

CURRENT CHALLENGES IN BIO- METROLOGY: THE JRC SUPPORT TO FOOD SAFETY POLICIES

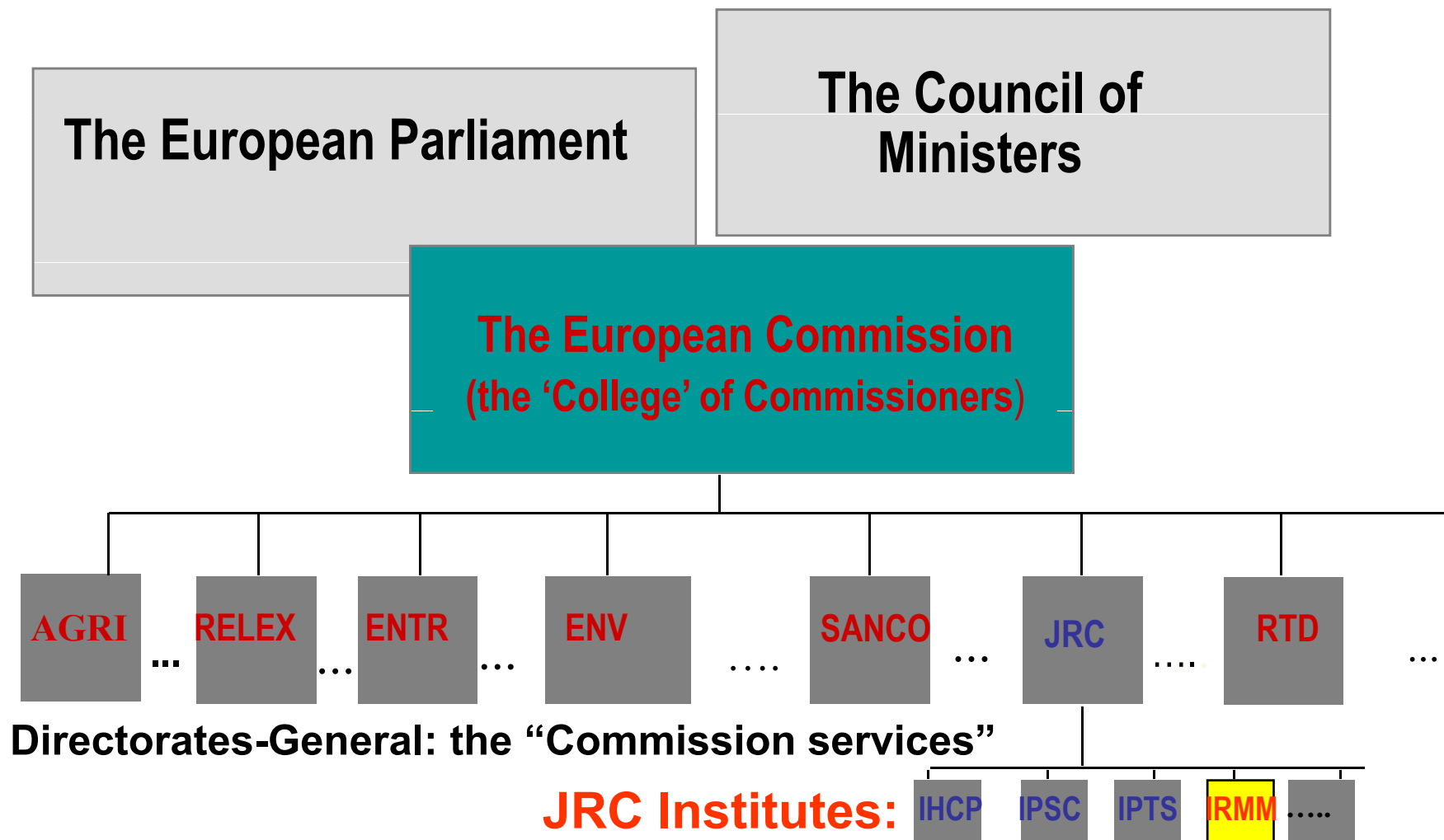


CENAM Symposium of Metrology
Queretaro, 22-24 October, 2008

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

www.irmm.jrc.be



Our Structure: 7 Institutes in 5 Member States

IRMM - Geel, Belgium
Institute for Reference Materials and Measurements
~340 staff

ITU - Karlsruhe, Germany
Institute for Transuranium Elements

IE - Petten, The Netherlands – Ispra, Italy
Institute for Energy

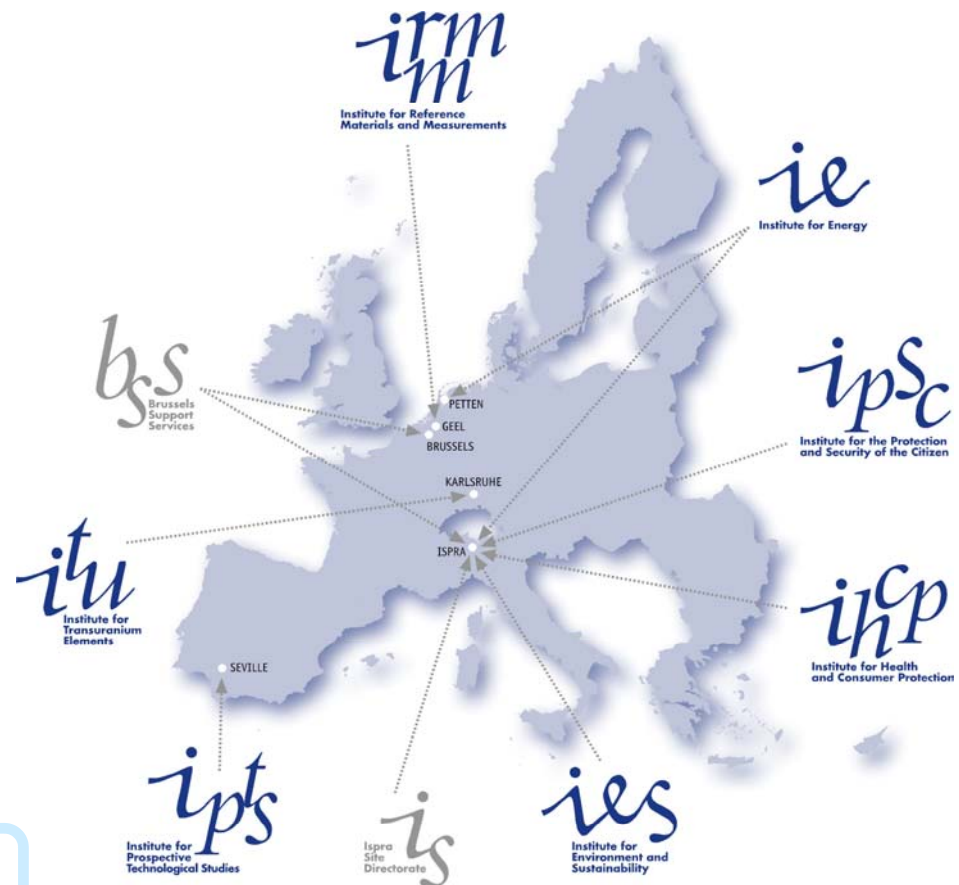
IPSC - Ispra, Italy
Institute for the Protection and Security of the Citizen

IES - Ispra, Italy
Institute for Environment and Sustainability

IHCP - Ispra, Italy
Institute for Health and Consumer Protection

IPTS - Seville, Spain
Institute for Prospective Technological Studies

~ 3000 staff
~ 330 M€/y budget (+ 40 M€/y competitive income)



The Mission of the Joint Research Centre

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

As a service of the European Commission, the JRC functions as a **reference centre of science and technology** for the Union.

Close to the policy-making process, it serves the common interest of the Member States, while being **independent of special interests**, whether private or national.



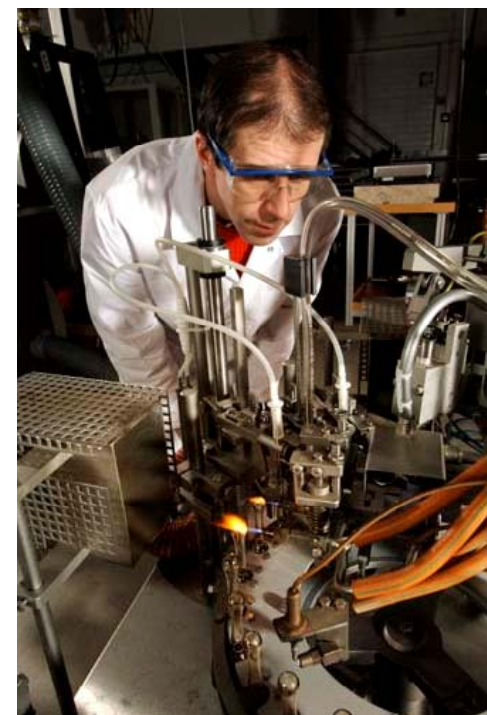
The role of JRC Institute for Reference Materials and Measurements

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

IRMM - CONFIDENCE IN MEASUREMENTS®

complementary to national activities:
providing quality assurance tools for all

<http://irmm.jrc.ec.europa.eu>



Millions of measurements are performed every year to implement European directives and regulations

- **The risk manager**

Making difficult choices on the basis of measurements results:
Who is right? Are the results comparable and reliable?

- **The industrial operators**

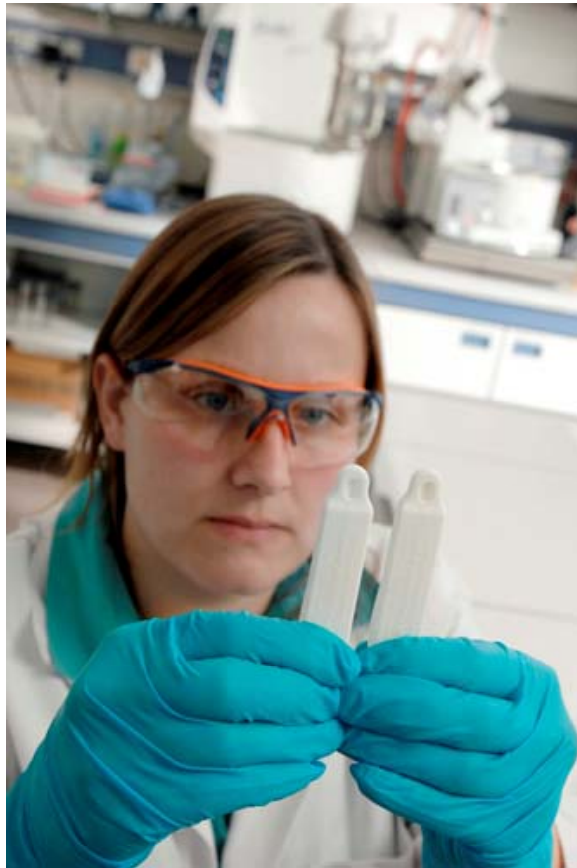
Are we being controlled by competent laboratories?
need for harmonising policy implementation in EU27+ and globally

- **The citizens**

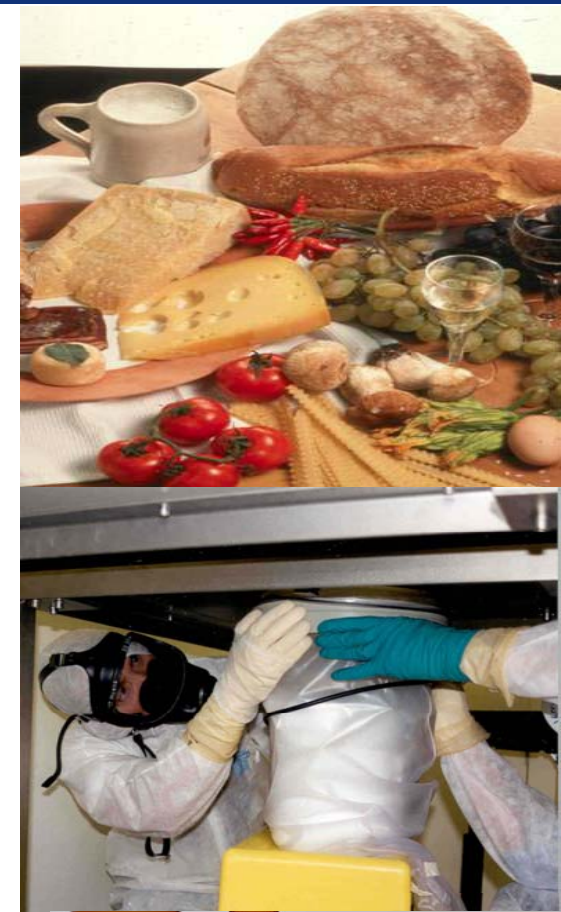
Who is checking the safety of our food and our environment?
What is the quality of the controls being made?



JRC-IRMM support to food safety

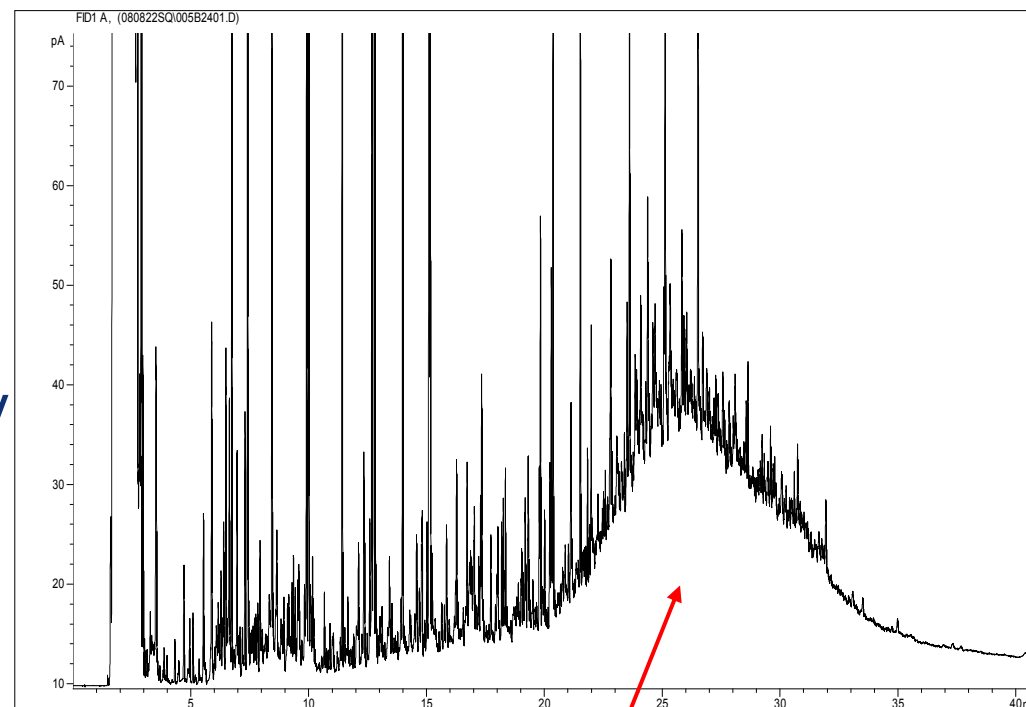


- Method development, validation & harmonisation
- Measurement evaluation programmes (e.g. heavy metals)
- Proficiency testing (e.g. acrylamide)
- Monitoring data bases (e.g. European wine)
- Reference materials
- Community Reference Laboratories
- Help desk and rapid interventions in
- emergency cases: some examples



Mineral contaminated sunflower oil

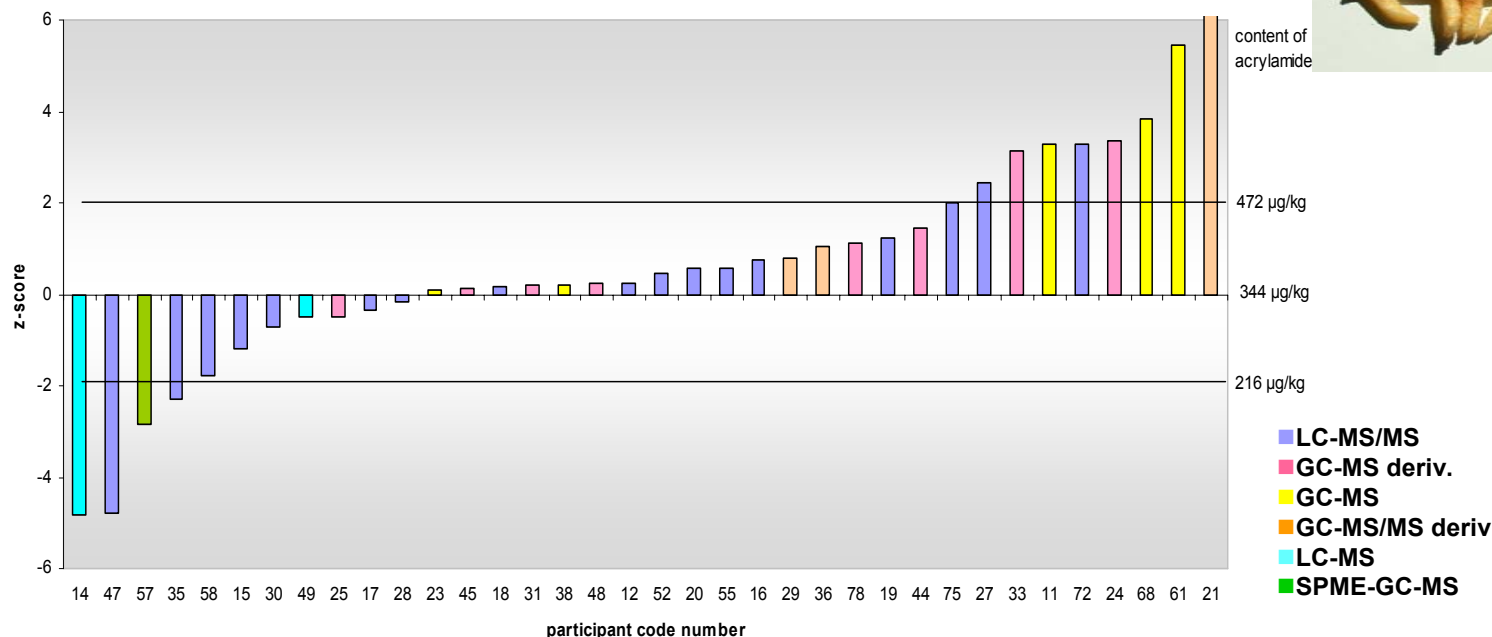
- Sunflower oil imported from Ukraine contaminated with mineral oil (up to 7 g/kg)
- Contamination source unclear
- Organisation of workshop together with expert laboratory
- Technical support to DG SANCO inspection in Ukraine
- Organisation of inter-laboratory comparisons with more than 70 participants ongoing



Mineral oil contamination

Support to solving the acrylamide problem

- Organisation of information exchange events
- Development of suitable method of analysis
- Four inter-laboratory comparisons
- Acrylamide data base (transferred to EFSA in 2008)
- Two method validation studies



JRC-IRMM develops and validates analytical methods: consensus building among EU27+

validated methods are submitted to...

- **Committee European for Standardisation (CEN)**
- **Association of Analytical Communities (AOAC) International**
- **International Standardisation Organisation (ISO)**
- **Codex Alimentarius**

... and become standards e.g. in the field of food allergens, mycotoxins, sweeteners, vegetable fats



Analytical laboratories designated by Community directives and regulations on the basis of their excellence

An integral part of European risk management system

Organised by sectors: 40 CRLs

Biological risks:	12
Animal Health:	13
Chemical risks:	13
GMOs:	1
Feed additives:	1



A CRL fulfills its tasks in collaboration with a network of National Reference Laboratories (NRLs) in the Member States: ~1200 labs!



- EU-wide standards for testing methods
- Organise comparative tests, train analysts from national laboratories and improve their performance in measurements
- Know international standards and practices
- Keep lists of reference substances and their suppliers

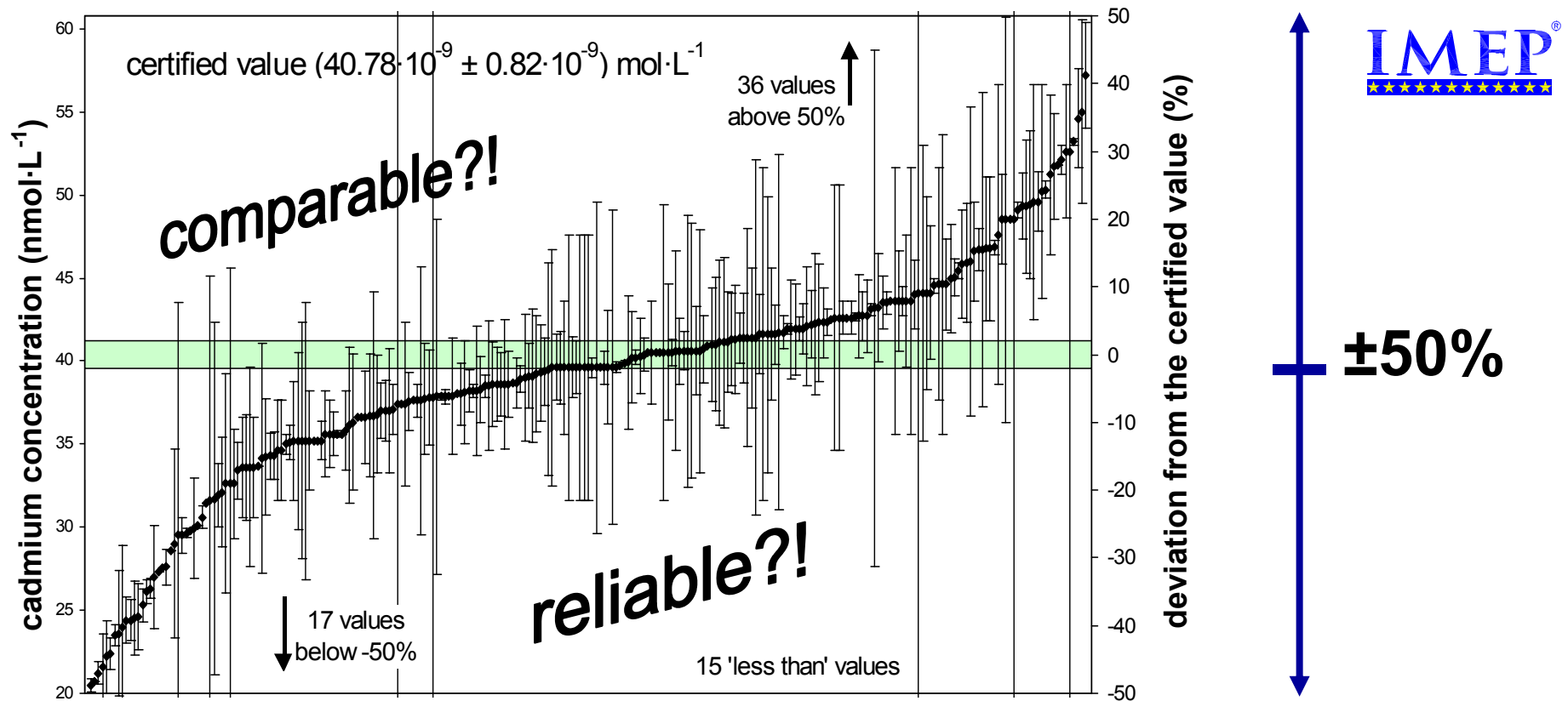
6 CRLs in the JRC:

- Mycotoxins
- PAHs
- Heavy metals in food and feed
- Feed additives
- GMOs in food and feed
- Food contact materials

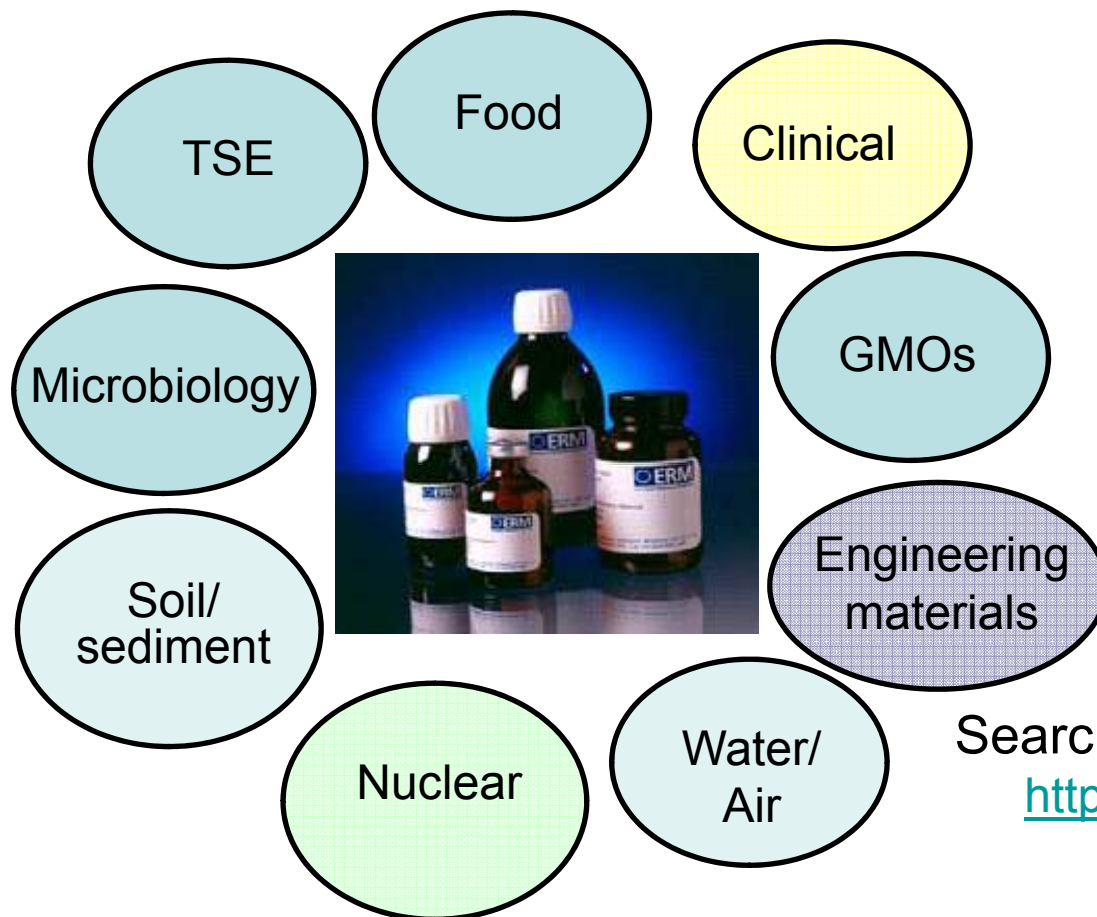
JRC coordinates networks of ~270 National Reference Laboratories in different fields

Improving EU testing laboratories' performance

- >3500 laboratories have participated in the International Measurement Evaluation Programme since 1989;
- ~ 1000 from new Member States



Certified reference materials (CRMs): standards for measurements



- > 650 reference materials = 'measurement standards'
- > 23 000 units distributed/yr
- 51 new sets released in 2007
- user support

European Reference Materials

Searchable reference materials catalogue:
<http://irmm.jrc.ec.europa.eu/rmcatalogue>

Challenges in bio-metrology



Bio-metrology: the science to face the measurement challenges in molecular biology

➔ **Research on fundamental measurement science concepts in molecular biology**

- **Many interested international bodies (CIPM/CCQM, EURAMET, EURACHEM, WHO, CITAC),**
- **industry, research community**
- **professional organisations (IFCC, AOAC, ...)**

▶▶ **Contribution to the development of common testing and measurements standards for food, environment and health, clinical biochemistry, epidemiology...
CEN, ISO, Codex, JCTLM ...**

Regulatory frameworks, should be supported by highest reliability and consistency of data

Measurements at different places, and made over time, should be **comparable**

To achieve comparability, the traceability paths to well defined standards, and the standards used, should be **reproducible** providing a stable measurement scale

New bio-metrological concepts should promote technical **innovation** and improvements in measurements **techniques and instrumentation**

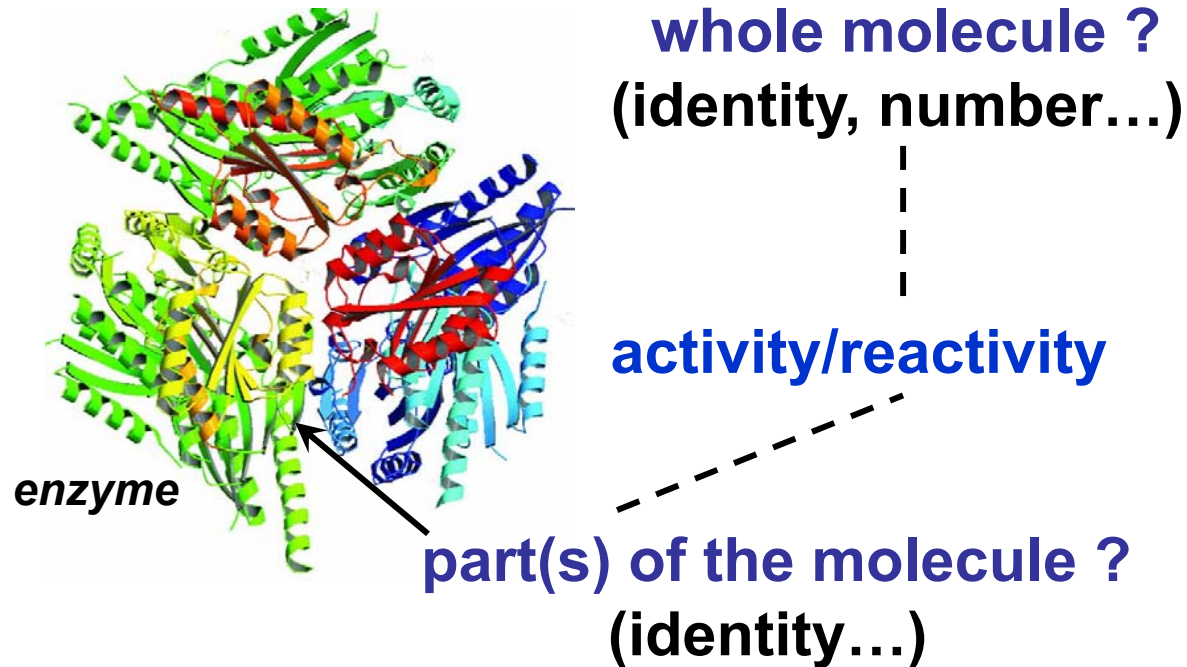
Measurements of biological compounds are complex and uncertainties can be large because:

The measurand is often not a single, well defined chemical entity (**do we know what are we measuring?**)

The outcome of measurements is not only depending on the amount of the measurand but also on its properties, e.g. intactness, structure, reactivity (**do we know how to measure it?**)

The sample properties and the way it is treated can have a drastic effect on the measurement results (**can we preserve the integrity of the measurand?**)

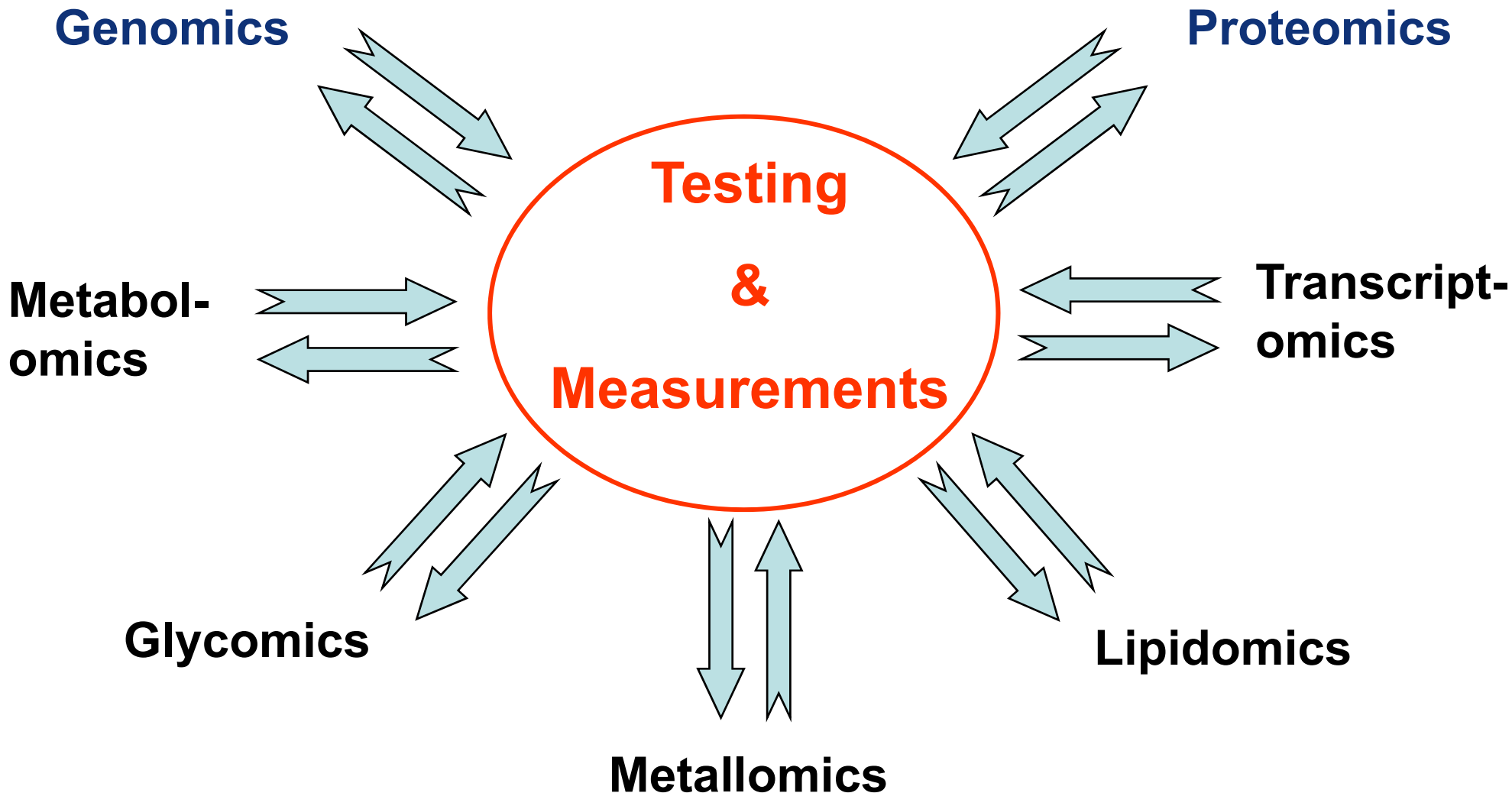
Biological variation and its expression at molecular level can influence the behaviour and detectability of the measurand (**can we compare results?**)



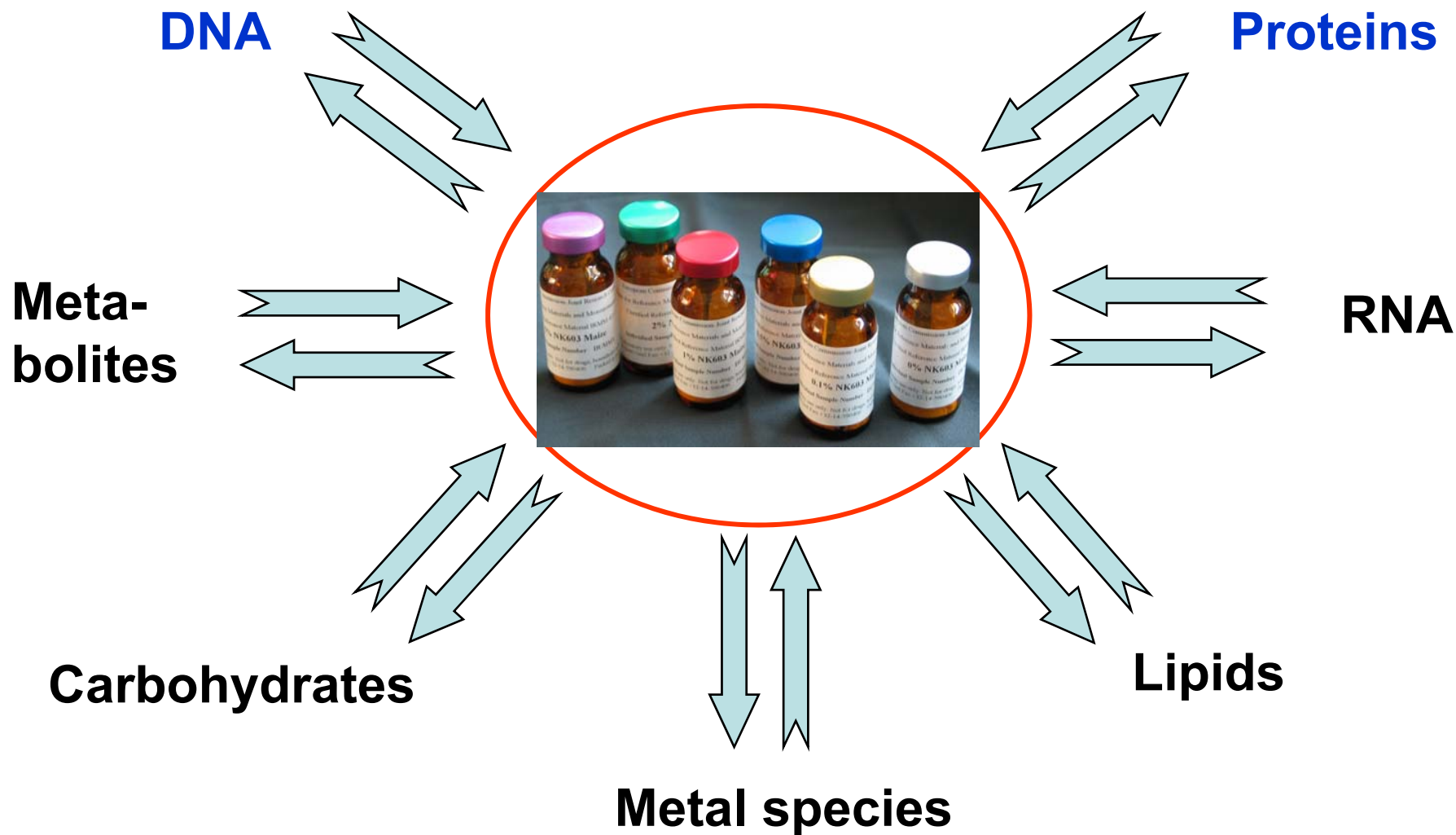
Challenge: Definition of measurand & unit

DNA: % or copy number?

The “Omics” Era



Pure substances & embedded in biological matrices

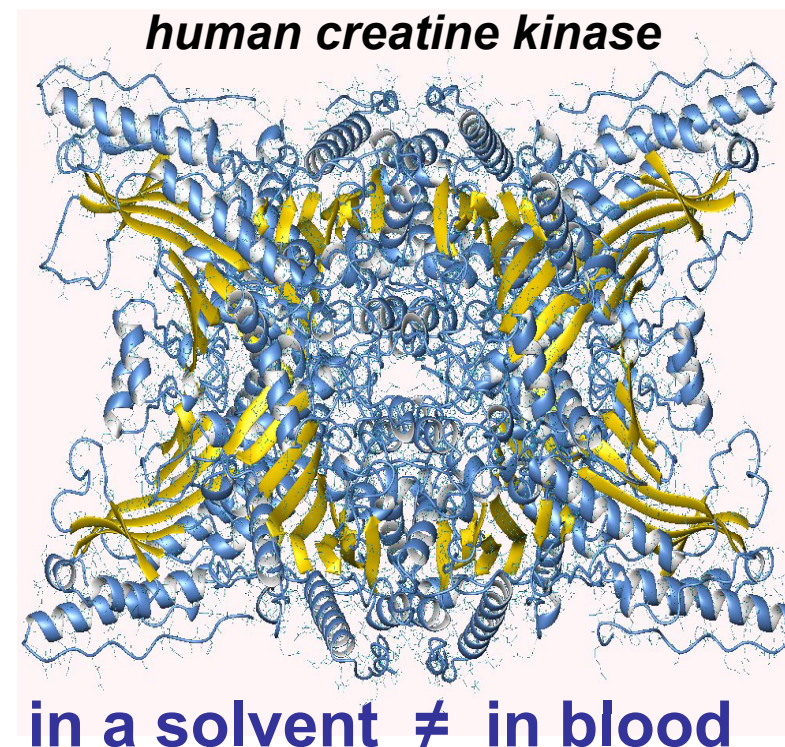
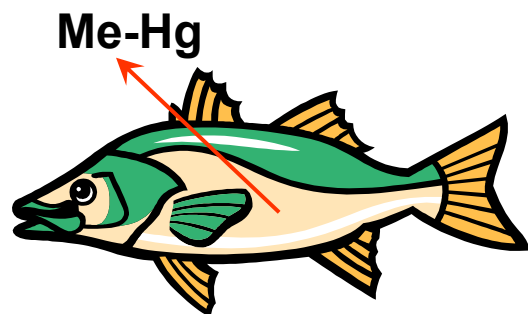


Requirements for producing further “omics” CRMs:

- **Development of very precise methods for homogeneity & stability studies of candidate RMs**
- **Development of reliable methods independent of routine methods for characterisation of RMs**
- **Development of commutable RMs and their validation for calibration and overall quality control purposes**
- **Design of QA schemes (calibration, method validation & verification, PTs)**

Possible “matrix effects”:

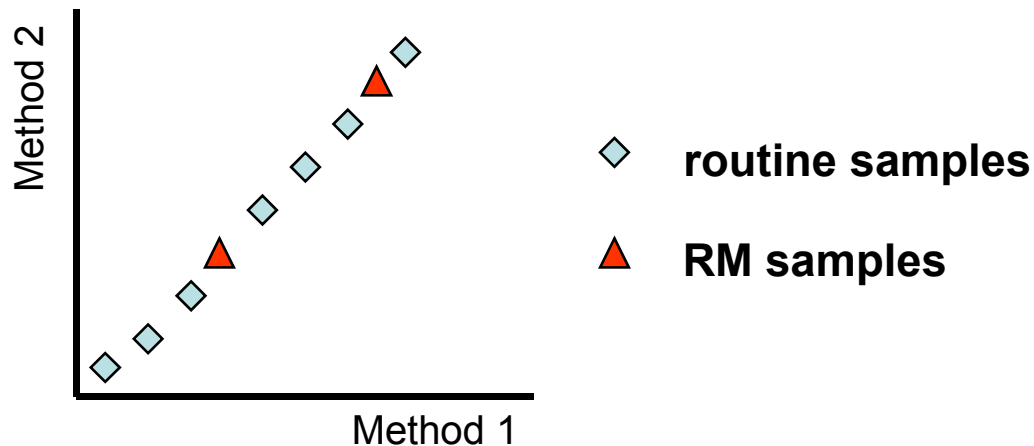
1. Different **interactions** between the ‘measurand’ and its molecular microenvironment **relevant for the measurement procedure**



- Standardisation of bio-molecular measurements requires:**
- a deep understanding of the analyte at molecular level (**structure**), and of the micro-environment where it is embedded (**matrix**)
 - a thorough knowledge and control of critical factors influencing the results of measurements (**“Robustness”**)
 - an adequate validation of the reference materials and calibrants developed as **“commutable”** to real world samples

“Closeness of agreement between the mathematical relationship of the measurement results obtained by two measurement procedures for a stated quantity in a given material, and the mathematical relationship obtained for the quantity in routine samples”

ISO 17511 (2003)

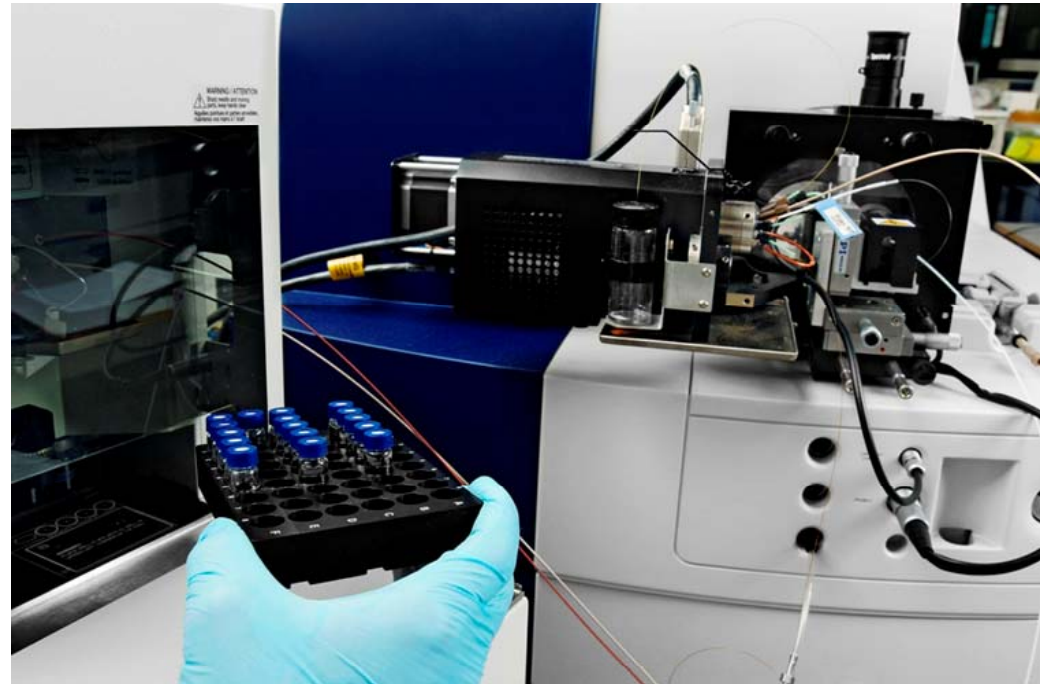


**comparable (identical)
'analytical behavior' of
reference material and
real (routine) sample ?**



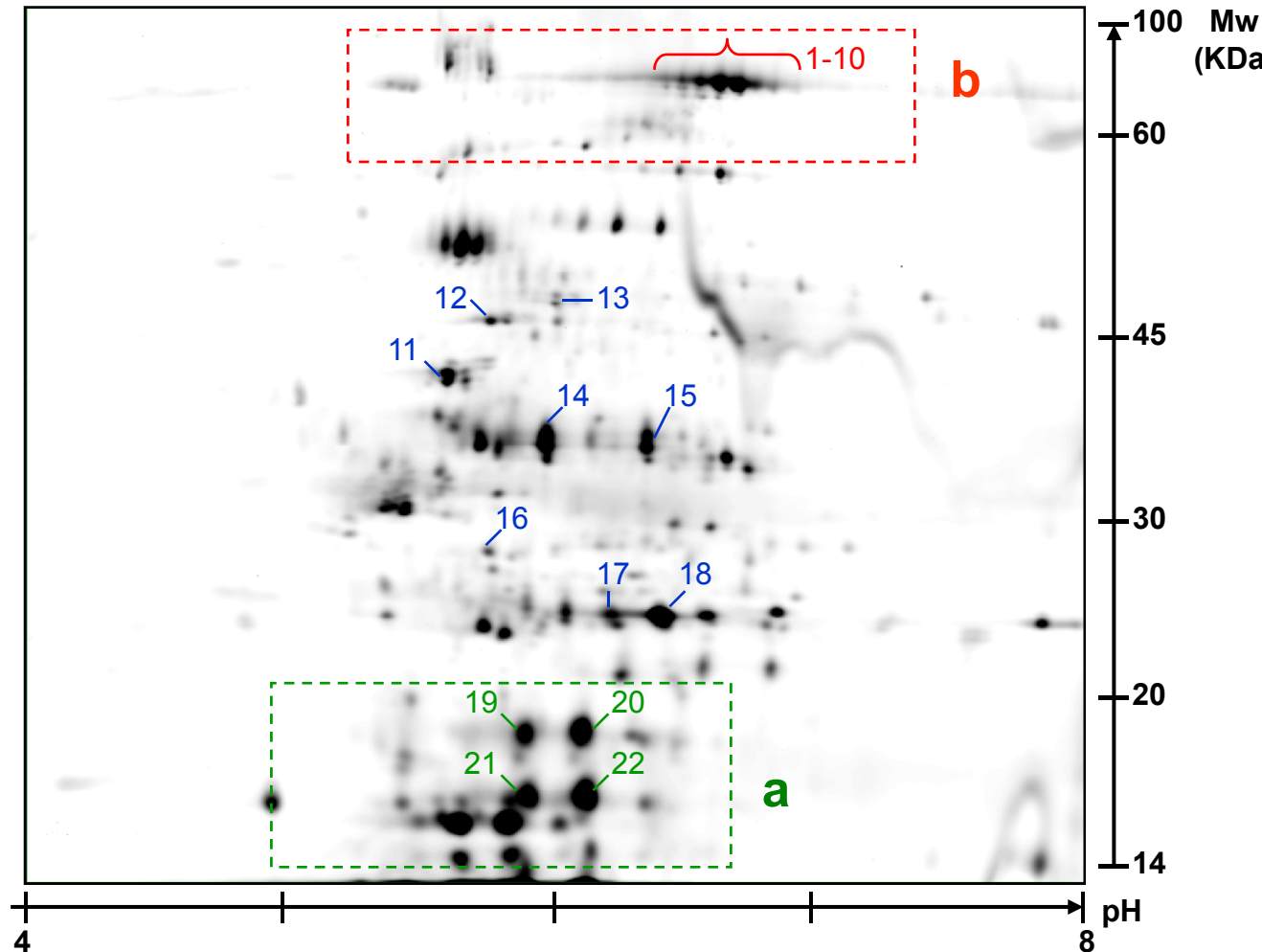
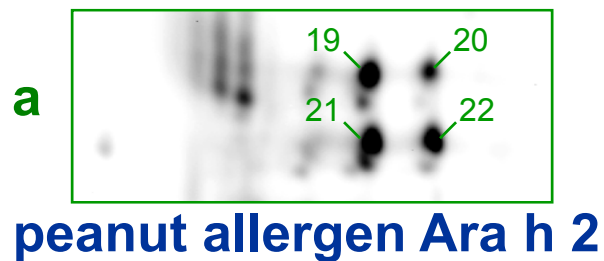
Scientifically sound and operationally feasible designs for commutability studies need to be further developed

Example 1. Allergens



Identification of major peanut allergens in 2D maps

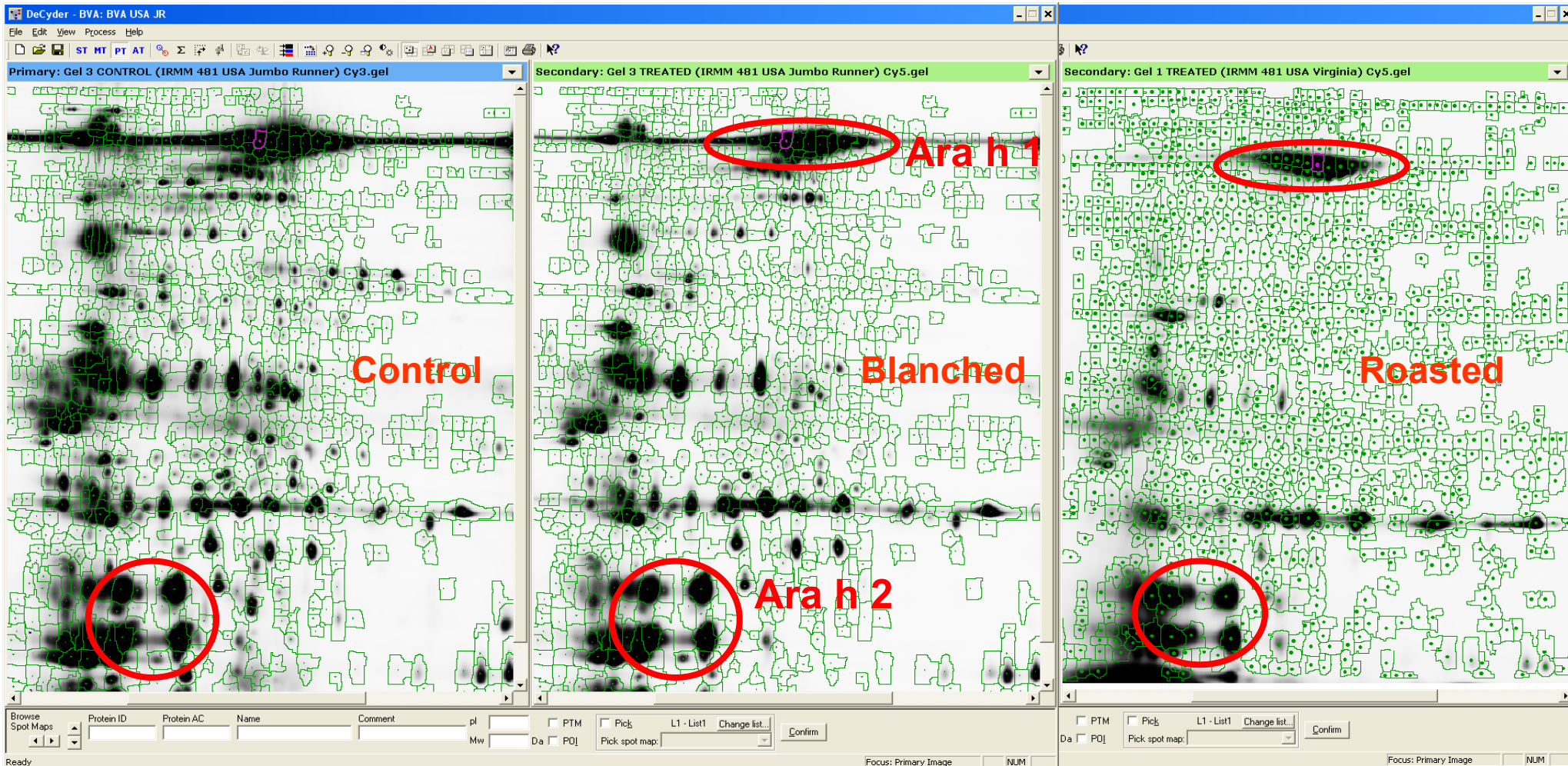
What to measure ?





What happens to allergens following different processes?

Effect of heat treatment



Example 2. Prions testing



by independent test evaluation

- JRC-IRMM

by quality control

- JRC-IRMM has developed a “golden standard”, in collaboration with Nobel Prize winner Prof. S. Prusiner

proficiency testing

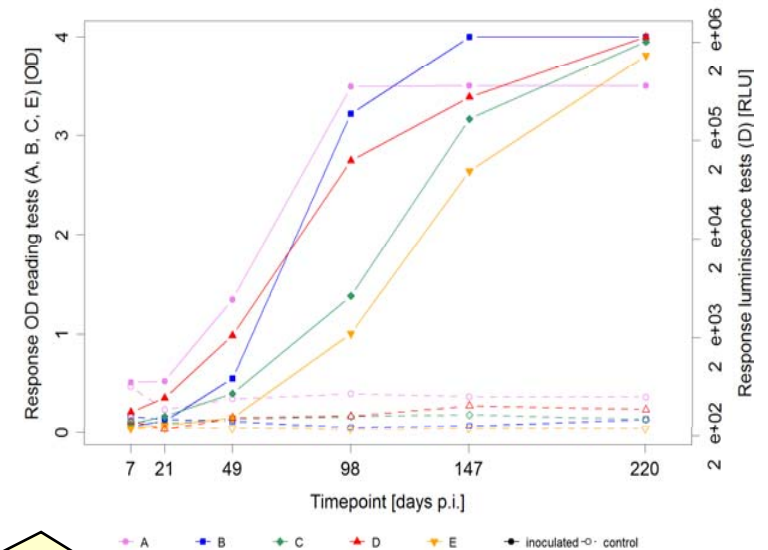
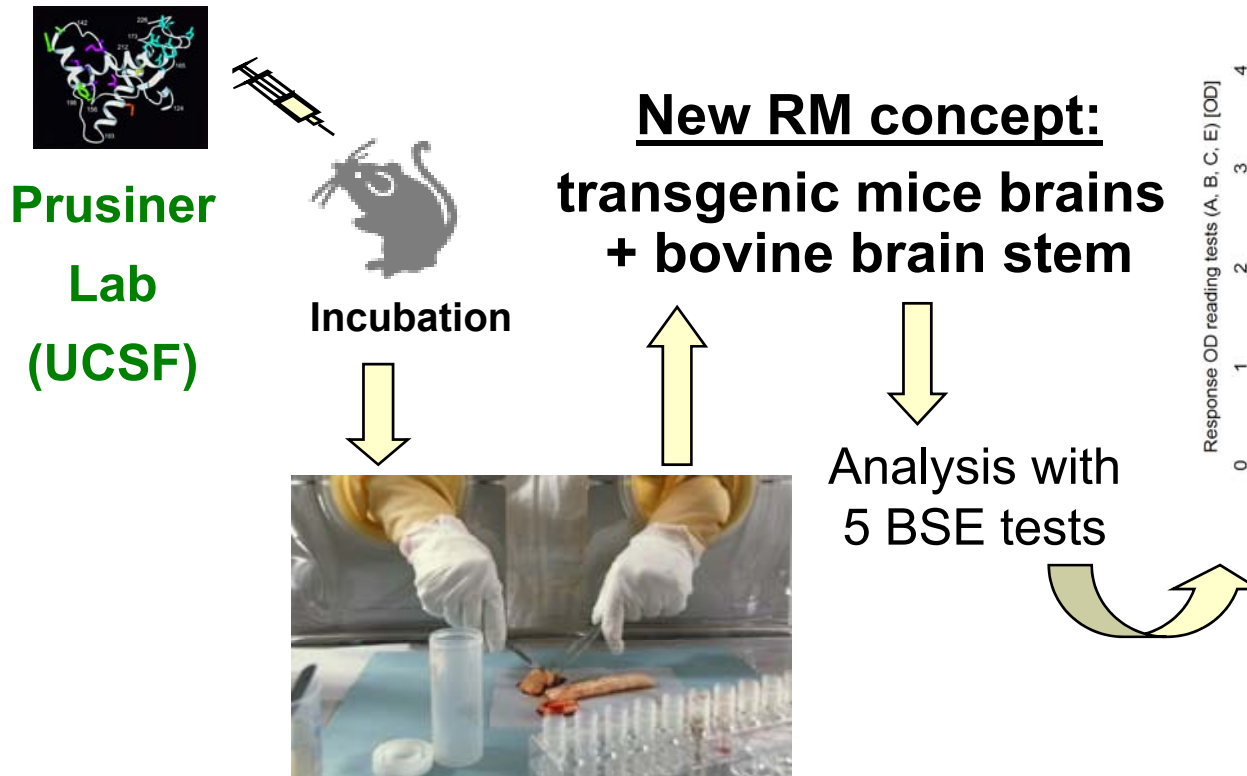
- all national reference laboratories of Member States and Candidate Countries
- Corrective measures



A) Test-specific control materials:

3 types of BSE RMs developed

B) Universal, sustainable BSE control material:



1999-2005: evaluation of 20 rapid *post mortem* tests for BSE and 10 for “Scrapies” (a total of 60.000 test samples prepared)

3 evaluation rounds (2001, 2003, 2005)

12 BSE tests approved for testing in EU

Cooperation with Nobel Laureate Stanley Prusiner



Approval of more tests opens up competition...

**...and brings about a significant drop in price
of the diagnostics kits**

**...and reduces the amount of subsidies paid by
the Commission to the Member States.**

***What would have been the cost of not doing the
second and third evaluation rounds?***

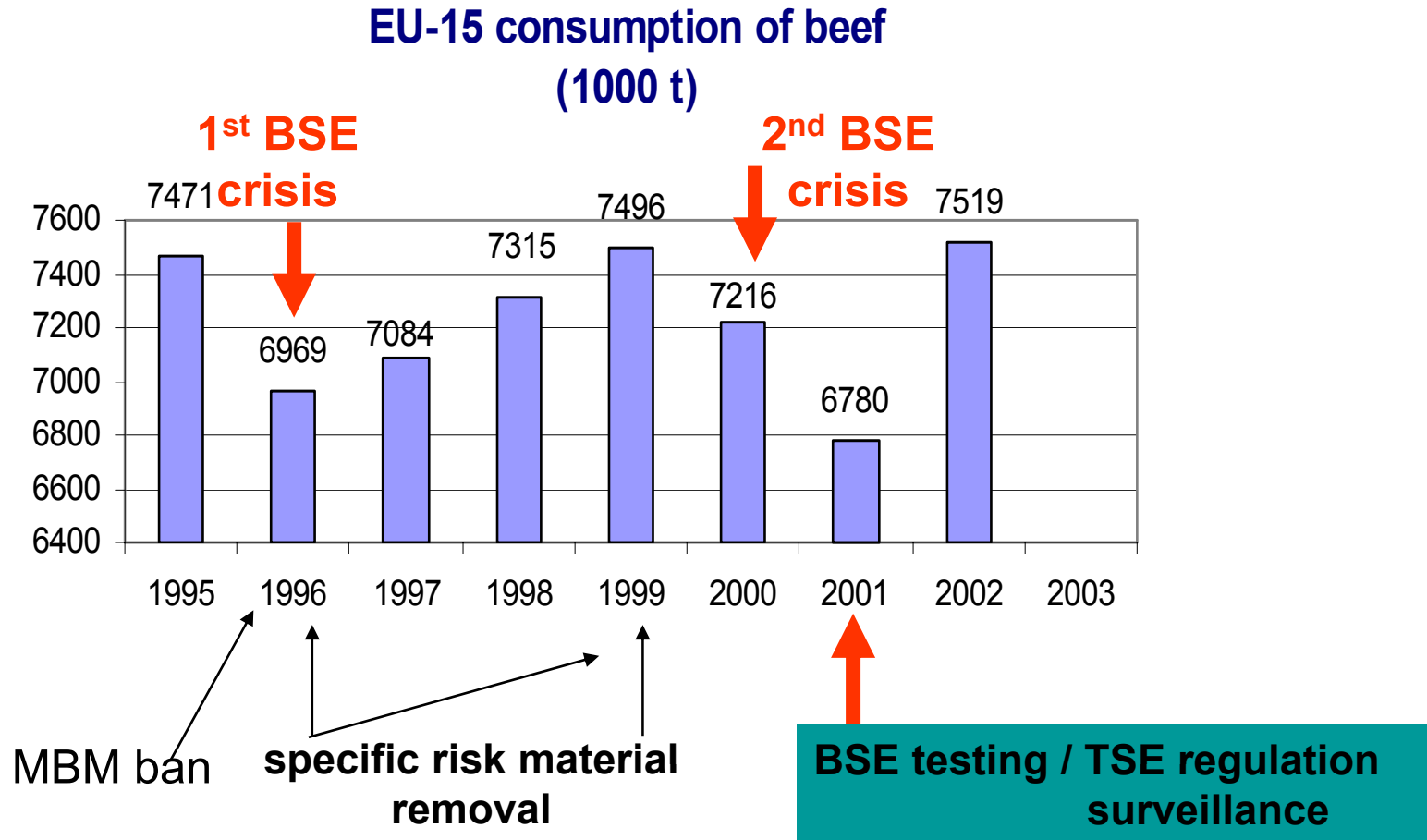
...and brings about a significant drop in price of the diagnostics kits (excluding labour costs)...

...and reduces the amount of subsidies paid by the Commission to the Member States

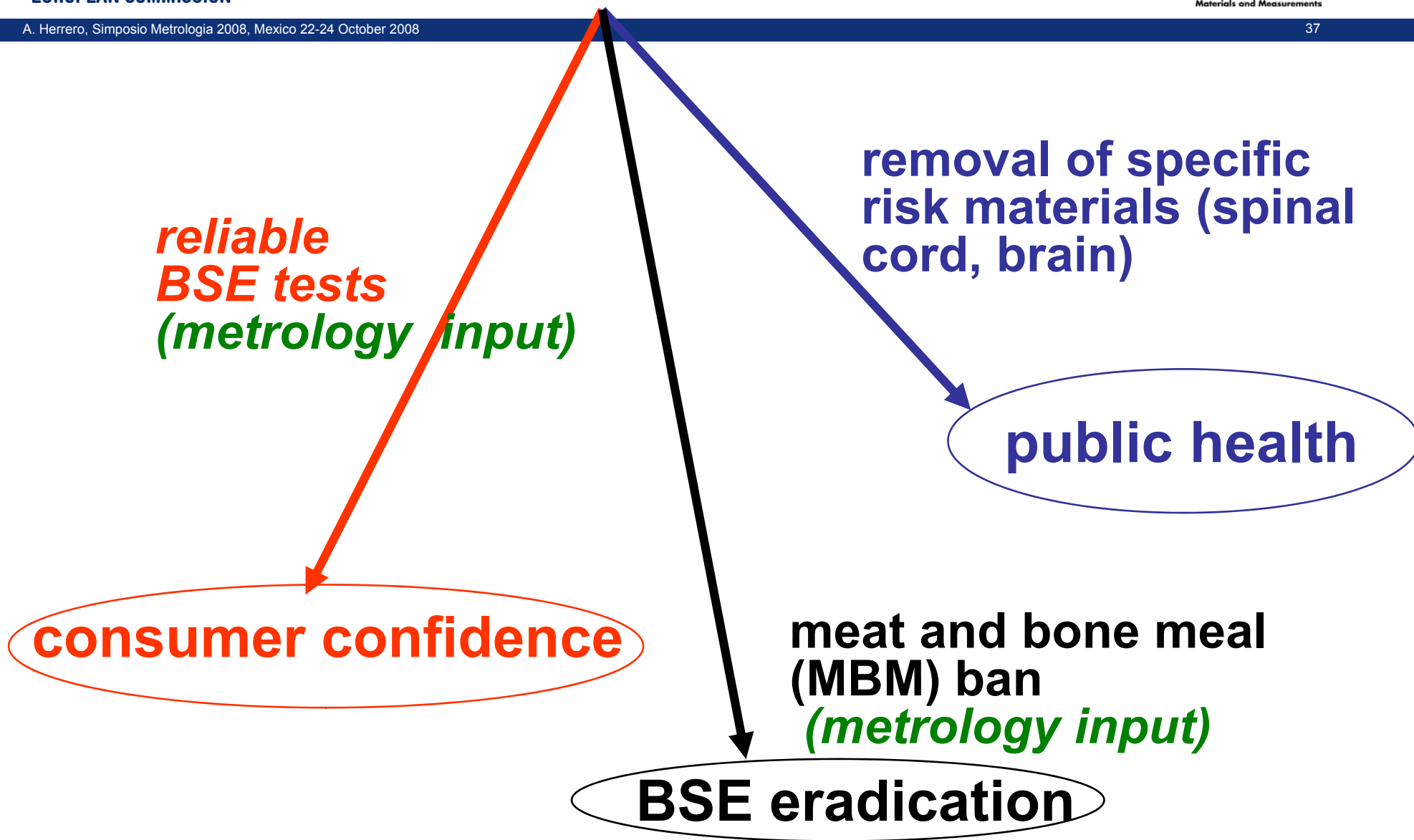
Direct subsidies (EC) per test reduced from 20€ to 7€ (a fraction of the diagnostics cost)

7/2001	2002	2003	2004	2005	2006
€ 20	€ 15	€ 12,5	€ 10	€ 8	€ 7
3 BSE tests		5 BSE tests		12 BSE tests	

Total savings (2002 as the base year) ~ 250 M€



**Economic Impact: 1800 M€ back into the
beef market**



- Cost of testing has decreased
- Subsidies could be reduced
- Consumer confidence has been restored
- EU-Legislation has benefited from metrological input



Thank you!

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Robust science for policy making

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