WORK PROGRAMMES

OF

COMMUNITY REFERENCE LABORATORIES

2010

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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, 2010

Group of substances: A5-B2a-B2b-B2e

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 2010

A **General tasks (~ 14 %)**

B **Development and validation of analytical methods (~ 35 %)**
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 (~ 18 %)**
Article 32, paragraph 1(b)

D **Technical and scientific support to Member States, the Commission, including arbitration and training activities (~ 33 %)**
Article 32, paragraphs 1(a)(d)(e)(f)

2. WORKING PLAN FOR THE PERIOD JANUARY - DECEMBER 2010

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 (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 largest 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 proficiency test 2009, the technical and financial reports on CRL working period 2009, the interim report 2010 as well as the cost estimate and work plan 2011. Other reports will be provided upon request.

B Development and Validation of Analytical Methods

sub items

1. **Development and validation of test method for nitroimidazoles in feed**
   Since the administration in feed is one possible pathway for the application of banned substances to food-producing animals, the development and validation of a method for the determination of nitroimidazoles at therapeutic concentration levels (estimated) in feed will be performed.

2. **Integration of further nitroimidazoles of B2b-group into existing methods**
   It will be tested whether additional representatives of the substance group of nitroimidazoles (those which are not explicitly banned, i.e. formally spoken belong to group B2b) can be included into already existing LC/MSMS methods.

3. **Adaptation of multi-method for anticoccidials to cattle/pig in muscle and liver**

   This activity was interchanged with the development of a benzimidazole method in 2009; was agreed upon with COM

4. **Validation of method for beta-agonists in hair**

   The validation of a method for beta-agonists in hair will be carried out including the test on how far the well-know wash-out effect during rinsing applies to different substances.

5. **Development of multi-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 project it is planned as multi-annual task.

6. **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 separately, 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.

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

   New or unknown compounds illegally used for veterinary purposes or illegally used as growth promoters 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 to 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. **Documentation, management of documentation**

   This is inherently included in the daily work of an accredited laboratory.

2. **Proficiency test on NSAIDs**

   A proficiency test on NSAIDs either in milk or plasma will be organised depending on the availability of appropriate material with sufficient concentration levels.

3. **Participation in PTs 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. Participation depends on the choice of PTs offered by commercial providers.

4. **Production of incurred sample material**

   It is planned to lyophilise the hair of the cattle treated between 2007 and 2009. The treatment included several beta-agonists. Moreover, blank hair will be produced.

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 of a responsible NRL.

5. **Visit to NRLs**

   In general 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. The following subjects are possible:
   - TOF,
     screening techniques,
   - validation criteria for TOF,
   - methodical aspects

   The evaluation of the 2009 PT and forthcoming 2010 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, Bilthoven, NL

Workprogramme

January 1st, 2010 – December 31st, 2010

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

HORMONAL GROWTH PROMOTING COMPOUNDS, SEDATIVES AND MYCOTOXINS

January 2010 – December 2010

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 2010 – DECEMBER 2010

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 CRL-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 2009 contract period will be prepared before 1 April, 2010. This activity remains the responsibility of RIVM, Bilthoven.

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 and the CRL website.

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

An evaluation of the Annual National Plans of 2009 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.

Specific products related to A:

Topic	Product	Planned for
1	Meeting minutes prepared by the Commission	To be set by the Commission
2	Advises (reports, e-mails or letters)	Ongoing on an Ad Hoc basis
3	Annual report and cost statement	1 April 2010
4	Co-operation	Ongoing on an Ad Hoc basis

5	Documentation and Information Services Evaluations of ANPs and results reported	Ongoing on an Ad Hoc basis February 2010

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, with special attention in 2010 to thyreostat analyses, based on the results of the PT-programme and problems with analyte stability.

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 was the topic of the 2008 mini-symposium during the annual CRL/NRL workshop in October 2008. The objective for 2009 was to further develop this approach, to set up a working group to further discuss, harmonize and validate this approach. Part of the discussions focuses 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. Based on the results obtained in 2009 it is foreseen that the work will continue in 2010 with a focus on generic approaches to analyte isolation and extract purification.

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 was continued 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. The objective for 2009 was to develop a set of decision criteria for the discrimination of treated and non-treated animals. For 2010 this approach will be validated based on animal experimental work and a research study within the CRL/NRL network. 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. This is a general ongoing activity.

Specific products related to B:

Topic	Product	Planned for
6	Maintenance and extension of methods, with special attention for thyreostats.	Ongoing
7	Development of generic (non-targeted) approaches	Report (December 2010) and scientific publications
8	Studies to detect abuse of	Report (December

	natural hormones	2010) and scientific publications
9 ongoing	Identification of new compounds, inclusive studies on metabolism	Ongoing activity, progress report December 2010

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. For 2010 a research study on natural hormones (multi residu) is foreseen in order to validate decision models developed in 2009. A PT will be organized using materials prepared in 2008.

12) Production of incurred sample material.

An animal studies in preparation of future proficiency tests are scheduled for 2010. Priorities will be set during the 2009 annual workshop.

Specific products related to C:

Topic	Product	Planned for
10	Annual re-accreditation	November 2009
11	Report proficiency study of Zeranol in bovine-urine Report research study Chlorotestosterone metabolites or Testosterone-ester in hair. Research study for	Preliminary reports are prepared within 2 months after conclusion of the proficiency tests. Full reports within 6 months

	validation natural hormones strategy	
12	Technical report animal study treatment with natural hormones	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. The choice for 2010 will be based on the current progress in the NRLs in the newer EU-Member States. Further, it is foreseen to use the Ghent "Hormone" Conference in May 2010 for further dissemination of the results of CRL-research programmes.

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 2009 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 2010
15	Ongoing	Annual overview
16	Ongoing written reports	On an Ad Hoc basis
17	Workshop proceedings	December 2010 / January 2011 (2010 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, B2f, B3e

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

Contract period: January 2010 – December 2010

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&

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AGENCE FRANÇAISE DE SECURITE SANITAIRE DES ALIMENTS
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LEGAL FUNCTIONS AND DUTIES

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1. OBJECTIVES FOR THE PERIOD JANUARY - DECEMBER 2010

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)

2. WORKING PLAN FOR THE PERIOD JANUARY - DECEMBER 2010

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

Article 32, paragraph 1 (a, c)

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

6.1 Non-targeted analysis of antibiotic residues in meat and in milk – Physico-chemical part (continued 2009/2011)

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 FT-Orbitrap MS. The CRL from AFSSA-LERMVD completed in 2008 the acquisition of such a technology, the LC-LTQ-FT-Orbitrap-MS, and now started to investigate in this area of research. During the 2009-2011 period, it is particularly proposed to get a better knowledge of the characteristics of the full-scan monitoring of about 50-100 antibiotic residues in meat and afterwards in milk with the objective to be in position to disseminate a methodology for exact mass and molecular identification of each antimicrobial 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.

6.2 Multi-antimicrobial family method by LC-MSMS (a 2010-2011 development restarted after a 2009 pause)

Following the validation of the 1st step development of the method regarding the selective identifying screening in meat and in milk for about 60 antimicrobials as completed in the 2007-2008 period, the method was disseminated to NRLs end-2007 and also submitted to publication in an international peer-reviewed journal in 2009. Now the project will be started again considering a new LC-MSMS equipment to be acquired end of 2009. An extension of the method to other antimicrobials will be proposed. An evaluation of another matrix of interest (honey) will also be considered with a development scheduled over a 2-year period during the 2010/2011 programmes.

6.3 Reconsidering the semicarbazide as a marker of nitrofurazone abuse (scientific survey)

Considering the findings since 2003 on the different sources of formation of semicarbazide (SEM) in food matrices and as a follow-up of the recent 2009 events regarding the control of nitrofurazone in food products of animal origin by means of its poor-relevant residue marker, the semicarbazide (SEM), the CRL intends to evaluate the advances of recent research in this area and possibly to develop further steps in finding alternative biomarkers of nitrofurazone abuse in animal derived food products. The outcomes of the "Sem/AlternativeBiomarker" project started in 2004 and coordinated by the JRC-IRMM will be reviewed. A scientific survey on the state-of-the-art in novel biomarkers for nitrofurans abuse will be drafted. The opportunity to building a new project of method development possibly in collaboration with other scientific groups will be evaluated.

6.4 Evaluation of a method to control additional dyes in aquaculture products - Fate of methylene blue in aquaculture (New development)

Considering the 2009 dye residue method now released to the network of NRLs (malachite green, cristal violet, briliant green) since our last workshop of June 2009, it is proposed to further evaluate the fate of another dye, the methylene blue, in the aquaculture production. The study will be conducted in a way to look for potential methylene blue metabolites in farmed fish and aquacultured shrimp. Additional dye(s) might then be recommended for monitoring.

6.5 Carbadox abuse biomarkers: DCBX against QCA? (scientific survey)

The carbadox (CBX) is banned for use in animal husbandry since 1998 in EU as of Commission Regulation No 2788/98. A confirmatory method had been proposed by the CRL and disseminated to the NRLs network in 2003 recommending the QCA as the biomarker for carbadox abuse in porcine meat. A recent publication proposes a different metabolite as a relevant biomarker of CBX abuse, the desoxycarbadox (DCBX). The CRL intends to make a scientific survey on the state-of-the-art in analyzing CBX from both metabolites QCA and BCBX in porcine tissues. It will be evaluated the interest to implement a new experimental study in order to compare bioavailability of both biomarkers before recommending any replacing of the QCA by the DCBX.

7. Study of screening tests (methods and kits).

7.1. 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.

7.2. Non-targeted analysis of antibiotic residues in meat and in milk – Biological part by the method of Inhibitory Plate Tests (continued 2009/2011)

Under this issue will be addressed a complementary microbiological study to the non-targeted analysis of antibiotic residues in meat and in milk from the physico-chemical part as expressed in the issue 6.1.

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 2010 to the organisation of a large Proficiency Testing Study dedicated to the evaluation of the overall strategies for monitoring antimicrobial substances in meat products.

8.a Antimicrobials

The antimicrobials of choice should be made from representative compounds of the following families 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 will be porcine muscle meat.

8.b Banned substances

The banned substance of choice shall be chloramphenicol (CAP) as a come back after the last 2007 PT for chloramphenicol and after having proceeded to interlaboratory analysis of nitrofurans (2008) and dyes (malachite green/ crystal violet) in 2009. The matrices of choice might be if technically possible a combination of products (honey, egg and/or milk).

8.c Proficiency test in relation with coordinated monitoring programme

No coordinated monitoring programme for 2010 is 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 2009/2010 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 2010, October 2010).

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.

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

11.a Projection of 3 visits to NRLs from the New 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 attention of the network of NRLs in charge of antimicrobial residue control in food will be organized. The main subject will be the screening of antimicrobials by microbiological methods.

15. Analysis of the National Residue Monitoring Plans of the 27 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 2010.

Programme 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 2010

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 01 January 2010 - 31 December 2010

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 of proficiency tests.

Article 32, paragraph 1 (b)

D. Technical and scientific support to NRLs and Third countries

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

2. Working plan for the period 01 January 2010 - 31 December 2010

A. General Tasks

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

1. Meeting of all CRL

If there will be a coordination meeting of the CRLs , the CRL-ISS will participate.

2. Technical and scientific support to the Commission

The CRL-ISS will provide the Commission with technical and scientific support upon request. An evaluation of the National Residue Monitoring Plans 2009 and the results of the NRLs relevant to 2008 will be performed. The report will be sent to the Commission in due time.

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.

4. Co-operation with international organisations

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

5. Documentation services, interchange of information

The CRL-ISS will also provide any information and/or technical and scientific assistance requested by the NRLs. In the CRL-ISS website, the EU-legislation and new relevant documents will be constantly updated. In the Restricted Area the NRLs can have access to the results of the Proficiency Tests, to information on the annual Workshop, and, finally to the Handbook of Analytical Methods of the NRLs. As for the last document, the reviewed analytical methods and/or new methods adopted by NRLs are yearly up-dated. Every year the CRL-ISS requests this information to NRLs.

B. Development and Validation of Analytical Methods

Article 32, paragraph 1 (a, c)

6. Analytical methods

6.1 Maintenance of analytical methods

This is an ongoing activity that can also include the updating/revision of accredited methods; it also comprises the additional validation necessary for the use of the“ flexible scope”.

6.2 Development of analytical methods

Although MLs for aluminium and arsenic are not set in the CR 1881, the study of analytical methods for these elements can be of concern for different reasons.

The diet is the major source of exposure to aluminium and, although the usual intake of this element through food doesn’t represent a risk for healthy people, a “Tolerable Weekly Intake” was established by EFSA, due to its neurotoxicity. For this reason it is necessary to have analytical methods for the determination of this element in food. Moreover, the analysis of aluminium can be of interest to NRLs due to the use of synthetic sodium aluminium silicate (zeolite) for the reduction of risk of “milk fever” in dairy cows. For these reasons a method for the determination of aluminium in meat, fish, and milk will be developed by means of the Graphite Furnace Atomic Absorption technique.

As for arsenic, the CRL-ISS has the methods for the determination of total element in food of animal origin, but, because of the different toxicity of the various forms of arsenic, the CRL-ISS deems it necessary to implement a method for the element speciation. Although several methods are reported in literature, some critical points of the analysis must still be studied more deeply. In particular: the mixture of extraction of arsenic and its compounds from the sample, even if methanol + water is the one mostly utilized; an evaluation of the yield of the extraction as function of our interest species; the probable utility of the introduction of a clean-up step in the pre-treatment procedure; the occurrence of changes in the chemical state of arsenic; the procedure for the separation of inorganic arsenic from the organic forms; etc.

The study will start evaluating the methods reported in scientific literature, the choice of fish that can be of greater interest to us, and some preliminary experiments on the yield of the extraction.

The objective of the study is to place the basis for the future development of a method that can be transferred to the NRLs.

C. 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

The CRL-ISS will carry out the QA/QC activities to maintain the accreditation status and to improve the Quality System. In order to monitor the QC, the CRL-ISS will apply to some external PTs.

8. Proficiency tests

The 14th Proficiency Test will be organised and conducted for the NRLs. The PT will deal with the most important foods of animal origin namely meat, milk, and fish while the elements proposed will be As, Cd, Pb and Hg. The 14th PT will consist of three rounds and each sample will approximately be sent in February (meat), June (milk) and November (fish). As for the last matrix, the round will be finished at the beginning of 2011.

The performance of the participants will be assessed by the z-scores approach fixing the σ_p at a value suitable to the performance of the NRLs but, in order to allow a comparison with the performances obtained in other programmes, the scores using the $\sigma_{pHorwitz}$ will be supplied as well.

Were applicable, the NRLs were requested to state the "acceptance of the sample" as indicated in the CR (EC) 333/2007 (point D.2.1).

As for the state of samples, milk will continue to be at a liquid status as in previous PTs. For meat and fish, instead, the freeze dried form, used till now, will be substituted by fresh frozen material. This will provide samples as similar as possible to those routinely analysed.

As for the preparation, samples will be prepared in the CRL-ISS laboratory and the elements concentration will be adjusted to obtain selected levels. As usual, preliminary analyses will be performed to choose the more suitable species.

Studies of feasibility on fresh samples of meat and fish were performed during 2009 producing positive results. However, all the process, including preparation and shipment of samples, will be tested by producing a test batch and by sending a sample to the most distant NRLs for which the foreseen delivery time is longer compared with the others.

After completion of each run, an evaluation report will be prepared for the Commission and the NRLs including those that did not participate in that round. As usual, the reports will be made available in the CRL-ISS web site.

D. Technical and Scientific Support to NRLs and Third Countries

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

9. Analytical support and training

Analytical support by means of advice or training will be given to the NRLs, to Official Laboratories of Candidates Member States and Third Countries when requested. In case it is useful to check the method or a particular step of the analytical procedure, the CRL-ISS will analyze specific samples (incurred samples, digested solutions, etc.) received from NRLs always upon request.

The technical personnel of the NRLs will be supported through their participation in the PTs since their analytical performance will be monitored by control charts. Some control charts will be examined during the annual workshop and, when necessary, these charts will confidentially be discussed together with the interested parties.

The CRL-ISS will perform official analyses if necessary.

10. Provision of reference materials

In the framework of the round on milk a high number of test items will be produced so that the NRLs will receive not only the sample for the round but also several vials they can use as reference material for their scopes (internal control charts, validation methods, etc).
The surplus of the reference materials produced for the rounds on meat and fish will be available to the NRLs upon request.

11. Visits to NRLs

A visit to two NRLs will be carried out to exchange information on their analytical techniques, problems of QA/QC, legislation etc. The full reports on the visits will be sent to the Commission and to the relevant NRLs as well.

12. Organisation of the workshop.

The CRL-ISS will organise the usual annual workshop where the evaluation of the 14th PT, the general performance achieved by the NRLs and issues of interest for participants will be discussed. During this event NRLs will receive two questionnaires where they are asked to anonymously give their opinion on the workshop itself and on the CRL-ISS activities.