



EU legislation and Analytical Laboratories : business as usual ?

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How are the potentials – and pitfalls – of the analytical laboratories seen in the light of the EU New Legal Framework?

*Institute for Reference Materials and Measurements (IRMM)
Geel, Belgium*

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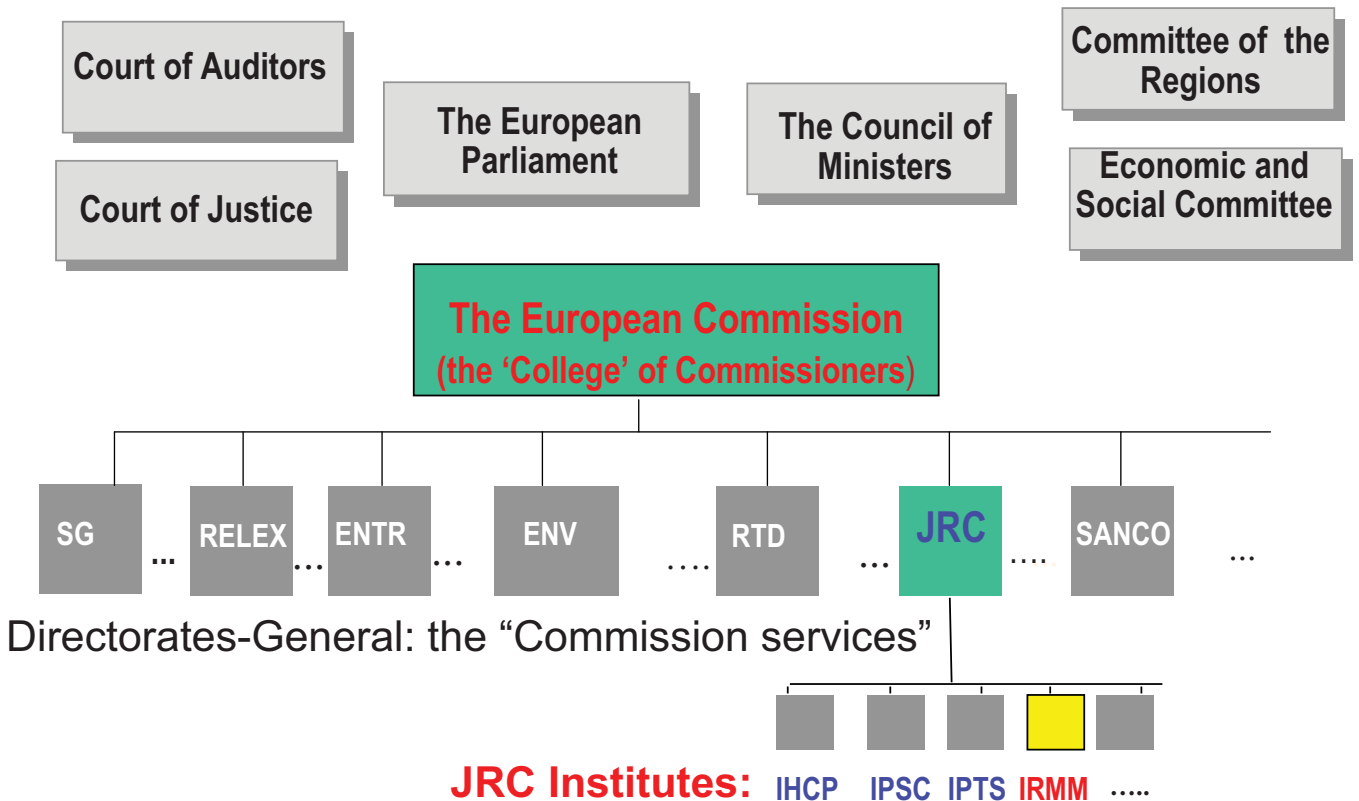
Mission of the JRC

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

“A research based, policy support Institution”



JRC among the EU Institutions



JRC-IRMM mission

The mission of the IRMM is to promote a common and reliable European measurement system in support of EU policies.

Particularly involved in monitoring and development aspects



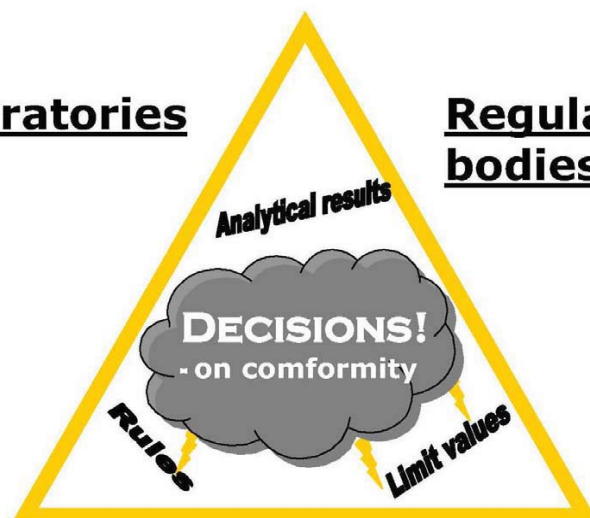
IRMM - CONFIDENCE IN MEASUREMENTS®



Scope of the seminar

Laboratories

Regulatory bodies



Decision makers





Scope of the seminar

...to look at the situation of decision making both from the side of

- the laboratories
- from the side of those setting the limits to which conformance/non-conformance has to be decided
- from the side of those who are finally going to make the decisions!

- 
- Setting limits and deciding
 - in trade
 - in production
 - **in legislation**
 - ...



So I will talk about legislation

- Challenge of communication when dealing with technical legislation
- An IRMM initiative within the EC
- A brief overview of the new EU legislative framework
- Challenges ahead





The challenge of communication



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So I will talk about legislation

- **As analytical chemist ...**
- **I interact with a lot of people with a background in economy, law, political sciences**
- **Easy to blame them, they do not understand**
- **Perhaps we do a lousy job in ...**
 - Explaining technical issues ?
 - Interacting pro-actively with those that are involved in the legislative process ?



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“Talking to the others”

- **We have sociology against us ...**
- **we like to stick with our “mates” :**
 - Easy : it requires less energy
 - Pleases our ego : I am important
- **Multi-disciplinarity is important**
 - Talking a “different language” is a challenge



Our brains work differently





Our brains work differently



GMO Legislation : our brains work differently



GMO legislation

- old legislation EC 258/97 and EC 49/2000
- a level was set (1%) based on weight, but it was not described how this should be measured



REGULATION (EC) No 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 January 1997

concerning novel foods and novel food ingredients

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

existing foods or food ingredients a simplified procedure should be provided for;

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

- (3) Whereas food additives, flavourings for use in food-stuffs and extraction solvents are covered by other Community legislation and should therefore be excluded from the scope of this Regulation;

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social

(4) Whereas appropriate arrangements should be made



Regulation (EC) No 1830/2003

specifies that food and feed products containing more than 0.9 % GMO have to be labelled

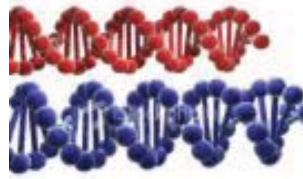
$$\frac{\text{GMO mass}}{\text{species mass}} \times 100$$

mass fraction



$$\frac{\text{copies of transgenic DNA}}{\text{species-specific DNA}} \times 100$$

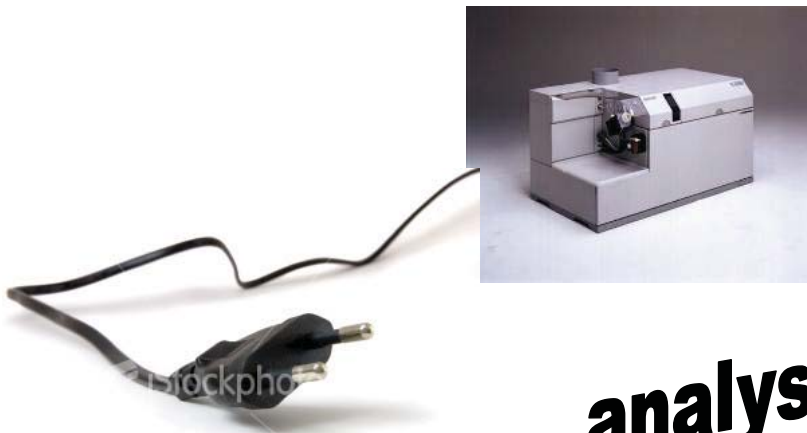
copy number ratio



Recommendation (EC) 787/2004 recommends to express the GMO content in DNA haploid genome equivalents (hge)



The plug and play idea !



analysis is trivial ?



Plug & play in bio-analysis



you just buy the kit, no ?



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Consequences

- Laboratories express their measurement results in different measurement units expressed in %: mass fraction or copy number ratio
- The numerical values differ in most cases



Farmers plant hybrid ;
Starch is in endosperm

- Hybrid (heterozygous for the transgene)
- Endosperm 3 n (2 n female, 1 n male)
- Transgene : endogene ratio in the GM plant is approximately 0.5
0.7 if comes from female, 0.3 if from male

- Laboratories are accredited either for GMO measurement results expressed in mass fractions or in copy number ratio



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- Now demands that CRMs are available at the time of authorisation
- CRM producers : certify these for mass fractions, copy number certification may follow later
- Conversion factors are associated with a high uncertainty, on top of high RSD of the method (e.g. 50%)

Slide S. Trapmann, IRMM



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confusion

Different approaches are used at national level:

- Denmark: Maize measurements expressed in mass fractions and soybean measurements in copy number ratio (conversion of 1/1 used)
- France: Measurement results are expressed in copy number ratios as this is the measurement unit of PCR
- etc.



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RASFF Portal

Search Page

Notification :

Reference
Subject or and

Date :

Week current week [21] previous week [20] other [week ▼ of year ▼]
Notified between and (dd/mm/yyyy)

Notified by :

Country

Type :

Type
Classification
Basis

Product :

Category
Distribution



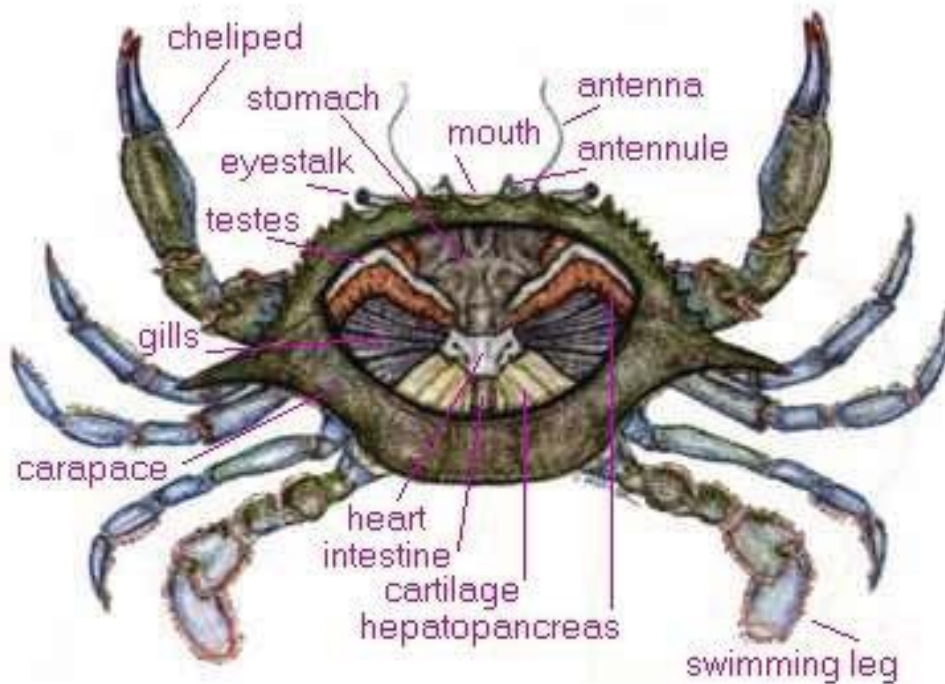
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Market Surveillance RASFF



- Cd in crab Regulation 1881/2006
- Member state X finds high values in crab exports member state Y
- Discussion on methods started
- “let us do intercomparison” ...
- By talking and listening : issue is really about sampling ...

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Who is involved in making legislation ?

- Proposal of the Commission, and therefore consultation with national experts
- Most often co-decision EP and EC :
 - Politicians are involved

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**The political process ... a lot of other arguments than
technical once come into consideration**

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Who is involved in making legislation ?

- **And ... VIM does not impress them**
- **Therefore : importance of technical people to
get involved at**
 - and EU level
 - But also at the national level

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Measurement issues form possible barriers to implementation EU policy

- Agriculture
- Customs
- Energy
- Environment
- External trade
- Fight against fraud
- Fisheries
- Food safety
- Health
- Internal market
- Consumer affairs
- Science/Technology
- Security policy
- Trade
- Transportation



www.eur-lex.eu : a great resource

EUR-Lex Access to European Union law English (en)

EUROPA > EUR-Lex Home > Thematic files > Genetically modified organisms (GMOs)

OFFICIAL JOURNAL
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Process and players
Legislative drafting

Genetically modified organisms (GMOs)

Genetically modified organisms (GMOs), for both human food and animal feed, are listed under European legislation, which has harmonised their authorisation procedure, labelling and traceability.

Since 2003, GMOs must be labelled GMO.

A single body is responsible for approving GMOs and placing them on the market: the European Food Safety Authority.

Approved GMOs have passed specific tests proving that they do not affect human or animal health.

▶ **Legislative instruments**
▶ **Preparatory acts**
▶ **Other acts**

Legislative instruments

▶ **32001L0018**
Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration
Official Journal L 106 , 17/04/2001 P. 0001 - 0039

▶ **32004R0065**
Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms

Last updated: 13/04/2010

an IRMM initiative striving
towards better regulation



ideally

EU legislation :
How does it tackle measurement technical issues ?

JLS

ENV

TREN

ENTR

SANCO

AGRI

TAXUD



Common policy on measurement technical issues



**Implement via Member States
organisations (labs, NAB, ...)**





today no common and no integrated approach inside EC to address measurement provisions and requirements :
from design to implementation



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In law, but left unclear on how to implement ...

- 2002/95/EC RoHS on the restriction of the use of certain hazardous substances in electrical and electronic equipment
- **national authorities and manufacturers very confused**
 - 1) 2002 : “electronic equipment put on the market does not contain Pb, Hg, Cd, CrVI, PBB or PBDE (this is impossible)
 - 2) 2005 : max level 0,1 % in homogeneous materials (this is also impossible)



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In law, but left unclear on how to implement ...

- Legislation : **Directive 98/79/EC** on in vitro diagnostic medical devices
- how to interpret and implement the legal text requiring **“traceability to higher metrological order”**



There is legal limit, but how do we decide?

- typically food and feedstuff, but also air quality, water quality
- decision criteria are often not stipulated inside the legislation





IRMM chairs an Inter Service Group to make better law via early detection and remediation of measurement barriers



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- To promote the establishment of a **harmonised approach**
- To provide **early coordination** and spread best practice about such issues
- To reflect and advise on the **measurement infrastructure and capabilities** needed for the implementation and monitoring of legislation
- To identify societal or economic implications or **risks**



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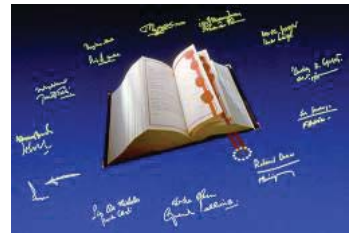
The New Legislative Framework

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Bit of history ...

- “technical legislation” : a lot originated from “goods/products” area
- **Single European Act : Europe 1992**
 - Before : detailed technical specifications in legislation (e.g. was extensively so in communist countries)
 - Removal technical barriers
 - Harmonisation
 - Voluntary standards
- **EU legislation talks about**
 - Accreditation (EA) : 3rd party assessment of competence
 - Standardisation (CEN) : documentary standards
 - Btw : not about metrology



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But as said ...

- There are different approaches
- In “goods” area
- Food
- Environment
- ...



Internal market : “revival”

- Aug 2008 : “Goods” package : set of horizontal measures to enhance functioning internal market in goods
 - Harmonised area (EU harmonised rules) : increase safety products
- **New** legislative framework : strengthen/complete existing rules, improve the way requirements are applied
 - Regulation 765/2008/EC accreditation and market surveillance
 - Decision 768/2008/EC common framework for marketing products



How a non-technical person sees the world



New Legislative Framework

Political trust or dispute

National Authorities

Technical trust

EA - Accreditation

Technical trust

National Authorities

CE Marking

Certifiers & Laboratories

Conformity Assessment Procedures

Manufacturers

Market – Products - Consumers

Market Surveillance



Regulation 765/2008/EC accreditation and market surveillance



- Rules for European **policy accreditation and market surveillance** and controls of products from third countries (01/01/2010) : one accreditation body per country ; monopoly
- **Market surveillance** : obligations for states and their authorities to ensure that products on their markets are safe and comply with legal requirements



“traditional sectors” discover the regulation

- Imports : different practice in different MS
- Sector discovers that there is new legislation



		<p>3. Product: blue plastic rattle with handle with a cat face. Country of origin: China</p> 	with the Toys Directive and the relevant European standards.	
3 0408/05	Poland	<p>Cars: Toyota Avensis and Toyota Corolla Type/number of model: a) Toyota Avensis manufactured from 21 February 2003 to 24 November 2004. B) Toyota Corolla manufactured from 1 April 2003 to 14 March 2005. c) Toyota Corolla manufactured from 7 June 2004 to 17 March 2005. Description: a) Toyota Avensis (TMUK), Country of origin: Great Britain and Turkey</p> <p>* No picture available</p>	Risk of injury. Decrease of the brake performance. The deformation of the resin portion of the brake vacuum hose may occur; this may result in a shortage of vacuum to the brake booster.	Voluntary recall from consumers and corrective actions.
4 0409/05	Poland	<p>Car, Toyota Land Cruiser 90/95 (JT and JTE) manufactured from 22 May 2001 to 30 September 2002. Country of origin: Japan</p> <p>* No picture available.</p>	Risk of injury. The scratched lower ball joint installed in the Land Cruiser after its long exploitation may wear and become loose. In extreme cases, the lower ball joint may separate from the knuckle causing a loss of vehicle steering control.	Voluntary recall from consumers and corrective actions.
5 0410/05	Czech Republic	<p>Kettle "KINGSTAR ELECTRICAL" (KS 6681).The kettle consist of two pieces, the supply cord H05VV-F 3G 1.0 mm2 is fitted with an</p>	Risk of electric shock. There is insufficient electric strength of the connecting device after moisture test. There is corrosion of	Placing on the market prohibited and

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Decision 768/2008/EC common framework for marketing products

- Common framework for EU legislation laying down **requirements for marketing** of products
- New : obligations for **importers**
- Relevant obligations on economic operators (**manufactures, importers, distributors, CABs**)
- More **consistency**
- **Toolbox** containing elements commonly used in technical harmonisation legislation in a standardised format
- To be **incorporated** into product legislation (10 directives : LVD, NAWI, ...)

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New Legislative Framework : in the next 18 months ...

- About 15 directives involving technical issues (different sectors) will go through EP and EC
- Alignment with the **New Legal Framework**



Low Voltage Directive: Directive 2006/95/EEC relating to electrical equipment designed for use within certain voltage limits

Simple Pressure Vessels Directive: Council Directive 2009//105/EC relating to simple pressure vessels

Non-automatic Weighing Instruments Directive: Council Directive 90/384/EEC relating to non-automatic weighing instruments

Civil Explosives Directive: Council Directive 93/15/EEC relating to the placing on the market and supervision of explosives for civil use

ATEX Directive: Directive 94/9/EC concerning equipment and protective systems intended for use in potentially explosive atmospheres

Lifts Directive Directive 95/16/EC of 29 June 1995 relating to lifts

Pressure Equipment Directive: Directive 97/23/EC concerning pressure equipment

Measuring Instruments Directive: Directive 2004/22/EC on measuring instruments

Electromagnetic Compatibility Directive: Directive 2004/108/EC relating to electromagnetic compatibility and repealing Directive 89/336/EEC

Pyrotechnic Articles Directive: Directive 2007/23/EC on the placing on the market of

pyrotechnic articles



Such directives

- **Contain essential requirements**
- **Procedures for manufacturers to demonstrate that they are compliant**
- **Problems identified in the Impact Assessment :**
 - Many goods do not fulfil
 - Enforcing difficulties (especially with imports) ; different practice in different MS
 - Lack of trust in CE marking
 - **Quality of services by CABs (notified bodies) : how reliable ?**
- **Inconsistency of the directives**



Notified bodies

- **By legal act, member state notifies the EC that this CAB is competent for this kind of conformity assessment**
- **Done in NANDO database** (New Approach Notified and Designated Organisations)
- **Competence : accreditation (or equivalent)**
- **Others can challenge**





Cross border accreditation : compromise in the making

- is meant for use only by companies within the same organisation
- one accreditation is sufficient provided all operate under the same global quality system and head office has the means to substantially influence and control subsidiaries
- only permitted if the formal legal possibility exists that the accredited CAB maintains the final legal responsibility
- local entity is entitled to offer directly to the local market conformity attestations under the multisite accreditation, but only on behalf of the accredited CAB.
- certificates issued under the accreditation of the head office without the logo of the local site



2010

REPORT OF THE EXPERT PANEL FOR THE REVIEW OF THE EUROPEAN STANDARDIZATION SYSTEM

Standardization for a competitive and innovative Europe: a vision for 2020





2011 ... 98/34 Directive changing ?

- obligation to notify EC and other countries all draft technical regulations concerning products and Information Society Services before they are adopted in national law.
- providing transparency and control with regard to those regulations.
- diminish this risk of unjustified barriers between Member States



Future outlook ?



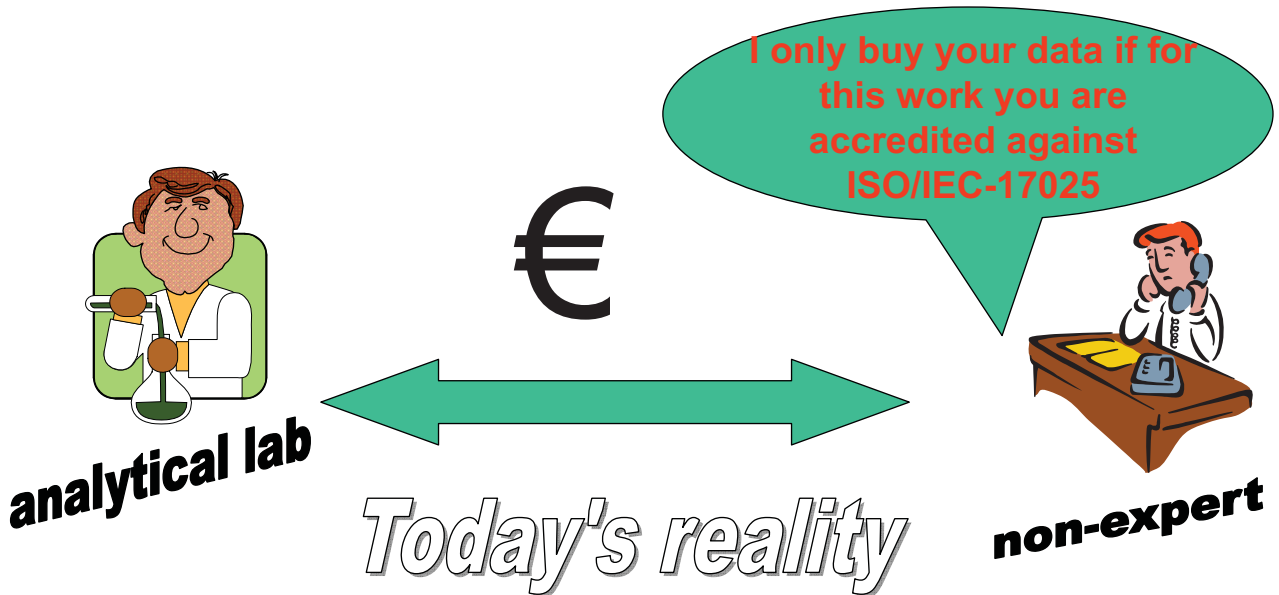
- **Quality infrastructure in Europe**
 - Accreditation
 - Standardisation
 - Market surveillance
 - Metrology
- **Their relevance ?**
- **Their cost ?**

Boiling frog : the danger of slow change



Big changes

financial crisis



accredited according to ISO/IEC-17025





Trends for laboratories

- **Market forces :**
 - Increased competition
 - Bigger companies
 - International players
- **Higher requirements : accreditation is a must**
- **Bigger liability**
- **Finding staff**

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importance of training and education

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national providers
life long learning

lab personnel
accred. assessors
agencies & ministeries

Euromaster

university curricula



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A FOCUS FOR
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Upgraded university curricula are needed



Measurement Science in Chemistry

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giving students in Europe
access to an education
that provides them with the knowledge and skills
to produce reliable results
in analytical chemistry



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Program: generic structure

Year 1

Fundamentals of Measurement Science (incl MS in Chemistry) (10 ECTS)

Data evaluation and management (10 ECTS)

Instrumental methods (10 ECTS)

Sampling, sample preparation and separation methods (10 ECTS)

Applications of analysis (20 ECTS)

Year 2

Summer School (30 ECTS)

Master's thesis (30 ECTS)
(research project with a topic related to measurement science)

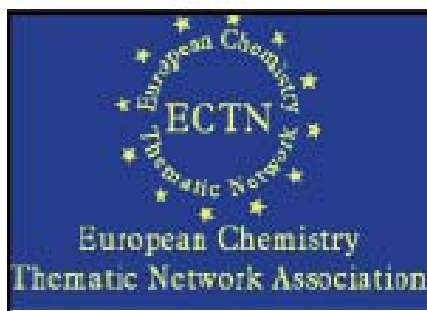
In addition

Possible other subjects required by the home university

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April 2008 : ECTNA awards Euromaster Measurement Science in Chemistry



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Euromaster MSC Summer Schools



- 2008 Celje, Slovenia
- 2009 Blagoevgrad, Bulgaria
- 2010 Tartu, Estonia



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Conclusions

- Ever changing world
- Facing communication challenges
- ... by Life Long Learning
- Education

