



European Union Reference Laboratory for Food Contact Materials

Work programme **2015**



Version 2 –20 October 2014

Executive summary

The work programme for 2015 was established on the basis of the priorities established together with DG SANCO in conformity with the objectives and priorities laid down in the Commission Implementing decision (SANCO/10932/2014 Rev1 Annex) on the work programme for 2015 and the financial contribution to the European Union reference laboratories. The work programme aims to contribute to a high level of health, ensuring a high level of protection for consumers and the environment, while favouring competitiveness and creation of jobs. It responds to the specific objectives to contribute to a high level of safety of food/feed and food/feed production and a higher animal health status and to improve effectiveness, efficiency and reliability of official controls. It follows the new layout for the specific operational objectives as laid down in the Annex of the Commission Implementation Decision. Deliverables are aimed to the different areas of the operational objectives as follows: 1) To ensure the development and use of high quality analytical methods across the EU-RL framework 2) To maintain appropriate level of proficiency testing ensuring efficiency of control analysis methods and 3) To ensure the availability of scientific and technical assistance provided by the EU-RLs.

It includes ILCs on the determination of multianalytes for the determination of specific migration from food contact materials, follow up on ILCS to form guidelines for the experimental determination of the nature of polymeric materials for plastics. It will continue exploratory work on development of multianalyte methods for substances under Reg. 10/2011.

In addition, the WP will also include a dedicated workshop on ceramics and one on migration testing with a focus on kitchenware towards the update of the 2009 guidelines in line to Reg. 10/2011.

In addition it aims to respond to specific objectives established for food contact materials as follows:

- development and validation of new and improved methods for testing metals migration from ceramic materials in the context of the revision of Council Directive 84/500/EEC ;
- preparation for accelerated collection of new methods for which method descriptions will be required under Commission Regulation (EU) No 10/2011 including the development of an online database for dissemination purposes;

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OPERATIONAL OBJECTIVE 1 –Development and use of high quality analytical methods

The mandate of the Commission Implementation Decision includes the following aspects:

- *Ensuring dissemination of analytical and reference methods from EU-RLs to NRLs;*
- *Monitoring of publication by EU-RLs of new developed methods and corresponding validation studies;*
- *Coordination of EU-RL activities on practical arrangements for the application of new analytical methods;*
- *EU-RLs, NRLs and Member States coordination for the preparation of the 2016 work programmes regarding new or improved methods, and/or dissemination information means on methods and reference materials;*
- *planning of trainings, meetings and workshops organised by the EU-RLs for the harmonization of diagnostic techniques and of methods of analysis;*
- *Initiation of EU-RLs collaboration with laboratories in third countries.*

The deliverables are:

Repository of references substances for FCM

This work focuses on the expansion (continuous) of commercial and /or analytical sources of substances for FCM according to the latest amendments of Regulation 10/2011 and the submission of dossiers by petitioners to EFSA. The work also include to prepare and send upon request 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. A short report listing the requests will be compiled.

Guidance document on test methods for the identification of polymers

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. The results demonstrated a spread and some level of difficulty for laboratories to identifying particular multilayer materials. A follow up was organised in 2014 specifically for multilayers, in order to ensure improved laboratory performance. Considering there are no reference methods and the novelty to tackle assessments of qualitative nature, EU-RL will make a compilation of methods as well as recommendations for qualitative methods and reporting of results for these essential screening tools. The deliverable will be the **development of a technical guide for testing approaches** for the identification of polymers used for FCM including multilayers.

Cost effectiveness for optimum performance of testing with 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 a first time PT was organised in 2013, with a follow-up in 2014.

Tenax is a very costly consumable averaging 200 € for 10g, and one test usually consumes at least 10g per sample. Thus being able to recycle this simulant would greatly increase the cost effectiveness of testing and of benefit to all member states. However, this cost effectiveness cannot come at the detriment of a reduced performance of the test. Therefore one aspect that has not been investigated at all nor in academic studies nor at commercial level is whether the regeneration of the Tenax is feasible, and in which case how many cleaning cycles the Tenax can withstand before the migration results are no longer comparable. It has also been noted by the EU-RL and several NRLs those even different batches of the same specification do have different appearances. Specifications on pore size etc. are included in the Regulation for historical reasons but it is unknown whether these qualities change with use and make the technical specifications not amenable to be respected in practice.

It is proposed to check how the performance of tenax might vary after as function of the recycling processes. The EU-RL-FCM will investigate and develop an experimental design in order for laboratories to be able to check the consistency of quality and performance of the new simulant E.

A test material consisting of a film spied with chemicals will be developed. The deliverable will be a **report and recommendations for improved performance in using simulant E** for compliance with specific migration from dry foodstuffs.

Coordination of EU-RL activities for the application of new analytical methods;

A new initiative to coordinate and increase the effectiveness of NRLs is to set up communities of competences for NRLs. This would palliate to the current unrealistic financial obligations to have every NRL to be an expert in everything, a clearly impossible task for such a wide ranging field of materials and expertise. As first step, a compilation will be done in 2015 of methods 1) in development, 2) validated and 3) accredited 4) in use/object of monitoring by the NRLs of the network.

EU-RL-NRL-FCM Network report

Analysis of the annual deliverables of the EU-RL-FCM for 2015 which will be included into the report for the National Reference Laboratories

Initiation of EU-RLs collaboration with laboratories in third countries.

Contacts with third parties laboratories and official controls will be sought further and increased with a focus on Asian countries. Exchanges with the Thai Department of Science Service will take place, and exchanges will be maintained with Chinese counterparts as follow up of the dedicated visit that took place in 2014. Other ad-hoc initiatives will be planned for the following years according to their relative priorities including in the context of Expo 2015.

OPERATIONAL OBJECTIVE 2: Appropriate proficiency testing ensuring efficiency of control methods

The mandate of the Commission Implementation Decision the following aspects:

- *ensuring planning and initiation of comparative testing by EU-RLs in accordance with internationally accepted protocols;*
- *address underperforming related issues within the EU-RL network;*
- *coordination of EU-RLs, NRLs and the Member States for the planning of performance testing in the work programmes.*

The deliverables are:

ILC 2015_001: Follow up to the PT of metals from plastics in regulation 10/2011

Regulation (EU) No 10/2011 establishes new limits for metals migrating from plastics. A first PT was organised in 2014. It was testing for the first time the proficiency of official control laboratories and participants were free to use any analytical method of their choice.

Based on the results of the PTs in 2015, a **guidance and protocol for multianalyte methods for inorganics** will be produced. Since no methods are available from CEN or other sources as reference or internationally agreed, this will be the first new protocol that will be developed on the basis of its performance in an ILC. The protocol will support a future validation for this new mandatory testing for metals regarding specific migration form plastics

ILC 2015_002: Optimisation of temperature control in migration testing protocols

The EU-RL as well as several NRLs have investigated the importance of the control of temperature on migration testing results. These studies indicated a relevant impact on migration results affecting several

types of articles (in particular kitchenware). The difference in numerous samples was not due to inhomogeneity of the materials but rather due to differences in the exposure phase, where it was not feasible to maintain a constant correct temperature over the whole length of the test. Following these alarming findings that directly affect the decision making on compliance vs. non-compliance, a **more stringent protocol needs to be developed, compared, validate and implemented**. A strategy has therefore been developed for the next two years. In a **first phase in 2015, a pilot exercise will therefore be carried out for the NRLs and associated OCLs** to carry out a migration test as they would do now and to monitor the temperature of the simulant throughout the exposure. Based on the results and root cause analysis, an improved protocol will be developed by the EU-RL in 2016 and validated by the NRLs which should greatly improve the migration testing carried out at temperatures at or above 40 degrees, which constitute 90% of the test performed. As a result of the validation, a more detailed guidance can be then developed.

ILC 2015_003: Follow up actions of NRLs underperformance

The work items will include the follow up actions of NRLs underperformance in Interlaboratory comparisons (ILCs). Report of actions on the follow up of under-performance from the 2014 proficiency tests and interlaboratory comparisons will be completed. The report will include protocols for improvement of harmonisation of analytical approaches at EU level.

ILC 2015_004: Cluster ILC to improve cost effectiveness

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 work item will consist of a dedicated ILC on the **general to specific capabilities of laboratories to conduct selective standard testing**. A clustering of competences will be defined in a workshop October 2013, and the **resulting clusters will be tested** in a cascading fashion over the **next ILC 2015-2016 into cycles of exercises**. These will likely include identification techniques (e.g. mass spectrometry etc), screening techniques (fingerprinting, extraction), calibrations, uncertainty measurements etc. The concept is further explained in the multiannual rolling plan. The first cluster will be the subject of the ILC 2015, and may focus on screening.

OPERATIONAL OBJECTIVE 3: Availability of scientific and technical assistance

This objective contains the following activities.

- *queries to EU-RLs for policy making and enforcement;*
- *initiation of EU-RLs collaboration with EFSA and international organisations;*
- *organisation of meetings for scientific and technical assistance from the EU-RLs;*
- *guidance initiation regarding analytical methods;*
- *networking activities for appropriate assistance by the EU-RLs.*

NRL expert workshop on ceramics

The workshop will have for purpose to discuss and brief NRLs and Stakeholders on the technical implication of the revision of the legislation on ceramics. It will provide a complete overview of progress and new or updated methods.

NRL expert forum on compliance for kitchenware

European legislation on food contact materials is long standing and has become extensive for plastics. In 2014 several (technical) guidelines in the framework of the implementation of Regulation (EU) No 10/2011 for plastic food contact materials are being published or 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 2015 and therefore a workshop needs to be organised to take stock of the **gaps that are still present for kitchenware** which are made of a multitude of materials and often not regulated at EU level. The event will **provide a most state of the art consensus advice to convey to competent authorities and stakeholders**. This will anticipate safety by design for articles not only manufactured in the EU but provide a critical guidance for imported articles.

Plenary Workshop for NRLs

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 also include 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.

Provision of expertise to Commission, member states, NRLs and EFSA

The activity encompasses support by means of information and technical advice to National Reference Laboratories, Commission services and EFSA. The work will also include maintaining close awareness of developments in methodologies, report and give advice, as relevant in Workshops and/or on an ad-hoc basis. In addition the EU-RL-FCM will also liaise via e-mail and via the Circabc platform to ensure rapid flow of information. Examples of activities include: providing support to DG SANCO in technical matters concerning analytical methodologies for food contact materials, if requested, participation to DG SANCO WG and/or EFSA meetings or working groups where indicated. It also includes research activities in support to commission and 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.

Networking activities and presentations

The deliverable will be a report of the activities performed regarding support to the various parties.

Reciprocal exchange of information with professional bodies and stakeholders

This activity is dedicated to provide support to standardisation bodies such as CEN and ISO for the standardisation of analytical methods for the determination of migrants from food contact materials. The JRC web portal 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 EU-RL 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 repository of documents under the JRC EU-RL FCM (<https://circabc.europa.eu/>). It will be continuously updated together with the list of NRLs contacts. The activities will also promote invited participation/presentation of EU-RL activities in international conferences in the area.

2015 SPECIFIC FCM PRIORITY 1: Pre-normative support to development of a regulation for ceramics

The Regulation on ceramic materials and articles is currently under revision. Under this revision a significant reduction of the limits for lead and cadmium is foreseen. 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. The regulation of other metals through introduction of migration limits may need to be considered as well. In addition, glass materials and articles may be brought into the scope of the regulation. The work programme will include a number of large deliverables related to the development and validation of new and improved

methods for testing metals migration from ceramic materials in the context of the revision of Council Directive 84/500/EEC, as follows:

Migration method from ceramics towards new limits for selected metals

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, a validation/PT will be conducted and opened to NRLs on a volunteer basis. The deliverable will provide 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(s) in support to the anticipation of a new Ceramics Directive.

Method for testing migration 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.

This work is done in cooperation with the professional associations for test samples and materials for the development and validation phases. The work therefore heavily relies of the provision - timely and adequate - of test articles. A test will be tested on a number of laboratories to generate precision data. The deliverable will be the report to the National Reference Laboratories and DG SANCO. 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 in support to the anticipation of a new Ceramics Directive

Method for testing migration from glassware

Currently there is no specific provision stipulated in the EU legislation for domestic glassware. The intention is to develop a legislative umbrella for domestic glassware, which implies development of an internationally agreed test. A method will be developed crystal ware and glassware for tableware, which is be related to testing on food itself (drinks) in order to develop fit for purpose conventional tests that can be both worst case scenario, but in line with exposure and with a pragmatic protocol from a laboratory standpoint. 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.

Protocol for migration testing from bakeware

Development for testing conditions to use for cooking/baking, towards establishing enforceability of new limits (e.g. Pb, Cd) for ceramics to extend the scope to include testing conditions for migration from cookware/bakeware. This work is done in cooperation with professional associations for 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.

2015 SPECIFIC FCM PRIORITY 2: Improved enforceability of Reg. (EU)10/2011

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 aim is to develop 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 year. 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 2015, the EU-RL work will consist in the preparation for accelerated collection of new methods for which method descriptions will be required under Commission Regulation (EU) No 10/2011 including the development of an online database for dissemination purposes; it will also conclude the work on the current availability of calibrants 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.

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 were retrieved in 2014. Those only available as printout have been scanned and text-recognised, EFSA petitions were accessed, reviewed and the methods being retrieved in 2014-2015. Collaboration with EFSA will be established to be able to obtain missing methods, and 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 analytical method descriptions for FCM according to the latest amendment of Regulation 10/2011 and SANCO FCM database. The report will in particular contain conclusions on 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.

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 the collection of substances that had been in the legacy of the JRC from submission of petitioners since 1996 no longer complies 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 commercial sources or EU producers. The report will in particular contain conclusions on substances currently on the positive list for which no information is available at all. This will provide a basis for further discussion and action at level of the working party with member states and stakeholders.

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.

OPERATIONAL OBJECTIVE 4: Sound and efficient management of EU-RL operations

Annual Report 2014

The Annual report for DG SANCO and National Reference laboratories of the deliverables of the EU-RL-FCM will be produced for 2014- financial report and technical report.

Submission of the WP 2016 of the EU-RL-FCM

The work programme and associated budget will be submitted to the Commission no later than 1st September 2015 for the operation of the laboratory and the work programme 2016.

Quality assurance and control

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.

Annex 1

Table 1: PT and validation design

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	06/2015
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	09/2015
JRC	Collection of results Statistical interpretation	2 months	10/2015 11/2015
JRC	Technical report	1 months	12/2015