

European Union Reference Laboratory for Food Contact Materials

Work programme 2013



Version 1.2



Executive summary

The work programme for 2013 was established during the June 2012 Plenary in consensus with the Network of NRLs and DG SANCO. It will include developments on testing for ceramics in support to the revisions currently discussed for the Directive on ceramics. It will also include 1) a follow up to the validation of method for Tenax consisting of a proficiency testing (PT) on the identification of polymeric materials of unknown nature, 2) a PT on fingerprinting as identification of the nature of plastics FCM materials, 3) an exercise on calculation of surface areas in contact for kitchen utensils using different methods, and 4) a workshop on Good Manufacturing Practices (GMPs) and requirements and evaluation of supporting documents for the establishment of compliance. It will also initiate exploratory work on testing of kitchen paper and napkins as a non regulated emerging issue.

Objectives for the period January 2013 – December 2013

The objectives are based on the duties listed in OFFC and based around related areas of activity. The classification corresponds to areas listed in Reg. EC 882/2004 and has been updated to reflect the classification adopted by DG SANCO in August 2012.

Core Activity 1 – Coordination of analytical methods by comparative testing Sub activity 1.1 Interlaboratory comparison exercise 2013_001: comparative testing (PT) on the dry simulant Tenax containing a mystery cocktail of 6

testing (PT) on the dry simulant Tenax containing a mystery cocktail of 6 substances

Sub activity 1.2 Interlaboratory comparison exercise 2013_002: identification of polymeric materials of unknown nature

Sub activity 1.3 Follow-up actions taken to assist NRLs in acquiring an improved performance in measurement of chemical release from FCM for the exercise of 2012-002 Formaldehyde in kitchenware.

Core Activity 2 – Production and validation of analytical methods

Sub activity 2.1 Provision of methods of analysis protocols

Sub activity 2.2 Expand the databases of reference calibrants of regulated substances

Sub activity 2.3 Establishment of testing methods in support of new release limits for Ceramic Food Contact Materials.

Sub activity 2.4 Development work towards emerging issue of PAAs

Sub activity 2.5 Meeting with external experts: strategies for multianalyte methods

Sub activity 2.6 Interlaboratory comparison exercise 2013_003: determination of surface contact area.

Core Activity 3 – Training and support to NRLs

Sub activity 3.1 NRL expert training: declaration of Compliance and Good Manufacturing Practice

Sub activity 3.2 Workshops for the Network of NRLs

Sub activity 3.3 Ad-hoc questions or exchange of information with NRLs

Core Activity 4- Provision of expertise to stakeholders (Commission, agencies, member states)

Core Activity 5- Reciprocal exchange of information with professional bodies and stakeholders

Support to CEN

Internal and external communication, web site

Core Activity 6: General tasks

Core Activity 1 – Coordination of analytical methods by comparative testing

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

Sub activity 1.1 Interlaboratory comparison exercise 2013_001: comparative testing (PT) on the dry simulant Tenax containing a mystery cocktail of 6 substances

Rationale

Regulation (EU) No 10/2011 establishes Tenax® as a food simulant E for testing specific migration into dry foodstuffs. Although research data have been available, there were to date no data on the ability of a method for the specific migration testing and subsequent quantification of representative substances from Tenax.

Therefore research done in 2010-2011 focused first on comparing, improving and harmonising method descriptions for the analysis of model substances in Tenax®. This scoping study also led to the development of a Standard Operating Procedure (SOP) which was based on modifications to standards CEN 1186-13 and CEN 14338.

This research led to the creation of a 2 reference materials: a spiked Tenax matrix with 5 substances and a film spiked with 5 substances. These substances for fortification also responded successfully to quality criteria developed for the purpose, i.e.: 1) be able to migrate in Tenax from a spiked film, 2) be amenable to be homogeneously spiked in Tenax and in a plastic sheet, 3) be stable in the film and in Tenax, and 4) be representative of a range of substances that are common food contact additives.

Consequently an interlaboratory comparison was organised and successfully completed in 2011-2012 to evaluate the laboratory performance and precision criteria of the harmonised methods: 1) for the determination and quantification of typical food contact migrants into Tenax® and 2) from a migration test from a fortified plastic film into Tenax and subsequent quantification. The exercise was based on volunteer participation due to the level of complexity of the exercise.

The work carried out in the ILC was a pioneering exercise never attempted before, since it allowed to obtain data on precision and laboratory performance for <u>both</u> migration and quantification.

The discussion of results in the June plenary 2012 concluded that the value of the exercise and its success obtaining precision data of a candidate method implied that it could be now extended to a full proficiency test on a further set of analytes and leaving more freedom in the protocol (e.g. extraction solvent in particular).

Objective

The objective for the exercise 2013 will therefore be a follow-up exercise on Tenax to further validate methodologies for further potential migrants (i.e. polarity and volatility) and as a novelty and added level of challenge to include screening of unknowns. 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.

Tenax will be fortified with 2 to 3 substances undisclosed out of a range of six, with different polarities. The spiked Tenax will contain one or more unknown substance for the NRLs to identify using an analytical screening methodology of their choice.

Instructions will be given, but freedom will be left to use more or less polar extraction solvents. Tenax in this case could be used a screening tool.

Impact

This exercise will provide more data to support the validation of the methodology as well as assessing each laboratory's ability to quantify migrants in Tenax and identify unknowns in migration extracts.

Workplan:

The test material for preparation of the migration solutions for the ILC will be Tenax containing the substances in targeted amounts most relevant for compliance testing.

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.

The homogeneity and stability studies will be performed by the EURL-FCM laboratory. The stability test will be performed according to ISO Guide 35:2006 at the chosen levels and 3 temperatures.

The assigned values will be obtained after applying the robust statistics to the results of the participants. Participants will be invited to report 4 results for each concentration level. Laboratory results will be processed using several algorithms: ISO 13528, Harmonised protocol, DIN 38402 A45 (Q-Hampel) and ISO GUIDE 35:2006. Standard deviations for proficiency assessment will be set based on Horwitz equation.

The results will be presented and discussed in the plenary of December 2013.

The work flow will be as follows:

Action	Task objective and description	Timeline	review
JRC	Technical consultation with NRLs to finalise technicalities of design	1 month	
JRC	Develop Standard/standard mixture or solutions, Experimental design for production of matrices Development of test samples (materials, solutions and or simulants) Development of fortification protocols for the matrix and substances Scale up of the fortification protocol to batch size as standard material Collection of variations expected in methods Verification of methods — compilation of method description In house check of expected repeatability Information / advice on implementation of test methods for NRLs	4 months	05/2013
JRC	Homogeneity testing of test material(s) Stability testing of test material – 3 temperatures (ISO Guide 35:2006) Material approval Develop response templates. Preparation of results reporting Launch of PT Reception of confirmation letters Shipping of samples	3 months	09/2013
JRC	Collection of results Statistical interpretation	2 months	11/2013
JRC	Presentation of results in the plenary of December 2013. Technical report	1 months	12/2013

Sub activity 1.2 Interlaboratory comparison exercise 2013_002: identification of polymeric materials of unknown nature

Rationale

The range of plastics polymers encountered for food contact materials is vast. The correct identification of a plastic material is a critical first step for enforcement purposes. Several recent Regulations such as Regulation EC No 284/2011 on polyamide

and melamine articles or Regulation 321/2011 restricting Bisphenol A use in plastic infant feeding bottles require the ability to correctly determine the polymer type.

Objective

The aim of the exercise will be to correctly identify the polymer type for a range of plastics that may be used as baby bottles as well as other FCM plastics.

Impact

This exercise will be assessing each laboratory's ability to identify unknown plastics materials via quick screening tools.

Workplan:

The test material for preparation of the migration solutions for the ILC will be samples of plastics polymers obtained from industry (who will be asked to support this exercise in the form of donation of typical materials).

The EURL will perform preliminary work checking the applicability of methods, such as physical tests (e.g. melting behaviour), chemical tests, spectroscopy, etc.

The preliminary testing of materials and methods will be performed by the EURL-FCM laboratory.

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.

The results will be presented and discussed in the plenary of December 2013.

The work flow will be as follows:

Action	Task objective and description	Timeline	review
JRC	Technical consultation with NRLs to finalise technicalities of design	1 month	
JRC	Research of test samples (risk analysis/assessment) Collection of methods and approaches Verification of methods – compilation of method descriptions In house check of expected repeatability Information / advice on implementation of test methods for NRLs	5 months	05/2013
JRC	Material approval Develop response templates. Preparation of results reporting Launch of PT Reception of confirmation letters Shipping of samples	3 months	09/2013
JRC	Collection of results Statistical interpretation	2 months	11/2013
JRC	Presentation of results in the plenary of December 2013. Technical report	1 months	12/2013

Sub activity 1.3 Follow-up actions taken to assist NRLs in acquiring an improved performance in measurement of chemical release from FCM for the exercise of 2012-002 Formaldehyde in kitchenware.

Rationale

One of the ILCs in the work programme 2012 involved the determination of melamine and formaldehyde in solutions of 3% acetic acid simulant exposed to a melamine-ware spoon. The exercise aimed at proficiency testing.

The test material used for preparation of the migration solutions were melamine kitchenware (spoons) containing formaldehyde and melamine, at three concentration levels. The migrate was diluted with different volumes of 3% acetic acid to generate the

3 test solutions F&M01 and F&M02 and without dilution to generate test solution F&M03. Sixty six participant laboratories submitted their results and 80% of the results reported for formaldehyde were properly estimated; The results for F&M01 and F&M02 were good with only 7 of the 62 laboratories returning questionable or unsatisfactory results. For the third solution, F&M03 (the one most concentrated and not compliant), 23 of the 62 laboratories returned questionable or unsatisfactory results. As this was an unexpected outcome, the EURL-NRL June plenary established that it was necessary to perform an in depth investigation in order to find out the possible sources of error which affected the analysis of the formaldehyde in highest concentration level sample.

Objective

The follow up will include 1) a questionnaire for root cause analysis and 2) a new exercise for participants with difficulties.

Impact

Demonstration of the improved capacity of NRLs and guests to perform optimally 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.

Workplan:

The new exercise will consist of unknown test solutions prepared ad-hoc for the exercise. As it was hypothesised that one reason might be in the protocol of the dilution of sample vs. derivatisation for analysis, the exercise will include recommendation for the dilution step that should be performed before the reaction with acetyl acetone or chromotropic acid.

Action	Task objective	Timeline	review
JRC	Preparation of new standard materials (migration solutions from spoons)	2 months	2012
JRC	Collection of results Statistical interpretation	2 months	01/2013
JRC	Technical consultation with NRLs on outcome of the ILC Presentation of results in the plenary of June 2013.	1 month	06/2013
JRC	Develop recommended protocols for development of experimental designs, standard operating protocols and implementation of test methods	4 months	11/2013
JRC	Synthetic report on recommendations	4 months	02/2014

Core Activity 2 – Production and validation of analytical methods

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

Sub activity 2.1 Provision of methods of analysis protocols

Objective:

To provide a databank containing methodologies for the analysis of plastic food contact materials monomers and additives. All methods received will continue to be made available on the EURL Circabc platform. For 2013, the methods will also be

systematically connected to their respective substance availability from analytical suppliers where possible.

Deliverable:

- Collect, transpose and make available technical descriptions of applicant's methods for which EFSA opinions are published and subsequently authorised in the EU legislation.
- Develop a database for the use of NRLs of direct access to the methods on the EURL Circabc platform or similar.
- Link systematically the database of substance characteristics and availability to the database of methods, to provide a one-stop portal.

Sub activity 2.2 Expand the databases of reference calibrants of regulated substances

Rationale:

Work has been initiated 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 further sought.

Objective:

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

Sub activity 2.2.1: Developing a bank of monomers, additives and starting substances Sub activity 2.2.2: Developing a database of information on suppliers of calibrants

Deliverables:

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

Task	review
Collect, transpose and make available technical descriptions of applicant's methods for which EFSA opinions are published.	
Develop a centralise system for classification of all methods	
Prepare and send upon requests methods to NRLs for use for research or enforcement purposes under approved programmes.	06/2013
Develop a mechanism for the provision of methods regulated in the EU in concert with DG SANCO	
and EFSA.	
Compile the results for the annual report	
Distribute the compilation of available methods to NRLs	12/2013
Reorganise the database collections of monomers and additives according to the new Regulation	06/2013
10/2011	
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

12/2013

Sub activity 2.3 Establishment of testing methods in support of new release limits for Ceramic Food Contact Materials.

Rationale:

The Regulation on ceramic materials and articles is currently under revision. In the first instance lower limits for Cd and Pb will be introduced taking into account the revised EFSA opinion for these elements. In a second phase limits for other metals (e.g. Co) and other substrates (e.g. glass) will be considered. The use of other simulants (e.g. organic acid) and different test conditions (e.g. repeat use) may also be considered. The current DG SANCO work programme with Member State highlights that any amendment to legislation may imply the need for changes in methodology, and such

Objective:

Anticipatory work is required by the EURL to evaluate/compare/develop methodologies prior to running an ILC in 2014 or 2015.

Description of work

The development would focus on the development or preparation of test or reference samples and homogeneity. C. Simoneau will work closely with B. Schupp (DG SANCO) and F. Bolle (NRL-BE) to prepare a stepwise project, following the consolidation of decisions at DG SANCO level.

Deliverables:

- An advice by the EURL and NRLs on laying down testing methodology in the legislation
- Experimental developments on methodologies
- Development towards the production of a test material.

changes must be supported by the NRLs and the new Regulation.

Sub activity 2.4 Development work towards emerging issue of PAAs

Rationale:

Enforcement and scientific data suggest that red and yellow napkins available on the market contain PAAs that are readily extracted into cold water. Typically o-anisidine, o-toluidine and chlorinated PAAs are present. It was noted that many of the NRLs and OCLs will not have these PAAs in their analytical suite and so any ILC may also need a method development phase.

This item is in support to non-regulated area where issues might be present in EU and import products potentially endangering the safety of the consumer. Although paper is not regulated by harmonized EU legislation currently, such harmonization is considered in the future and method development in this area helps to identify priorities on future legislative work. This activity also supports control and enforcement of migration of PAAs from other materials in regulated areas.

Objective:

Collaborate on and contribute to the development and improvement of emerging methods for the analysis of dyes from napkins

Description of work

An exploratory work item will be initiated on the topic by the EURL and volunteer laboratories to investigate the release from napkins in cold extracts compared to other test methods. The results will be collected into an information platform.

Deliverable:

Report on the activities carried out in 2013 and their outcome.

Sub activity 2.5 Meeting with external experts: strategies for multianalyte methods

Rationale:

The field of FCM covers more than 960 regulated substances, whereas only 28 methods have had a restricted validation under CEN. There are notably no official methods, no Codex methods, and very little validated methods with full data traceability. There is therefore a need to develop strategies for multianalyte method and towards non targeted sample preparation and multianalyte analysis methods. For economic reasons laboratories tend to cover as many parameters as possible per analysis. However, the EU-RL is concerned about the reliability of analysis results gained by such analysis methods.

Therefore the EU-RL aims to discuss with experts in this field the advantages and limitations of these methods with regard to FCM contaminants determination.

Objective:

A maximum of 5 experts will be invited to the EU-RL premises. The outcome of the discussions will be made available to the NRL network.

Deliverable:

The results will be collected into an information platform.

Impact

This will allow to strategise effectively for a next phase of the next 2 years. In phase 2, all the methods held in the databank of the EURL FCM will be grouped by analytical analogy on their amenability to be clustered as multianalyte analysis. Further preliminary development work will be carried out on selection of multianalyte methods applicable for screening and with potential to tackle non intentionally added substances (NIAS).

Sub activity 2.6 Interlaboratory comparison exercise 2013_003: determination of surface contact area.

Rationale

The work programme 2012 had for one ILC the determination of migration of formaldehyde from solutions and also as optional from a kitchen articles (spoon). Nineteen volunteer laboratories from the NRL-FCM network participated in an exploratory optional part of the exercise to determine the contact area of the utensils. Only a small number of laboratories returned results, however the distribution of results was wide. Considering that the reliability of results directly depends on the correct measurement of the surface area, this aspect needs improvement by a targeted exercise.

Objective

The exercise will aim at both proficiency testing and comparison of methods. As there are no formally established methods, a number of methods will be compared, including the use of 3D scanners.

Impact

The purpose of the exercise to demonstrate the capacity of NRLs to perform adequately the measurement of surface area of kitchen utensils in the implementation of controls under both Regulation EU No 10/2011 and EU No 284/2011.

The EURL will collate information/approaches on surface area determination and a follow up exercise will be carried out in second half of 2013.

As a follow up to the variable results obtained in the exercise held in 2012 to determine contact area of a melamine-ware spoon, a range of utensils will be provided and the area determined. Information on methods to determine surface area will also be provided.

Workplan:

The work flow will be as follows:

Resp.	Tasks	Timeline	Review
JRC	Technical consultation with NRLs to finalise technicalities of design Questionnaire to NRLs on methods of analysis. Research and purchase of adequate test samples Material approval	3 months	04/2013
JRC	Collection and compilation of method descriptions information and implementation of test methods	2 months	06/2013
JRC	Develop response templates. Preparation of results reporting Shipping of samples	1 month	09/2013
JRC	Collection of results Interpretation	2 months	11/2013
JRC	Technical report	1 month	12/2013

Core Activity 3 - Training and support to NRLs

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

Sub activity 3.1 NRL expert training: declaration of Compliance and Good Manufacturing Practice

Rationale

Declaration of Compliance and Good Manufacturing Practice (GMP) are topics causing a great deal of confusion for NRLs and their inspection services.

National reference laboratories are frequently asked how the GMP Regulation 2023/2006 and declaration of compliance (DoC) should be interpreted and enforced. The reason for this is that the regulation is both complex (requiring in depth chemical knowledge) and poorly defined. For enforcement to be equal throughout Europe, it is important that the EURL provides the NRLs with guidelines for the interpretation of 2023/2006 and DoC,

There have been extensive activities from various Member States on the specific requirements for parts of 2023/2006, but these have focused mainly on the declaration

of compliance itself. The more difficult question of how to evaluate the "in-house documentation" has been largely neglected.

Objective

It was thus requested from NRLs that the EURL should hold a workshop to establish what the Member States are doing with respect to the enforcement of these two important aspects of legislation.

Deliverable

A 2-day workshop where the current state of the art will be presented. One day will be dedicated to DoCs while the other will focus on the supporting documentation.

Outlook and Impact

The overall impact is to gather critical information which then can be collected into a consensus of approach. The item could then continue during the following 2 years with 1) the formation of a special working group 2) the drafting of a harmonised guidance document for checking compliance; and 3) the possible organisation of a future ILC on the assessment of DoCs and "in-house documentation".

The impact of a document on consensus of approach will be the ability for inspection services (including the FVO), Official Control Laboratories, National Reference Laboratories to ensure a harmonised enforcement and be able to provide the state of the art advice to their Member State Competent Authority. In addition, documents that may exist at industry level will be surveyed, therefore providing further value added for stakeholders at large, helping to understand what is expected and offering tools to provide the best compliance supporting documents.

Task	Timeline	review
Develop training programme Prepare the training materials Look for speakers Invite speakers Prepare the logistics of the visit.	3 month 2 month 0.5 month 0.2 month	11/2013
Prepare customer satisfaction surveys	0.1 month	12/2013

Sub activity 3.2 Workshops for the Network of NRLs

Coordinated EURL-NRL workshops will take place in two occasions. The workshops serve 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 first will be in June 2013. The agenda will include the preparation of the work programme 2014, as well as discussion of results of the ILC follow-ups and current ILCs. The workshop will include a session of general exchange of information and information from the Commission.

The second will take place in November 2013, focusing on a review of the results of the ILCs 2013. The workshop will include a session of general exchange of information and information from the Commission.

The workflow will include the preparation the programme and working documents for the Annual Plenaries and Workshops of National Reference Laboratories.

Sub activity 3.3 Ad-hoc questions or exchange of information with NRLs

The activity will encompass work to evaluate reported problem areas. It will provide support by means of information and technical advice National Reference Laboratories. The work will also includes maintaining close awareness of developments in methodologies, report and give advice, as relevant, at the Annual Plenaries and Workshops of National Reference Laboratories.

In addition the EURL-FCM will also Formally liaise with National Reference Laboratories via e-mail and via the Circa platform to ensure rapid flow of information

Core Activity 4- Provision of expertise to stakeholders (Commission, agencies, member states)

Training of laboratory personnel on analytical methodology for food contact materials (on request of the NRLs). Priority will be given to underperforming NRLs.

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

Participation to DG SANCO WG meetings

Participation to EFSA meetings and or working groups where indicated

Research activities in support to commission e.g. Ceramics, modelling, guidance to Regulation 10/2011

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.

Core Activity 5- Reciprocal exchange of information with professional bodies and stakeholders

Support to CEN

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

Internal and external communication, 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 Network of NRLs will be more strongly emphasized in new pages in 2013.

The dedicated website on Circabc specifically for NRLs is designed to support dissemination of information and network activities https://circabc.europa.eu/ under Joint Research Centre, JRC EURL-FCM.

The platform represents a main source of information exchange between the EURLs and the NRLs as well as is used for repository of working documents and traceability purposes. It also holds forms, sheets and other documents thus facilitating the management of tasks. It will be continuously updated.

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 Circabc website.

Core Activity 6: General tasks

6.1 Operational procedures

6.1.1 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 technical reports for workshops 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 2013 for the Annual Report 2012 Submit to the Commission a workprogramme and associated budget on the operation of the laboratory no later than 1st September 2013 for the work programme 2014.

6.2 Quality assurance and control

6.2.1 Maintenance of equipment, documentation, audits management

6.2.2 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.