tea or coffee.
Sample preparation	Test the article itself
Test type	Actual use
Test conditions	Test with Simulant A For plastic / electric kettles: test under condition of actual use or, if not possible, 0.5 hours at 100°C For metallic kettles to be used on a stove, test under condition of actual use or 2 hours at 100°C Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. As water is the food in contact, the simulant is A. The type of article allows the use of actual use. If not it is assumed a normal use of usually about 30 min between the heating and the keeping hot, therefore corresponding to test conditions of 30 min. in the Directive 82/711/EEC, as amended. For metallic heating elements in plastic kettles; then national legislations for metal are applicable.

8.5.7 Food serving (FS)

8.5.7.1 FS Baby Bottles

Illustration	
Definition	A baby bottle is a bottle with a teat (also called a nipple in the US) to drink directly from.
Sample preparation	Test the article itself
Test type	Article fill
Test conditions	Test with simulant B and 50% ethanol; A two-phase testing scheme is recommended: For plastics, the article should be sterilised according to the producer's instruction or for 10 min. at 100°C, then test conditions of 2 hours at 70°C should be applied For glass, either apply specific conditions set in national legislations if any or the conditions given as guidance for plastics. Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The conditions referred to as hot fill are applied from Directive 82/711/EEC, as amended.

8.5.7.2 Food trays

Illustration	
Definition	A tray is a shallow platform designed for carrying things. Trays are flat, but with raised edges to stop things from sliding off of them. Some examples have handles, and/ or short feet for support.
Sample preparation	Cut specimen (sawing might be needed for thick samples)
Test type	Total immersion
Test conditions	Simulant B, simulant D and 50% ethanol 2 hours at 70°C Repeat use conditions (to verify, may not be all cases)
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The conditions referred to as hot fill are applied from the Directive 82/711/EEC, as amended. Evaluation whether repeat use is made on the basis of the use of the object or material

8.5.7.3 FS Carafe / Jugs/ decanter/ flasks (also fitness or bicycle bottles)

Illustration	
Definitions	A decanter is a vessel supplied with a stopper that is used to hold the decantation of a liquid (such as wine) which may contain sediment. A jug is a type of container for liquid (e.g. beer). A hip flask is a thin flask for holding a distilled beverage. A sport bottles is a container with an easy to drink device such as a spout or a straw to allow its use while moving. Typical materials include glass, crystal, plastics, metals (hip flasks for ex are often made of stainless steel)
Sample preparation	Test the article itself
Test type	Article fill
Test conditions	Simulant B and 50% ethanol (for alcoholic beverages) If the use can be foreseen also to include hot beverage, then 2 hours at 70°C, If there are no indications that elevated temperatures may be used then 24 hours at 40°C. Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that the usage corresponds to conditions referred to as hot fill are applied from the Directive 82/711/EEC, as amended, and in case of cold use can be used to store the drink for a day, therefore having the test conditions of 24hrs at the temperature for ambient storage.

8.5.7.4 FS Cup glasses (including disposable) – drink ware

Illustration	
Definition	Drink ware or beverage ware is a term for the class of vessels from which people drink. Glassware is a class of objects that include drink ware made from glass as well as other items e.g. cup, chalice, goblet, mug, teacup etc. Materials include glass, plastics, ceramics, metals
Sample preparation	Test the article itself
Test type	Article fill
Test conditions	Simulant B and 50% ethanol If the article is labelled for use with cold drinks only: 24 hours at 40°C. If it is not labelled: 2 hours at 70°C In the cups could foreseeably be used for cold storage, the test should include also 24 hours at 20°C. If re-use, perform under repeat use conditions If disposable, then migration test is performed once
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that the usage corresponds to conditions referred to as hot fill are applied from the Directive 82/711/EEC, as amended, and in case of cold use can be used to store the drink or food for a day at temperature colder than room temperature, therefore having the test conditions of 24hrs at the temperature for less than ambient storage (using 20C as test conditions based on the Directive 82/711/EEC, as amended)

8.5.7.5 FS_Plates –dishware

Illustration	
Definition	A plate is a type of dishware, being a broad, concave but mainly flat vessel on which food is served.
Sample preparation	The article itself is tested
Test type	Article fill
Test conditions	Simulant B, Simulant D and 50% ethanol 2 hours 70°C Repeat use conditions if applicable
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. Plates are intended to serve food and their use does not imply storage; therefore they are treated in this edition of the guidelines as serving dishware. The rationale is that the usage corresponds to conditions referred to as hot fill are applied from Directive 82/711/EEC, as amended.

8.5.7.6 FS_Thermos

Illustration	
Definition	A vacuum flask is a vessel or insulated container which keeps its contents hotter or cooler than their environment by interposing an evacuated region to give thermal insulation
Sample preparation	The article itself is tested.
Test type	Article fill
Test conditions	Simulant B and 50% ethanol Fill the object at boiling temperature and leave it closed for 24 hours (do NOT open). Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is to use worst conditions of actual use.

8.5.8 Food serving implements (FSI)

8.5.8.1 FSI_Cutlery/silverware/tableware/spoon/knife/fork etc.

Illustration	
Definition	Refers to any hand implement used in preparing, serving, and eating food. Typical materials include silver or stainless steel, plastics, wood (e.g. chopsticks), Picks, scissors, stirrers, straws
Sample preparation	The article should be tested intact. Non-food contact parts can be removed for ease of testing
Test type	Total immersion
Test conditions	Simulant B, simulant D, and 50% ethanol: 2 hours at 70°C If the contact time is < 30 minutes, e.g. scissors, stirrers, picks 0.5 hours at 70°C. Repeat use conditions
Remarks	National legislations should be taken into account or other relevant guidance to show compliance. The rationale is that foods may be in contact with these articles for short periods of time (up to 15 minutes) at temperatures between 70 and 100°C. Test conditions given in Directive 82/711/EEC , as amended, which are equivalent to this contact are 2 hours at 70°C. For very short contact times, these guidelines consider that the shortest test time is 30 min for kitchen articles.

9 PRESENTATION OF RESULTS

9.1 Choice of Units and tolerance for migration results

9.1.1 Criteria for choosing units

In accordance with Plastics Directive 2002/72/EC,as amended, the migration should be reported in units of mg/dm^2 except in the following cases:

- ❖ Articles that are containers of 500 ml to 10 l.
- ❖ Articles that can be filled and for which it is not possible to estimate the surface in contact with food
- ❖ Caps, joints, gaskets, corks and other closing systems

where the migration should be reported in units of mg/kg.

9.1.2 Particular cases.

Excerpt from EN 1186-1 (also in 13130-1)

For articles that cannot be filled of volume between 500 ml and 10 l, for which the ratio surface to volume is known in the real conditions of use and when tests have been done in those conditions,. The results must be expressed in mg/dm^2
For articles that can be filled of volume between 500 ml and 10 l, for which the ratio surface to volume is known in the real conditions of use and when tests have NOT been done in those conditions,. The results must be expressed in mg/dm^2.
When it is not possible to calculate the surface of an article that can be filled, the actual quantity of food in contact with the articles is requested to the "client" in order to express the results in mg/dm^2 .

9.1.3 Tolerance (analytical) of results

The tolerances are described in part 1 of both EN 1186 and EN 13130, the excerpt below shows for example part 1 of EN -1186 (version July 2002)

12.3.1 Aqueous food simulants
The following analytical tolerances are allowed: **6 mg/kg or 1 mg/dm² for all aqueous food simulants**.
The test result for each individual test specimen is valid if it differs from the mean of the triplicate test results by not more than the permitted analytical tolerance. If a minimum of three results is not within the analytical tolerance, then the test is repeated using fresh test specimens from the sample.

12.3.2 Fatty food simulants for single use applications
The following analytical tolerances are allowed: **20 mg/kg or 3 mg/dm² for all fatty food simulants and substitute test media.** The tolerances are valid also after application of a reduction factor to the results of the test. If a reduction factor does not apply, results above 10 mg/dm^2 shall not differ by more than 30 % from the mean of the set of results. The determination of overall migration into the fatty food simulant is normally carried out in quadruplicate to allow three valid results to be obtained even if one determination is discarded. Where four results have been obtained from four determinations i.e. no single determination has been rejected because of an obvious manipulative error, all four results are valid when if each individual result differs from the mean of the four results by not more than the analytical tolerance. If one of the four results is greater or less than the mean by an amount more than the tolerance, then this result can be rejected and the mean recalculated on the remaining three results. If two results are greater or less than the mean by amounts more than the tolerance, the result with the largest difference from the mean can be rejected and a new mean calculated from the remaining three results. The remaining three test results are valid if they are within the analytical tolerance. If a minimum of three results do not meet the above criteria of being within the analytical tolerance, then the test shall be repeated using fresh test specimens from the sample. A material or article with a mean overall migration result that exceeds the overall migration limit by an amount not exceeding the analytical tolerance shall be deemed to be in compliance with the overall migration limit.

12.3.3 Fatty food simulants for repeated use applications
The permitted tolerances are as indicated in 9.8.3. "When repeated testing is used to determine the overall migration into a fatty food simulant the individual results for each set of the determinations (M_1, M_2 or M_3) shall be deemed valid if at least three results are obtained in each set which do not differ from the mean for that set by more than 30% for results above 10 mg/dm² or by more than 3 mg/dm² for results below 1 mg/dm². Results which exceed this tolerance shall be discarded according to the procedure given in 12.3.2." A material or article with a mean overall migration result that exceeds the overall migration limit by an amount not exceeding the analytical tolerance, shall be deemed to be in compliance with the overall migration limit.

9.1.4 Precision of results

According to EN-1186-1 and 13130-1, precision data enables an assessment of the significance of a test result obtained from tests performed with the standard test method, and the significance of the result in comparison with a result obtained by another analyst in a different laboratory. The basic precision data which are required for each test method are: *'r'* - repeatability value and *'R'* - reproducibility value.

9.2 Particular aspects of expressing migration results

9.2.1 Specimen taken from a material and article

Overall migration is a measure of inertness and may be expressed in different ways according to the following circumstances. The excerpt of EN-1186 (2002) is provided below as example (also described in EN-13130-1). These standards are available for purchase via the National Members listed in the CEN website.

12.1.2 For unknown surface to volume ratios
When the surface to volume ratio in actual use is not known the results obtained under the test conditions shall be reported in milligrams per square decimetre and shall be recalculated to the "conventional" surface to volume ratio of 6 dm² to 1 kg of food and expressed in milligrams per kilogram.
For articles which can be filled and for which it is impracticable to estimate the surface area which is in contact with the foodstuff the results shall be expressed in milligrams per kilogram.

12.1.3 For known surface to volume ratios and tested under these conditions
When the surface to volume ratio in actual use is known, and the tests have been carried out under these conditions and the plastics articles are containers or articles which are comparable to containers or which can be filled, with a capacity of not less than 500 ml and not more than 10 l, the results shall be expressed in milligrams per kilogram.
When the surface to volume ratio in actual use is known, and the tests have been carried out under these conditions and the plastics articles are not containers or articles which are comparable to containers or which can be filled, with a capacity of not less than 500 ml and not more than 10 l, the results shall be expressed in milligrams per square decimetre.

12.1.4 For known surface to volume ratios and tested under different conditions
When the surface to volume ratio in actual use is known, but the tests have not been carried out under these conditions and the plastics articles are containers or articles which are comparable to containers or which can be filled, with a capacity of not less than 500 ml and not more than 10 l, the results shall be recalculated to the actual conditions of use and expressed in milligrams per kilogram.
When the surface to volume ratio in actual use is known, but the tests have not been carried out under these conditions and the plastics articles are not containers or articles which are comparable to containers or which can be filled, with a capacity of not less than 500 ml and not more than 10 l, the results shall be expressed in milligrams per square decimetre.

12.1.5 Conversion recalculation
Where the migration tests are carried out on samples taken from the material or article or on samples manufactured for the purpose, and the quantities of foodstuff or simulant placed in contact with the sample differ from those employed in the actual conditions under which the material or article is used, the results obtained shall be corrected by applying the following formula:

$$M = \frac{m \times a_2 \times 1000}{a_1 \times q}$$

where:

M is the migration in milligrams per kilogram;
m is the mass in milligrams of substance released by the sample determined by the migration test;
a_1 is the surface area in square decimetres of the sample in contact with the simulant during the migration test;
a_2 is the surface area in square decimetres of the material or article intended to come into contact with foodstuff in real conditions of use;
q is the quantity in grams of foodstuff in contact with the material or article in real conditions of use.

9.2.2 Repeat use articles:

3 exposures are conducted also with a factor time and results of the 3rd exposure counted, as described in the standard EN 1186-1 and EN 13130-1: repeat use: 3 times. An excerpt (e.g. 1186-1) is illustrated below:

9.8.1 Criteria for testing
It is accepted that where a material or article is intended to come into repeated contact with foodstuffs, the migration tests are carried out three times on the same test sample in accordance with the conditions laid down, using a fresh sample of the food simulant on each occasion. The compliance of the material shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of migration does not increase in the second and third test and if the migration limit is not exceeded on the first test, no further test is necessary.
Experience has shown that some thermosetting plastics, e.g. melamine/formaldehyde resins, can give rise to increasing levels of migration on second and subsequent exposure to foodstuffs. However, for the majority of polymers migration levels will fall in the second and subsequent extracts. Proof of this may be found from past experience with similar polymer types. For these plastics it is only necessary to show that the migration limit is met in the first extract

9.8.2 Aqueous simulants
For aqueous simulants, no increase in migration is deemed to have occurred if the mean of the results for the second and third test do not exceed the mean of the result for the first extract by more than the permitted analytical tolerance.

9.8.3 Fatty food simulants
With fatty food simulant, the repeated exposure of the same test specimen to fresh portions of food simulant is not a feasible procedure, since the procedure requires solvent extraction to remove the fatty simulant. Therefore, the test is carried out on three sets of test specimens from the same sample of the material or article. One of these is subjected to the test appropriate for articles intended for single use by the standard procedure and the mean result calculated (M_1). The second and third samples are exposed in a manner identical in every respect to the first sample except for the period of exposure. The second sample is exposed for a period of twice that of sample one and sample three is exposed for a period three times that of sample one. The mean result for sample 2 is calculated (M_2) as is that for sample 3 (M_3).
The migration as a result of the second or third period is calculated as follows:
- migration caused by first period = M_1;
- migration caused by the second period = $M_2 - M_1$;
- migration caused by the third period = $M_3 - M_2$.

No increase in migration into fatty food simulant is deemed to have occurred if the results ($M_3 - M_2$) and ($M_2 - M_1$) do not exceed M_1 by more than the analytical tolerance.
The true values for M_1, M_2 or M_3 are subject to uncertainty owing to the lack of precision inherent in the method. Systematic errors in the determination of the overall migration are likely to apply equally to the determination of M_1, M_2 or M_3 and therefore need not be allowed for. Random errors do need to be recognized and allowed for.

When repeated testing is used to determine the overall migration into a fatty food simulant the individual results for each set of the determinations (M_1, M_2 or M_3) shall be deemed valid if at least three results are obtained in each set which do not differ from the mean for that set by more than 30% for results above 10 mg/dm² or by more than 3 mg/dm² for results below 10 mg/dm². Results which exceed this tolerance shall be discarded according to the procedure given in 11.3.2.

When the plastics material or article is intended for use with a class of foodstuff where a reduction factor may be used, this shall be applied to the individual determinations before the mean of $M_{1\ or}$ M_2 or M_3 is calculated.

The material and articles are deemed to be in compliance with the overall migration limit provided that either M_1 or $M_3 - M_2$ do not exceed the specified overall migration limit.

The end

Annex 1. 85/572/EEC

LIST OF SIMULANTS

1. In the following tables, which make up a non-exhaustive list of foodstuffs, the simulants to be used in migration tests with a particular foodstuff or group of foodstuffs are identified by the letters shown:

   Simulant A: distilled water of water of equivalent quality;

   Simulant B: 3% acetic acid (w/v) in aqueous solution;

   Simulant C: 10% ethanol (v/v) in aqueous solution;

   Simulant D: rectified olive oil[1]; if for technical reasons connected with the method of analysis it is necessary to use different simulants, olive oil must be replaced by a mixture of synthetic triglycerides[2], or by sunflower oil[3].

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.

3. When 'X' is followed by an oblique stroke and a figure, the result of the migration tests should be divided by the figure indicated. In the case of certain types of fatty food, this conventional figure, known as 'Simulant D Reduction Factor' (DRF), is used to take account of the greater extractive capacity of the simulant compared to the food.

4. Where the letter 'a' is shown in brackets after the 'X', only one of the two simulants given should be used:

   – if the pH value of the foodstuff is higher than 4,5, simulant A should be used,

1.1.1

[1] **Characteristics of rectified olive oil**

Iodine value (Wijs)	= 80 to 88
Refractive index at 25 °C	= 1,4665 to 1,4679
Acidity (expressed as % of oleic acid)	= 0,5% maximum
Peroxide number (expressed as oxygen milliequivalents per kg of oil)	= 10 maximum

[2] **Composition of the synthetic triglycerides mixture**

Fatty acid distribution

No of C-atoms in fatty acid residue	6	8	10	12	14	16	18	others
GLC area (%)	~1	6 to 9	8 to 11	45 to 52	12 to 15	8 to 10	8 to 12	≤ 1

Purity

Content of monoglycerides (enzymatically)	≤ 0,2%
Content of diglycerides (enzymatically)	≤ 2,0%
Unsaponifiable matter	≤ 0,2%
Iodine value (Wijs)	≤ 0,1%
Acid value	≤ 0,1%
Water content (K. Fischer)	≤ 0,1%
Melting point	28 ± 2°C

Typical absorption spectrum (thickness of layer: d = 1 cm; reference: water at 35°C)

Wavelength (nm)	290	310	330	350	370	390	430	470	510
Transmittance (%)	~2	~15	~37	~64	~80	~88	~95	~97	~98

At least 10% light transmittance at 310 nm (cell of 1 cm, reference: water at 35°C)

[3] **Characteristics of sunflower oil**

Iodine value (Wijs)	= 120 to 145
Refractive index at 20°C	= 1,474 to 1,476
Saponification number	= 188 to 193
Relative density at 20°C	= 0,918 to 0,925
Unsaponifiable matter	= 0,5% to 1,5%

– if the pH value of the foodstuff is 4,5 or less, simulant B should be used.

4a. Where the letter (b) is shown in brackets after the 'X', the indicated test should be carried out with ethanol 50% (v/v).

5. Where a foodstuff is listed under both a specific and a general heading, only the simulant(s) indicated under the specific heading is (are) to be used.

Reference number	Description of food	Simulants to be used			
		A	B	C	D
01	**Beverages**				
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5% vol.:				
	Waters, ciders, fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other	X(a)	X(a)		
01.02	Alcoholic beverages of an alcoholic strength equal to or exceeding 5% vol.:				
	Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol.:				
	Wines, spirits and liqueurs		X(*)	X(**)	
01.03	Miscellaneous: undenaturated ethyl alcohol		X(*)	X(**)	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**				
02.01	Starches				
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)				
02.03	Cereal flour and meal				
02.04	Macaroni, spaghetti and similar products				
02.05	Pastry, biscuits, cakes and other bakers' ware, dry:				
	A. With fatty substances on the surface				X/5
	B. Other				
02.06	Pastry, cakes and other bakers' ware, fresh:				
	A. With fatty substances on the surface				X/5
	B. Other	X			
03	**Chocolate, sugar and products thereof**				
	Confectionery products				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products:				
	A. In solid form:				
	I. With fatty substances on the surface				X/5
	II. Other				
	B. In paste form:				
	I. With fatty substances on the surface				X/3
	II. Moist	X			
03.03	Sugar and sugar products				
	A. In solid form				
	B. Honey and the like	X			
	C. Molasses and sugar syrups	X			
04	**Fruit, vegetables and products thereof**				
04.01	Whole fruit, fresh or chilled				
04.02	Processed fruit:				
	A. Dried or dehydrated fruit, whole or in the form of flour or powder				
	B. Fruit in the form of chunks, purée or paste	X(a)	X(a)		
	C. Fruit preserves (jams and similar products - whole fruit or chunks or in the form of flour or powder, preserved in a liquid medium):				
	I. In an aqueous medium	X(a)	X(a)		
	II. In an oily medium	X(a)	X(a)		X
	III. In an alcoholic medium (≥ 5% vol.)		X(*)	X	
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine				

		kernels and others):				
		A. Shelled, dried				
		B. Shelled and roasted				X/5(***)
		C. In paste or cream form	X			X/3(***)
04.04		Whole vegetables, fresh or chilled				
04.05		Processed vegetables:				
		A. Dried or dehydrated vegetables whole or in the form of flour or powder				
		B. Vegetables, cut, in the form of purées	X(a)	X(a)		
		C. Preserved vegetables:				
		I. In an aqueous medium	X(a)	X(a)		
		II. In an oily medium	X(a)	X(a)		X
		III. In an alcoholic medium (≥ 5% vol.)		X(*)	X	
05		**Fats and oils**				
05.01		Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)				X
05.02		Margarine, butter and other fats and oils made from water emulsions in oil				X/2
06		**Animal products and eggs**				
06.01		Fish:				
		A. Fresh, chilled, salted, smoked	X			X/3(***)
		B. In the form of paste	X			X/3(***)
06.02		Crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells	X			
06.03		Meat of all zoological species (including poultry and game):				
		A. Fresh, chilled, salted, smoked	X			X/4
		B. In the form of paste, creams	X			X/4
06.04		Processed meat products (ham, salami, bacon and other)	X			X/4
06.05		Preserved and part-preserved meat and fish:				
		A. In an aqueous medium	X(a)	X(a)		
		B. In an oily medium	X(a)	X(a)		X
06.06		Eggs not in shell:				
		A. Powdered or dried				
		B. Other	X			
06.07		Egg yolks:				
		A. Liquid	X			
		B. Powdered or frozen				
06.08		Dried white of egg				
	07	**Milk products**				
	07.01	Milk:				
		A. Whole				X(b)
		B. Partly dried				X(b)
		C. Skimmed or partly skimmed				X(b)
		D. Dried				
	07.02	Fermented milk such as yoghurt, buttermilk and similar products		X		X(b)
	07.03	Cream and sour cream		X(a)		X(b)
	07.04	Cheeses:				
		A. Whole, with not edible rind				
		B. All others	X(a)	X(a)		X/3*
	07.05	Rennet				
		A. In liquid or viscous form	X(a)	X(a)		
		B. Powdered or dried’				
08		**Miscellaneous products**				
08.01		Vinegar		X		
08.02		Fried or roasted foods:				
		A. Fried potatoes, fritters and the like				X/5
		B. Of animal origin				X/4
08.03		Preparations for soups, broths, in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes:				
		A. Powdered or dried:				
		I. With fatty substances on the surface				X/5
		II. Other				
		B. Liquid or paste:				
		I. With fatty substances on the surface	X(a)	X(a)		X/3
		II. Other	X(a)	X(a)		
08.04		Yeasts and raising agents:				

	A. In paste form	X(a)	X(a)		
	B. Dried				
08.05	Salt				
08.06	Sauces:				
	A. Without fatty substances on the surface	X(a)	X(a)		
	B. Mayonnaise, sauces derived from mayonnaise, salad creams and other oil in water emulsions	X(a)	X(a)		X/3
	C. Sauce containing oil and water forming two distinct layers	X(a)	X(a)		X
08.07	Mustard (except powdered mustard under heading 08.17)	X(a)	X(a)		X/3(***)
08.08	Sandwiches, toasted bread and the like containing any kind of foodstuff:				
	A. With fatty substances on the surface				X/5
	B. Other				
08.09	Ice-creams	X			
08.10	Dried foods:				
	A. With fatty substances on the surface				X/5
	B. Other				
08.11	Frozen or deep-frozen foods				
08.12	Concentrated extracts of an alcoholic strength equal to or exceeding 5% vol.		X(*)	X	
08.13	Cocoa:				
	A. Cocoa powder				X/5(***)
	B. Cocoa paste				X/3(***)
08.14	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered				
08.15	Liquid coffee extracts	X			
08.16	Aromatic herbs and other herbs: Camomile, mallow, mint, tea, lime blossom and others				
08.17	Spices and seasonings in the natural state: Cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and other				

(*) This test is to be used only where the pH is 4,5 or less.
(**) This test may be carried out in the case of liquids or beverages of an alcoholic strength exceeding 15% vol. with aqueous solutions of ethanol of a similar strength.
(***) If it can be demonstrated by means of an appropriate test that there is no `fatty contact' with the plastic, the test with simulant D may be dispensed with.

Annex 2. NRL Network

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Abstract
Comparability of results is the most important feature of the measurements for official controls purposes. Reliability of results is in turn strongly dependent on test conditions, on how well a method performs and how it is performed by the laboratory that does it.
The Community Reference Laboratory (CRL) and its National Reference Laboratories (NRLs) for Food Contact Materials (FCM) have recognised that technical specifications are not always detailed in standards or legislative documents, and consequently there are sometimes gaps and lack of harmonisation in how official controls are practically performed. Therefore several guidelines were been initiated. The scope is to develop a unified understanding of the practical implementation of existing or new legislation in the context of official controls for FCM. The expected impact is to constantly improve the ability for NRLs to give the same competent advice in this field to National Authorities, food Inspection and private compliance laboratories for the practical implementation of official controls for FCM.
This guide contains practical information to define the parameters of an overall or specific migration test according to the nature of the materials and objects in contact with food, with a focus on kitchenware. This focus was chosen because kitchenware is typically placed in contact with food in the home and thus the challenge is to define worst foreseeable conditions of use.
This guide is intended as a dynamic document and therefore will evolve and expand into further editions to cover more aspects. This is the first edition. These guidelines have been endorsed by the EU official Network of National Reference Laboratories and approved by the EU Commission competent service DG SANCO.

This work also highlights an important deliverable for the Network of NRLs. In particular, the members of the task force on test conditions that have dedicated time and effort to provide input into the development of these guidelines. They are gratefully acknowledged here for their contribution: N NRL-BE (Fabien Bolle, Tina n'Goy), NRL-DE (Oliver Kappenstein), NRL-DK (Jens Petersen), NRL-ES (Juana Bustos), NRL-FR1 (Patrick Sauvegrain), NRL-EL (Timokleia Togkalidou), NRL-IT (Maria Rosaria Milana), NRL-NL (Durk Schakel, Dita Kalsbeek-van Wijk), NRL-PL (Kazimiera Cwiek-Ludwicka), NRL-SI (Viviana Golja), NRL-UK (Emma Bradley).

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