



**WORK PROGRAMME 2015 OF THE
EUROPEAN UNION REFERENCE LABORATORY FOR
CHEMICAL ELEMENTS IN FOOD OF ANIMAL ORIGIN
AT THE
ISTITUTO SUPERIORE DI SANITÀ
ROME, ITALY**

LEGAL FUNCTIONS AND DUTIES

The functions and duties of the European Union Reference Laboratory, formerly named Community Reference Laboratory, are described in Article 32 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 (Official Journal of the European Union L 165, 30.04.2004, corrected and republished in the Official Journal of the European Union L 191, 28.05.2004).

The objectives of the 2015 EC Workprogramme are taken into consideration.

1. OBJECTIVES FOR THE PERIOD 01 JANUARY 2015 - 31 DECEMBER 2015

A. General tasks

Article 32, paragraph 1 (e)

B. Development and validation of analytical methods

Article 32, paragraph 1 (a, c)

C. Quality Assurance and Quality Control, including the organisation of proficiency tests and the development of test material.

Article 32, paragraph 1 (b)

D. Technical and scientific support to NRLs and Third countries

Article 32, paragraph 1 (a, d, e, f)

Each of the objectives above will report the relevant 2015 EC workprogramme objective when appropriate.

2. WORKING PLAN FOR THE PERIOD 01 JANUARY 2015 - 31 DECEMBER 2015

A. General Tasks

Article 32, paragraph 1 (e)

1. Meeting of all EURLs

An EURL-CEFAO representative will participate in the coordination meetings of the EURLs.

Objective: participation in at least 1 meeting of EURLs.

Expected Output: reporting of the information to EURL management and sharing of the outcome with personnel involved in the EURL activities.

2. Technical and scientific support to the Commission, co-operation with international organisations and participation in international congresses

The EURL-CEFAO is available to offer professional expertise and to provide technical and scientific support upon request to the European Commission (EC) and related Institutes. (*Operational Objective 3 of the 2015 EC Workprogramme*)

The evaluation of the National Residues Control Plans (NRCP) of the EU Member States will be performed. The indication of the EC will be taken into consideration in the assessment. Particular attention will be given in checking if MSs have fulfilled

the actions according to the comments of the EURL-CEFAO expressed the year before. Specific observations will be made, if necessary.

The EURL CEFAO is also available to co-operate with international organisations. The EURL carefully selects the scientific conferences to attend either as speaker or simply as participant according to the interest and pertinence of the topics that need to be strictly connected with the activity of the EURL or provide new issues for the future work.

Therefore, the EURL is willing to participate in at least one international congress.

Objective: to provide technical and scientific support upon request of the EC or international Institutes. To perform the annual evaluation of the NRCPs.

Participation in international congresses to spread information on the EURL activity and to up-date topics of interest.

Expected Output: Report regarding the evaluation of NRCPs to the European Commission.

Providing information for any other request (e-mails/letters/documents) of the European Commission/EC related to the Institutes and International Organizations within the scope of the EURL CEFAO's competences.

Presentation of at least one lecture or poster in an international congress.

3. Compilation of annual reports

The reports on the activities carried out for the relevant contract period will be regularly issued both for EC and NRLs.

Objective: Drawing up of Reports for European Commission within the due date.

Expected Output: Releasing of: Interim Annual Report, Final Activity Report, reports on Workshop and NRLs visits to regularly inform the EC regarding the EURL-CEFAO activity and follow-up action for NRLs.

4. Documentation services, interchange of information

Operational Objective 3 of the 2015 EC Workprogramme:

the EURL-CEFAO website will be regularly updated with the EURL CEFAO activities and legislation. In case of amendments of the EU legislation, the latest versions will be included in the website and the NRLs will be informed by e-mail. The bibliography and the section dedicated to the EURL-CEFAO publications will be regularly updated.

In the restricted area, the control charts of the z-scores obtained by NRLs in the PTs will be updated.

As for the Handbook of the NRLs Analytical Methods, the format will be improved to further facilitate the retrieval of the details of interest.

As for the interchange of information, the EURL-CEFAO will be available, upon request, to give support to the NRLs and to Official Laboratories of Third Countries.

Operational Objective 2, line 3 of the 2015 EC Workprogramme:

the collaboration and interchange of information on PTs with the EURL for Feed and Food (Geel) will be continued.

Objective: Regular updating of the restricted area regarding indicators related to the performance of NRLs in PTs; reports of workshop, analytical methods, EU legislation.

Expected Output: Reports related to PTs; issuing of updated z-scores Control Charts of each NRL; updating of Handbook of Analytical Methods of the NRLs; list of Official Methods, bibliography for the network and EURL-CEFAO publications.

B. Development and Validation of Analytical Methods

Article 32, paragraph 1 (a, c)

5. Analytical methods

Operational Objective 1 of the 2015 EC Workprogramme:

the analytical activity of the EURL-CEFAO consists in both the development of new analytical methods and the maintenance of those that are accredited/validated.

As for the new methods, the combination matrix/element, foreseen for the PTs, is of great importance and strongly influences this activity.

The EURL prefers to develop easy-to use procedures to be disseminated to NRLs also bearing in mind the different analytical techniques used in the network. For this reason the distribution of new methods, developed using different analytical techniques, is an important aspect of the strategy followed during the activity planning.

5.1 Maintenance of analytical methods

The maintenance of the accredited methods (included in the fixed and flexible scope) entails an important analytical activity since ISO/IEC 17025:2005 requires a regular updating/validation reassessment of the accredited methods. For this reason, the methods for the determination of Cadmium (Cd) and Lead (Pb) by Graphite furnace atomic absorption spectrometry (GF-AAS), Arsenic (As), Cd, Pb by Inductively coupled plasma mass spectrometry (ICP-MS) and Mercury (Hg) by Cold-vapour atomic absorption spectrometry (CV-AAS) will undergo a validation reassessment.

The performance of the methods will be regularly monitored by means of control charts and reference materials.

Depending on the availability and pertinence of analytes and matrices offered by commercial PT providers, the participation in at least one external Proficiency Test with an accredited method is foreseen in order to check the performance of the laboratory.

Objective: give evidence that the performance of the accredited analytical methods is steady. Revision of Cd, Pb, Hg in fish by AAS and As, Cd, Pb by ICP-MS.

Expected Output: confirmation of all methods included in the scopes of accreditation by the Accreditation Body.

5.2 Development of analytical methods

Operational Objective 1, line 1, 2 and 3 of the 2015 EC Workprogramme:

in the framework of the 21st PT on mussels (2014) the EURL provided guidelines to NRLs on a method based on Direct Mercury Analysis (DMA).

Considering the increasing dissemination of this technique, a complete validation of a method will be performed including a fish matrix. The method and the validation procedure set by the EURL will be provided on the occasion of the 23rd PT on fish (2015). This effort will give NRLs using DMA the opportunity to achieve a comparable performance in the network.

In the workprogramme 2014, the development of a method for the determination of Mo in food was foreseen. In 2015, taking the results obtained in 2014 on the determination of Molybdenum in food matrices, a method on infant formulae based on animal protein by ICP-MS will be developed.

The possibility to develop a method by GF-AAS for this element/matrix combination will be explored considering the minor sensitivity of this technique compared with ICP.

Since the studies on As speciation are of great interest and considering the positive results obtained till now, the EURL will complete the validation of a method on fresh matrices. The method will be disseminated among the NRLs.

Objective: development of above indicated analytical methods. Completion of an on-going study on inorganic arsenic speciation.

Expected Output: full validation of the method for Hg by DMA according to the relevant validation procedure. Dissemination of the method and the procedure to NRLs. Guidelines on the determination of Mo in infant formula will also be distributed at least for ICP-MS.

C. Quality Assurance and Quality Control, including the organisation and implementation of proficiency tests

Article 32, paragraph 1 (b)

6. Maintenance of the QA/QC system

Operational Objective 2, line 1 of the 2015 EC Work programme the accreditation according to ISO 17043 is maintained:

the EURL-CEFAO is accredited according to ISO/IEC 17025:2005, extended with the flexible scope. Since 2010 the EURL PT Scheme is accredited according to ISO/IEC 17043.

Even if ISO/IEC 17043 does not impose the use of an accredited method for the homogeneity assessment, the EURL considers that the application of accredited methods can better qualify the PT scheme. For this reason the flexible scope is often used by the EURL CEFAO when new matrices/elements are proposed in the PTs.

The maintenance of the accreditation status, according to all the above mentioned regulations, implies the carrying out of analytical and documental activity requested by the QA/QC systems.

Two surveillance audits (ISO/IEC 17025:2005 and ISO/IEC 17043) by the Italian Accreditation Body ACCREDIA, to check the maintenance of the accreditation status, will be regularly carried out.

Objective: maintenance and improvement of a proper Quality System according to both regulation EN ISO/IEC 17025:2005 and ISO/IEC 17043:2010

Expected Output: maintenance of the accreditation status and successful outcome from the surveillance audits by the Accreditation Body without Non Conformities.

7. Proficiency test

Operational Objective 2 of the 2015 EC Workprogramme

The EURL CEFAO will organise two PTs: the 22nd PT on As, Cd, Mo and Pb in infant formula (IF) based on animal protein and the 23rd PT on Cd, Pb, total As and Hg, in freeze dried fish.

In the PTs, the NRLs are free to use their methods as routinely applied or the EURL guidelines. For this reason “Results Forms” will be especially designed in order to retrieve the details on sample preparation and measurement parameters that could cause underperformances.

The performance of the participants will be assessed by the z-scores approach. The algorithms developed by the EURL to calculate the standard deviation for proficiency assessment (σ_{pEURL}) will be used to evaluate the performance of the NRLs. In order to allow the comparison with commercial programmes, the z-scores calculated by the Horwitz equations ($\sigma_{pHorwitz}$) will be supplied as well.

A “Short Report”, containing a summary statistics, the results and the z-scores, will be published in the Restricted Area of the website within 40 days from the deadline of each PT. The “Final report” giving additional information and general network performance will replace the Short Report on the website.

For both PTs, the test items will be prepared in the EURL-CEFAO facilities. Element concentrations will be adjusted with the aim of pursuing specific objectives. The lyophilisation process for both samples, as well as the sterilization for fish will be subcontracted to qualified suppliers.

As far as the production of both freeze dried samples is concerned, preliminary studies will be conducted considering the endogenous content of elements and the yield of the lyophilisation process; the solubility of the powder for IF. The stability of Cd and Pb in IF and fish is well known from previous PTs, whilst, for As and Mo in IF, this parameter will be verified.

As for the production of the 23rd PT test items, the starting material will be purchased on the market. The research of the suitable species will be conducted by exploring the natural content of the elements and the yield of the lyophilisation process for some freshwater and marine fish.

Preliminary batches for both matrices will be produced to allow the EURL to adjust the final concentration levels in the freeze-dried material for the PT in order to organise profitable exercises.

22nd PT on As, Cd, Mo and Pb in infant formula (IF) based on animal protein

The activity of the EURL-CEFAO as PT Provider is also addressed to try to help NRLs to face new combinations matrix/element that can be included in the European legislation (CR 1881:2006 and following amendments). With this aim, in 2012 the 17th PT was organised on powdered infant formula (IF) based on animal protein considering that a new Maximum Level (ML) was going to be set for Cadmium on this complex matrix. The outcome of the PT confirmed that IF was a more difficult matrix than raw milk.

Since as of 01/01/2015 MLs for Cd in infant formulae and follow-on formulae, both in liquid and powdered form, will come into force according to Commission Regulation (Eu) No 488/2014, a PT on powdered IF based on animal protein will be organized.

As for Cd and Pb, the compliance statement will be also requested.

Molybdenum (Mo) will be also included in the exercise. The reason for this inclusion is in the EFSA “Scientific Opinion on Dietary Reference Values for molybdenum” (EFSA Journal 2013; 11(8):333) that evidences the difficulty to set a Dietary Reference Values for this element due to unavailability of data on its intakes. In this way NRLs could find it easier to face this element and produce data.

Arsenic instead has been included as this element was considered in this matrix for the first time.

23rd PT on Cd, Pb, total As and Hg, in freeze dried fish

The 23rd PT will be based on freeze dried freshwater fish.

The freeze dried state will enable the EURL to provide participants with stable and easy to use extra materials for their scope, such as internal quality control. The compliance statement of the sample with the ML set in the 1881/2006 for Lead, Cadmium and Mercury will also be requested.

As for Arsenic in fish, some NRLs had previously showed to be underperforming on this matrix. For this reason the concentration of this element will be carefully selected.

Objective: 22nd PT on IF: monitoring of the network performance on this matrix; comparing the performance with results obtained in the previous PT; training the network on the analysis of an element (Mo) proposed for the first time in the EURL PTs, seldom analyzed.

23rd PT: verifying network performance proposing fresh water fish. Production of suitable materials to avoid inconveniences or non-conformities to the PT scheme

Expected Output: from the EURL point of view, the issuing of 2 Short reports within forty days after the deadline of each PT; the issuing of 2 Final Reports including analytical and statistical comments, and the comparison with performance in previous PT, when appropriate.

At least 50% of NRLs are expected to provide the results of Mo in the 23rd PT.

From the NRLs, maintenance of the network performance in terms of z-score for consolidated analytes (Cd, Pb in IF and Cd, Pb and Hg in fish); achievement of satisfactory z-scores for As in IF; expected improvement of the network performance for Arsenic in fish.

8. New Reference materials for PTs

Further to the interest some NRLs showed in more than one occasion to determine chemical elements in fat animal matrices, feasibility of the preparation of a sample of butter or other animal fat samples will be studied.

Objective: production of new homogeneous material containing the elements of interest at planned concentrations. Development of a relevant analytical method for the determination of its sufficient homogeneity and stability.

Expected Output: set up of a procedure for the preparation of a homogeneous material, stable for the period of the exercise.

D. Technical and Scientific Support to NRLs and Third Countries

Article 32, section 1 (a, d, e, f)

9. Analytical support and training

Operational Objective 1, line 5 and 6 of the 2015 EC Workprogramme:

the EURL-CEFAO monitors the performance of NRLs through the control charts of z-scores, updated and made available to NRLs in the restricted area of the website. From control charts laboratories that need analytical support or training are identified, contacted by telephone or e-mail. Specific exercises or training are organised if convenient.

The EURL will organize at least one training course in its premises for the representatives of the NRLs. The NRLs these criteria will be selected considering: underperforming laboratories, new laboratories in the network or laboratories that have changed their analytical technique, visited laboratories evidencing the need of a extra dedicated training.

However the EURL is ready to welcome the representatives of the NRLs in its laboratories and, upon request, is willing to organize training courses for them. In the same way, the EURL can also organize training courses for Official Laboratories of Candidates Member States and Third Countries, always upon request.

Official analyses are performed, if necessary.

During the "Annual Workshop of NRLs" a technical training will be conducted by the EURL and/or international experts.

Objective: meet the needs of NRLs by organising an *ad hoc* training, if necessary, and providing proper analytical support.

Expected Output: general satisfaction evidenced through the questionnaire distributed to participants.

10. Provision of reference materials

Operational Objective 1, of the 2015 EC Workprogramme:

In 2015, being both PTs based on lyophilised materials, it will possible to have some extra samples of infant formula and fish to distribute to NRLs. Upon request the EURL will distribute them to the laboratories.

In order to perform the follow-up actions, reference material will be produced and/or distributed to the laboratories, if necessary.

Objective: provision of extra samples of infant formula and fish useful for the NRLs analytical activity. Provision of reference material for specific exercises foreseen for the follow up activity.

Expected Output: use of material by NRLs for their internal scopes and for specific extra exercises.

11. Visits to NRLs and international mission for scientific information

Operational Objective 1, line 5 of the 2015 EC Work-programme:

the EURL-CEFAO carefully selects the NRLs to visit in order to offer analytical support to the NRLs and enhance the follow-up actions.

Two visits to the underperforming laboratories, new laboratories or laboratories that have changed their analytical technique will be arranged. During the visit the EURL representatives assist and train the NRL staff on practical and theoretical topics.

Objective: visits that may be useful for NRLs from a practical point of view and to strengthen the relationship with the laboratories as well.

Expected Output: general satisfaction expressed in the questionnaire dedicated to NRLs after the visit and an improvement of the laboratory's analytical performance.

12. Organisation of the workshop.

Operational Objective 1, line 5 of the 2015 EC Work-programme:

an "Annual NRLs–EURL Workshop" will be organised and specific topics of common interest will be proposed.

The EURL-CEFAO representatives will show the outcome of the PTs carried out adding analytical comments on the difficulty or underperformance of the laboratories. Experts will be invited to present topics of common interest and/or to train the participants.

In order to increase the active participation of NRLs the EURL will propose them to give a presentation based on a topic of common interest during the Workshop.

Objective: to organize a workshop with topics of interest for the NRLs. To create occasions to exchange ideas and points of view among participants.

Expected Output: general satisfaction through the questionnaire dedicated to NRLs and participation of the representatives of all Member States.