European Commission

European Union Reference Laboratory for Food Contact Materials

Work programme **2016-2017**

EURL
European Union Reference Laboratory
for Food Contact Materials

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Executive summary

The Institute for Health and Consumer Protection of the Joint Research Centre operates the European Union Reference Laboratory for Food Contact Materials (EURL-FCM). It provides methods, inter-laboratory comparisons and proficiency tests in order to monitor the quality and comparability in the official control and enforcement of the official controls legislation regarding FCM and in support of Regulation No EC 882/2004. The EURL-FCM also coordinates a network of National Reference Laboratories (NRLs) and acts as coordinator for dissemination of information, technology transfer, trainings and networking. It also develops methods in agreement with DG SANTE in priority areas for intended legislative developments in order to ensure ex-ante the potential enforceability of future legislative options (in 2015-2017, ceramics).

The work programme 2016-2017 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. The work programme was established on the basis of the priorities established to together with DG SANTE in accordance with the objectives and priorities laid down in the Commission Implementing decision (C(2015)4993 final).

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 EURL 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 EURLs.
It includes ILCs on the determination of specific migration from food contact materials by verification and/or by screening.
In addition, the WP will also include dedicated workshops including on migration testing guidance with a focus on kitchenware towards the update of the 2009 guidelines in line to Reg. 10/2011.

Finally 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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Background information

The European Commission's Joint Research Centre (JRC) is the European Union Reference Laboratory for Food Contact Materials (EURL-FCM). The unit in which it is located has currently 40-50 staff members of which around 10 are executing tasks primarily linked to the EURL.

As the Commission's in-house science service, the Joint Research Centre's mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle. Working in close cooperation with policy Directorates- General, the JRC addresses key societal challenges while stimulating innovation through developing new methods, tools and standards, and sharing its know-how with the Member States, the scientific community and international partners.

In accordance with its mission statement, different units of the JRC provide scientific and technical support to the policy development and implementation of the EU's regulatory framework for Food Contact Materials. As a part of its overall work, it hosts since 2004 the EURL-FCM and contributes to the implementation of this framework through the execution of the Regulation (EC) No 882/2004[1] on Feed and Food Controls. The EURL is supported by the European Network of National Reference Laboratories on FCM of the EU, Switzerland, and Norway.

In line with its mission, the JRC covers activities in support to Commission from its own budget, many of which benefit the EURL, but specific dedicated activities of the EURL need additional financial support from the Commission, similar to other EURLs for food and feed under Regulation (EU) No 652/2014[2].

This work programme 2016-2017 gives a complete overview of the activities while the requested budget only concerns activities relating to tasks specified in the Commission Implementing Decision of 24 July 2015 on the adoption of the work programmes of the Commission for the years 2015 and 2016 and on the financing of the Union contribution to the European Union reference laboratories (C(2015)4993 final).

Challenges specific to food contact materials

Assuring the highest standards of food safety is a key priority for the Commission and for Member States. The harmonisation and implementation of food legislation is a major task which requires scientific and technical consensus amongst Member States (such as on validated reference methods and materials for quality and safety controls). Safe and high-quality food supplies rely on efficient protection from deterioration. Food processing equipment, packaging, distribution and storage materials as well as kitchenware have an important role to accomplish in this matter.

Food contact materials are subjected to specific legislations. The globalisation of a highly complex chain of business operators coupled with a technologically driven field highlights an increasing need for mutual recognition and comparability between laboratories to facilitate a single market and for

[1] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. OJ L 165, 30.4.2004, p. 1-141, as corrected by OJ L 191, 28.5.2004, p. 1-52.

[2] Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC, OJ L 189, 27.06.2014, p. 1-32

fostering free trade[3]. Substances used in manufacturing are regulated with maximum limits that may migrate into foodstuffs without causing any health concerns. These materials need to be tested for compliance with migration limits. Testing compliance in anticipation, conception and implementation of policies for consumer protection and towards smoother trade also requires the development of performant methods and cover both regulated substances but also those that may occur via inadvertent reaction of materials during processing or during their contact with foodstuffs.

Regulation (EC) No 1935/2004 supports the food safety for food contact materials. For plastics Regulation (EU) 10/2011 represents > 900 chemicals. Yet, only 28 substances have a CEN method, and there are notably no official methods, no Codex methods, and very little validated methods with full data traceability. As substances have been petitioned since the 1970's the pool of methods from petitioners can only be found for less than 30% of substances. This highlights the critical need to play a more cost effective role in the standardisation process. Since validation of methods is a costly endeavour, the standardisation work needs to find more cost effective approaches. In addition, despite efforts from National and EU authorities, current harmonised European legislation covers only a fraction of all food contact materials on the market[4]. There is therefore a need to collect and offer to NRLs methodologies for substances from as many source materials as possible, which is an extremely complex task as the number of materials is ever increasing in step with technological innovations. The impact of the work aim to provide to Member State-DG SANTE 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. This ground work also serves a greater purpose to pave the way for expansion to cover materials not yet harmonised at the EU level for which Member States may maintain or adopt their own national provisions on food contact materials. These Legislations may set out individual rules on different materials and substances, but those may differ from one Member State to another. According to some stakeholders, such differences introduce inconsistencies in the approach to regulating food contact materials and can hinder the free movement of those materials and articles within the internal market.

This is expressed in the FCM work programme as follows and using a separation as recommended between EURL activities under the EURL AA and those under the institutional heading but requested by DG SANTE. The work also aims to report also to the European Food Safety Authority (EFSA) which has the role of evaluating the suitability of methods under the Framework Regulation 1935/2004.

Priorities and rolling plan for the work programme 2016-2018

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 EURL 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 EURLs.
In addition it aims to respond to 2 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;

[3] http://www.foodpackagingforum.org/news/ngo-pushes-for-regulation-of-fcms-in-the-eu ;
[4] https://chemicalwatch.com/24315/eus-jrc-assesses-need-for-non-plastic-fcm-legislation

1. Ensure the development and use of high quality analytical methods

1.1 – Enforceability of EU harmonised legislation.

In this context the work programme aims to develop a cost effective approach for testing compliance for Regulation (EU) No 10/2011. The emphasis is placed on providing methodologies for the NRLs, including single substance and multianalyte methods. The actions are to research, collect classify assess harmonise analytical methods. The JRC itself is already a key technical bridge with already established links with EFSA in the collection of calibrants and of methods from EFSA[5] since any substance petitioned to EFSA must be sent to the JRC for safe keeping and representation of the market of authorised monomers and additives for FCM since 1996.

A first set of deliverables aims to 1) develop **sources for substances authorised** under Regulation (EU) No 10/2011 currently sold in the EU as raw materials (towards the expansion of the JRC repository of monomers and additives regulated for plastics FCMs), 2) develop a JRC **repository of analytical methods** for FCM substances authorised under Regulation (EU) No 10/2011 and 3) develop a **web site freely searchable**. This set of deliverables, goes much beyond Regulation (EU) No 882/2004, and serves the Framework Regulation (EC) No 1935/2004 in which articles 19 stipulates that once a substance is authorised, the corresponding methods of analysis should be made available publically[6]. This role in the portfolio of the JRC is an institutional added value to the function of EURL FCM.

A second set of deliverables targets the creation of 1) a **collection of information of physicochemical parameters** for the substances regulated such as Log Po/w[7], functional groups etc. 2) Methods of analysis (identification quantification from simulant or polymer with **compilation of descriptions and techniques** (Headspace, GC/GC-MS[8], HPLC, LC-MS[9], etc) 3) a **platform of mass spectra** - the pilot phase will target a construction of a JRC GC mass spectrometric library.

This will lead to the third set of deliverables with the development of a **mapping of characteristics** will allow to define which and when substances can be clustered as having similar extraction and method of analysis (e.g. search by method type/fields). This compilation will be the basis of a **strategy report for the development of multi-analyte methods** of chemical analyses for a more cost efficient method validation, laboratory proficiency testing and enforcement control. Another hurdle in standardisation is that there are no specific guidance other than that of JRC[10] specific to food contact materials on method validation published in 2009 for which an update and expansion is expected. In this context, the final set of deliverables (2018-2020) will focus on simplified schemes for method validation specific to food contact materials will be developed to **provide defined quality criteria and measurement uncertainty** for the practical implementation of official controls and compliance testing.

Expected ex-ante:
The main instrument for this is the **method repository** held within the JRC and currently free of use for the EURL function. In 2015 a review was made of the extent of regulated substances were covered by methods of analysis. SCF archives and EFSA petitions were accessed, reviewed and the methods retrieved. This accessibility was only 33% of the substances regulated.
The second instrument available is the **repository of substances** held by the JRC since 1996. EFSA has JRC as repository for substances submitted for evaluation or a re-evaluation. However, there is an absence of mechanism to guarantee that substances sold as regulated on the EU market can be available for purchase for enforcement and compliance checks. Currently 50% of substances on the positive list still have NO information on commercial or analytical supply.

[5] Food contact materials, "Note for guidance for petitioners presenting an application for the safety Assessment of a substance to be used in food contact materials prior to its Authorisation", p. model cover letter No 1 to petitioners for request to evaluation of a new substance, model letter No 2 for request for the re-evaluation of a substance, Annex 2 to Chapter I and Annex 3 to Chapter I: models letters, Annex 4 to Chapter I legend to model letters.

[6] "Applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of Regulation (EC) No 178/2002".

[7] Log Po/w: octanol/water partition coefficient

[8] GC/GC-MS: gas chromatography, gas chromatography mass spectrometry;

[9] HPLC, LC-MS: High performance liquid chromatography, liquid chromatography mass spectrometry

[10] Bratinova, S., Raffael, B., Simoneau, C. Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials. A CRL-NRL-FCM Publication, 1st edition 2009; EUR 24105 EN. ISBN 978-92-79-144-7. ISSN 1018-5593; DOI 10.2788/49046 Luxembourg (Luxembourg): OPOCE; 2009. JRC53034

The work in 2016-2017 will include:

1.1.1 Expansion of the database of methods

This work has been started in 2015 and will be completed in 2017, as follows:

- 2016- Continuing the collection of method from petitioners via JRC's access to the EFSA intranet.
- Develop a mechanism with EFSA on access to methods for JRC to render publicly available.
- 2016-2017. Search via science literature (peer referred journals) for methods description. The references and abstracts will be collected and made available for open access journals.

1.1.2 Expansion of the repository of regulated substances for FCM

This has been started in 2015 and will be completed in 2017, with the following tasks:

- Establish a comprehensive list of current substances (monomers, additives and starting substances) to be renewed or refreshed based on age and/or stability criteria.
- Establish collaboration with the association of chemicals (e.g. CEFIC) for the renewal of substances.
- Develop a stricter mechanism under the Note for guidance of EFSA on access to substances for JRC.

1.1.3 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 the database of substances and availability to the database of methods. This portal will be on-line and searchable.

1.1.4 Shipping of substances or methods for research purpose upon request

The work will also include preparing and sending upon request standard calibrants substances regulated in the EU for FCM and 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.

Milestones activity 1.1

- Method inventory
- Substance inventory
- Web interface
- monitoring provision of substances
- A MoU with EFSA for closer collaboration on methods and substances
- Collaboration with CEFIC

Deliverables EURL activity 1.1

Report of sources of substances and of methods for FCM according to the latest amendment of Regulation 10/2011 and SANTE FCM database will be produced.
The report will in particular contain conclusions on substances currently on the positive list for which no information is available at all.

Impact: *This bottom-up approach and strong database of methods will allow defining cost-effective and stream-lined priorities. An regulatory impact of the work is to provide a strong technical basis to discuss what should be done at level of the working party with Member State-SANTE and stakeholders for substances for which there is no method or calibrant available, and consequently no enforceability.*

1.2 – Coordination of EURL activities for the application of new analytical methods;

This work targets the clustering of substances in the EU Regulation 10/2011 based on their physical-chemical properties for the development of multi-analyte methods. There are currently very few methods at ISO, CEN or internationally agreed standards. The work feeds directly into NRLs and EURLs PTs responding to a better strategy to tackle a span of >900 substances regulated in the EU for FCM. It responds to the priorities of standardisation and to JRC support in the context of the Commission communication on annual Union work programme for European standardisation for 2016 [11]. It could also alleviate standardisation by CEN TC 194 and/or TC 172. A stepwise approach will be developed towards combined PTs for 2018-2020 and beyond. The deliverables 2016-2017 are:

1.2.1: Mapping of substances for multi-analyte methods

A collection of information of physicochemical parameters for the substances regulated will be developed (in particular Log Po/w). This has been started in 2015 and will be completed in 2017.

1.2.2: Mapping of technical specifications of method descriptions

The methods collected in activity 1.1.1 (descriptions) will be reviewed categorised an organised by indicators related to the identification/ quantification techniques, type of test (migration/extraction) and type of instrumental techniques (Headspace, GC/GC-MS, HPLC, LC-MS, etc). This part will support the clustering into multi-analyte methods. This started in 2015 and will be completed in 2017.

1.2.3 Development of shared platform of mass spectra with NRLs

This deliverable will develop a prototype in-house MS library on representative substances regulated under Reg 10/2011 to provide NRLs with unequivocal means to identify migrants subjected to compliance. It will use the JRC assets of the reference collections of substances (1.1.2). The first phase will deliver a pilot size GC MS library to share with NRLs. This will start in 2016 and progress in 2017.

1.2.5 Strategies for PTs by analyte cluster

This phase aims to cluster key parameters (substance/method classifiers) into a report in order to derive combined proficiency testing of FCM. This work derives from activity 1.2.1 and 1.2.2 with substances being grouped by methods or by classes of physical chemical characteristics. A strategy will be proposed for classes of exercises (e.g. multiple target ILCs) according to also screening or specific migration or modelling. This will be started in 2016 (clustering) and progress in 2017 (strategy).

Milestones activity 1.2

- Collection of physicochemical characteristics for substances regulated under Reg. 10/2011
- Compilation of methods categorisation for the substances regulated under Reg. 10/2011
- An implemented inventory of information above
- A GC MS mass spectra pilot in-house library

Deliverables activity 1.2

Report of clustering key parameters (substance/method classifiers) containing conclusions for multianalyte analytical methods as base to derive to derive modules for proficiency testing of FCMs.

[11] COM(2015) 686 final, Communication from the Commission to the European Parliament, the Council and the European economic and Social Committee; The annual Union work programme for European standardisation for 2016 {SWD(2015) 301 final} http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0686&from=EN

1.3 - Underpinning work for the development of Ceramics legislation:

This theme has been defined for 2015-2017 into a specific priority objective for 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[12], which foresees reduction of limits for lead and cadmium, potentially limits for other metals, and extension of scope for materials (crystal, bakeware, etc). This implies changes in testing methodologies and new developments. This work is thus done in cooperation with the professional associations (established over 2014-2015). The work package includes a large set of deliverables as follows: 1) comparison, proficiency testing and precision data for quantification of metals encompassing from plastics to ceramics, 2) development of migration method(s) based on real life kinetic scenarios on real foodstuffs for ceramics 3) scoping studies on migration kinetics for a range representative products from the market including sensitive and niche products 4) development, harmonisation, comparison of methods for method for testing migration from the lip or rim of decorated glass and ceramics articles 5) development of conventional time temperature exposure test on simulants for tableware 6) development of underpinning kinetics in alcoholic beverage for glassware/crystalware 7) development of conventional time temperature migration tests for glassware/crystalware 8) development of underpinning kinetics for bakeware in foods 9) development a conventional migration test design for bakeware. This work has been started in 2014 and will be completed in 2017. It is on-going and on-track. The upcoming deliverables are as follows:

1.3.1- Method for testing migration of 1) ceramics, 2) rim

The development work for testing migration under repeat use regime will be continued and completed in 2016-2017. The comparisons and options for the rim test (currently on going) will be completed. The work on ceramics will be completed by ILCs on volunteer laboratories (see section ILCs).

1.3.2- Method for testing migration from crystalware

Underpinning research is being conducted towards the development of a test mimicking the worst case food exposure scenarios on drinks. The work includes kinetics on wine and the development of cost effective and safe conventional tests to deliver experimental options in 2016-2017.

1.3.3- Protocol for migration testing from bakeware

In a first phase various kinetics on acidic sauces have been initiated in 2015. These comparisons of kinetics on bakeware and food will be completed in 2016 and conventional tests amenable to operators safety, limited energy cost and ease of operations will be developed and tested by time temperature exposure to simulants in order to provide experimental designs options over 2016-2017.

Milestones activity 1.3

- 2016 – test options for rim + test options for ceramics
- 2017 – test options for crystal
- 2017 – test options for bakeware

Deliverables activity 1.3:
Report on method development and comprehensive policy support data on testing regimes to provide technical options for future enforceability. Based on the results, a validation at EU level may be planned in collaboration with ISO TC166 to generate new test protocol(s) in support to a new Ceramics Directive.

[12] Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs OJ L 277, 20.10.1984, p. 12–16.

2. Proficiency testing ensuring efficiency of control analysis methods.

This core aims to develop cost effective approaches for the organisation of proficiency testings in the field of FCM. Regulation (EC) No 1935/2004 supports the food safety for food contact materials. For plastics only, Regulation 10/2011 already represents > 900 chemicals. For other materials the number of substances have been estimated to more than 6,500[13]. Yet, only 28 substances have a CEN methods, and candidate methods from petitioners can only be found for less than 30% of already regulated substances. In addition, the text of Regulation (EC) No 882/2004 on OFFC specifies that control of the application of the rules within its scope applies also to materials and articles in contact with food, and can be implemented in terms of actions such as monitoring, surveillance, verification, audit, inspection, sampling and analysis. Yet, a hurdle not easily overcome in the area of FCM is that there are no systematic control plans for monitoring under 882/2004 or other legislation[14]. Member States focus control on materials and articles for which specific legislation is established at EU level or within the Member States. This means that the entire field of all substances and all materials are amenable to be considered. If considering only the harmonised legislation (e.g. plastics), this means a combination of >900 substances, millions of foods simplified into 7 simulants and 3 alternates media for simulants, as well as 4 types of migration test (immersion, pouches, single surface of contact, article filling). This represents close to 180,000 combinations of proficiency testing, which is clearly not viable. Therefore there is a need to develop a **combined approach to these proficiency testing (PTs) or interlaboratory comparisons (ILCs)**. An immediate implication of the complexity of the situation is the absolute necessity to take better **advantage of the organisation of proficiency testing** exercises to use them as cost effective **streamlined precision criteria for the estimation of method validation** for official control and industrial compliance laboratories. Another implication of the absence of methods is the need to target the priorities to the development of a holistic map of dedicated ILCs covering from the **general to specific capabilities of laboratories to conduct selective standard testing**. This will allow to clustering sets of required competences and **to test the resulting clusters** in a cascading fashion over the **next ILC 2016-2020 into cycles of exercises**. These will include identification techniques (e.g. mass spectrometry etc), screening techniques (fingerprinting, extraction), tolerance calibrations, migration modelling etc.
The next phase will then take advantage of the advances made in the work on development of multianalyte methods for substances under Regulation (EU) No 10/2011. It will focus on conducting ILC not only as PTs but also as validation for multianalyte methods. With this approach, if a crisis emerges ILCs can be used to address the need for a method straight away rather than having to wait until the next years' work programme. To that effect, a proposal for a **strategy pilot initiative will be developed in 2016-2018**. It will include ILCs on the determination of specific migration from food contact materials by verification and/or by screening with a focus on multilayers materials and pouch testing.

Expected ex-ante: Up to 2 ILCS with 70% participation of NRLs in line with Regulation (EC) No 882/2004. All underperforming NRL participants receive follow-up. 80% of the underperforming that have completed the follow up perform satisfactorily in an ad-hoc ILC is such ILC is necessary (necessary: more than 50% NRLs does not reach satisfactory score in a new ILC)

2.1 –ILC on specific migration/screening

An Interlaboratory comparison (ILC) will be conducted on screening test(s) described in the upcoming JRC migration testing guidelines in support to Regulation 10/2011 on plastics as tools for compliance.

[13] Oldring, P, O'Mahony, C., Dixon, J., Vints, M., Mehegan, J., Dequatre, C., Castle, L., Development of a new modelling tool (FACET) to assess exposure to chemical migrants from food packaging, Food Add. & Contam.: Part A, 2014, Vol. 31, No. 3, 444–465,
GeuekeB., Wagner C. and Muncke J., Food contact substances and chemicals of concern: a comparison of inventories, Food Additives & Contaminants: Part A, 2014, Vol. 31, No. 8, 1438–1450

[14] DG SANTE Roadmap: Food Contact Materials - Specific provisions for materials other than plastics – implementing measure (07/2012)

The implementation of the work is developed in a cluster form, hence the title remaining generic until the polymer availability and testing has been completed in 2016.

2.2 –Phase 2 to ILC on temperature control in migration testing protocols

The EURL 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 constant correct temperature tolerances 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, validated and implemented. A strategy has therefore been developed over two years. In a first phase in 2015, a pilot exercise was 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. A root cause analysis will be conducted on the results, and an improved protocol will be developed in 2016. This improved protocol will be tested in 2017, which should improve the migration testing carried out at temperatures at or above 40 degrees, which constitute 90% of the tests performed. As a result of the validation, a more detailed guidance can be then developed.

2.3 – ILC migration of elements from ceramicware

Report of a validation/PT from ceramicware reflecting the lower intended future limits to the revision of Dir EEC/84/500. The results will also be provided to ISO TC166 to contribute to new reference method(s) in support to the anticipation of a new Ceramics Directive.

2.4 - 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 2015 proficiency tests and interlaboratory comparisons will be completed.

3. Ensure the availability of scientific and technical assistance

3.1 Development of innovative approaches for oligomers

It will include two foresight work items of interest to the strategy of JRC support to policy. As such, the work will be supported in the development phase from the institutional JRC budget.

The first work item focuses on oligomers, as they are the most relevant upcoming issue for both DG SANTE and EFSA. This priority has been laid out by DG SANTE in Commission Decision C(2015)4993. This work also constitutes a preparatory research to future JRC support in the context of the Commission communication on annual Union work programme for European standardisation for 2016 [15].

The work was started in 2015 in a preparatory and feasibility form (as generically non intentionally added substances) and has been re-focused specifically on oligomers as they are a major issue from both an exposure and unknown toxicology standpoints. The work was developed with a collaboration with the professional EU association of plastics converters to obtain samples of typical formulations for

[15] COM(2015) 686 final, Communication from the Commission to the European Parliament, the Council and the European economic and Social Committee; The annual Union work programme for European standardisation for 2016 {SWD(2015) 301 final} http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0686&from=EN

multilayer materials. This is also a pioneering work in a different strategy towards practical safety by design and ground fundamental work for the impact of compositional formulation and materials processing on potential migration and formulation of reaction products as inadvertent contaminants from packaging into foods. 70 samples have been selected in collaboration with EUPC, prepared and received from typical formulas. An experimental design was developed to simulate migration. The experiments on migration will be conducted in 2016 and interpretation and further refinement in 2016-2017 in order to develop some insight into predictive migration, migration modelling applicability, potential mapping of chemistry of reaction and interaction package-product and new data towards diffusion modelling from multilayer polymers. This can be used both by EFSA for improved risk assessment and DG SANTE towards a potential risk management of oligomers which was originally intended for the 6th amendment of the plastics regulation.

Deliverables activity 3.1.: (2017)
Report on the developments of methods to quantify unexpected migrants from food contact materials. This may include screening and/or release of chemicals from food packaging, such as oligomers, non-intentionally added substances (NIAS).

3.2 Inherent scientific and technical assistance

3.2.1 - Expertise to Commission, member states, NRLs

This core theme has currently as priority the correct implementation of the EU harmonised legislation. European legislation on food contact materials is long standing and has become extensive for plastics. In 2014-2015 several (technical) guidelines in the framework of Regulation (EU) No 10/2011 for plastic food contact materials were foreseen to support the practical implementation of the Regulation. In particular, **migration testing from an enforcement and compliance standpoint needs a technical guidance as bridge** between the conceptual texts expressed in the legislation and their technical application that needs to follow state of the art and a highly documented scientific traceability. In this context the JRC was entrusted to develop technical guidelines supporting technical aspects of testing under a number of specific FCM legislation frameworks. The development of guidelines by JRC has now reached an established track record with development for kitchenware[16], guidance supporting the Regulation 284/2011[17] on imports for testing kitchen utensils and imports[18] made from melamine and polyamide, guidance on the legislation on phthalates, functional barriers[19], and the application of correction factors[20], or the applicability of migration models under the former plastics directive 2002/72[21] and now regulation 10/2011[22].

[16] Simoneau C. Guidelines on Testing Conditions for Articles In Contact With Foodstuffs (With A Focus on Kitchenware) - A CRL-NRL-FCM Publication, 1st Edition 2009. EUR 23814 EN. Luxembourg (Luxembourg): OPOCE; 2009. JRC51601

[17] Commission Regulation (EU) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China OJ L 77, 23.3.2011, p. 25–29.

[18] Simoneau C, Hoekstra E, Bradley E, Bustos J, Golja V, Kappenstein O, Kalsbeek D, Keegan J, Milana M, Cwiek-Ludwicka K, Petersen J, Polz M, Sauvegrain P, Vanhee F, authors Simoneau C, editor. Technical guidelines on testing the migration of primary aromatic amines from polyamide kitchenware and of formaldehyde from melamine kitchenware - 1st edition 2011. EUR 24815 EN.

[19] Hoekstra E.J., Petersen J.H., Bustos J. (2011) Guidance document on fat reduction factor, functional barrier concept, phthalates and primary aromatic amines. Publication Office of the European Union, Luxembourg, JRC Scientific and Technical Report, EUR 25112 EN

[20] Petersen J.H., Hoekstra E.J. (2011) Calculator for the correction of the experimental specific migration for comparison with the legislative limit in Regulation (EC) No 10/2011 on plastic food contact materials (version January 2012)

[21] Simoneau C. (ed) R. Brandsch, B. Brands, R. Franz, M. Klatt, M.R. Milana, O. Piringer, A. Schaefer, C. Simoneau, X. Trier and O. Vitrac (2010) Applicability of generally recognised diffusion models for the estimation of specific migration in support of EU Directive 2002/72/EC, Publication Office of the European Union, Luxembourg, JRC Scientific and Technical Report, EUR 24514 EN

[22] In progress in 2015

The current work has focused on the **development of migration testing guidelines** to support Regulation (EU) 10/2011 which is on-going and expected since the implementation of the regulation has the transitional phase ended in January 2016. The draft guidance has been is completed and undergone several rounds of consultation. In addition, the development of this guide has led to making some amendments to the regulation itself for consistency and to keep the practical and conceptual aspects in line. Consequently, the guidelines will await the publication of the 6th amendment be in turn published. This editing will be completed in 2016. The new guidance from EFSA[23] cites that "On testing with food simulants, new rules are provided in Regulation (EU) 10/2011 and will be further explained in the European Commission guidelines on migration testing, which are currently being prepared by the Joint Research Centre (JRC)".

Ex- ante:
The work is on-going and expected since the implementation of the regulation has the transitional phase ended in January 2016. The technical guidelines for migration testing will be published as public document upon completion of endorsement in a comitology procedure (e.g. going to MS competent authority and standing committee of the Commission).

This activity is fully covered by JRC institutional funds and no additional budgetary support is requested.

In addition, the Technical guidelines on **migration testing of kitchenware** that are made of harmonised and non-harmonised materials will be updated as satellite to the main migration testing guidelines. The specific guidelines to kitchenware made of different parts potentially of different materials required a consensus with national legislations and practices in place in the absence of EU harmonised framework. This was achieved with a consensus interpretation and collaborative work from the Network of National Reference Laboratories, and led to the publication of a first time edition of guidance in 2009. This guidance must now be updated to the Regulation (EU) No 10/2011. This work will also anticipate safety by design for articles not only manufactured in the EU but provide a critical guidance for imported articles. The update is especially crucial as the Council of Europe refers to the JRC former edition which will now become obsolete in its "Technical guide on metals and alloys used as food contact materials and articles: A practical guide for manufacturers and regulators "[24]. The update has also been requested by the Council of Europe to assist their work in non-harmonised area[25].
This work will be started in 2016 and will be progressed in 2017 towards completion in 2018.
Budgetary support is requested for the meetings of a small dedicated task force.

Deliverable activity 3.2.1:
- Meeting report(s)
- Updated or new JRC guidance documents.

3.2.2 – dissemination by technical advice to NRLs, EFSA, stakeholders

The activity encompasses support. 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 JRC also liaises via e-mail and via the Circabc platform to ensure rapid flow of information. Examples of activities include: providing support to DG SANTE in technical matters concerning analytical methodologies for food contact materials, if requested, participation to DG SANTE

[23] Draft Scientific Opinion on Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) DRAFT for public consultation http://www.efsa.europa.eu/en/consultations/call/150707.htm
[24] https://www.edqm.eu/en/Cosmetics-packaging-guides-1486.html p. 181 " Where appropriate, see JRC Guideline1 on testing conditions for articles in contact with foodstuffs"; p. 182 " For other uses, see JRC Guidelines on testing conditions"; p.183 " For the purpose of the test, contact times and temperatures should reproduce the intended and worst foreseeable conditions of use of the material or article (see JRC Guidelines on testing conditions1)";
[25] letter to come

WG and/or EFSA meetings or working groups where indicated. It also includes research activities in support to commission and providing information and advice.
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 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 repository of documents under the JRC EURL 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 EURL activities in international conferences in the area.
This activity is fully covered by JRC institutional funds and no additional budgetary support is requested.

Deliverable activity 3.2.2:
- Timely and adequate ad hoc advice as delivered.
- Annual customer survey.

3.2.3 - Plenary, Workshops and events for NRLs

All NRLs nominated under Regulation (EC) No 882/2004 will be invited to participate to the annual 2-day plenary and in at least one training activity. Depending of the interest by the NRLs, additional experts could be invited to the NRL workshop and/or the training activity to update participants on relevant topics. In 2016-2017, additional workshops / training courses will be organised for NRLs nominated under Regulation (EC) No 882/2004, depending on interests and needs identified by the NRLs in 2015. At the end of the workshop and the training activity, the EURL will circulate a satisfaction survey questionnaire. Negative replies will be followed-up with a view to improve as much as possible, e.g. by bi-lateral feedback with un-satisfied participants.
Plenary meeting of NRL-FCM Network and EURL-FCM
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.
Stakeholders' workshop on kitchenware
The workshop will have for purpose to discuss **the update to the guidance for kitchenware** which are made of a multitude of materials and often not regulated at EU level. This will anticipate safety by design for articles not only manufactured in the EU but provide a critical guidance for imported articles.
Stakeholders' workshop on ceramics
The workshop will have for purpose to discuss **the update of the work of ceramics**

Deliverable activity 3.2.3:
- workshop/events reports and proceedings
- customer survey

3.2.4 - Initiation of EURLs 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.

- Chinese counterparts as follow up of the dedicated visit that took place in 2014 (AQSIQ /CAIQ)
- Other ad-hoc initiatives will be planned for 2016-2017 according to their relative priorities including in the context of a follow up to the Expo 2015.

Operational management

The Annual report for DG SANTE and National Reference laboratories of the deliverables of the EURL-FCM will be produced - financial report and technical report.
The work programme and associated budget will be submitted to the Commission for the operation of the laboratory and the work programme 2017-2018.
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.
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 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 SANTE.