# WORK PROGRAMMES

# FOR

# COMMUNITY REFERENCE LABORATORIES

# 2009

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# VETERINARY PUBLIC HEALTH

# (Residues)

1. Berlin **(Beta-agonists, coccidiostats, anthelmintics, NSAIDs)**
2. Bilthoven **(Hormonal growth promoters, sedatives, mycotoxines)**
3. Fougères **(Antibiotics, forbidden substances, dyes)**
4. Rome **(Heavy Metals)**

# WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR RESIDUE TESTING, 2009

## Group of substances: A5-B2a-B2b-B2e

CRL FOR RESIDUES, BVL IN BERLIN, DE

## I. LEGAL FUNCTIONS AND DUTIES

The functions and duties of the 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, pp. 1 – 141, corrected and republished in Official Journal of the European Union L 191, 28.05.2004, pp. 1 - 52).

## 1. OBJECTIVES FOR THE PERIOD JANUARY - DECEMBER 2009

**A** **General tasks (~ 10 %)**

**B** **Development and validation of analytical methods (~ 26 %)**
*Article 32, paragraph 1(c)*

**C** **Quality assurance and quality control including the development of incurred test material and the organisation of a proficiency test (~ 25 %)**
*Article 32, paragraph 1(b)*

**D** **Technical and scientific support to Member States, the Commission, including arbitration and training activities (~ 39 %)**
*Article 32, paragraphs 1(a)(d)(e)(f)*

## 2. WORKING PLAN FOR THE PERIOD JANUARY - DECEMBER 2009

### A General Tasks

**sub items**

1. **Meeting 4 CRLs**

   EC-4 CRL for residues management

2. **EC/CRL related EC and International Bodies; Co-operation with international organisations**

   Technical and scientific support will be provided to the Commission institutions DG SANCO as e. g. the evaluation of the NRCPs of the MS, DG JRC and EFSA.
   The cooperation with international organisations is an ongoing task and will be intensified to the extent possible. At the moment the CRL is participating in ISO working groups for standardisation, in CEN working groups for standardisation, in the Codex alimentarius committee CCMAS and in the CCQM working group OAWG of the CIPM.

3. **Reports, cost estimate, documentation**

   Several reports will be issued, e.g. the workshop report, the report on the proficiency test 2009, the technical and financial reports on CRL working period 2008, the interim report 2009 as well as the cost estimate and work plan 2010. Other reports will be provided upon request.

### B Development and Validation of Analytical Methods

**sub items**

1. **Development and validation of a method for nitroimidazoles in honey by LC-MS/MS**

   Originally, in 2005 (Five-Year-Plan), the determination of homogeneity in pig muscle and plasma had been planned for 2009 but could already be finalised in 2007 in the framework of the production of incurred material. Instead, the development and validation of a method for the detection of nitroimidazoles in honey is planned due to some incidents which occurred in Third Countries, mainly in China. The validation should be finished within the working period.

2. **Development and validation of a method for benzimidazoles in muscle by LC-MS/MS**

   The adaptation of the multi-residue method for anticoccidials had originally been planned, but will be postponed to 2010 since the results of the 2008 PT for benzimidazoles in milk were not satisfying. This is why the proficiency test will be repeated in 2009, but using the matrix muscle. For this purpose a method has to be developed and validated, which has to be finished in the beginning of 2009 in order to be able to analyse sample material for homogeneity and stability.

3. **Development and validation of a method for metamizol in milk**

   Metamizol is a basic NSAID which cannot be analysed together with the acid NSAIDs like phenylbutazone, diclofenac, flunixin, etc. Therefore a method will be developed and validated for the group of compounds which also comprises ramifenazone, antipyrine and their metabolites.

4. **Development of multi-target screening methods**

   More and more often, multi-analyte/multi-substance-group methods are requested for the screening of sample material. Therefore an LC-MS/TOF method will be developed. Due to the complexity of this work it is planned as multi-annual task.

5. **Stability studies for all substance groups**

   The stability testing of analytes in solution and in matrix is required by CD 2002/657. It was agreed upon that it is not necessary for each individual laboratory to carry out these investigations on its own, but that they can use stability data provided by the CRLs. Therefore and for the production of proficiency test material and in-

house reference material as well as for the CRL's own needs, stability studies are and will be carried out for all analytes we are responsible for in several incurred matrices and in solutions.

6. **Research and identification of unknown compounds**

   New or unknown compounds illegally used for veterinary purposes or illegally used as growth promotors will be investigated and identified. On the basis of sample material obtained or information gathered from other sources, studies will be carried out to identify individual compounds. Special attention will be paid to derivatives of known substances or unknown metabolites.

## C Quality assurance and quality control including the development of incurred test material and the organisation of a proficiency test

**sub items**

1. **Maintenance of equipment, documentation, audits, management**

   Maintenance of in-house QA/QC activities as a consequence of the accreditation according to ISO 17025.

2. **Proficiency test on benzimidazoles in muscle**

   Originally a proficiency test on beta-agonists had been planned for 2009, but due to the unsatisfying results for benzimidazoles in milk in 2008, a PT for benzimidazoles in muscle will be performed instead.

3. **Participation in PT by commercial providers**

   In order to document our proficiency not only in the framework of our own proficiency tests, it is necessary to participate in commercially offered PTs as well. Furthermore, this way, PT providers can be checked for quality.

4. **Production of incurred sample material**

   It is planned to treat cattle with several beta-agonists to study the depletion in urine and hair.
   Moreover, cattle will be treated with different benzimidazoles for the production of the material for PT 2009.

## D Technical and scientific support to Member States, the Commission, including arbitration and training activities

**sub items**

1. T**echnical, scientific support and training**

   Technical and scientific support and training will be provided on request to NRLs and official routine labs as well as to official laboratories of Third Countries.

2. **Follow-up of PT**

   Follow-up measures will be carried out if necessary in compliance with the Commission draft guidelines of 2007.

3. **Provision of standard substances incl. procuring, storage, administration, documentation, shipment**

   Small amounts of standard substances will be provided to official laboratories on request.

4. **Analysis of official samples**

   Official samples will be analysed in case of disputes between MS and in case of analytical problems within a responsible NRL.

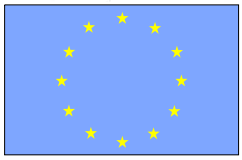
5. **Visit to NRLs**

   Normally one NRL will be visited per year after consultation with the Commission on necessity. Scientific information and technical support in form of methods, SOPs etc will be provided and discussions on specific problems like QA, QC, validation, legislation etc will be led.

6. **Organisation and performance of a workshop**

   A workshop will be organised on benzimidazoles. The evaluation of the 2008 PT and forthcoming 2009 PT will be treated and further specific questions will be discussed depending on the needs of the participants. For this purpose a questionnaire will be distributed beforehand.

It is understood that the above-mentioned objectives are not exclusive of other work of more immediate priority which may arise during the reference period in question.



# COMMUNITY REFERENCE LABORATORIES IN THE FIELD OF VETERINARY PUBLIC HEALTH WITHIN THE EUROPEAN UNION

## CRL for residues RIVM-ARO at Bilthoven, NL

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## Workprogramme

## January 1st, 2009 – December 31st, 2009

**Status 8 September 2008**

# WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR RESIDUE TESTING, RIVM, Bilthoven

## HORMONAL GROWTH PROMOTING COMPOUNDS, SEDATIVES AND MYCOTOXINS

# January 2009 – December 2009

### LEGAL FUNCTIONS AND DUTIES

The functions and duties of the 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, 30.04.2005, pp 1-141, corrected and republished in Official Journal of the European Union L 191, 28.05.2005, pp 1-52.

| 1. OBJECTIVES FOR THE PERIOD JANUARY 2009 – DECEMBER 2009 |
|---|

**A: General Tasks**

**B: Development and validation analytical methods** *Article 32, paragraph 1(c)*

**C: Quality Assurance and Quality control including the organisation and implementation of proficiency tests** *Article 32, paragraphs 1 (a)(d)(e)(f)*

**D: Technical and scientific support to NRLs and third countries**

| Work programme for the period January 2009 – December 2009 |
|---|

General Tasks

1) Meeting 4 CRLs, CRLs for residues management

Participation in annual co-ordination meeting and general management activities

2) Technical and scientific support to the Commission

Upon request, technical assistance will be given to the European Commission and its offices and its related institutes like the Joint Research Centre (JRC), the European Food Safety Authority (EFSA) and the European Agency for the Evaluation of Medicinal Products (EMEA).

3) Compilation of annual report and cost-statement

Annual reports and cost statements with respect to the 2008 contract period will be prepared before 1 April, 2009.

4) Co-operation with international organisation

Specific: EC/CRL related co-operation with International Bodies (e.g. AOACi, Eurachem, Codex, CVMP, TAIEX, EMEA, EFSA, JRCs, IRMM) on method validation, analytical methodology, reference materials and performance quality criteria (communication, co-ordination, and harmonisation).

5) Documentation and information services

Specific: Developments with respect to analytical methodology, (EU) legislation and the results of relevant scientific studies are constantly monitored. In addition, information on the use of new compounds or alternative approaches to improve the growth of livestock will be collected and used as input for future studies. Communication about issues of interest for NRLs will be through the annual workshop.

This CRL-website is maintained by the CRL-documentation services. The CRL website will be maintained with the objective for 2009 to further implement its use within the CRL/NRL network.

An evaluation of the Annual National Plans of 2008 will be produced. A more direct response is possible now that the information is available on-line through the internet. A list of matrix/method combination which was prepared by the CRLs (Guidance paper of December 2007), has been distributed as a reference that will be the basis for further evaluations. When necessary, specific suggestions for improvement will be included in the report. This product is scheduled for January 2009.

Specific products related to A:

| Topic | Product | Planned for |
|---|---|---|
| 1 | Meeting minutes prepared by the Commission | January 2009 |
| 2 | Advises (reports, e-mails or letters) | Ongoing on an Ad Hoc basis |
| 3 | Annual report and cost statement | 1 April 2009 |
| 4 | Co-operation | Ongoing on an Ad Hoc basis |
| 5 | Documentation and Information Services | Ongoing on an Ad Hoc basis |

| | | |
|---|---|---|
| | Evaluations of ANPs and results reported | February 2009 |

**B: Development and validation of analytical methodology** (Article 32, paragraph 1c)

Development and validation of analytical methods is one of the major tasks of the CRL. New analytes, or metabolites of compounds, will have to be included on a regular basis, new technologies will have to be implemented, based on the results of research activities within the CRL-NRL network and methods will have to be re-evaluated on specific aspects. Adequately validated methods for all analyte: matrix combinations included in the list of MRPL-values will be maintained and made available on request. Regular updates are foreseen.

Specific

6**) Maintenance of analytical methods**, inclusive additional validation in case of extension of the scope. In spite of the wide range of analytical methods currently validated, there will be a remaining need to extend the scope of such methods in order to include additional compounds, newly identified metabolites or new matrices. This is an ongoing activity.

**7) Development of generic (non-targeted) approaches** for the screening and confirmation of anabolic compounds. Over the past years, numerous targeted analytical methods have been developed with the objective to detect and confirm the presence of specific residues in biological samples. Currently, NRLs have a wide choice when selecting appropriate analytical methods for their Annual Residue Plan, based e.g. on the compounds listed in the CRL guidance paper of December 2007. Though highly suitable for their purpose, these methods all have in common that they are targeted, meaning that there always has to be a pré-determined specific list of compounds. During the previous years the CRL has worked on new approaches, using advanced Mass Spectrometric techniques (MS) based on Time of Flight (ToF) MS. These so-called fast scanning techniques enable us to collect far more data than previously, opening possibilities for non-targeted analyses. Proof of principle was published by us during the EuroResidue VI conference (May 2008, The Netherlands). Non-targeted analyses for anabolic compounds will be the topic of the 2008 mini-symposium during the annual CRL/NRL workshop in October 2008. The objective for 2009 is to further develop this approach, to set up a working group to further discuss, harmonized and validate this approach. Part of the discussions will focus on the integration for instrumental techniques with generic approaches based on bio-recognition (response) approaches as they are currently being developed e.g. within the BIOCOP project. This work was previously undertaken as ToF method development.

8) **Studies to detect abuse of natural hormones**. Based on the methods developed within the CRL, which were presented during Euroresidue VI (May 2008, The Netherlands), selected populations of samples were analysed for their steroid profiles (precursors, physiological active compounds and their metabolites). Already in 2008 this approach proved to be useful in identifying treated animals in practical cases where a good correlation was found with the results of hair analyses. This work will continue in 2009 with the further extension of the database of compounds. Previously collected data are of limited interest because most of the metabolites were not included. Moreover, conjugated steroids were not measured before. This work will continue of close cooperation with a group of laboratories, partly also involved in a UK (HFL) study sponsored by DEFRA. Next to this general approach, specific studies will continue focussing on making the detection of steroid-esters in hair more generic, continued evaluation of the practicability of C12/C13 measurements and the detection of Somatotropin.

9) **Identification of new compounds.** Identification of new and unknown compounds illegally used for growth promoting purposes. On the basis of sample materials received (biological samples, cocktails or animal feed) or information obtained through other sources, studies will be undertaken to identify individual compounds. When necessary, based on *in vitro* studies, the metabolism will be studied. Special attention will be given to the use of e.g. pro-hormones.

Specific products related to B:

| Topic | Product | Planned for |
|---|---|---|
| 6 | Maintenance and extension of methods | Ongoing |
| 7 | Development of generic (non-targeted) approaches | Progress report (December 2009) and scientific publications |
| 8 | Studies to detect abuse of natural hormones | Progress report (December 2009) and scientific publications |
| 9<br><br>ongoing | Identification of new compounds, inclusive studies on metabolism | Ongoing activity, progress report December 2009 |

PM activities within EU framework projects, e.g. BIOCOP and MONIQA

**C: Quality Assurance and Quality Control.**

**10)** Maintenance of in-house QA/QC activities in consequence of the ISO 17025 accreditation of all analytical work done within the CRL (no costs included).

***11)*** Organisation of proficiency tests for Clortestosterone-acetae (metabolite of) in bovine urine. Further, research studies will be organized for Testosterone, inclusive the intact ester in hair, and/or Zeranol. Proficiency tests are organized on a regular basis, on average 3 tests per period of 2 years. Priorities are set on an annual basis, after consultation of the NRLs, amongst others during the workshops. As a rule, the proficiency tests are based on incurred materials, obtained during a controlled animal experiment.

***12)*** Production of incurred sample material.

An animal studies in preparation of future proficiency tests are scheduled for 2009. Priorities will be set during the 2008 annual workshop.

Specific products related to C:

| Topic | Product | Planned for |
|---|---|---|
| 10 | Annual re-accreditation | November 2009 |
| 11 | Report proficiency study CLAD (metabolite Chlorotestosterone-acetate) of Zeranol in bovine-urine<br><br>Report research study Testosterone-ester in hair. | Preliminary reports are prepared within 2 months after conclusion of the proficiency tests. Full reports within 6 months |
| 12 | Technical report animal study | Following animal study |

**D: Technical and scientific support to Member States and the Commission, inclusive arbitration and training activities.**

**13)** Analytical support and training. Analytical support, both by means of advise or training, will be given to NRLs upon their request.

Missions to NRLs and diffusion of scientific information. Missions will be undertaken to specific NRLs on the basis of their individual needs, e.g. in order to discuss and evaluate the results of a proficiency test. Analytical support. For 2009 a visit of the NRL to one or more of the Baltic states is foreseen. This choice is based on the current progress in the NRLs in the newer EU-Member States.

Provision of standard substances including storage, administration, documentation and shipment. *Annex V, Chapter 2, section 1 (j).* When necessary and possible, selected compounds will be purchased or (custom) synthesised.

Analyses of official samples. *S*amples submitted by EU Member states in case of dispute between Member States or in case of analytical problems within a responsible NRL will be analysed.

Organisation of annual workshop on residue analysis. The topic will be selected on the basis of a consultation of the NRLs during the 2008 workshop.

Specific products related to D:

| Topic | Product | Planned for |
|---|---|---|
| 13 | Training documentation and/or report | On an Ad Hoc basis |
| 14 | Visit report | December 2009 |
| 15 | Ongoing | Annual overview |
| 16 | Ongoing written reports | On an Ad Hoc basis |
| 17 | Workshop proceedings | December 2009 / January 2010<br><br>(2009 workshop) |

COMMUNITY REFERENCE LABORATORY

# WORK PROGRAMME OF THE COMMUNITY REFERENCE LABORATORY AT THE FRENCH FOOD SAFETY AGENCY (AFSSA)

Antimicrobials and dyes

Group of substances: B1, A6, B3e

**Laboratoire d'études et de recherches sur les médicaments vétérinaires et les désinfectants**

***Contract period: January 2009 – December 2009***


**P. SANDERS**
**Head of C.R.L.**

**&**

**E. VERDON**
**Deputy Head of C.R.L.**

REPUBLIQUE FRANÇAISE
**AGENCE FRANÇAISE DE SECURITE SANITAIRE DES ALIMENTS**
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**LEGAL FUNCTIONS AND DUTIES**

The functions and duties of the 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, pp. 1-141, corrected and republished in Official Journal of the European Union No L 191, 28.05.2004, pp. 1-52).

## 3. OBJECTIVES FOR THE PERIOD JANUARY - DECEMBER 2009

**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 and implementation of proficiency tests.**
*Article 32, paragraph 1 (b, c)*

**D. Technical and scientific support to NRLs and third countries**
*Article 32, paragraph 1(a, d, e, f)*

## 4. WORKING PLAN FOR THE PERIOD JANUARY - DECEMBER 2009

### A. General Tasks
*Article 32, paragraph 1 (e)*

1. Meeting 4 CRLs, CRLs residues management,
2. Technical and scientific support to the Commission,
3. Compilation of annual report and cost estimate,
4. Co-operation with international organisations,
5. Documentation services, inter change of information via the website.

### B. Development and Validation of Analytical Methods

**A** *Article 32, paragraph 1 (a, c)*

6. Development and Confirmatory method for antimicrobials in different matrices (muscle, milk, eggs, …).

6.1 Multi-antimicrobial family method by LC-MSMS (discontinued)

The validation of the 1st step analysis of the method regarding the selective identifying screening is now completed for muscle tissue and for milk. A

workshop with a hands-on training session was proposed to the EU-NRLs in October 2007. Some adaptations of the method for specific antibiotics and further validation for the milk matrix were implemented during 2008.
Now validation for the two main matrices (muscle, milk) along with training session for the network of NRLs are effective, consequently further development activity for this multi-antibiotic LC-MSMS method will be paused in 2009 and efforts will be made to investigate and solve specific possible problems of transfer of the method to laboratories. Extension to other matrices (egg, honey) will be evaluated afterwards.

6.2 Confirmatory method for dyes in fish and aquaculture products (extended development)

Following new findings in the residue control of imported aquaculture products and new developments regarding pharmacologically active dyes possibly found in these products, a particular attention will be paid to extend the malachite green LC-MSMS method previously developed and validated in 2003 and transferred to EU-NRLs in 2004 (CRL workshop of 21-22 October 2004). Additional dye residues will be considered including at least crystal violet, leucocrystal violet and brilliant green.

6.3 Non-targeted analysis of antibiotic residues in meat and in milk – Physico-chemical part (new development)

Research and development on non-targeted monitoring of antibiotic residues by physico-chemical methods is now getting possible thanks to enhancement of new high resolutive technologies such as time-of-flight mass spectrometric instruments (ToF, Q-ToF) and/or even newer high resolutive mass spectrometric instruments such as Orbitrap MS. The CRL from AFSSA-LERMVD completed in 2008 the acquisition of such a technology, LC-LT-Orbitrap-FT-MS, and will now start to investigate in this area of research during the 2009-2011 period. It is particularly proposed here to get a better knowledge of the characteristics of the full-scan monitoring of about 50-100 antibiotic residues in meat and in milk with the objective to be in position to give a methodology for exact molecular identification of each compound in biological samples. The final aim of this study will be to implement an analytical strategy able to evaluate any relevant unspecified molecular signals by means of high resolution exact mass measurements (30,000 < Resolution < 100,000) whatever the biological matrix of concern it is.

7. Study of screening tests (continued).

A continuous evaluation of the performance of different screening kits for antimicrobial residue testing (either microbiological or immunological) proposed by manufacturers to be applied on different matrices will be investigated.

1. Evaluation of a biological kit for malachite green analysis in aquaculture products
2. Evaluation of a microbiological kit for the screening of antimicrobial residues in fish (i.e; PremiTest, DSM, The Netherlands).

8. Non-targeted analysis of antibiotic residues in meat and in milk – Biological part (new development).

Under this issue will be addressed a microbiological study complementary to the physico-chemical part of the non-targeted analysis of antibiotic residues in meat and in milk as expressed under issue 6.3.

## C. Quality Assurance and Quality Control

*Article 32, paragraph 1 (b, c)*

8. Organisation of proficiency tests (characterisation of the material, packaging, evaluation, report)

According to our agreement with the network of NRLs, the CRL will proceed in 2009 to the organisation of a large Proficiency Testing Study dedicated to the evaluation of the overall strategies for monitoring antimicrobial substances in meat or milk products.

8.a Antimicrobials

The antimicrobials of choice should be at least one representative compound of each family of antimicrobials, ie. penicillins, cephalosporins, tetracyclines, aminoglycosides, macrolides, sulfonamides, quinolones, amphenicols which are registered in Annex I of Directive 2377/90/EC. The matrix of choice might be either porcine muscle meat or cow raw milk.

8.b Banned substances

The banned substance of choice shall be the malachite green (MG) as a come back after the last 2005 PT for malachite green and after having proceeded to interlaboratory analysis of carbadox and olaquindox (2006), chloramphenicol (2007) and nitrofurans (2008). The matrix (ces) of choice might be if technically possible a combination of aquaculture products (fish, shrimp).

8.c Proficiency test in relation with coordinated monitoring programme

No coordinated monitoring programme for 2009 was defined by the Commission.

9 Production of incurred sample material

9.a According to the previous point, the different sampling materials will be produced by the CRL in accordance with the standards of testing material preparation (homogeneity and stability studies).

9.b Following the collaboration with DG-JRC-IRMM (Reference Material Unit), and according to the need in the Quality Control of analytical methods for antibiotic residues in food, new CRM might be investigated by CRL-AFSSA-LERMVD-Fougères with rounds of homogeneity-stability studies in 2009 for some antimicrobials.

## D. Technical and Scientific Support to NRLs in the Member States, the Commission and Third Countries

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

10. Analytical support and training

10.a Participation to SARAF training courses (June 2009, October 2009).

10.b Organisation of CRL-AFSSA-LERMVD training courses for scientists from Member States, Acceding Countries and/or Candidate Countries and from Third Countries, on request.

An already forecast study is a one week training of the Lithuanian NRL of Vilnius in microbiological screening and in LC-MSMS post-screening analyses of antibiotics scheduled for 1st semester 2009.

11. Missions to NRLs and Third Countries - diffusion of scientific information

11.a Projection of 3 visits to NRLs of the network in the 27 Member States

11.b International missions for scientific information dissemination

11.c Follow-up and improvement of the 5-year-old CRL Website

12. Provisions of standard substances including storage, administration, documentation, shipment, etc

13. Analysis of official samples

As a CRL, the AFSSA-LERMVD laboratory will go on with analysing at a reference status some of the official samples coming from the NRLs and at their demand.

The specific requests rising from certain NRLs to analyze in their place a part or all of the confirmatory sets of samples coming from their National Monitoring Plan especially for confirmation of Group B1 compounds will not be accepted as this kind of workload is neither a priority in CRL activities nor a specific task requested by the Directive 96/23/EC.

14. Organisation of a workshop

A workshop for the network of NRLs in charge of antimicrobial residue control in food will be organized. The main subject will be the confirmatory analysis of dyes including malachite green, crystal violet, and brilliant green, and possibly other relevant dyes, together with their metabolites in fish and shrimp by LC-MSMS.

Other possible issues to be taken into account during this workshop:

- Advances in Validation of Screening and Confirmatory Methods for Antimicrobial Residue Monitoring (Group B1).

- Evaluation of the results of the most recent Proficiency Testing Studies provided by the CRL.

15. Analysis of the National Residue Monitoring Plans of the Member States

According to the request of the Commission, the CRL will consult on line the RESIDUE database dealing with proposed National Residue Monitoring Plans and their Year N-1 results. Existing tables will be loaded at the CRL location. Information will be extracted and analysed by a CRL scientist to check for the adequateness of methods/matrices/combinations proposed by each of the Member States and at the European level. The CRL will publish a report for the Commission before the end of March 2009.

# Work Programme and budget request of the Community Reference Laboratory for Chemical Elements in Food of Animal Origin at the Istituto Superiore di Sanità (CRL-ISS) Viale Regina Elena 299 00161 Rome, Italy

**Contract period: 1 January – 31 December 2009**

**LEGAL FUNCTIONS AND DUTIES**

The functions and duties of the 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, pp 1 – 141, corrected and republished in Official Journal of the European Union L 191, 28.05.2004, pp 1 – 52).

## 5. OBJECTIVES FOR THE PERIOD 01 JANUARY 2009 - 31 DECEMBER 2009

**A General tasks**

*Article 32, paragraph 1 (a, c, e, f)*

**B Development and validation of analytical methods**

*Article 32, paragraph 1 (a, c)*

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

*Article 32, paragraph 1 (b)*

**E. Technical and scientific support to NRLs and Third countries**

*Article 32, paragraph 1 (a, b, c, d, e, f)*

## 6. WORKING PLAN FOR THE PERIOD 01 JANUARY 2009 - 31 DECEMBER 2009

**E. General Tasks**

*Article 32, paragraph 1 (a, c, e, f)*

**1**. ***Meeting of all CRLs.***

The CRL-ISS will participate in the coordination meeting of the CRLs in order to exchange information on the activities performed during the established period. The outcome of activities will be discussed to harmonise the approaches adopted to assist the National Reference Laboratories (NRLs) and to optimise their interaction with the Commission services.

*(anticipated break-down: 1%; anticipated duration: as requested by the meeting and preparation of the relevant documents; resources needed: missions )*

**2**. ***Technical and scientific support to the Commission.***

*(anticipated break-down of these activities: 4%)*

- The CRL-ISS will provide the Commission with all the necessary support as regards the administrative duties and coordination services with the Commission in order to harmonise approaches and performance of activities among the NRLs.
- Technical and financial reports of the CRL-ISS activities will be prepared.
  *(anticipated break-down: 1%; anticipated duration: throughout the year, as necessary; resources needed: staff).*
- Whenever a dispute should arise between two Member States (MSs) or between an MS and a non-EU country on the results of the determination of substances under its responsibility, the CRL-ISS will offer its assistance in solving the problem.
  *(anticipated break-down: 1%; anticipated duration: research for a limited period; resources needed: staff, consumables)*
- An evaluation of the National Residue Monitoring Plans 2007 of the NRLs will be performed. The report will be sent to the Commission in due time.
  *(anticipated break-down: 2%; anticipated duration: 1 months; resources needed: staff)*

**3. *Compilation of annual report and cost estimate.***

- The reports on the activities carried out for the relevant contract period will be regularly submitted to the Commission.
- The Work-programme with the future work to be undertaken, together with the cost estimates, will be sent to the Commission as well.

(anticipated break-down: 1%; anticipated duration: throughout the year, as necessary; resources needed: staff, consumables)

**4. *Co-operation with international organisations.***

The CRL-ISS will cooperate with International Organizations (EMEA, EFSA, IRMM) as regards the analytical methodology and performance quality criteria.

(anticipated break-down: 1%; anticipated duration: throughout the year, as necessary; resources needed: staff, consumables)

**5. *Documentation services, interchange of information.***

*(anticipated break-down of these activities: 3%)*

- The CRL-ISS will also provide any information and/or technical and scientific assistance requested by the NRLs.

- All the activities performed by the CRL-ISS will be available in the web site. The NRLs can have access to the results of the Proficiency Tests carried out (Restricted Area), information on the Workshop organized, the *Handbook of Analytical Methods* for chemical elements, legislation and new relevant documents.

  *(anticipated break-down: 1%; anticipated duration: throughout the year, as necessary;* r*esources needed: staff, consumables)*

- The NRLs will be requested to submit to the CRL-ISS the revised information on the analytical methods already in use, as well as on the new methods adopted. This information will be collected for the NRLs in the *Handbook of Analytical Methods* for chemical elements.

  (anticipated break-down: 2%; anticipated duration: 1 month; resources needed: staff, consumables)

## F. Development and Validation of Analytical Methods

*Article 32, paragraph 1 (a, c)*

*(anticipated break-down of these activities: 45%)*

***6**. Analytical methods*

- In relation to a study that will be undertaken for the development of complex matrices for PTs, adequate analytical methods for the determination of As, Cd, Pb will be developed.

  (anticipated break-down: 25 %; anticipated duration: 6 months; resources needed: staff, consumables)

- A method for the determination of total tin in food is being developed and will be ended within the 2008. The work will be continued with the validation of the method and its application on canned food.

  (anticipated break-down: 20 %; anticipated duration: 6 months; resources needed: staff, consumables)

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

*Article 32, paragraph 1 (b)*

**7**. ***Maintenance of the QA/QC system to ISO/IEC 17025***.

- The CRL-ISS is accredited according to ISO/IEC 17025:2005 by the accreditation body Swedac. The activities relevant to accreditation status of the CRL-ISS will be constantly run.

- In order to implement quality, the following actions will be undertaken:
    - an ordinary Management Review will be carried out before the end of January 2009 to discuss some aspects of the Quality System.
    - a meeting for the evaluation of the CRL-ISS participation to external PTs will be held.
    - specific Standard Operative Procedures will be prepared when necessary
    - all accredited methods will be regularly applied in order to maintain their performance.
- the CRL-ISS will apply to the FAPAS, Central Science Laboratory, UK and to the Swedish National Food Administration, to carry out external PTs on metallic contaminants in food.

  *(anticipated duration: throughout the year, as necessary)*

**8**. ***Proficiency tests***

The CRL-ISS plans to become accredited as PTs provider according to the ISO IEC, Guide 43-1 and Guide 43-2, 1997.

- the 13th Proficiency Test on trace elements will be organised and conducted for the designated NRLs and the candidate countries.
- the PT will consist in two runs on As, Cd, Pb and Hg determination in two matrices/products to be agreed with the NRLs needs expressed during the Annual CRL-ISS Workshop 2008.
- the candidate materials (liquid or freeze-dried) will be tested for homogeneity, analysed and sterilized before the shipping to participants. After completion of each run of the exercise, the evaluation report will be prepared for distribution to the Commission and to the NRLs.
- A study will be undertaken for the development of complex matrices of animal origin such as processed food (cheese, sausages, wurstel, etc.) for the preparation of reference materials for PTs.

  *(anticipated break-down: 36%; anticipated duration: throughout the year, as necessary; resources needed: staff, consumables, comparative tests, subcontracting).*

## H. Technical and Scientific Support to NRLs and Third Countries

*Article 32, section 1 (a, b, c, d, e, f)*

(anticipated break-down of these activities: 9%)

**9**. ***Missions to NRLs and diffusion of scientific information***.

- Technical assistance will be given to the NRLs as required by circumstances, including visits to their premises, facilities and laboratories at the appropriate locations.
- A visit to two NRLs (probably Estonia and Finland) will be carried out to exchange information on their technical capabilities and scientific expertise in the analytical field and to provide them with any support needed. Details about MSs and the date will be agreed upon with the NRLs.
- The full reports on the visits will be sent to the Commission and to the relevant NRLs.

(anticipated break-down: 3%; anticipated duration: throughout the year, as necessary; resources needed: staff, missions)

**10**. ***Analytical support and training***.

- The technical personnel of the NRLs will be supported through their participation in the proficiency test.
- All problems related to performance detected by such proficiency test will be examined with the interested parties in order to minimise their occurrence in future activities.
- NRLs will also be assisted in the implementation of the performance of analytical methods and the interpretation of results.
- Technical and scientific support will be also provided to the NRLs of the Candidates Member States, on request.
- The reference materials produced for PTs will be made available to the NRLs on request for specific analytical needs.
- The information on reference materials and certified reference materials will be made available to the NRLs with particular regard to their proper use, subsampling, storage and general management.

(anticipated break-down: 1 %; anticipated duration: throughout the year, as necessary; resources needed: staff, consumables)

**11**. *Analysis of official samples*.

When a dispute between two MSs or between an MS and a non-EU country arises, the CRL-ISS will perform the official analyses of the samples for which there is disagreement.

(anticipated break-down: 1%; anticipated duration: throughout the year, as necessary; resources needed: staff, consumables).

**12**. ***Organisation of workshops***.

The results of the proficiency test mentioned under point 8 will be fully discussed during the relevant Annual Workshop 2009.

(anticipated break-downs: 4%; anticipated duration: throughout the year, as necessary; resources needed: staff, consumables, workshop).