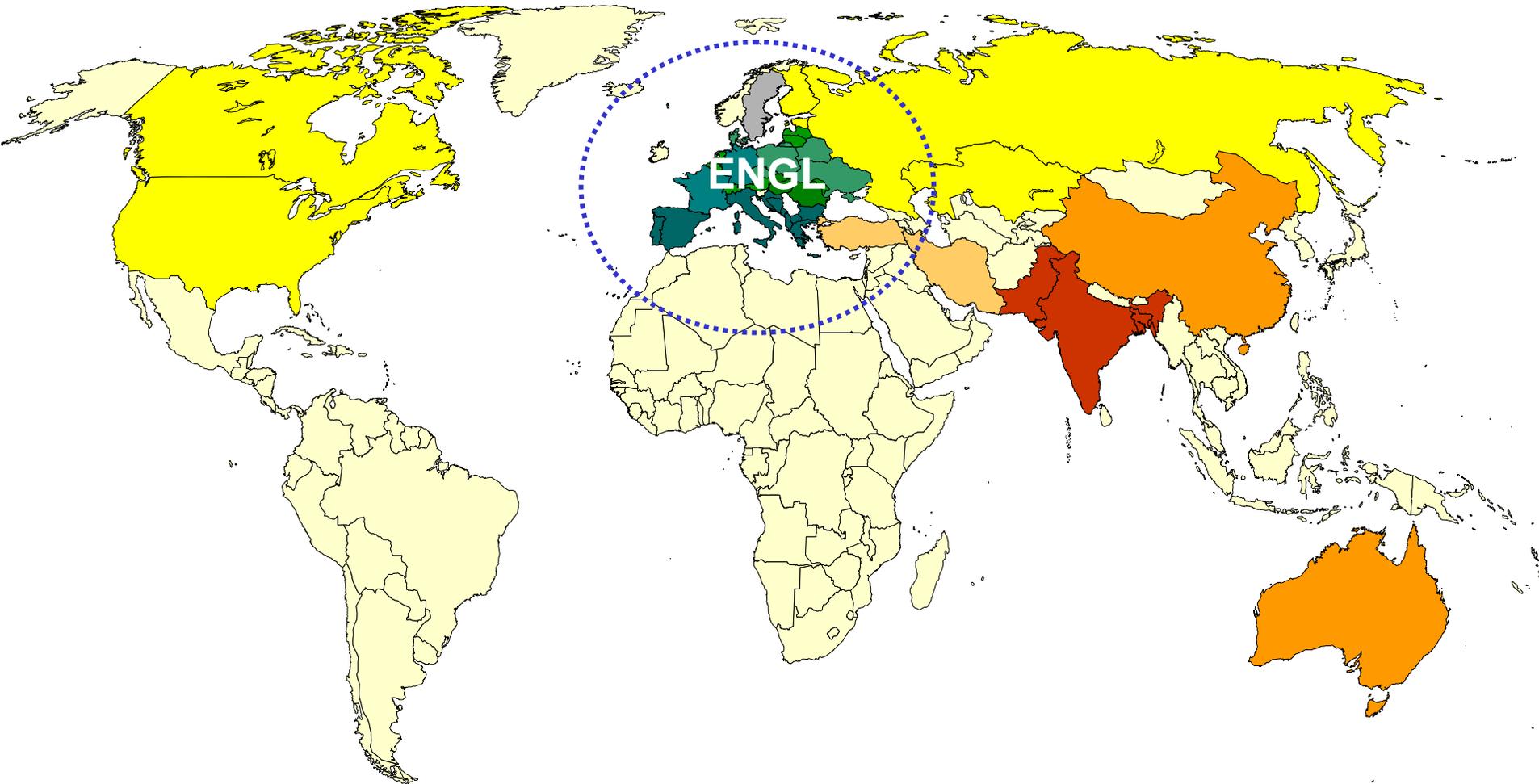


2009-2010 progress in GMO analysis and presentation of the '*Compendium of validated reference methods*'

Guy VAN DEN EEDE

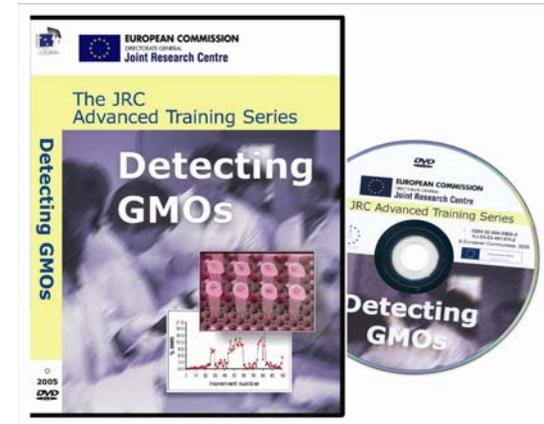
Molecular Biology & Genomics Unit
Institute for Health and Consumer Protection (IHCP)
European Commission Joint Research Centre





TRAINING:

- In-house;
- Cyprus, Hungary, Tunisia, ...
- Together with ILSI, ICGEB, ...
- *Ad hoc*, e.g. Rumania, FVO



USER MANUAL:

- English
- French
- Spanish
- Russian
- Chinese
- Turkish
- Portuguese (*in preparation*)

The way towards the ‘Enlargement, International Collaboration and Capacity Building’ Project

- 1998 – *ongoing* Expertise in molecular approaches for GMO analysis
- 2000 – *ongoing* Training and capacity building programme
- 2002 Establishment of the European Network of GMO Laboratories (ENGL)
- 2003 EU Reference Laboratory for GM Food and Feed (EURL-GMFF)
- 2004 EU-RL Mandate according to Regulation (EC) No 882/2004
- 2008 1st Global Conference on GMO Analysis



- **2009** International Collaboration and Capacity Building Project kick-off







1st Global Conference on GMO Analysis

Villa Erba, Como, Italy
24-27 June 2008

<http://gmoglobalconference.jrc.it/>

 **JRC**
EUROPEAN COMMISSION

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

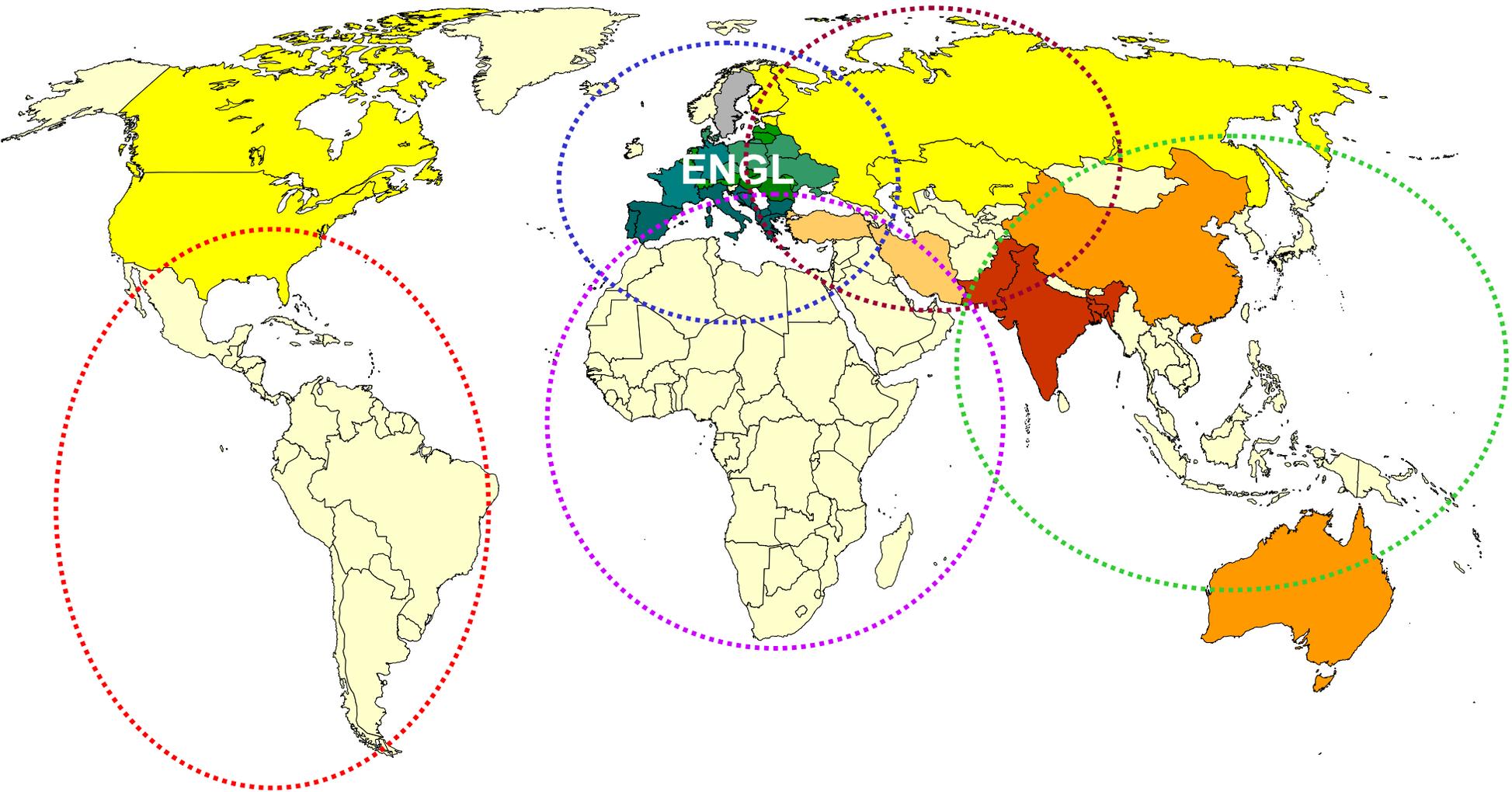
‘Enlargement, International Collaboration and Capacity Building’ Project

Project Aim

- To share the networking experience and the advantages derived from the implementation of the ENGL in the EU
- To support the establishment of regional networks outside the EU
- To help building capacity by providing training to enforcement laboratories

Developed through:

- Networking workshops
- Support toward the establishment of regional networks
- Regional training courses
- Dedicated web page



Enlargement, International Collaboration & Capacity Building

**International Workshop on
Harmonisation of GMO Detection and Analysis**

Foz do Iguaçu (Brasil), 4-5 December 2009

<http://mbg.jrc.ec.europa.eu/capacitybuilding/>



Roadmap 2009 - 2012

Latin America

- Cuba, October 2009 - Training Course for Central & South American Countries
- Brazil, 3 - 4 December 2009 - Regional Networking Workshops for Central & South American Countries
- Ispira, 8-12 November 2010 - Study Tour on GMO Analysis for Central & South American Countries
- Mexico, January 2011 - 2nd Regional Networking Workshop for Central & South American Countries
- January 2012 - 3rd Regional Networking Meeting for Central & South American Countries

Roadmap 2009 - 2012

Asia

- Malaysia, 16 -17 June 2009 - Regional Networking Workshop for Asian Countries
- Malaysia, 15 -19 June 2009 - Training Course for Asian Countries (EC BTSF Initiative)
- Singapore, 7-8 June 2010 - 2nd Regional Networking Workshop for Asian Countries
- Singapore, June 2011 – 3rd Regional Networking Workshop for Asian Countries

Roadmap 2009 - 2012

EU neighbourhood

- Turkey, 27 - 28 April 2009 - Enlargement/Networking Workshop for new MS, Candidate Countries, Potential Candidate Countries and Territories, Countries incl. in the European Neighbourhood Policy
- Turkey, 12-16 April 2010 - Training Course for new MS, Candidate Countries, Potential Candidate Countries and Territories, Countries incl. in the European Neighbourhood Policy
- Croatia, 27-28 September 2010 - 2nd Enlargement/Networking Workshop for new MS, Candidate Countries, Potential Candidate Countries and Territories, Countries incl. in the European Neighbourhood Policy
- October/November 2011 - 1st Regional Networking Workshop for the Middle East

Roadmap 2009 - 2012

Africa

- Tunisia, 18-22 September 2006 – Training course on the analysis of food and feed samples for Maghreb region
- South Africa, 28-29 October 2010 – 1st Regional Networking Workshop for African Countries
- January/February 2012 – 2nd Regional Networking Workshop for African Countries

Legal notice 

 European Commission
Joint Research Centre
Institute for Health and Consumer Protection

European commission > JRC > IHCP > MBG Unit > Capacity Building

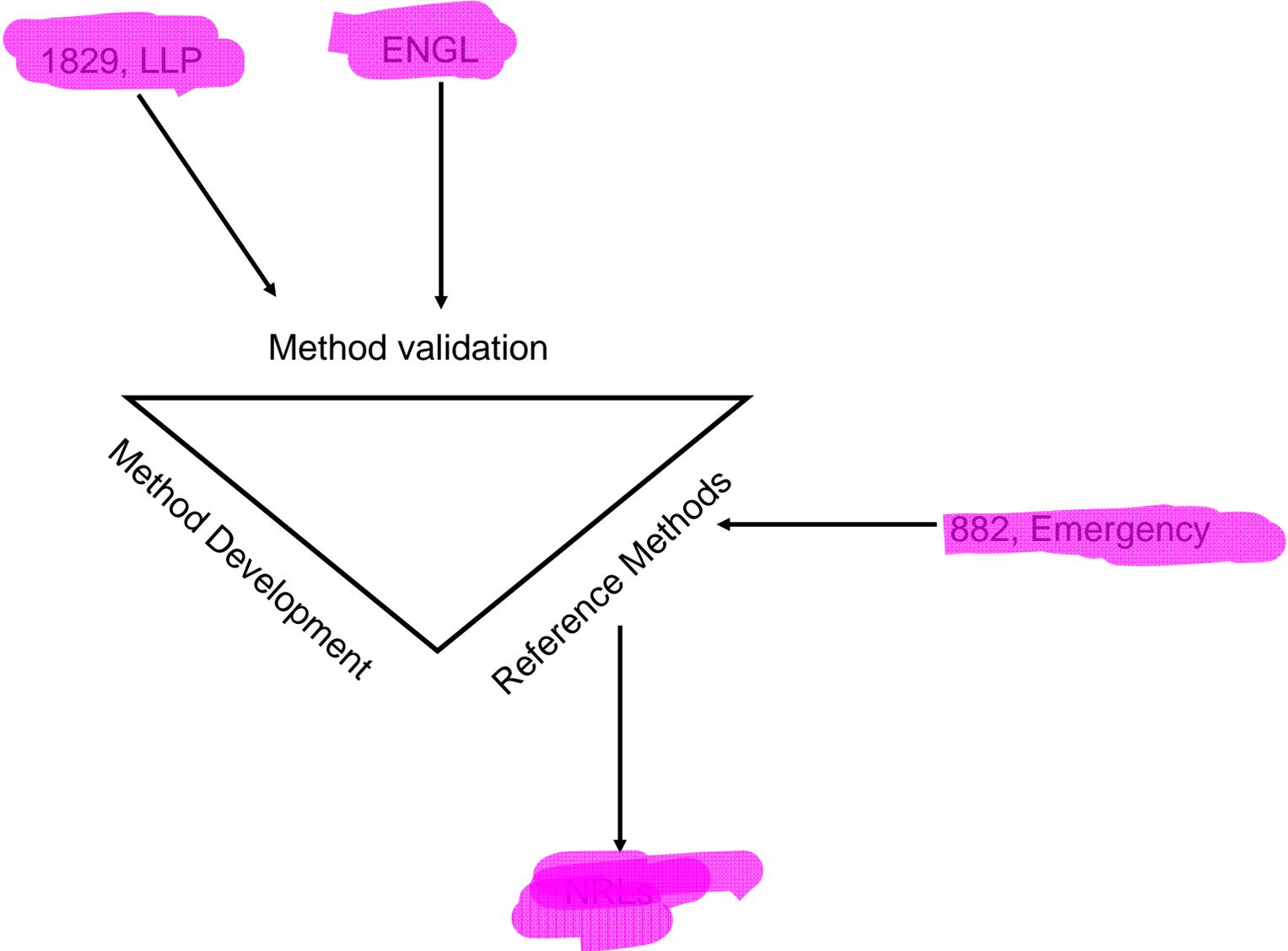
Enlargement, International Collaboration & Capacity Building



The Molecular Biology and Genomics Unit of the Institute for Health and Consumer Protection (European Commission, Joint Research Centre) plays a leading role in the area of analysis of food, feed and environmental samples for the presence of genetically modified organisms (GMOs).

Here we present the international activities related to capacity building and training and we provide regular updates on workshops, training sessions and conferences we organise that aim to increase expertise and to foster international collaboration and harmonisation.





Article 32(1) of Regulation (EC) No 882/2004:

*“the European Union Reference Laboratories for feed and food are responsible, amongst others, for “providing National Reference Laboratories (NRL) with **details of analytical methods, including reference methods**”*

Concept of “Reference Methods”

- Not strictly defined in EU GMO legislation

- **ENGL & EURL-GMFF criteria:**

- 1: DNA-based detection methods (Recommendation EC/2004/787) - Polymerase Chain Reaction (**PCR**) based methods

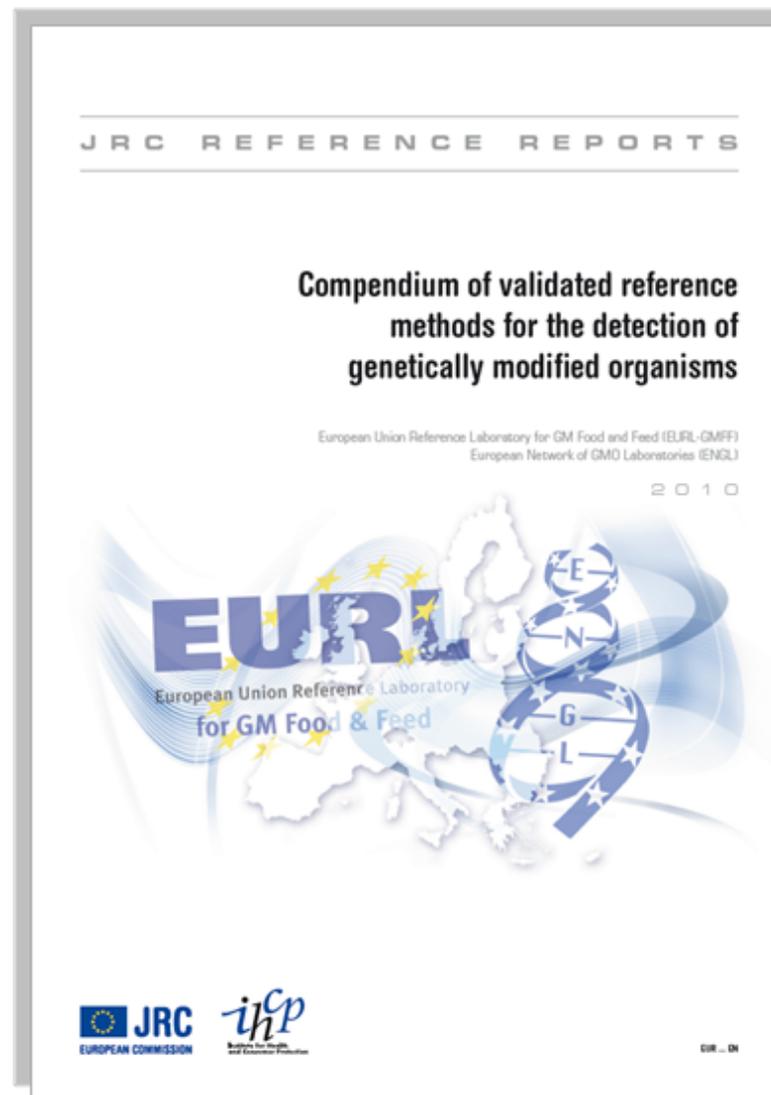
- 2: Validated through collaborative trial according to the principles of and in compliance with **ISO 5725** standard and/or the **IUPAC** guidelines

Aim:

Provide an up-to-date reference for all collaborative trial validated methods for the detection of Genetically Modified Organisms (GMO)

Collaboration between the EURL-GMFF & European Network of GMO Laboratories (ENGL)

Official Release: 10th November 2010



Overall structure of the Compendium:

Introductory part

Chapter 1: Quantitative Methods

Chapter 2: Qualitative Methods

Quantitative GMO detection PCR Methods:

- Type: (EURL-GMFF) Event-specific, Element- & Taxon-specific methods

- Method Performance Parameters:

 - Trueness & Bias

 - Reproducibility

 - Repeatibility

 - PCR efficiency, LOD, LOQ

Qualitative GMO detection PCR Methods (= screening methods)

- Type: Element-, Construct-, Event-, & Taxon-specific methods

- Method Performance Parameters:

 - False positive/negative results

 - LOD

GMO detection PCR Methods:

Chapter 1: Quantitative GMO detection PCR methods (48)

Maize quantitative PCR methods (20)

Soybean quantitative PCR methods (9)

Cotton quantitative PCR methods(8)

Oilseed rape quantitative PCR methods (4)

Potato quantitative PCR methods (1)

Rice quantitative PCR methods (1)

Sugar beet quantitative PCR methods (1)

Element- and Taxon-specific quantitative PCR methods (4)

Chapter 2: Qualitative GMO detection PCR methods (31)

Element-specific qualitative PCR methods (15)

Construct-specific qualitative PCR methods (8)

Event-specific qualitative PCR methods (2)

Taxon-specific qualitative PCR methods (6)

Compendium distribution:

- Official presentation: 10 November 2010
- Compendium booklet distribution
- Compendium document available as PDF file
(http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_2010_11_gmo_analysis_compendium.pdf)
- **Web application in preparation**

FUTURE ROADMAP OF THE COMPENDIUM

- Consolidation of content (by march 2011)
- Yearly update
- Guidelines to method acceptance criteria
- *Other types of methods (protein, arrays, DNA extraction...)*

WWW-Compendium Dbase (*Web application in preparation*)

- All GMO detection methods described in the Compendium
- Search functions at various levels (event, target, crop ...)
- Open access
- Contains all info retained in the Compendium

Comparative Testing

General definition:

‘evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons’

Standard ISO/IEC 17043:2010(E) (Ed1 from 01-02-2010)

Scope: very broad (quantitative, qualitative, sequential, simultaneous, single occasion, continuous scheme...)

Comparative Testing

- Comparative Testing (CT) is a quality tool which measures the outputs of a laboratory
- CT is complementary to other quality assurance tools which are concerned with inputs such as use of CRMs, implementation of a formal Quality System, etc.
- CT is concerned with a laboratory routine methods with routine sample types
- CT is educational - there should be no “pass” or “fail”

General Comparative Testing Procedure

Step 1 Dispatch

Step 2 Analysis

Step 3 Statistics

Step 4 Report

Step 1 Dispatch

- Test materials are dispatched to participating laboratories
- Specific instructions about storage or handling of the test material and the closing date by which the results should be returned.
- Some instructions may be included with the analysis to allow results to be compared but no specific methods to be used are indicated

Laboratories are encouraged to use their own methods and procedures to reflect the handling of real samples as closely as possible.

Step 2 Analysis

Participants analyse test materials and report results and methods (e.g. via the web)

Step 3 Statistics

A statistical analysis of results is performed and a **z-score** is awarded to the laboratory, which provides an assessment of the individual performance.

Full details of the statistical procedures used to calculate z-scores are detailed in the protocol.

Step 4 Report

After the closing date a *confidential* report is made available to participants.

This report identifies the performance of the laboratory and the *anonymous* performances of other laboratories in the test for comparison.

The report also contains details of the test material preparation, the testing carried out to ensure the test material is homogenous and methods used by participant laboratories.

NEW: Proficiency Test Provider should give ‘comments or recommendations, based on the outcomes of the proficiency testing round’ (ISO/IEC 17043)

Proficiency test Providers:

- **FAPAS/GEMMA (UK) (powders, DNA)**
- **ISTA (CH) (Seeds)**
- **BIPEA (F) (powders)**
- **GIPSA (US) (powders, DNA)**
- **JRC-IHCP/IRMM (EU) (powders)**

INTERPRETATION of PT outcome

Key evaluator: z-score (acceptable between ± 2)

- Indicates results as equally well performing as the other participating labs in the PT

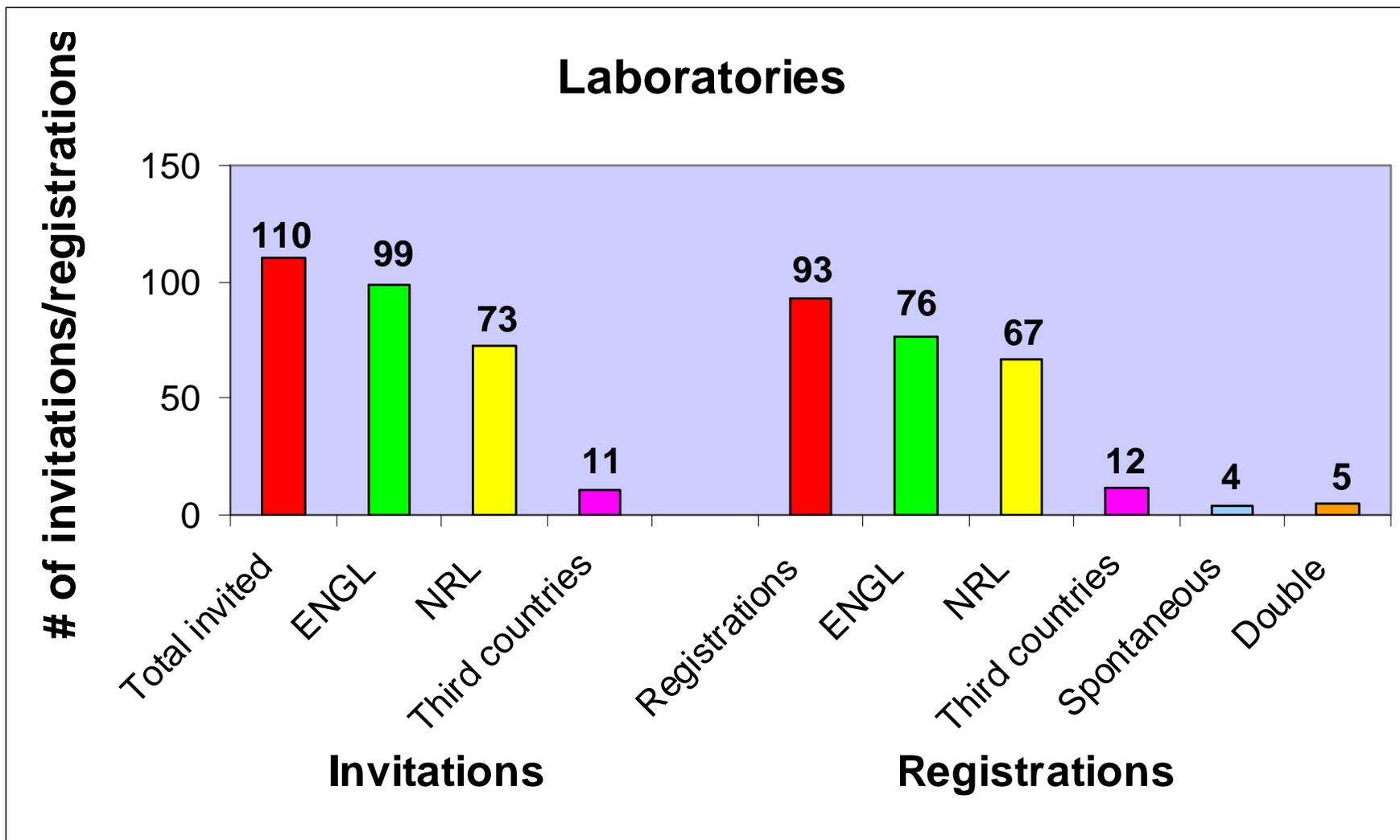
- what if falling ‘out of scope’

- compare with other failing labs (similar methods, equipment ...)

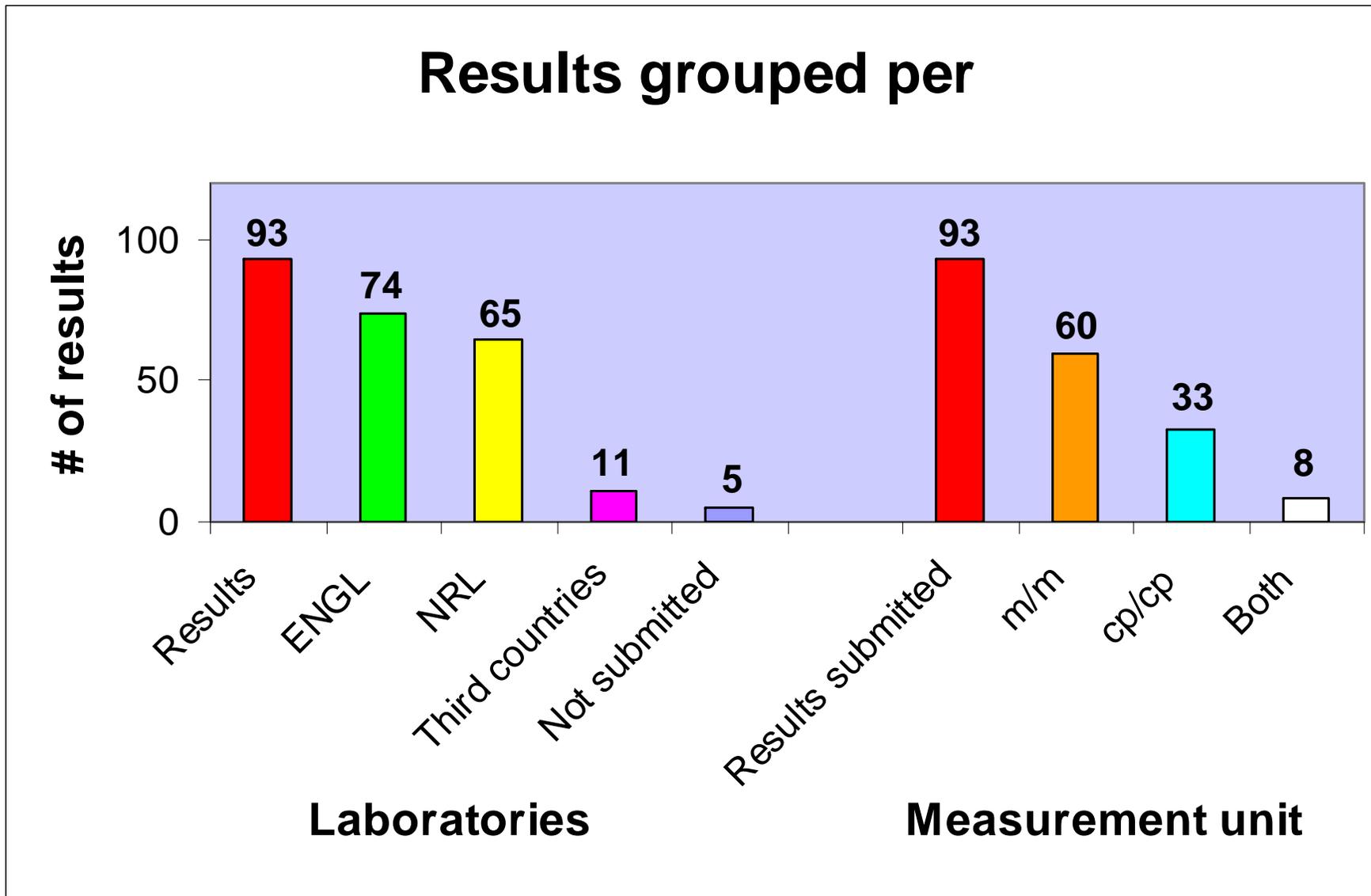
- call on ‘Non Conformity’: repeat analysis

JRC-IHCP Proficiency Test 1

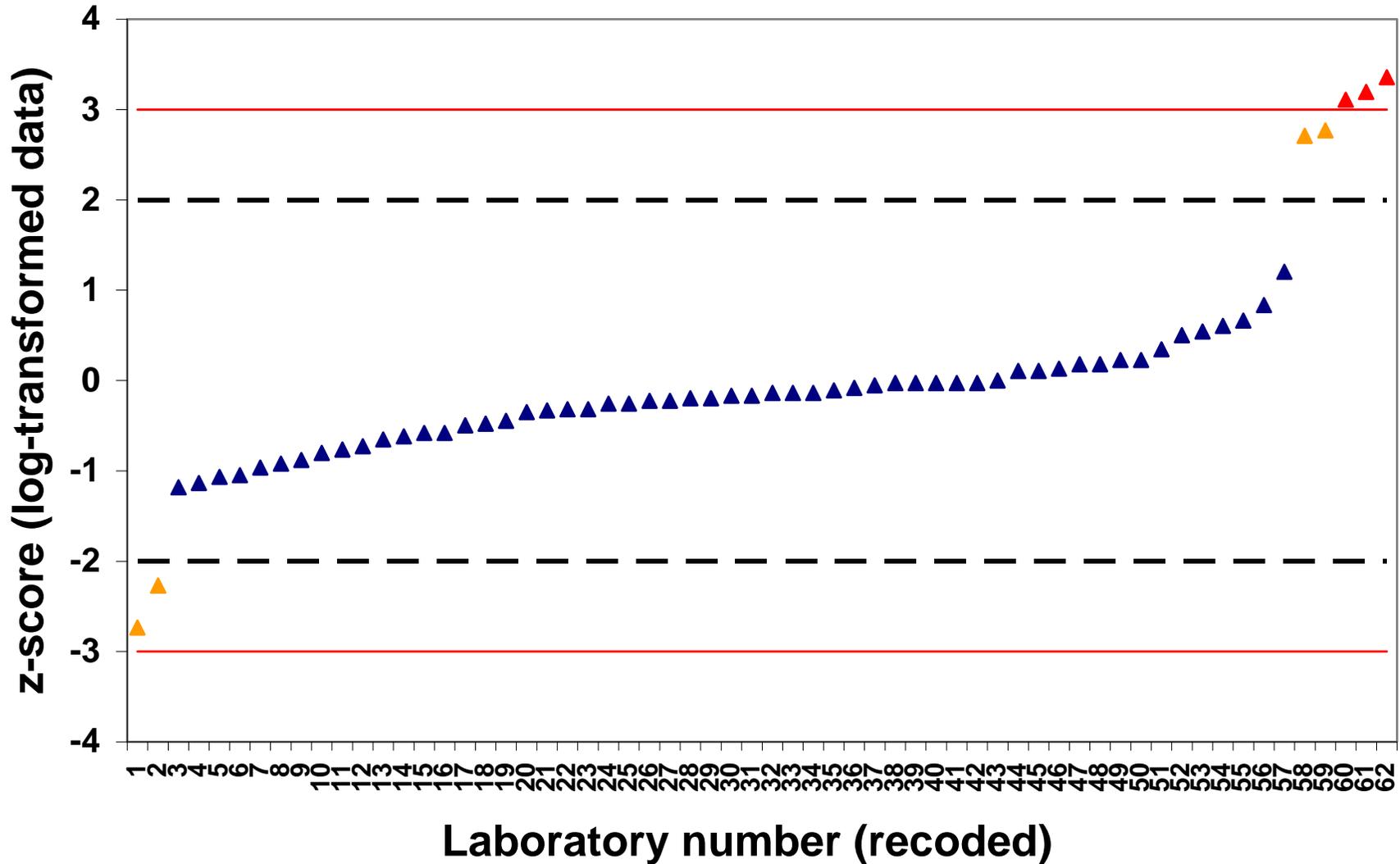
GM level 1	m/m [%]	cp/cp [%]
Assigned value	0.1	-
Robust mean	0.12	0.102
<hr style="border-top: 1px dashed black;"/>		
GM level 2		
Assigned value	1.69	-
Robust mean	1.71	1.52



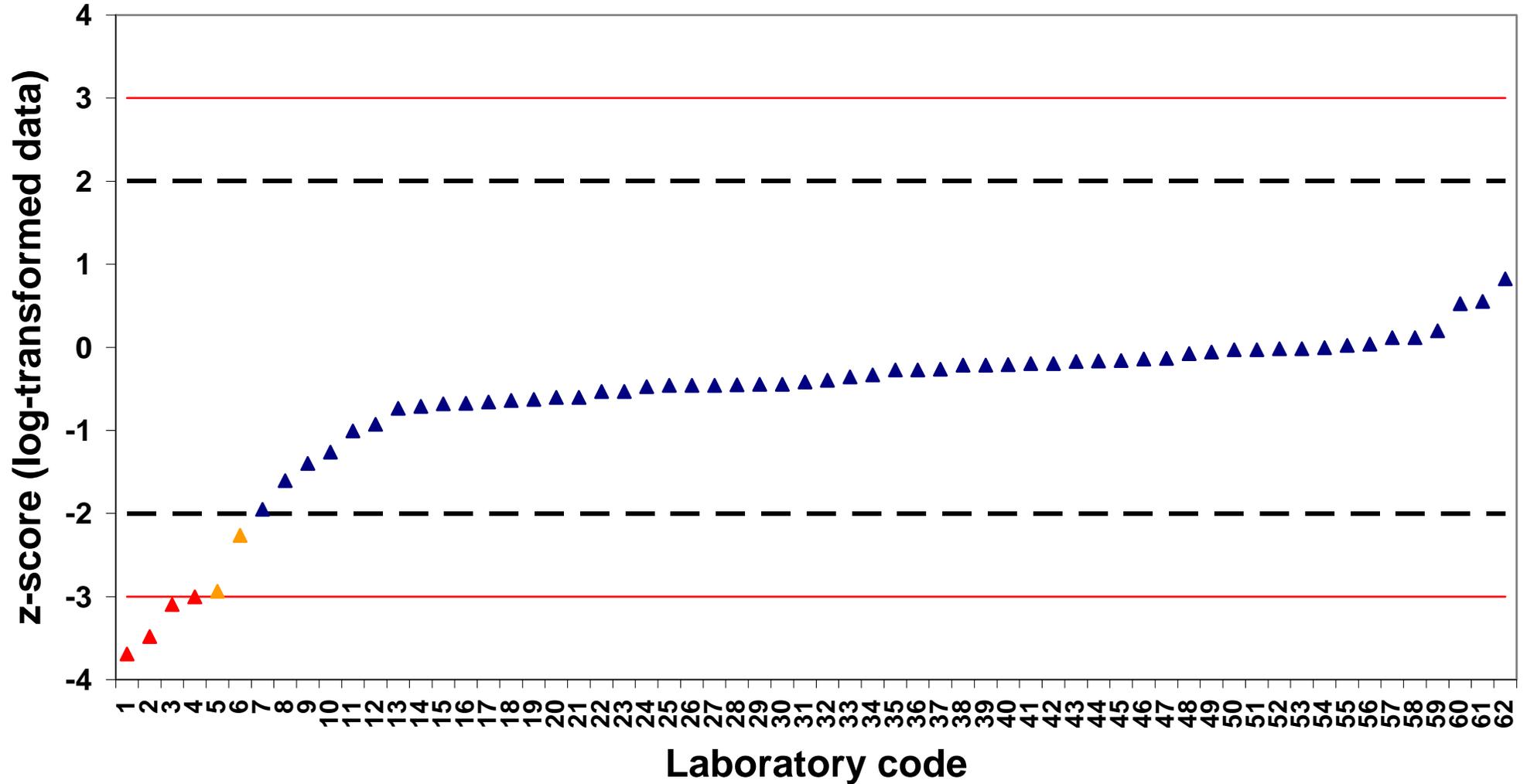
Participants from third countries: Brazil, Chile, China, India, Rep. Of Korea, Malaysia, Mexico, Singapore, US, Switzerland



GM Mass fraction Level 1

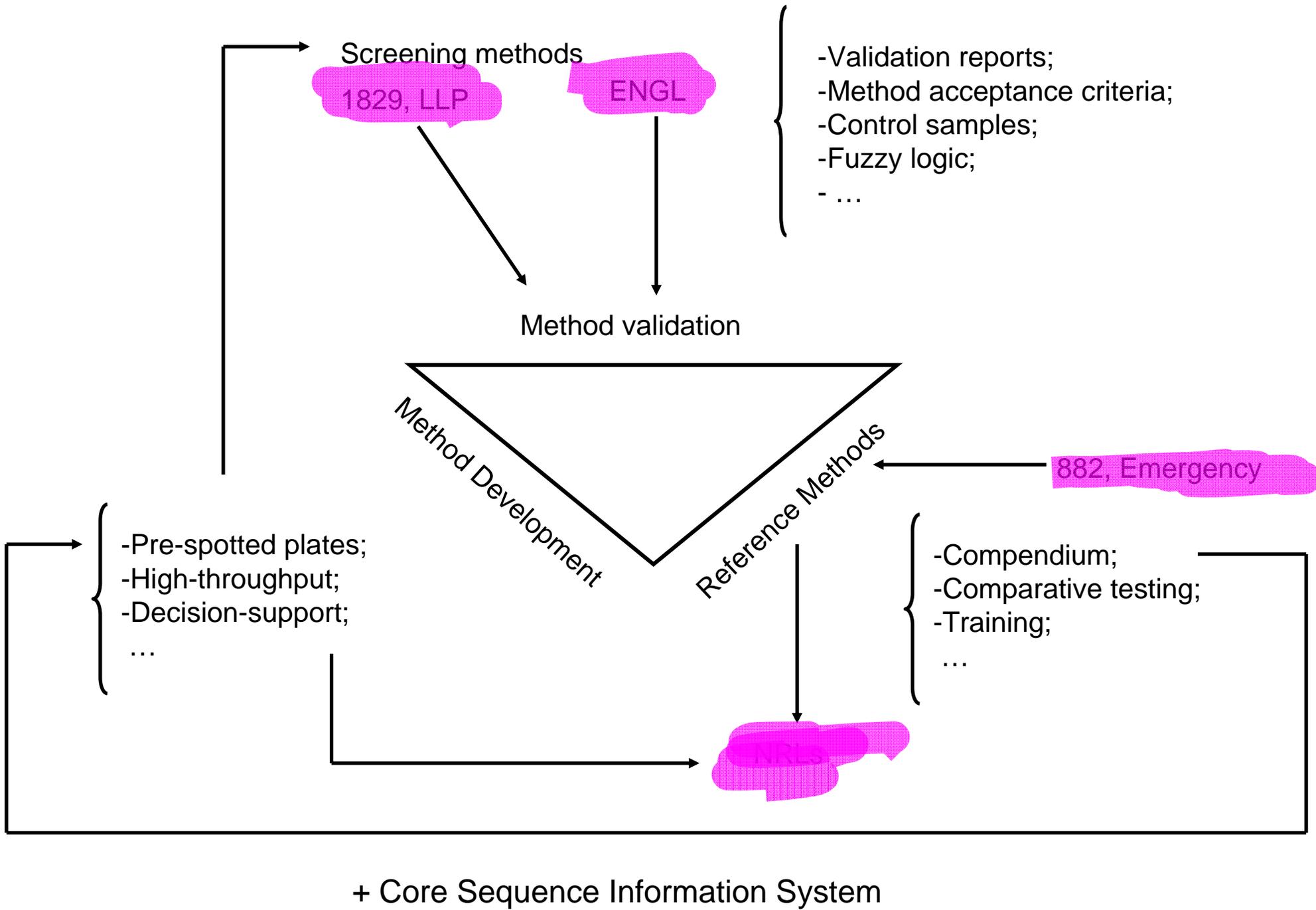


GM Mass fraction Level 2



JRC-EURL-GMFF-CT-01/11

- **RoundUp Ready Soybean**
- **Two test items containing different GM %ages**
- **Shipment planned: March 2011**
- **Test items: produced in-house**



Thank you!

Gracias!

