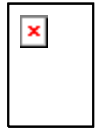


Work Programme for 2012

1. General tasks of EURL

- 1.1. Participation in annual co-ordinating meetings and general management activities of other EURLs for residues, as far as necessary.
- 1.2. Technical and scientific support to the Commission and its offices.
- 1.3. Compilation of the Technical and Financial Report for 2011 by 31 March, 2012
- 1.4. Compilation of the planned activities and estimated budget for 2013 by 1 September 2012.
- 1.5. Maintenance of contacts to already existing National Reference Laboratories (NRLs) and build-up of contacts to newly selected NRLs. The tasks of the EURL and NRLs is to cover dioxins, dioxin-like PCBs and indicator PCBs in food and feed with both confirmatory and screening methods. However, the structure and capabilities of NRLs differ from Member State to Member State requiring a more complex system of linking the NRLs with the EURL/NRL network. Therefore, the EURL compiled a list with all NRLs and contact points in this field and keeps this list updated. The list includes contact data and information about analytical capabilities.
- 1.6. In cooperation with the competent NRLs, maintenance of contacts to Official Laboratories (OFLs) and build-up of contacts to newly selected OFLs in cooperation with NRLs, for inclusion of OFLs in proficiency tests (PTs).
- 1.7. Cooperation with international organizations, in particular EFSA, CEN, WHO and UNEP (also for harmonization of requirements in the field of POPs analysis), where necessary.
- 1.8. Documentation services (updating of the CIRCA platform/publicly accessible EURL-website on regular basis with focus on disseminating information to NRLs. Constant monitoring of analytical methodology and EU legislation).
- 1.9. Participation and presentation of EURL activities at most important international conferences in the relevant area.

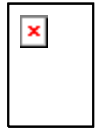


2. Development and validation of analytical methodology

- 2.1. Performance of **two proficiency tests (PT) for determination of dioxins and PCBs in food and/or feed** for further improvement of analytical methods with regard to correct determination of PCDD/Fs and PCBs by screening or confirmatory methods (see 3.3).
- 2.2. Testing, comparison of performance, further development and validation of **automated extraction methods** (pressurized liquid extraction: PLE system [FMS]; ASE system [Dionex]; SpeedExtraktor [Büchi]) and **manual extraction methods** (Twisselmann/Soxhlet extraction and ultrasonic extraction) for different food and feed matrices using different extraction solvents/solvent mixtures and conditions as permanent task. Inclusion of the important aspect of the application of different drying agent for pre-treatment of the sample before extraction.
- 2.3. In combination with the different extraction methods the EURL will continue the evaluation of **automated and semi-automated clean-up procedures** using a fully automated system and combinations of automated clean-up steps for further improvement of the complete methods for PCDD/F and PCB analysis.
- 2.4. Development of a fast **HRGC/HRMS** methods for control of EU regulations in food and feed for sum TEQ of dioxins, furans and dioxin-like with particular consideration of the comparison of the applicability of different stationary phases of GC columns for separation of all relevant PCDD/F, DL-PCB and NDL-PCB congeners
- 2.5. Evaluation of performance of **HRGC/MS-MS screening methods** for the analysis of PCDD/Fs, DL-PCBs and especially NDL-PCBs in food and feed matrices. Therefore the comparison of a HRGC/TripleQuad MS system (Thermo) will be evaluated, especially regarding limit of quantification, trueness and precision.
- 2.6. In order to have a more comprehensive overview on substances with dioxin-like activities, the EURL initiates the further development of suitable methods for the inclusion of **polybrominated dibenzo-p-dioxins and dibenzofurans (PBDD/Fs)** in the scope of the analysis of different food and feed matrices for PCDD/Fs and PCBs. This will be a permanent task of the EURL.
- 2.7. Focus will remain on **performance studies and evaluation of applicability of the CALUX technology** commercially available within Europe for screening of samples within the scope of official feed and food control, involving the DR-CALUX (Bio-Detection Systems, Netherlands, using H4IIE rat hepatoma cells, the XDS-CALUX (Xenobiotic Detection Systems, USA), using H1L7.1c2 mouse hepatoma cells, and H1L6.1c2 mouse hepatoma cell lines from University of California Davis, USA - referred to as "UCD cell lines" - being the source of the cells distributed by the XDS company.



European Union Reference Laboratory for Dioxins and PCBs in Feed and Food

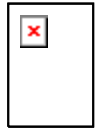


State Institute for Chemical and Veterinary Analysis of Food, Freiburg, Germany

Performance studies will be based on new comprehensive criteria for bioanalytical methods laid down in amendment of Commission Regulation (EC) No 1883/2006, currently available as SANCO/10376/2011 (Food), and in amendment of Commission Regulation (EC) No 152/2009 available as SANCO/10557/2011 (Feed). Studies will include extensive matrix-matching calibration experiments for most food and feed matrices of interest, aiming at deriving matrix-matching performance characteristics such as sensitivity, recovery, precision, working range, false-compliant and false-noncompliant rates, as well as bioassay cut-off concentrations to be used in routine for checking sample compliance with EU legal limits. These studies shall be carried out in 2 sets each, i.e. they shall be based on 1. spiked samples (“initial validation”), and 2., on “naturally” contaminated samples (“re-validation”) for each sample matrix, involving most significant congener patterns. They will comprise sample extraction and clean-up, cell growth and handling, measurement of the cell response, and calculation and interpretation of results, allowing for evaluation of matrix effects, optimum cell culturing conditions and overall analytical performance. After an agreement was signed with UC Davis (USA) in June 2010, the EURL has received new “3rd generation” (G3) H4L7.5c1 rat and H1L7.5c3 mouse hepatoma cell lines, recently developed by Prof. Mike Denison, UC Davis. These cell lines contain 20 DREs (DRE = dioxin responsive element). In comparison to the cell lines currently in use containing only 4 DREs, those new G3 cell lines are much more sensitive, but possibly also more susceptible to adverse effects from sample matrices. First promising tests and optimization studies were carried out in 2011 on H1L7.5c3 mouse hepatoma cells, during which the background response could be significantly reduced, a pre-requisite for their use as detection systems for checking low action and maximum levels in European feed and food control. Slightly deviating new cell clones also containing 20 DREs currently developed by Prof. Denison, probably less sensitive towards background interference to be made available to the EURL in early 2012 may serve this purpose even better.

Using these new “G3” cell lines with 20 DREs as detection systems in dioxin screening might require comprehensive fine-tuning of extraction and clean-up methods most of which are already optimized by EURL for use with the cell lines currently commercially available. Part of the contract with UC Davis aims at the further use of these cell lines after validation by the EURL, within the EURL/NRL network and European official laboratories for feed and food control.

All procedures, and validation and quality control data derived will be prepared, handled and evaluated according to EU legislation, involving the new comprehensive criteria for bioanalytical methods and DIN ISO 17025 standards for apparatus and general working procedures.



3. Quality assurance and quality control

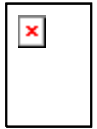
- 3.1. Maintenance of in-house QA/QC activities within the scope of the ISO 17025 accreditation of all analytical work done within the EURL.
- 3.2. Further evaluation of QA/QC tools, measures and techniques for cell culturing in bioassays for several different cell lines. Cooperation with NRLs using bioassays will be further intensified and possibilities for validation in interlaboratory studies evaluated
- 3.3. Organisation of **two interlaboratory studies (proficiency test, PT)** on determination of dioxins, furans, dioxin-like PCBs and marker PCBs in **food** and / or **feed** (see 2.2). The PT will be addressed to NRLs with **confirmatory methods** (based on GC/HRMS, GC/MS or GC/ECD, depending on the analyte) and **screening methods**. Results will be discussed and conclusions be drawn at two EURL/NRL workshops organized in the first respectively second half of 2011.

4. Technical and scientific support to Member States and the Commission, inclusive arbitration and training activities

- 4.1. Analytical support and training to Member States (NRLs) and Commission upon request
- 4.2. During evaluation of the new criteria for bioanalytical methods it became obvious that a guideline for how to put into practice what has been laid down in EU legislation (currently defined in SANCO/10376/2011 (Food) and SANCO/10557/2011 (Feed)) might help to better apply EU legislation. A **Bioassay Expert Working Group** was formed in May 2011 to draft a "Guideline for performance criteria and validation procedures of bioanalytical screening methods used in controls of dioxins and dioxin-like compounds in feed and food" to be issued by the EU-RL/NRL network in early 2012. The scope of this guideline will be to provide rules and ways to demonstrate sufficient performance of bioanalytical methods to make sure that those methods
 - comply with the analytical criteria as currently defined in SANCO/10376/2011 (Food) and SANCO/10557/2011 (Feed)
 - have been validated according to the procedures described in this guideline
 - are suitable for checking of sample compliance with EU legal limits
- 4.3. Mission to NRLs and dissemination of scientific information if necessary
- 4.4. Individual follow-up and assistance to NRLs of which the analytical results from the interlaboratory study are not satisfactory



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- 4.5. Analyses of official samples (submitted by EU Member States in case of dispute between Member States or in case of analytical problems with a responsible NRL)
- 4.6. Organisation of two annual workshops and discussion of interlaboratory studies in both fields food and feed for dioxins, dioxin-like PCBs and indicator PCBs (see 2.2, 3.3 and 3.4) for NRLs using confirmatory methods (based on GC/HRMS, GC/MS or GC/ECD, depending on the analyte) and / or bioassay screening methods with follow-up for underperforming NRLs. The workshop concept will be based on organization (at least) of one workshop per year at the EURL in Freiburg and allow the organization of the second workshop at one of the NRLs.
- 4.7. Organisation of specific training for NRLs on request
- 4.8. For specific tasks, working groups might be formed to address specific needs with regard to physical-chemical or bioanalytical aspects, e.g. regulation, development of physical-chemical screening methods, validation schemes, or practical guidelines on validation (in particular for bioanalytical methods).