JRC
EUROPEAN COMMISSION

JRC/IHCP/CAT/EURL-FCM/ WP2012
Version 1: July 11 2011
Version 2: August 29 2011
Version 3: November 22 2011
Version 4: January 16 2012

European Union Reference Laboratory for Food Contact Materials

Annual Work Programme

January 2012 – December 2012

EURL
European Union Reference Laboratory
for Food Contact Materials

History:

Draft sent for comments to NRLs: 14 July 2011–draft; comments by 30th July
Revised proposal submitted to SANCO- Version 2: August 29 2011
Further revisions due to financial limitations – Version 3: November 22 2011
Further revisions due to financial limitations – Version 4: January 16 2012

Legal functions and duties:

Regulation (EC) No. 882/2004 (OJ L 165 vol 47 of 30.04.2004, page 1-141) of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OFFC), includes provisions for the management of European Union Reference Laboratories (EURLs) in the whole sector, including (Article 32) on their responsibilities (mission/duties).

Article 32 - EURLs (referred to in Annex VII) shall be responsible for:

(a)	*Providing national reference laboratories (NRLs) with details of analytical methods, including reference methods;*
(b)	*coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organizing comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;*
(c)	*Coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;*
(d)	*Conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;*
(e)	*Providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;*

Note: National Reference Laboratories: NRLs

Objectives for the period January –December 2012

The objectives are based on the duties listed in OFFC and based around activities areas related. The classification mirrors the areas listed in Reg. EC 882/2004 :

Core Area 1: Methodologies for sampling and analysis

1a – methods of analysis protocols (Art 32 1(a))

- 1a-1 Guidelines on sampling, test conditions with an emphasis on articles to be placed in contact with food for home use – 2nd edition in support to new Regulation 10/2011
- 1a-2 Continuation of repository of methods of analysis from EFSA /petitioner's sources
- 1a-3 Support to Official Controls with calibrants
- 1a-4 Follow up of the interlaboratory comparison on Tenax

1b – Organisation of comparative testing (Art 32 1(b))

- 1b1 Interlaboratory comparison No1: Formaldehyde and melamine from migration solution
- 1b2 Interlaboratory comparison No2: Primary aromatic amines from migration solution

1c - Emerging issues and methods (art. 32 1(c))

1d – Training (Art 32 1 d)

1e- Technical / scientific support to Commission in case of disputes

Core Area 2: General tasks

2.1 Operational procedures

2.1.1 Compilation of annual report and cost estimates

2.1.2 Documentation services, internal and external communication, interchange of information via the web site

2.1.3 Ad-hoc questions or exchange of information with NRLs

2.1.4 Technical and scientific support to the Commission (EURL context)

2.1.6 Organisation of plenary and workshops

2.2 Quality assurance and control

2.2.1 Maintenance of equipment, documentation, audits management

2.2.2 Maintenance of the QA/Qc systems

Core Area 1: Methodologies for sampling and analysis

Activity area 1a – methods of analysis protocols (Art 32 1(a))

1a-1 2 nd edition of Guidelines on sampling, test conditions for articles to be placed in contact with food for home use (continuation of 2011)

Type of work item: medium work item – total project duration 2 years

Rationale:

A 2nd edition to adapt the Guidelines on kitchenware to Regulation (EU) No 10/2011 needs to be undertaken in line with development of a technical guidance for the Regulation (EU) No 10/2011 itself.

Objective:

Develop a new edition of the guidelines for official controls on test conditions for food contact articles such as kitchenware, in support of the new Regulation on plastics 10/2011 and its guidance. The guidelines aim to address sampling, treatment of specimen, exposure testing (e.g time/temperature, simulant etc), interpretation of results.
The priority tasks for revisions are: 1) the fit to the new regulation (test conditions and choice of simulants), 2) the removal of some extraneous items 3) indications for bakeware

Deliverables:

- Minutes of at least one meeting to NRL network and SANCO at t + 2 months
- Complete a working document towards the edition of the guidelines (emerging from the plastics legislation)

1a-2 Provision of methods of analysis protocols

Type of work item: yearly/continuous

Objective:

To provide a databank containing methodologies for the analysis of plastic food contact materials monomers and additives following to the published EFSA Opinions.

Deliverable:

- Collect, transpose and make available technical descriptions of applicant's methods for which EFSA opinions are published.
- Maintain and distribute the compilation of available methods to NRLs
- Prepare and send upon requests methods to NRLs for use for research or enforcement purposes under approved programmes.

1a-3– Support to official controls with calibrants

Rationale:

Work has been carried out to establish sources of analytical standards required as calibrants for the enforcement of Regulation (EU) No 10/2011. Several are not commercially available and are not included in the EURL standards collection (consisting of monomers, additives and BFR standards collections and those chemicals received supporting recent EFSA petitions). In collaboration with EFSA and the Commission analytical standards for the outstanding chemicals will be sought. In principle the applicant of the risk assessment of substance to EFSA should send the substance to JRC. This has not been done systematically in the past. Co-operation with EFSA needed or a mechanism needs to be developed in the future to guarantee the provision of substance according to the letter of submission for evaluation or reevaluation of a substance.

Objective:

To provide sources of substances regulated in the EU for FCM for ad-hoc provision to official controls upon request. (follow up of work item of 1b2 of the WP 2011).

Deliverables:

- Maintain and distribute the database collections of monomers and additives.
- Prepare and send upon requests standard calibrants to NRLs for use for research or enforcement purposes under approved programmes.
- Trace the provision for certain substances of the EU list towards the search and obtention of supply sources for calibrants that currently are not available as analytical sources
- Develop a mechanism for the provision of substances regulated in the EU in concert with DG SANCO and EFSA.
- Compile the results for the annual report

1a-4– Follow up of the interlaboratory comparison on Tenax

Rationale:

The EURL has prepared and proposed a SOP describing the exposure of a plastic material or article (intended for use with dry foods) to Tenax and the subsequent extraction of the Tenax and analysis of the extract. An Interlaboratory comparison has been organised and has covered: 1) one part using a spiked Tenax for which the ILC focused on extraction from Tenax itself and quantification of surrogate substances 2) another part using a film specifically contaminated with a selection of substances for which the ILC consisted of the exposure of a film to Tenax and subsequent extraction. This allowed to generate data on precision and laboratory performance for both migration and quantification.
The ILC was launched in November 2011.

Objective:

The results need to be reviewed and discussed in 2012 to provide recommendations for enforcement and compliance testing.

Deliverables:

Report and recommendations.

Activity area 1b – Organisation of comparative testing (Art 32 1(b))

Type of work item: medium work item – project duration expected 1 year
2 exercises are foreseen –

1b1– Interlaboratory comparison exercise 2012_001: Formaldehyde and melamine in 3% acetic acid from a migration solution

Objective and Rationale

The exercise will aim at proficiency testing. The purpose of the exercise is 3 fold:

- Demonstration of the continued capacity of NRLs and guest to perform adequately the measurement of formaldehyde from a migration solution in the context of support to Regulation (EU) No 284/2011 for melamine kitchenware.
- Demonstration and provision to the accreditation body of the third line control for the accreditation of NRLs and guests for the method for formaldehyde.
- Demonstration of the capacity of NRLs and guests to execute the measurement (quantification) of melamine from melaware at the new limit foreseen under an upcoming amendment of Regulation (EU) 10/2011

Workplan:

This ILC of the EURL-FCM will focus on the quantification of formaldehyde as well as melamine in migration solutions of 3% acetic acid from food contact materials. Spiked simulant samples (migration extracts) will be prepared (by the EURL) and NRLs will test the spiked simulant.

Resp.	*Tasks*	*Timeline*
JRC	*Technical consultation with NRLs to finalise technicalities of design (topic of investigation)* *Questionnaire to NRLs on methods of analysis.* *Collaboration with stakeholders (industrial) for production of materials* *Production of adequate test samples*	*3 months*
JRC	*Develop Standard/standard mixture or solutions, experimental design for production of matrices* *Develop test samples (materials, solutions and or simulants)* *information and implementation of test methods*	*3 months*
JRC	*Homogeneity testing of test material(s)* *Material approval*	*2 months*
JRC	*Develop response templates.* *Preparation of results reporting and lab training* *Shipping of samples*	*2 months*
JRC	*Collection of results* *Statistical interpretation*	*2 months*
JRC	*Technical report*	*2 months*

The test material for preparation of the migration solutions for the ILC will be melamine kitchenware (spoons, laddles) containing formaldehyde released in relevant amounts (and if possible melamine available to migrate).
The solutions prepared will include three concentration levels of migration solutions.
The general aim of the exercise will be to assess the proficiency of the official control laboratories and consequently the participants will be free to use any analytical method of their choice.

However, in the case of formaldehyde, in view of the support to Regulation 284/2011, the methods of choice will be the two procedures included in CEN technical specification TS 13130-23.
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 3 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 were set based on Horwitz equation.
The results will be presented and discussed in the plenary of December 2012.

1b2– Interlaboratory comparison exercise 2012_002: Primary aromatic amines (PAAs) in 3% acetic acid from a migration solution

Objective and Rationale

The exercise will aim at proficiency testing. The purpose of the exercise is 2 fold:

- Demonstration of the continued capacity of NRLs and guests to perform adequately the measurement of PAAs from a migration solution in the context of support to Regulation (EU) No284/2011 for polyamide kitchenware
- Demonstration and provision to the accreditation body of the third line control for the accreditation of NRLs and guest for a method of PAAs.

Workplan:

Resp.	*Tasks*	*Timeline*
JRC	*Technical consultation with NRLs to finalise technicalities of design (topic of investigation)* *Questionnaire to NRLs on methods of analysis.* *Collaboration with stakeholders (industrial) for production of materials* *Production of adequate test samples*	*3 months*
JRC	*Develop Standard/standard mixture or solutions, experimental design for production of matrices* *Develop test samples (materials, solutions and or simulants)* *information and implementation of test methods*	*3 months*
JRC	*Homogeneity testing of test material(s)* *Material approval*	*2 months*
JRC	*Develop response templates.* *Preparation of results reporting and lab training* *Shipping of samples*	*2 months*
JRC	*Collection of results* *Statistical interpretation*	*2 months*
JRC	*Technical report*	*2 months*

This ILC of the EURL-FCM will focus on the quantification of PAAs in migration solutions of 3% acetic acid from food contact materials. Spiked simulant samples (migration extracts) will be prepared within a collaboration with FERA and NRLs will test the spiked simulant. The UK-NRL will contribute to the provision of already existing samples and their confirmation. The EURL will perform the statistical evaluation of the ILC.

The test material for preparation of the migration solutions will be polyamide kitchenware (spoons) containing if possible PAAs. If the levels are not sufficient they will be adjusted y spiking relevant PAAs.

The solutions prepared will include three concentration levels of migration solutions.
The general aim of the exercise will be to assess the proficiency of the official control laboratories and consequently the participants will be free to use any analytical method of their choice. However, in view of the support to Regulation 284/2011, the methods of choice will focus on the procedures described in the Annex of the JRC technical guidelines (EUR 24815 EN 2011) in support of Regulation 284/2011.
The homogeneity and stability studies will be performed. The stability test will be performed according to ISO Guide 35:2006 at 3 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 were set based on Horwitz equation.
The results will be presented and discussed in the plenary of December 2012.

Activity Area 1c - Emerging issues and methods (art. 32 1(c))

Mineral oils: collaborative study

Context:
A conference forum in September 2011 organised by BFR (NRL-DE) highlighted the occurrence, methodology, toxicity and various methods in the context of mineral oisl from cardboard. In this context, a 'method development kit' including standard solutions of n-alkanes, standard solutions of typical mineral oils, extracts of carton board and mineral oil spiked food (rice) have been developed.

Objective:

- Collaborate on and contribute to the development and improvement of emerging methods for the analysis of mineral oils from paper and board.

Milestone:
Voluntary participation and exchange of information during the plenaries.

Deliverable:
Report on the activities carried out in 2012.

Activity area 1d – Training (Art 32 1 d)

Provide targeted Ad-hoc training on topics based on requests and current work for NRLs or third countries – Requests have been received fro RO, HU, SE.

Activity Area 1e- Technical / scientific support to Commission in case of disputes

In case of dispute the EURL could provide help as best agreed between parties involved to help resolve the disputes.

Core 2: General tasks

2.1 Operational procedures

2.1.1 Compilation of reports and cost estimates

- Collect and edit material for a report covering the EURL-NRL workshops
- Prepare and publish articles and reports associated with the above work.
- Submit to the Commission a financial and technical report for each workshop of the EURL-FCM
- Submit to the Commission a financial and technical report on the operation of the
- EURL-FCM no later than 31 March 2012 (Article 10 of Regulation (EC) No 1754/2006) for the Annual Report 2011
- Submit an Intermediate 2012 report of the EURL-FCM (Period 01/01/2011-31/07/2012) by 1st September 2012
- Submit to the Commission a workprogramme and associated budget on the operation of the laboratory no later than 1st September 2012 for the work programme 2013.

2.1.2 Documentation services, internal and external communication, interchange of information via the web site

The 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 Circa specifically for NRLs is designed to support dissemination of information and network activities (http://circa.europa.eu/Members/irc/jrc/jrccrlfcm/library) . 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.
Forms and related documentation for NRLs to conduct ILCs will be uploaded in a specific location where any news or next steps to follow can be found quickly.

Deliverable: quarterly updates for public website and continuous update throughout the year for Circa website.

2.1.3 Ad-hoc questions or exchange of information with NRLs

- Conduct work to evaluate reported problem areas.
- Support by means of information and technical advice National Reference Laboratories
- Maintain close awareness of developments in methodologies, report and advise, as relevant, to the Annual Plenaries and Workshops of National Reference Laboratories.
- Formally liaise with National Reference Laboratories via e-mail and via the Circa platform to ensure rapid flow of information

2.1.4 Technical and scientific support to the Commission (EURL context)

- Support by means of information and technical advice the European Commission.

2.1.6 Organisation of plenary and workshops

Prepare the programme and working documents for the Annual Plenaries and Workshops of National Reference Laboratories.

Coordinated EURL-NRL workshops will take place in two occasions.

The first will be in June 2012. The agenda will include the preparation of the work programme 2013, as well as discussion of results of the ILC 2011 formaldehyde and the drafting of the compilation of outputs and recommendation of The ILC Tenax. The workshop will include a session of general exchange of information and information from the Commission.

The second will take place in December 2012. The programme will include an expert workshop on the drafting of the second edition of the guidelines on testing conditions of kitchenware under Regulation 10/2011. A review of the results of the ILC 2012 on formaldehyde and PAAs. The workshop will include a session of general exchange of information and information from the Commission.

2.2 Quality assurance and control

2.2.1 Maintenance of equipment, documentation, audits management

2.2.2 Maintenance of the QA/Qc systems in consequence of the ISO 17025 accreditation and ISO 9001 certification of all analytical work done by the EURL-FCM

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 .

Deliverables: financial reports, technical report, auditing, certification and accreditation.

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.