



European  
Commission

# European Union Reference Laboratory for Food Contact Materials

## Work programme 2014



Version 3

## Executive summary

The work programme for 2014 was established during the June 2013 Plenary in consensus with the Network of NRLs and DG SANCO. The WP includes developments on testing for ceramics to provide the technical basis to revisions and expansion of the Directive on ceramics. It includes as ILCs 1) A first time proficiency testing of a method for the determination of metals for the restrictions introduced by Regulation EU 10/2011. 2) Validations for the new levels of lead and Cadmium from ceramics under the new repeat use conditions 3) a follow up PT on simulant E for dry foods, 4) a follow up on the PT of identification of polymeric materials of unknown nature, 5) recommendations post ILC for the measurement of surface. The EURL will initiate exploratory work on development of multianalyte methods for substances under Reg. 10/2011. It will conclude the work on availability of calibrants and methods to provide to Member State-SANCO a strong technical basis to discuss what should be done for substances for which there no enforceability. In addition, the WP will also include a training on the new technical guidelines for migration testing.

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## Core Activity 1 – Coordination of analytical methods by comparative testing

Mandate: To provide NRLs/OLs with details of analytical methods, including **reference methods** and coordinating their application by the NRLs/OLs, in particular by organising **comparative testing** and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols;

### Objective 1.1      Methods in support to a new regulation for ceramics and glass

The Regulation on ceramic materials and articles is currently under revision. Lower limits for lead and cadmium will be introduced and limits for other metals may also be introduced. In addition the umbrella for limits is likely to be extended to cover domestic glass. The current DG SANCO work programme with Member State highlights that a reduction of the existing limits implies the need to investigate changes in methodology, which has led the necessity of this work.

#### *D1      Validation of method towards new limits for selected metals from ceramics.*

The focus will be primarily lead and cadmium since those are the ones first affected for the revision of the Directive EC 85/400. Due to the much lower intended limits, the validation will be conducted on two 2 calibrations ranges (upper and lower). The validation will be opened to NRLs on a volunteer basis.

The deliverable will be the report to the National Reference Laboratories and DG SANCO on in-house precision criteria. Based on the results, a further full validation at EU level may be planned in collaboration with ISO TC166 to generate a new reference method.

#### *D2      Development of a migration test from flatware and holloware*

The focus will be firstly lead and cadmium since those are affected for the revision of the Directive EC 84/500. Due to the much lower intended limits, the new test must consider repeat use (i.e. 3 migration tests for enforcement/compliance) into migration simulant solutions. It will target migration from ceramics as well as crystal glass samples (as preliminary feasibility for a future expansion of the Directive to glass). This work is done in cooperation with the professional associations which have agreed to the responsibility of providing adequate test samples and materials for the development and validation phases. The work therefore heavily relies of the provision - timely and adequate - of test articles.

This test will be developed and will include some duplicate experiments with a limited number of laboratories to generate more data.

The deliverable will be the report to the National Reference Laboratories and DG SANCO. Based on the results, a validation at EU level may be planned in collaboration with ISO TC166 to generate a new reference method.

#### *D3      Development of a new migration test of rim*

Currently there is no specific provision stipulated in the EU legislation for rim. The intention is to include limits also for the rim, which implies the development of an internationally agreed test.

The focus will be firstly lead and cadmium since those are affected for the revision of the Directive EC 84/500. A review of worldwide approaches will be conducted, upon which methods will be compared and further developed.

This work is done in cooperation with the professional associations which have agreed to the responsibility of providing adequate test samples and materials for the development and validation phases. The work therefore heavily relies of the provision - timely and adequate - of test articles.

This new test will be developed This test will be developed and will include some duplicate experiments with a limited number of laboratories to generate more data.

The deliverable will be the report to the National Reference Laboratories and DG SANCO. Based on the results, a validation at EU level may be planned in collaboration with ISO TC166 to generate a new reference method.

## Objective 1.2 Interlaboratory comparisons (ILCs) and follow ups

### D4 ILC 2014\_001: metals from plastics according to regulation 10/2011

Regulation (EU) No 10/2011 establishes new limits for metals migrating from plastics. No methods are available from CEN or other sources as reference or internationally agreed.

The objective for the exercise 2014 will focus on the compilation of methods from NRLs, literature and other fields (e.g. Council of Europe) to provide as grounds for NRLs.

These methods will be made available for an ILC. A test material will be prepared with a number of substances in targeted amounts most relevant for compliance testing. The general aim of the exercise will be to test for the first time the proficiency of the official control laboratories and consequently the participants will be free to use any analytical method of their choice. The homogeneity and stability studies will be performed by the EURL-FCM laboratory. The stability test will be performed according to ISO Guide 35:2006 at the chosen levels and 3 temperatures. The assigned values will be obtained after applying the robust statistics to the results of the participants. Participants will be invited to report 4 results for each concentration level. Laboratory results will be processed using several algorithms: ISO 13528, Harmonised protocol, DIN 38402 A45 (Q-Hampel) and ISO GUIDE 35:2006. Standard deviations for proficiency assessment will be set based on Horwitz equation.

The work flow will be as follows:

Action	Task objective and description	Timeline	review
JRC	Technical consultation with NRLs to finalise technicalities of design	1 month	
JRC	Develop Standard/standard mixture or solutions, Experimental design for production of matrices Development of fortification protocols for the matrix and substances Scale up of the fortification protocol to batch size as standard test material Collection of variations expected in methods Verification of methods – compilation of internal method description In house check of expected repeatability Information / advice on implementation of test methods for NRLs	4 months	06/2014
JRC	Homogeneity testing of test material(s) Stability testing of test material – 3 temperatures (ISO Guide 35:2006) Material approval Development of response templates. Preparation of results reporting Launch of PT - Shipping of samples Reception of confirmation letters	3 months	09/2014
JRC	Collection of results Statistical interpretation	2 months	10/2014 11/2014
JRC	Technical report	1 months	12/2014

This exercise will assess the performance of laboratories and support a future validation for this new mandatory testing for metals regarding specific migration from plastics

### D5 ILC 2014\_002: follow up for the correct use of food simulant E

Regulation (EU) No 10/2011 established poly (2,6-diphenyl-p-phenylene oxide, PPPO) as a food simulant E for testing specific migration into dry foodstuffs. A validation of method took place in 2012 and as consequence a PT was organised in 2013. Since it is the first ILC of this type for NRLs a follow up is foreseen because of the difficulty of the exercise and the wide range of proficiencies. A follow up will therefore be organised in 2014. Underperformance will be addressed with a the

preparation of a test material similar to that of 2013 to allow underperforming laboratories to achieve an adequate proficiency to be able to in turn train their official controls. The new test material prepared will be in lesser quantities than a full size PT, but will still comply with the international standard for homogeneity and stability assessment (e.g ISO Guide 35:2006). Laboratory results will be processed using several algorithms: ISO 13528, Harmonised protocol, DIN 38402 A45 (Q-Hampel) and ISO GUIDE 35:2006. Standard deviations for proficiency assessment will be set based on the Horwitz equation.

The deliverable will be a report and recommendations for improved performance in using simulant E for compliance with specific migration from dry foodstuffs.

#### *D6 Follow up PT for on identification of polymers*

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A PT was organised in 2013 which for the first time aimed at estimating performance of qualitative analysis. The aim of the exercise was to test the laboratories' ability to identify unknown plastics materials via quick screening tools. Considering there are no reference methods and the novelty to tackle assessments of qualitative nature, the results have demonstrated a spread and some level of difficulty for laboratories to identifying particular multilayer materials. A follow up will be organised on 2-3 multilayers, in order to insure laboratory performance.

In addition, the EURL will make a compilation of methods as well as recommendations for qualitative methods and reporting of results for these essential screening tools.

#### *D7 Follow up PT for surface area*

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The work programme 2013 performed a first-time ILC on the determination of the contact area of kitchen utensils. Considering that the reliability of results may directly depend on the correct measurement of the surface area, this aspect needed improvement by a targeted exercise. The exercise was completed and allowed to develop methods and evaluate the uncertainty of this measurement. The follow up will consist of an evaluation of the final impact of this uncertainty on the overall evaluation of compliance vs. non-compliance and recommendations to improve the uncertainty currently associated with the expression of results of compliance from specific migration testing.

## **Core Activity 2 – Production of analytical methods**

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Mandate: To coordinate, within their area of competence, practical arrangements needed to apply **new analytical methods** and to inform NRLs of advances in this field.

### **Objective 2.1 Provision of analytical methods and state of the art to NRLs**

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Regulation (EC) No 1935/2004 supports the food safety for food contact materials. For plastics Regulation 10/2011 represents > 900 chemicals. Yet, only 28 substances have a CEN method, and candidate methods from petitioners can only be found for less than 20% of substances.

This project aims to develop a cost effective approach for testing compliance for Reg. 10/2011. The project develops sources for calibrants, develop a database of analytical methods for FCM substances authorised under Re. 10/2011 and develop a web site freely searchable, providing a one stop portal for checking compliance of FCM. The work is a continuation of activities over the past years. The work on availability of calibrants stems from a collection of substances that had been acquired over the years (yearly item) but have now to be renewed to reflect the current market. The work on methods stems from a collection of methods collected over the years (yearly item) from old dossiers of the ex- scientific committee for food as well as from EFSA and that must now be reviewed critically, consolidated, updated to latest availability and have remaining gaps evaluated.

In 2014, the EURL will conclude the work on availability of calibrants and methods as described below with the aim to provide to Member State-SANCO a strong technical basis to discuss what should be done for substances for which there is no of method or calibrant available, and consequently no enforceability.

#### *D8 New database of complete descriptions of methods of analysis*

The objective is to create a database of analytical methods from petitions for substances regulated under Reg. 10/2011 for which JRC can obtain from the relevant petitioner's dossiers (e.g. as per Note for guidance from EFSA). These will be the complete method descriptions. All the method descriptions from SCF, SANCO archives have been previously obtained. Those only available as printout have been scanned and text-recognised. The SANCO list will be compared to the methods available and the missing ones will be sought from EFSA petitions. A collaboration with EFSA will be established to be able to obtain missing methods, and a collaboration with CEFIC will also be organised for the same purpose of filling the gaps.

A new repository of methods will be created. The deliverable will be a report of petitioners and other sources of analytical method descriptions for FCM according to the latest amendment of Regulation 10/2011 and SANCO FCM database. The report will in particular contain as conclusion the substances currently on the positive list for which no information on methods is available at all. This can provide the basis for further discussion and action at level of the working party with member states and stakeholders on whether the enforceability of those substances is feasible or not.

#### *D9 New repository and databank of reference calibrants of regulated substances*

The objective is to provide sources of substances regulated in the EU for FCM for ad-hoc provision to official controls upon request.

Work has been initiated to establish sources of analytical standards required as calibrants for the enforcement of Regulation (EU) No 10/2011. Several were not commercially available. In addition some substances are currently not at all into the database of substances that had been in the legacy of the JRC from submission of petitioners since 1996 but tis now too old to comply with quality requirements for substances.

A new repository of current substances will be created in collaboration with the industrial association of chemicals related to food contact materials (e.g. CEFIC). A new bank will be created for monomers, additives and starting substances. The deliverable will be a report of commercial and /or analytical sources of substances for FCM according to the latest amendment of Regulation 10/2011 and SANCO FCM database, but also a physical repository for substances from EU producers. The report will in particular contain as conclusion the substances currently on the positive list for which no information is available at all. This can provide a second basis for further discussion and action at level of the working party with member states and stakeholders on potential grounds for leaving or eliminating the substances if no substance and no methods are available.

#### *D10 Web portal for methods and sources of calibrants*

The current listing of database of information on suppliers of calibrants and for methods will be transferred into a web accessible portal. It will link systematically the database of substance characteristics and availability to the database of methods, to provide a one-stop portal. This portal will become on-line and searchable.

#### *D11 Provision of calibrants to NRLs where needed*

Prepare and send upon requests standard calibrants not available commercially to NRLs (if present in the reference collections) and other stakeholders for use for research or enforcement purposes under approved programmes.

## **Objective 2.2 Development work for multi-analyte methods**

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There are more than 900 regulated substances under regulation (EU) 10/2011, whereas only 28 methods have had a restricted validation under CEN. There are notably no official methods, no Codex methods, and very little validated methods with full data traceability. There is therefore a need to develop strategies towards non-targeted sample preparation and multianalyte analytical methods. This project aims to develop a cost effective approach for testing compliance for Reg. 10/2011.

### *D12 Compilation of analytical methods according to key parameters*

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All the methods held in the databank of the EURL FCM will be grouped by analytical analogy to develop a scale that will allow in the following year to develop clustering of methods/substances for multianalyte analysis. The establishment of key parameters will be established and for each substance/method the corresponding classifiers (e.g solubility, polarity, other physicochemical characteristics, extraction, analytical preparation and instrumental determination) will be sought. This will allow foreseeing a more systematic potential grouping.

## **Core Activity 3 – Training and support to NRLs**

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To conduct initial and further **training courses/staff exchanges** for the benefit of staff from **NRLs** and of experts from third countries;

### *D13 Report of an NRL expert workshop on ceramics*

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Discuss and brief NRLs and Stakeholders on the technical implication of the revision of the legislation on ceramics. A 2-day workshop where the current state of the art will be presented.

### *D14 Report of an NRL training on food contact compliance*

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European legislation on food contact materials is long standing and has become extensive for plastics. In 2013 several (technical) guidelines in the framework of the implementation of Regulation (EU) No 10/2011 for plastic food contact materials are being finalised. In particular the JRC has been entrusted to develop the technical guidelines supporting migration testing under Regulation (EU) No 10/2011. This work will be completed early 2014 and therefore the workshop should provide priority training for NRLs in these developments to enable them to provide the most state of the art advice to their competent authorities and stakeholders.

### *D15 Report of the Plenary Workshop for NRLs for the preparation of the WP2015*

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The workshop serves to strengthen the structure of the network and to identify the needs of the NRLs. Specific topics concerning the specific analysis of FCMs will be addressed during the workshops as well. The agenda will include the preparation of the work programme 2015, as well as discussion of results of the ILC follow-ups and current ILCs. The workshop will include a session of general exchange of information and information from the Commission.

## **Core Activity 4- Provision of expertise to Commission, member states, NRLs**

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- Providing support to DG SANCO in technical matters concerning analytical methodologies for food contact materials, if requested.



- Participation to DG SANCO WG meetings
- Participation to EFSA meetings and or working groups where indicated
- Research activities in support to commission
- Providing information and advice on the use and training opportunities of the FACET RTD tool for the exposure assessment of contaminants from food contact materials.

The activity encompasses work to evaluate reported problem areas. It provides support by means of information and technical advice to National Reference Laboratories. The work will also include maintaining close awareness of developments in methodologies, report and give advice, as relevant, at the Annual Plenaries, Workshops and on an ad-hoc basis. In addition the EURL-FCM will also liaise with National Reference Laboratories via e-mail and via the Circabc platform to ensure rapid flow of information, training of laboratory personnel on request of the NRLs. Priority will be given to underperforming NRLs.

*D16 reports from activities and presentations*

### **Core Activity 5- Reciprocal exchange of information with professional bodies and stakeholders (CEN/ISO, websites, conferences etc)**

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Providing support to standardisation bodies such as CEN for the standardisation of analytical methods for the determination of migrants from food contact materials. This can require a regular participation in the meetings of CEN TC 172/WG3 and CEN TC194/SC1 WGs and ISO TC 166 where applicable.

The web portal [http://ihcp.jrc.ec.europa.eu/our\\_labs/eurl\\_food\\_c\\_m](http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m) will be maintained and updated. The platform supports the public dissemination of the work on food contact and serves as a reference, contact and service point for laboratories involved in the analysis of food contact materials in Europe and worldwide. The website holds information about the activities and events carried out by the EURL as well as published reports available and scientific papers.

The dedicated website on Circabc specifically for NRLs is designed to support dissemination of information and network activities <https://circabc.europa.eu/> under Joint Research Centre, JRC EURL-FCM. The platform represents a main source of information exchange between the EURLs and the NRLs as well as is used for repository of working documents and traceability purposes. It also holds forms, sheets and other documents thus facilitating the management of tasks. It will be continuously updated. It will also update for lists of NRLs contacts.

The activities will also promote invited participation/presentation of EURL activities in international conferences in the area.

*D17 reports from activities and presentations*

### **Core Activity 6: General tasks**

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#### **Operational procedures**

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*D18 Annual Report 2013*



Annual report for DG SANCO and National Reference laboratories of the deliverables of the EURL-FCM for 2013 - financial report and technical report.

#### *D19 Submission of the WP 2015 of the EURL-FCM*

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Submit to the Commission a workprogramme and associated budget on the operation of the laboratory no later than 1<sup>st</sup> September 2014 for the work programme 2015.

#### **Quality assurance and control**

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The Quality System (QS) implemented since 2003 will continue overseeing, controlling and reporting upon the activities, ensuring they are executed timely and to the expected standards of excellence. It will also make sure that the budget is properly allocated.

The QS will supervise all meeting minutes and will keep a summary of all documents ready for external audits.

Continuous evaluation/improvement of the quality of the service deliveries will be a must and corrective actions will be taken. Evaluation sheets as feedback from NRLs and Official Laboratories will be presented to the European Commission when requested, as well as questionnaires and other relevant documents for traceability purposes .

**NOTE: It is understood that the above mentioned items are not exclusive of other work of more immediate priority which may arise during the reference period in question and after the agreement of DG SANCO.**