



The role of EU Community Reference Laboratory in the frame of official control of feed samples

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Europe-Asia
Exchange of experiences*

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More than 25% of all EU legislation has a significant S&T basis

- e.g. food, chemicals, environment, energy

As a Directorate General (DG) of the European Commission, the Joint Research Centre (JRC) provides scientific and technical support to Community policy making



... to provide customer-driven scientific and technical support for the conception, development, implementation and monitoring of EU policies ...



...the JRC functions as a reference centre of science and technology for the EU, independent of private and national interests...

7 Institutes in 5 Member States



IRMM – Geel, Belgium

- Institute for Reference Materials and Measurements
Staff: \cong 300



IE – Petten, The Netherlands

- Institute for Energy
Staff: \cong 180



ITU – Karlsruhe, Germany

- Institute for Transuranium elements
Staff: \cong 250



IPSC - IHCP - IES – Ispra, Italy

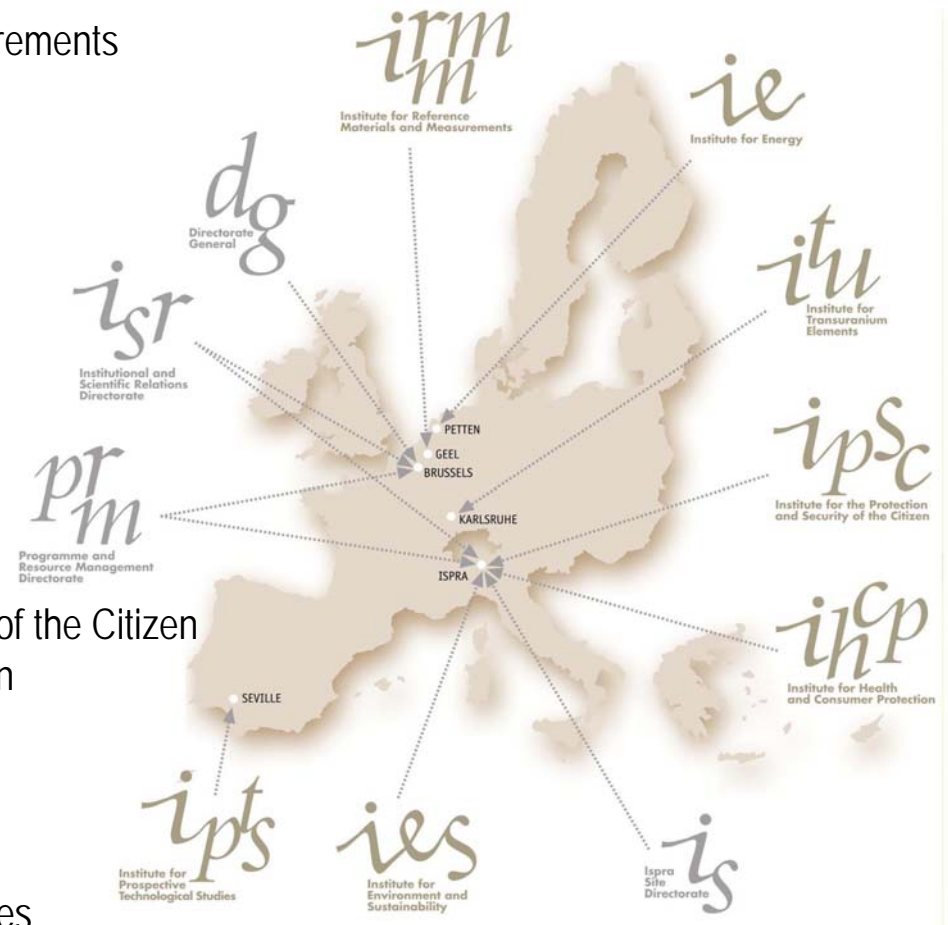
- Institute for the Protection and the Security of the Citizen
- Institute for Health and Consumer Protection
- Institute for Environment and Sustainability
Staff: \cong 350, 250, 370



IPTS – Seville, Spain

- Institute for Prospective Technological Studies
Staff: \cong 100

Total staff: ~ 2200 people



- **Legal limits** for substances such as feed additives and undesirable substances in feed are set at **European level**
- They are **legally binding** for all Member States of the EU
- Objective of **official control**: Compliance of feed samples with legal limits
- The official control is task of **Member States**
- The way **how official control** is conducted needs **harmonisation**
- The European Commission nominates **Community Reference Laboratories (CRLs)** for defined subjects to ensure a harmonised approach amongst Member States regarding official control
- **CRLs** within the **JRC** or **national expert laboratories**

Official food and feed
regulation 882/2004

Examples

PCBs/dioxins

Mycotoxins

Banned veterinary
drugs

Banned meat and
bone meal

Two legal branches



Authorisation
regulations

Examples

GMOs (*Regulation*
1829/2003)

Feed additives
(*Regulation*
1831/2003)

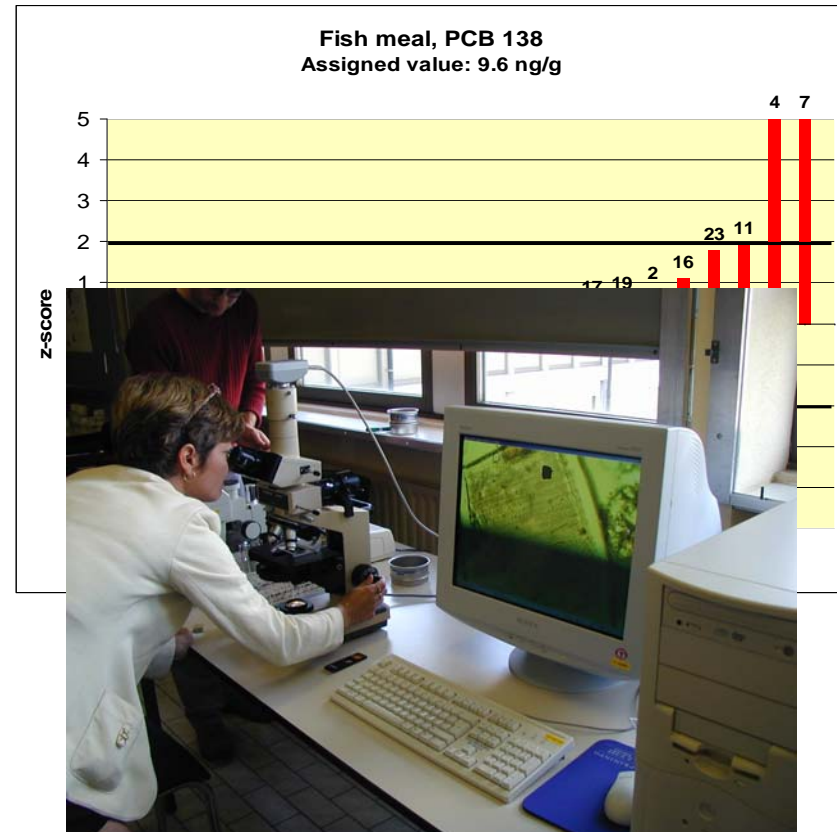
*Two types of
Community Reference
Laboratories*



*Compliance with European Legislation: Control by
Member States' official laboratories*

- To evaluate the *proficiency of National Reference Laboratories* to determine correctly the target analyte
- To organise *training courses* for National Reference Laboratories (NRL)
- providing national reference laboratories with details of analytical methods, including reference methods
- providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses.....

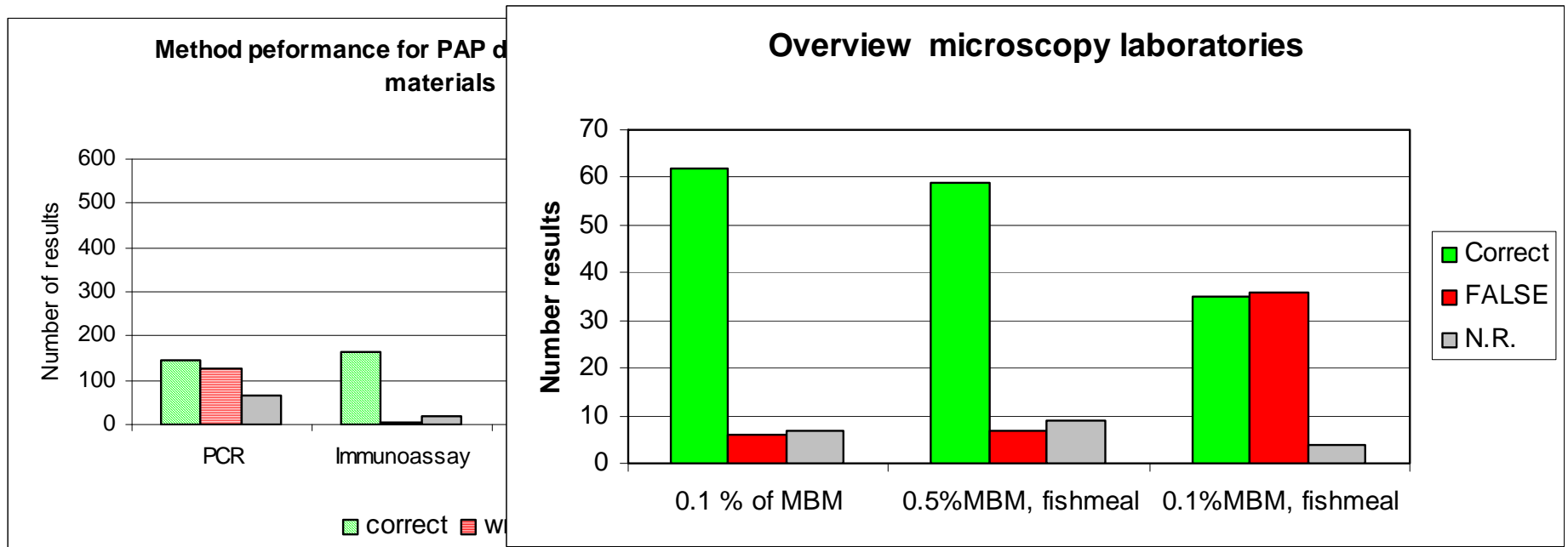
Determination of PCBs in feed



Example 1

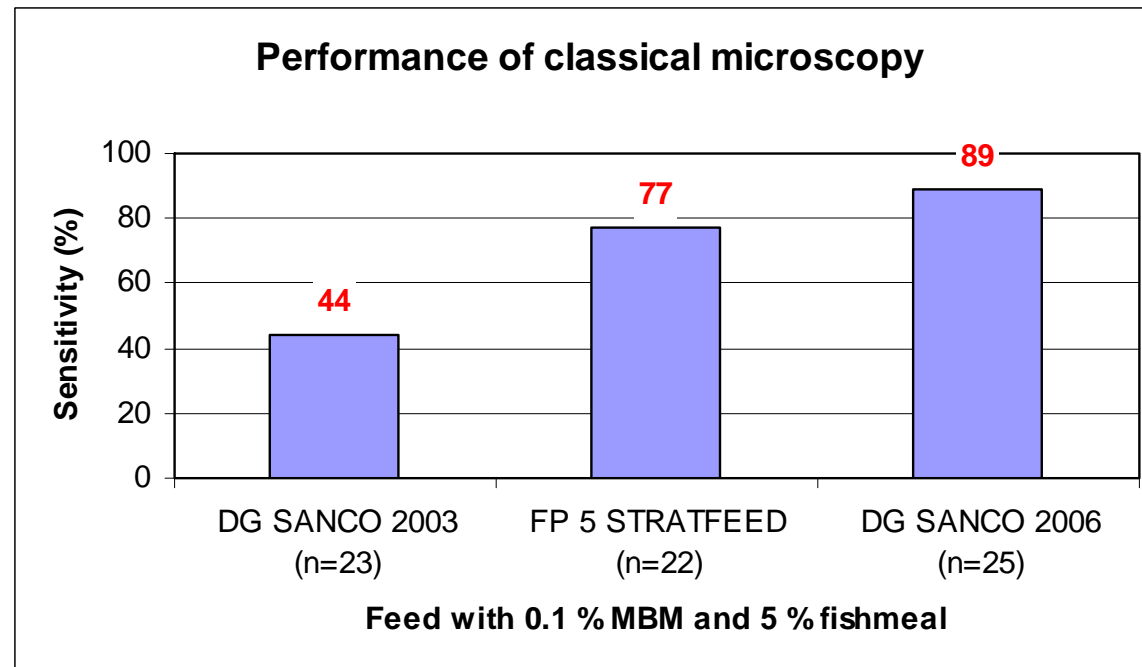
Determination of meat and bone meal (MBM) in feed

- The discrimination power of 1) different methods and 2) microscopy-Results from a proficiency test: Situation in Europe in 2003



Gizzi et al. (2004) *J AOAC International* 2004, 87, 1334-1341

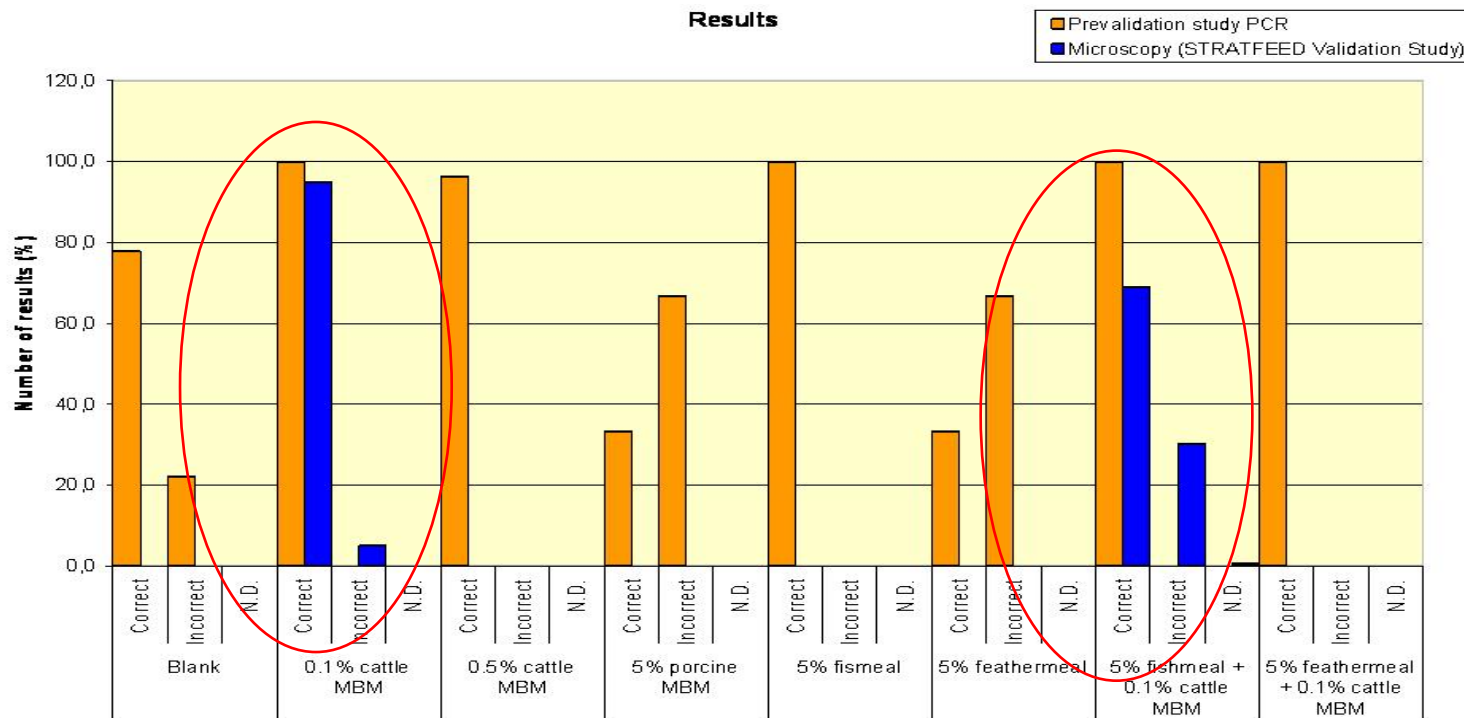
- Repeated participation of laboratories in training
- Harmonisation of the official methods (classical microscopy) leading to a new protocol
- Repeated participation in interlaboratory studies



1) von Holst et al. in “Strategies and methods to detect and quantify mammalian tissues in feeding stuffs (Ed: European Communities)” ISBN 92-894-7356-8 (2005)

2.) Veys et al. “CRL-AP Interlaboratory Study 2006”, CRA-Gembloux, Belgium

- The evaluation of the results from the interlaboratory study of 2003 showed that the severe heat treatment of PAPs poses problems to PCR
- The poor results triggered the development of more robust PCR methods, especially by selecting shorter DNA targets
- An interlaboratory study from 2006 demonstrated significant improvement



Example 2

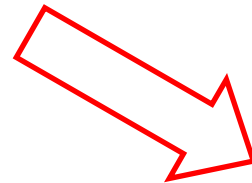
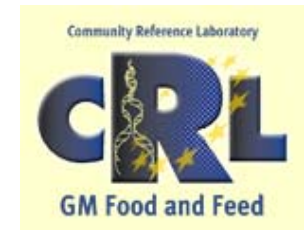
Authorisation of products that are added to feed on purpose: *Feed additives*

Products which are placed on the market on purpose and that need authorisation (Regulations 1829/2003 and 1831/2003)

Risk assessment



Validation/evaluation of analytical methods to detect the target analytes



Risk management: Authorisation



- For each feed additives applicants have to prepare a dossier including **methods of analysis** for the submitted feed additive
- The regulation established a **Community Reference Laboratory** at the JRC to look at the analytical methods.
- The work of the CRL is supported by a consortium of Member States' **National Reference Laboratories (NRLs)**
- Regulation EC (No) 378/2005 specifying the tasks of the CRL requires that the analytical methods need to be validated against their **suitability for official control** (*link to Regulation EC (No) 882/2004*)
- Focus on the determination of the **active substance in feed**

Additive Name	Active Substance	Rapporteur
ELANCOBAN [®]	<i>Monensin sodium</i>	CISTA (J. Petrova), CZ
ALKOSEL [®] /SELSAF	<i>Selenium</i>	C.Re.A.A (M. C. Abete, D. Marchis), IT
NATUPHOS [®]	<i>3-Phytase</i>	Plant Directorate (Annette Plöger), DK
LEVUCCELL [®] SC (for dairy goats and dairy ewes)	<i>Saccharomyces cerevisiae</i> <i>CNCM I-1077</i>	CRL-FAA (R. Leuschner)
LEVUCCELL [®] SC (for horses)	<i>Saccharomyces cerevisiae</i> <i>CNCM I-1077</i>	CRL-FAA (R. Leuschner)
O35	<i>Bacillus subtilis</i> DSM 17299	NVL (R. Bubulienė), LT
VITALYS [®] liquid & dry	<i>L-Lysine</i>	CRL-FAA (G. Simone)
BIOSAF [®] Sc47 (for dairy small ruminants)	<i>Saccharomyces cerevisiae</i> <i>NCYC Sc47</i>	CRL-FAA (R. Leuschner)
L-HISTIDINE monohydrochloride monohydrate	<i>L-Histidine</i>	CRL-FAA (G. Simone)
BIOGALACTOSIDASE [®]	<i>α-D-Galactosidase</i>	RENNES (Roger Ziebal), FR
HEMICELL [®] Feed Enzyme	<i>β-D-Mannanase</i>	LUBLIN (W Korol), PL
BELFEED B1100 MP/ML	<i>Endo-1,4-beta-xylanase</i>	CRL-FAA (D.Garalevičienė)

- Official feed laboratories are enabled to enforce *conditions of use* of the authorised product regarding the content of the *active substance* in feedingstuffs.

ANNEX

Registration number of additive	Name and registration number of person responsible for putting additive into circulation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %	

Coccidiostats and histomonostats

E 1701	Huvepharma NV Belgium	Monensin sodium Coxidin	Active substance: $C_{36}H_{61}O_{11}Na$ Sodium salt of polyether monocarboxylic acid produced by <i>Streptomyces cinnamonnensis</i> , 28682, LMG S-19095 in powder form.	Chickens for fattening	—	100	125
				Turkeys	16 weeks	90	100

COMMISSION REGULATION (EC) No 429/2008 Of 25 April 2008

on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives

2.6. Methods of analysis and reference samples

.... The CRL evaluation shall **focus** on the methods specified in sections **2.6.1** and **2.6.2**.

2.6.1 *Methods of analysis for the active substance in the **feed additive, premixture and feed***

2.6.2. *Methods of analysis for the determination of the residues of the additive or of its metabolites in **food***

...

- Method protocol in ISO 78-2 format.
 - Scope
 - Protocol
 - Method performance profile

.....must be written in a way that *another* laboratory can apply the protocol

- For many products exclusively single-laboratory methods are available
- Due to the rather diverse analytical methods, there is no detailed guideline that fits for all cases
- A list of potential method performance characteristics are given in the Official Food and Feed **Regulation (EC) No 882/2004**

- For implementation consult the IUPAC harmonised protocol for single-laboratory validation
(*Pure Appl. Chem.*, Vol. 74, No. 5, pp. 835–855, 2002.)

- **When evaluating single laboratory validated methods**
- *"Performance characteristics of in-house validated methods shall be verified by testing the method in a second, accredited, and independent laboratory [...]"*
 1. **definition of suitable performance characteristics by single-laboratory (*in house*) validation;**
 2. **verification of the relevant performance characteristics by a second independent laboratory;**

We want to ensure that the method can be utilised by another laboratory

- Is the protocol understandable and complete?
- Can some performance characteristics be repeated ?
- In the case of single laboratory-method, check in a second laboratory
- Where to find the guideline for the verification study:

Examples for Commission/CEN/ISO methods

Priority of methods

1. Community methods
2. CEN methods
3. Ring trial validated methods
4. Single laboratory methods

Regulation EC (No) 882/2004, art .11

Analyte	Source	Status
Vitamin A	Commission Directive 2000/45/EC	Commission method
Amino acids	Commission Directive 98/64/EC	Commission method
Lasalocid	Commission Directive 1999/76 EC	Commission method
Monensin, Narasin, Salinomycin	ISO 14183: 2005	Official ISO standard
Trace elements	EN 15510 (2007)	Official CEN standard
6 Probiotics	Results from ring trials published in peer reviewed journals	Draft CEN standard
Phytase	Results from ring trial published in peer reviewed journal	Draft CEN standard

CEN TC 327 WG 3 is working on more standards

If the applicant proposes a method of level 1,2 or 3: Experiments showing that the method works on the applicant's product are sufficient

Consult the CRL web site:

http://irmm.jrc.ec.europa.eu/html/CRLs/crl_feed_additives/index.htm

Other feed safety: Community Register of feed additives

http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm

CRL evaluation reports:

http://irmm.jrc.ec.europa.eu/html/CRLs/crl_feed_additives/authorisation/evaluation_reports/index.htm

**Thank you very much for your
attention !!**