



Safety and traceability of feed composition in the EU- Current examples

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EPSO workshop: The European Feed Value Chain

26 and 27 June 2007

<http://www.jrc.cec.eu.int>



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The JRC Food Cluster

- **Institute for Reference Materials and Measurements (IRMM), Geel (Belgium)**
Certified reference materials
Safety and quality of food and feed (several CRLs)
- **Institute for Health and Consumer Protection (IHCP), Ispra (Italy)**
Genetically modified organisms (CRL, ENG network)
Food contact materials (CRL), European wine data bank (BEVABS)
- **Institute for Prospective Technological Studies (IPTS), Seville (Spain)**
Prospective studies



Traceability and Safety: Important aspects

Feed hygiene regulation: 1831/2003:

Annex II: Documentation relating to the raw materials used in final products must be kept by the manufacturer in order to ensure traceability

DIRECTIVE 2002/32/EC on
undesirable substances in
animal feed

Risk assessment and
authorisation



Focus of this lecture

- Analytical methods an important tool to enforce **European legislation**
- The role of Community Reference Laboratories (**CRLs**)
- The **CRL for feed additives**



Feed safety: A complex issue

Official food and feed
regulation 882/2004

Examples

PCBs

Mycotoxins

Banned veterinary
drugs

Banned meat and
bone meal

Two legal branches



Authorisation
regulations

Examples

GMOs (*Regulation*
1829/2003)

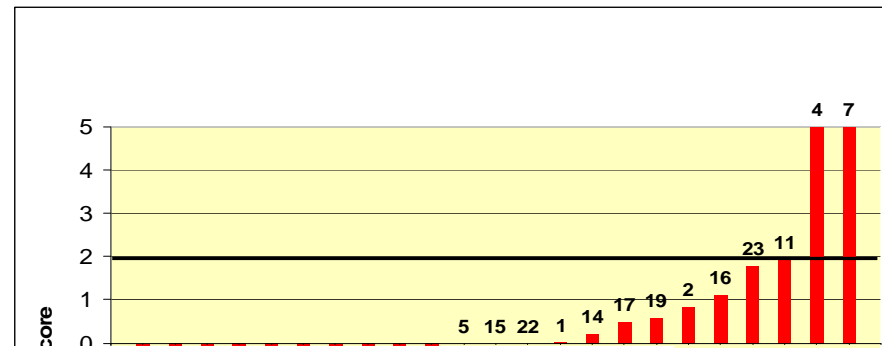
Feed additives
(*Regulation*
1831/2003)



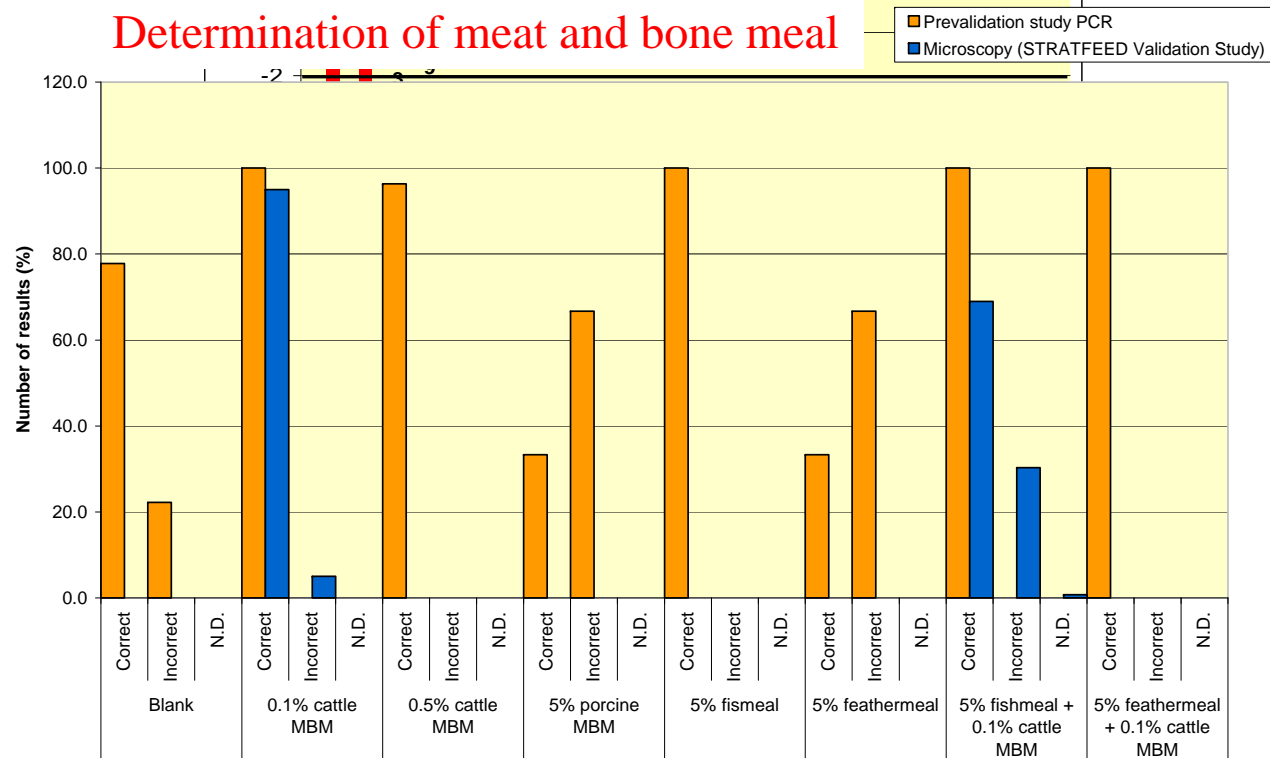
Typical tasks of CRLs under the *Regulation* *882/2004*)

- To evaluate the *proficiency of laboratories* to determine correctly the target analyte
- To organise *interlaboratory studies* to assess state of the art of methods

Determination of PCBs in feed



Determination of meat and bone meal



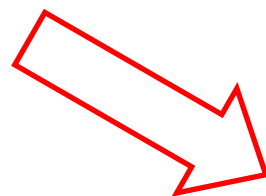


Authorisation in the field of feed additives and GMO

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



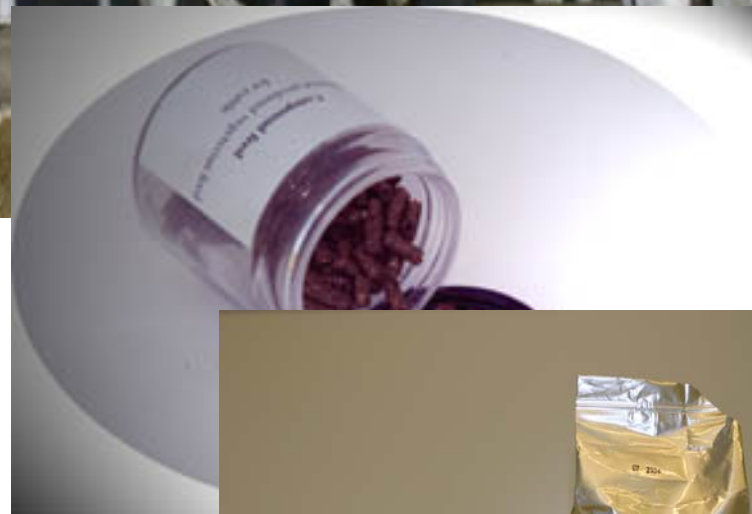
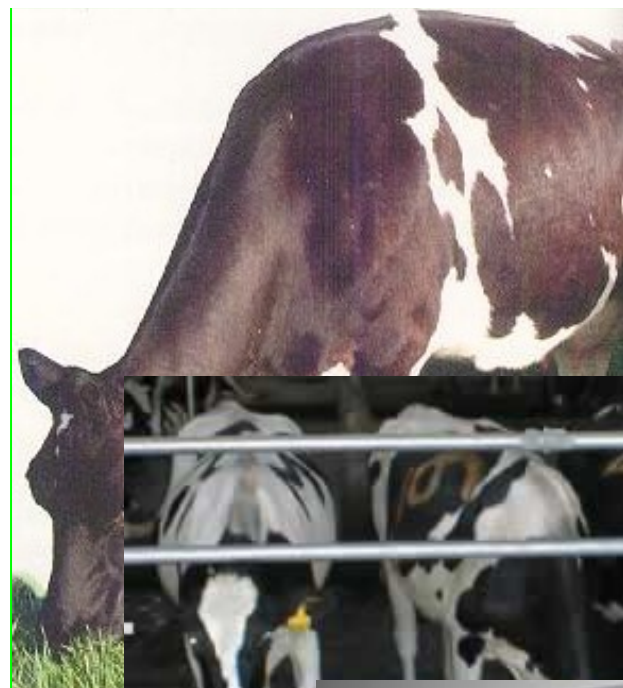
Risk management: Authorisation





Animal nutrition

- Traditional farming
- Intensive farming
- Compound feed



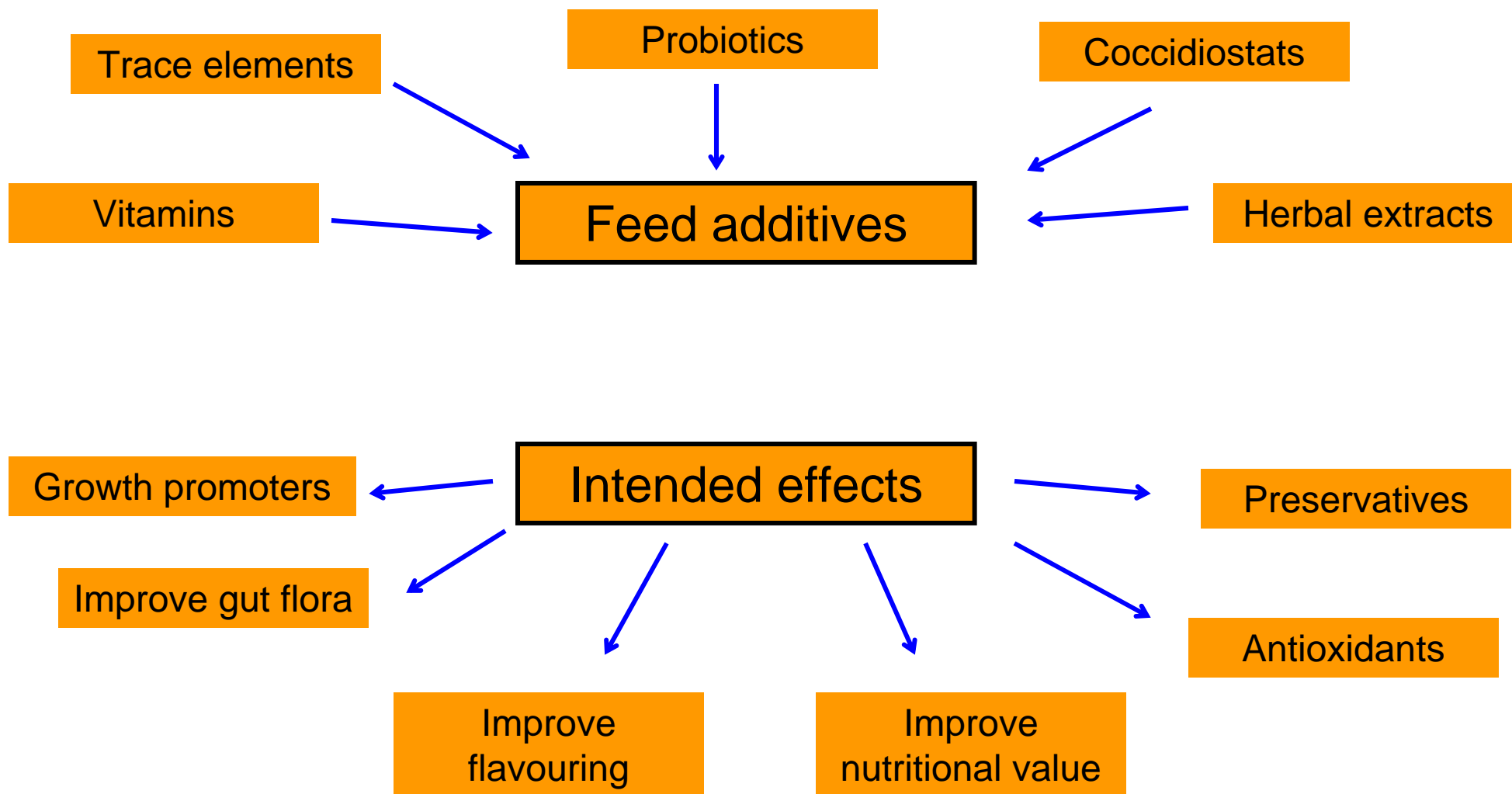
FEED FOR DAIRY COW

	%
Corn	44
Wheat	30
Wheat bran pellets	10
Soya	8.9
Sunflower	5
Calcium carbonate	1
NaCl	0.7
Calcium phosphate	0.4

- Feed additive



Examples for additives and effects





New authorisation of feed additives - Contribution to feed/food safety

- *Taken from the preamble of the Regulation (EC) 1831/2003*
- Livestock production occupies a very important place in the agriculture of the Community. Satisfactory results depend to a large extent on the **use of safe and good quality of feedingstuffs**.
- In order to **protect human health, animal health and the environment, feed additives** should undergo a **safety assessment** through a Community procedure **before being placed on the market**
- **Replacement of antibiotics** as growth promoters by alternative products



The new authorisation of feed additives according to Regulation No 1831/2003

- The European Food Safety Authority (**EFSA**) is doing the **risk assessment** whereas the **Commission grants authorisation** to the applicants
- For each feed additives applicants have to prepare a dossier including **methods of analysis** for the submitted feed additive to **control the conditions of use**
- The regulation established a **Community Reference Laboratory** to look at the analytical methods.
- The CRL operates for three years.



Key activities of the CRL

- Evaluation/testing/validation of the **analytical methods**
- Fitness for purpose and *suitability for official control* (*link to Regulation 882/2004*)
- Storage of **feed additive samples**
- Management of the dossiers between the CRL and the NRLs
- Evaluation/testing/validation of the **analytical methods**
- Drafting/finalising **reports to EFSA**
- Development of concepts for dossier evaluation and for the future activities from the OFFFC regulation



Analytical methods **and** authorisation

- Authorisation is **linked** to “conditions of use” specified in the **product specific** regulation (e.g. COMMISSION REGULATION (EC) No 1750/2006)
- Characteristics of the **additive** (*taken from the Regulation*)
- Legal limits of the **active substance in feed** (*taken from the Regulation*)
- Need for suitable analytical methods to enforce this limits in the **frame of official control**

Additive composition:

Benzoic acid (≥ 99,9 %)

Characterisation of the active substance:

Benzenecarboxylic acid, phenylcarboxylic acid, C₇H₆O₂

CAS number 65-85-0

Maximum level in:

Phthalic acid

Biphenyl:

Heavy metals

Arsenic: ≤

Analytical

Reversed F

UV detection

	Minimum content	Maximum content
mg of active substance/kg of complete feedingstuff		
	5 000	5 000



Characteristics of the new system focusing on the **analytical methods**

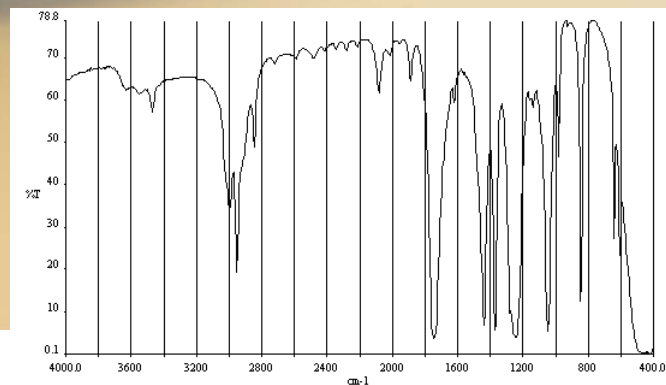
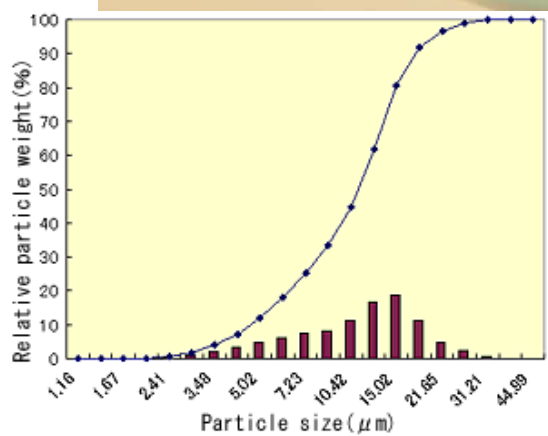
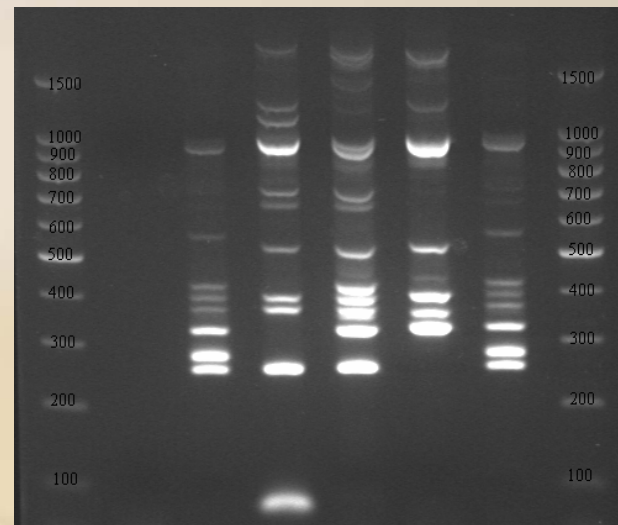
- The **evaluation** of the method is **harmonised**, since the **same criteria** apply to all applications
- **Pivotal** role of the consortium of National Reference Laboratories (**NRLs**)
- Best use of **available experience** and knowledge of the consortium of National Reference Laboratories
- **Dissemination** of knowledge within the network by organising workshops, establishing a method data base and intercomparison studies
- **Storage** of a **reference samples** for each feed additive



Characterisation of the feed additive

PCR of probiotic yeast strains

Composition	
Benzoic acid	99.9 %
Phtalic acid	100 mg/kg
Biphenyls	100 mg/kg
Heavy metals	10 mg/kg
Asenic	2 mg/kg

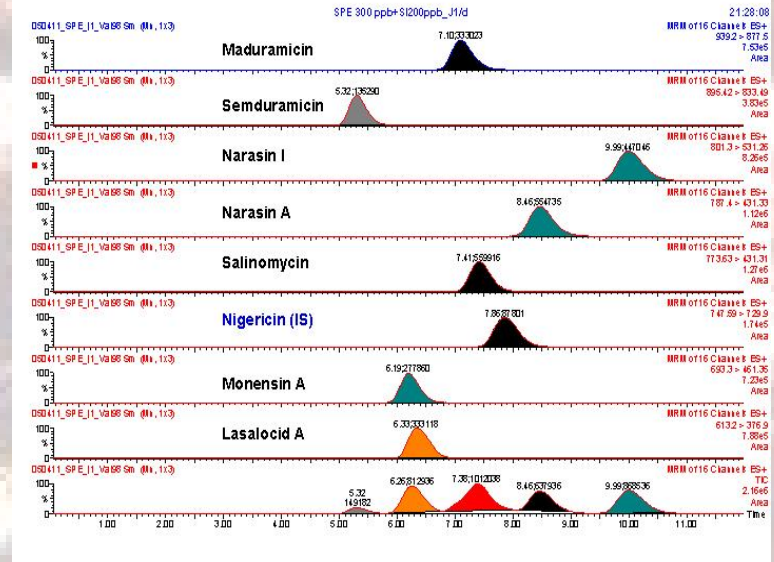




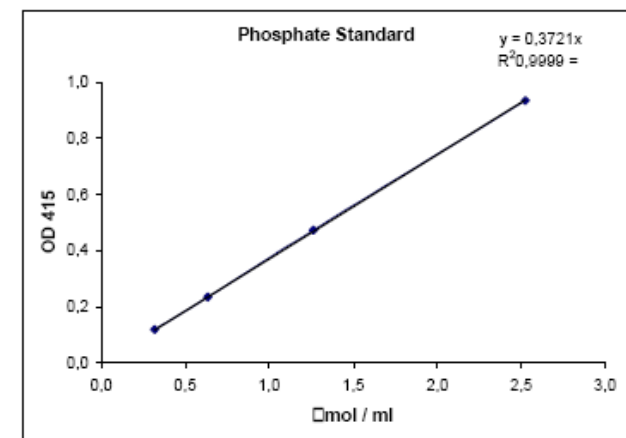
Determination of the active substance in compound feed: A multidisciplinary approach

Coccidiostat analysis by LC/MS

Enumeration of probiotics



Determination of enzymatic activity of phytase





How to evaluate the analytical methods ?

Three levels of evaluation

- (1) **Assessment of the protocol** without conducting experiments
 - In general the CRL's evaluation has to be finalised within three months
- (2) **Application of the method** of analysis in the laboratory
 - dedicated cases
- (3) **Conducting an interlaboratory study**
 - dedicated cases

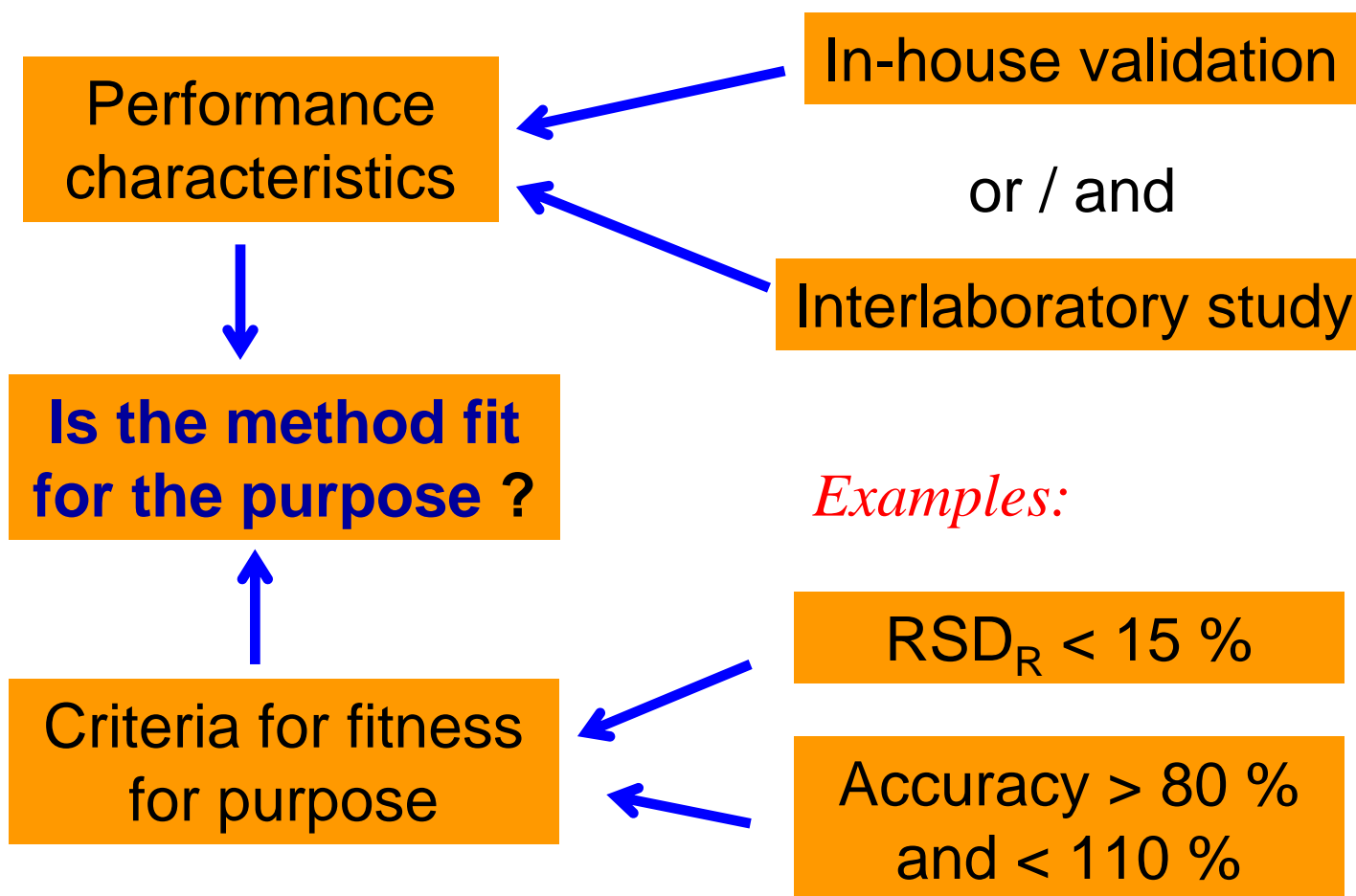


The role of the network laboratories

- The implementation regulation (EC) No 378/2005 places emphasis on role of NRLs
- Importance of consortium of National Reference Laboratory (NRL):
 - For each case the CRL nominates a **rapporteur laboratory** from the consortium. Also the CRL can be the rapporteur laboratory
 - **All NRLs can comment** on the dossier
 - The Rapporteur laboratory reports to the CRL



How to evaluate the method ?



..... clear structure but not always straightforward!!



Challenges for the evaluation of the analytical methods

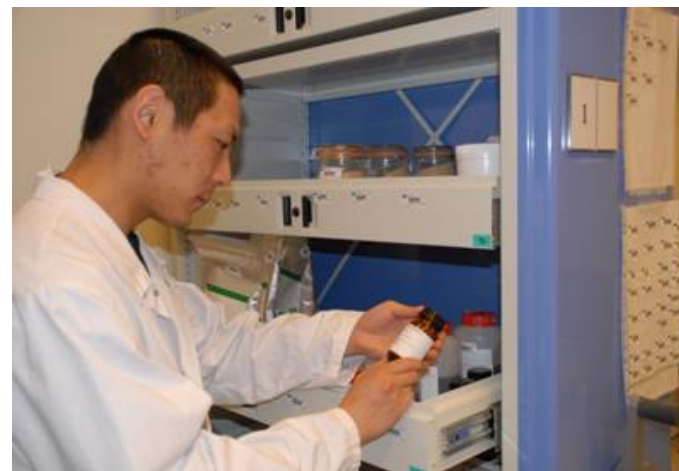
- **Chemical analysis** of **defined substances** (e.g. coccidiostats)
 - IUPAC-Guidelines are available for validation by single-laboratory and intercomparison study
 - Fitness for purpose criterion for repeatability and reproducibility: Horwitz equation
- **Lack of guidelines** for many methods e.g.
 - Enzyme activity (phytase), *target defined* by method conditions
 - Microbiological tests
 - PCR tests
 - Microscopy



How does the CRL contribute to the authorisation system for feed additives?

Main aspects

A sample bank of all authorised products



Evaluated methods: Protocol is public domain

COMMISSION REGULATION (EC) No 1284/2006

of 29 August 2006

concerning the permanent authorisations of certain additives in feedingstuffs

(Text with EEA relevance)

(¹) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlfaa/



Achievements – together with the NRLs

- About 50 evaluation reports to EFSA
- Web based method databank
- Internal CRL management too
- Finalising the validation study for the determination of phytase activity in feed (CEN activity)
- Drafting conceptual documents
- Contributions to new DG SANCO dossier guidelines
- Organising workshops with NRLs
- Accreditation according to ISO 17025

Additive Name	Active Substance	Rapporteur
ELANCOBAN®	<i>Monensin sodium</i>	CISTA (J. Petrova), CZ
		C.Re.A.A (M. C. Abete, D.

The screenshot shows the IRMM website interface. A central window displays a validation study titled "Phytase activity: Validation study" with the subtitle "Target value and reproducibility standard deviation". Below this, an accreditation certificate is shown, issued by BELTEST (Belgisch Accreditatiesysteem / Système Belge d'Accréditation). The certificate is for the "Institute for Reference Materials and Measurements IRMM, Food Safety and Quality Unit (FSQ), Retieseweg, 111, 2440 GEEL". The certificate number is "Nr. 357-T". The text on the certificate states: "In compliance with the provisions of the Royal Decree of December 22nd 1992 concerning the setting up of BELTEST, the Minister of Economy, hereby confirms, on advice of the Accreditation Bureau, that the test laboratory".



Conclusions: Important aspects to assure safety and traceability

- Implementation of **feed hygiene regulation**
- Availability of **analytical methods** to enforce legal limits
- Experienced laboratories showing **sufficient proficiency**
- Use of marker substance
 - Example: as foreseen in the frame of the animal – by product regulation 1772/2002

http://www.irmm.jrc.be/html/CRLs/crl_feed_additives/index.htm



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