Technical guidelines

Food contact materials technical guidance documents

Technical specifications of performing official controls practically and how to perform compliance testing are generally not detailed in legislative documents, and therefore there can be gaps in a harmonised approach. The food contact material group develops technical guidelines for the implementation of legislation related to food contact materials. This can be done in two ways. Technical guidelines can be developed on request of or in close cooperation with DG SANCO. This is mainly done by the formation of a task force consisting of experts in the field and covering all stakeholders.

The EURL-NRL network can also develop technical guidelines. The guidelines provide a unified understanding of the practical implementation. The impact has been the ability for NRLs to be able to give a harmonised competent advice in this field to their National Authority, Food Inspection and private compliance laboratories. The work is normally organised in the form of dedicated workshops and smaller task forces of volunteer experts within the NRLs. This has allowed generating several much needed guidelines within two years.

These guidelines are published as public documents (see below). These are not legally binding but represent a consensus for the official controls regarding food contact materials.

Testing conditions for kitchenware articles in contact with foodstuffs - Part 1: Plastics

The European Union Reference Laboratory for Food Contact Materials (EURL-FCM) and the National Reference Laboratories (NRLs) of the network have agreed on a set of test conditions for plastic food contact materials and kitchen small appliances to ensure the comparability of measurement results reported in the frame of the implementation of official controls for FCM.

The comprehensive tables included in this report replace for plastics the tables in the "JRC's Guidelines on Testing Conditions for Articles In Contact With Foodstuffs (With a Focus on Kitchenware) of 2009" (https://europa.eu/!RH66Bd). The testing conditions presented will allow the harmonised implementation of Regulation (EU) No 10/2011 when testing kitchen and tableware made of plastic or containing plastic parts that potentially come in contact with food.
A range of conditions in terms of contact temperature (cold, ambient and hot) and contact time (short or long term storage) are to be taken into account when selecting the article preparation for testing and the suitable migration test to be performed.

The first table provides examples of items clustered in different classes and subclasses of kitchen and tableware.

The second table presents the relevant testing conditions for each class, including food simulants, testing conditions (i) based on the foreseeable worst case use of the article (e.g. contact time and contact temperature) or (ii) according to the instructions on the label, together with the surface-to-volume (s/v) ratios to be applied when calculating the final migration result.

The selection of food simulants is based on the foods expected to be used for a particular item (class/subclass). Often the food simulants are for all foods (cf. A, B, D2). When the article is used only in contact with specific foods, the food simulant is to be selected from Annex III of the Regulation.

These harmonised tables drafted by the Task Force on Kitchenware have been thoroughly reviewed by the National Reference Laboratories and Official Control Laboratories dealing with food contact materials, in accordance with Article 94 (2)(a) of Regulation (EU) 2017/625. The authors wish to acknowledge their valuable contribution.

G. Beldi; N. Jakubowska; P. Robouch; E. Hoekstra; Testing conditions for kitchenware articles in contact with foodstuffs - Part 1: Plastics, JRC116750

**Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials**

This guidance document covers specific directions for sampling and analysis of mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in food and FCM in the frame of Recommendation (EU) 2017/84 for the monitoring of mineral oils.

It provides guidance on the minimum performance requirements of the analytical methods fit for MOSH/ MOAH monitoring. The guidance should be used by all stakeholders involved in the determination of mineral oil hydrocarbons in food and FCM, i.e. food inspectors, official control laboratories, laboratories in industry and laboratories of non-governmental organisations.

This guidance aims to support the generation of reliable data for the occurrence of both fractions - MOSH and MOAH - and to enable reporting by laboratories that are already familiar with the analytical approaches and have proven their analytical performance in relevant proficiency testing (PT) schemes.

For laboratories that are not familiar with MOSH/MOAH analysis, this guidance gives the minimum performance requirements and references to current analytical approaches described in the scientific literature. It does not provide standard operating procedures.
NOTE on reporting to EFSA:

1. The sentence "For the datasets generated in the past and fulfilling the requirements laid down in the chapters before, a symbol "0" could be entered when there are no data for some of the mandatory elements, in order to be able to proceed" on page 19 of this report should be neglected. For those mandatory elements nothing needs to be filled in.

2. For correspondence of SSD1 and SSD2 Data Element Codes see Standard Sample Description version 2.0 Appendix B.4 page 95: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3424

Guidance on characterisation of the composition of plastic multi-layers

This guidance describes how to characterize the composition of a multilayer plastic film for food packaging, with respect to the consecutive order of the layers and their identity. It provides necessary background information on the general composition of multilayer plastic packaging and it illustrates in detail the separation of layers for some examples. It also provides in annexes additional information related to the use of a microtome and of optical microscopy using one common instrument for illustrative purposes.


Task force on migration modelling

The European legislation requires verification of compliance for migration of substances from plastic food contact materials with existing specific and overall migration limits. To do so, there are migration tests to carry out using food/food simulants under the test conditions specified in Regulation (EU) No 10/2011. Numerous scientific investigations during the last two decades have demonstrated that migration from food contact materials into food and food simulants are predictable physical processes. In the absence of specific interactions of the migrant with food and in the absence of degradation of the polymer by the food simulant, migration is a mass transfer of substances from a plastic material into food and obeys in most cases to Fick's laws of diffusion. Hence, in addition to experimental methods, an alternative tool based on theoretical migration
estimations can be applicable.

The aim of this work item is to assist the users of the described model to predict conservative, upper bound migration values. This will be accomplished in three directions:

- Publication of the guide on the updated current validity of the fields of application for the overestimation of diffusion coefficients based on the validation of the model for a given number of polymers and migrants.
- Development and drafting of experimental procedures for the production of data towards the validation for migration models to include multilayers.
- Compilation and review of updated data (institutions, industry, CEN) towards the publication of an updated guide on application field of modelling for migration.


Guideline on testing migration of primary aromatic amines from polyamide utensils and for formaldehyde from melamine-based kitchenware in support of Regulation (EU) No 284/2011 on imports from China and Hong-Kong

For the conception of a specific Regulation on imports of certain plastic kitchenware from China and Hong-Kong targeting polyamide and melamine-based kitchen utensils, the role of the EURL-NRL network was to develop specific technical guidelines on sampling and analytical requirements. This work was a pioneering effort giving guidance on sampling of heterogeneous articles and differentiating between types of consignments. The harmonisation of sampling is extremely critical and has its effect on reliability of results and ultimately trust in the ensuing legal decisions for non-compliant articles both under the Regulation (EC) No 882/2004 on official feed and food controls and under this new Regulation.

Calculator for the correction of the experimental specific migration for comparison with the legislative limit

The EURL-NRL-FCM Taskforce on the Fourth Amendment of the Plastic Directive 2002/72/EC developed a calculator for the correction of the test results for comparison with the specific migration limit (SML). This calculator was updated for the Plastic Regulation (EU) No 10/2011. The calculator calculates the maximum acceptable specific migration under the given experimental conditions in food or food stimulant and indicates whether the test result is in compliance with the legislation. This calculator includes the Fat Reduction Factor, the simulant D2 Reduction Factor and the factor of the difference in surface-to-volume ratio between test and real food contact.


Guidelines on test conditions for kitchenware

Please note that this guideline is under revision from 2019. The tables in section 8.5 are updated and will be published separately on this page.

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. 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 at home and thus the definition of worst foreseeable conditions of use is a challenge. This guide is intended as a dynamic document and therefore will evolve and expand into further editions to cover more aspects.


Guidelines to evaluate method performance and conduct validation studies of analytical methods for FCM

Please note that this guideline is under revision from 2019.

The Community Reference Laboratory and National Reference Laboratories for food contact materials (FCM) prepared the present Guidelines to illustrate the required performance criteria for
the analytical methods applied in the laboratories for FCM and provide procedures for method validation in order to estimate their performance characteristics. The scope of these guidelines is to provide rules for the performance of the analytical methods to be used in the verification of compliance with the migration limits defined in Directive 2002/72/EC, as amended, and in accordance with Directive 82/711/EEC, as amended, and others defined in the European legislation, in order to ensure the quality and comparability of the analytical results.

The document presents 4 approaches, according to the different purpose of performance assessment.

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.


Links