

# Joint Research Centre (JRC)



## *Proficiency Testing (support to ISO17025)*

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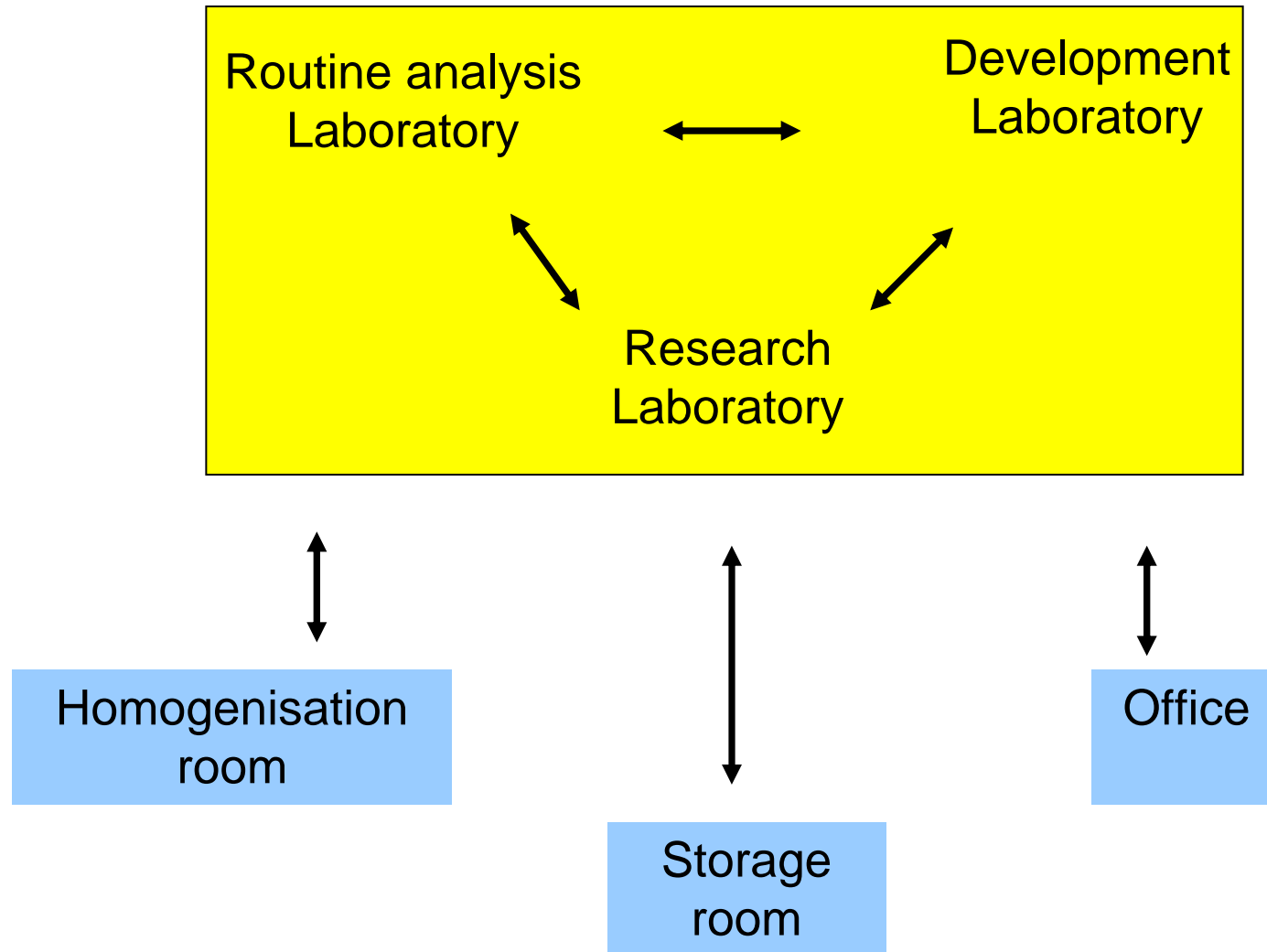
**AGR 42006 - TAIEX - 28/29 October 2010**

## **General outlay of GMO activities for enforcement**

- **Laboratory Organisation**
- **Sample Analysis Workflow**
- **Proficiency Testing**

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## General requirements for the competence of testing and calibration laboratories



- Documents (SOP, DOC, Forms, and traceability)
- Staff training
- Non Conformity
- Intern & extern audits
- Management review
- Proficiency testing

## **General outlay of GMO activities for enforcement**

- **Laboratory Organisation**
- **Sample Analysis Workflow**
- **Proficiency Testing**

**4 Steps process:**

**Sample collection**



**Reception & registration**



**Analysis**



**Report**

**Sample collection**



**Reception & registration**



**Analysis**



**Report**

- **Verification of invoice conformity & intact pack**
- **Sample registration (indicator)**
- **Sample file opening**
- **Working page**
- **Contact :Technicians and GMO-Lab**



**Sample collection**



**Reception & registration**

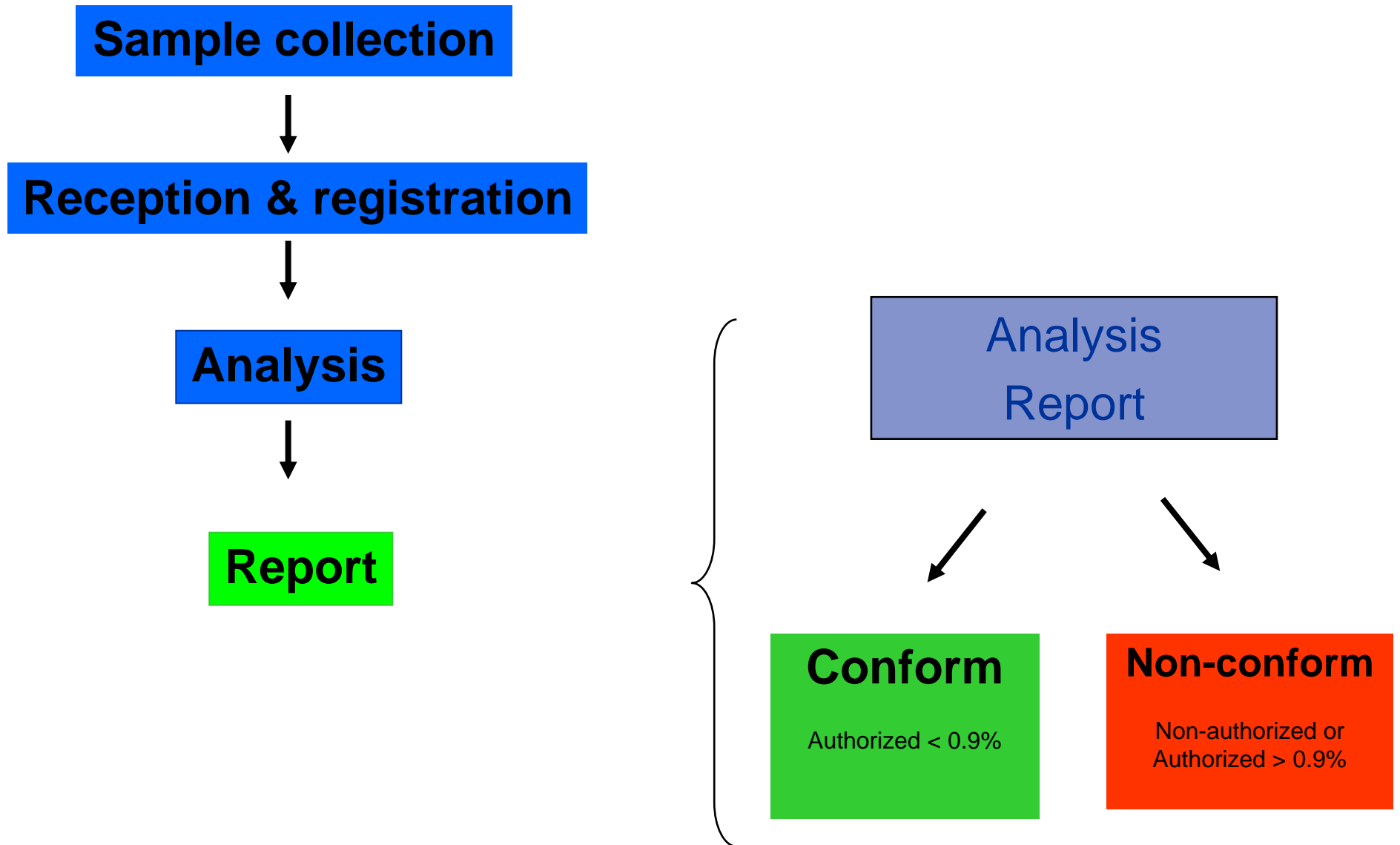


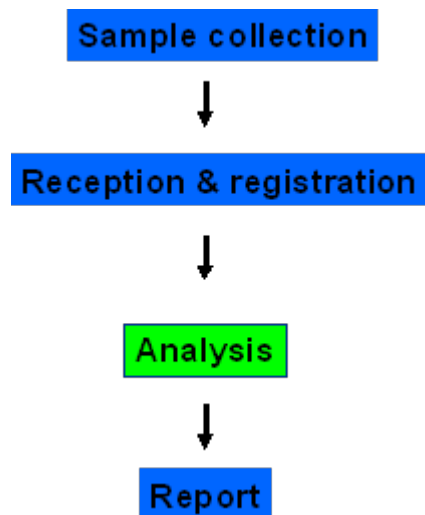
**Analysis**



**Report**

1. **Sample grinding**
2. **DNA extraction and quantification**
3. **Q PCR Analysis**





## Step 1 : sample grinding

Subsampling: > 0.5 kg

Direct grinding: < 0.5 kg



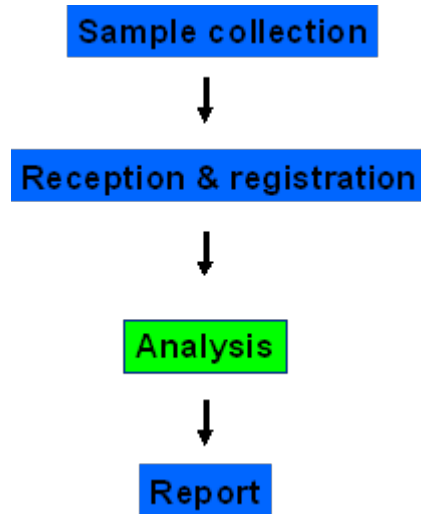
RETSCH  
ZM-200



MS

Analysis  
(50g)

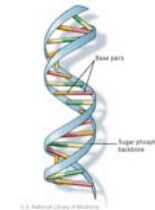
Storage room



## Step 2: DNA extraction and quantification



**DNA extraction (CTAB)**  
(4x 250mg or 4x1g)



**DNA quantification**  
(fluorimeter)



Sample collection



Reception & registration



Analysis



Report

## Step 3: Real-time PCR analysis

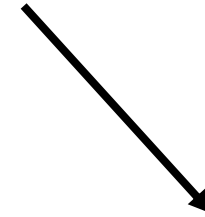
**Screening** (50ng/analysis)  
(SYBR®Green)



**Identification** (50ng/analysis)  
TAQMAN

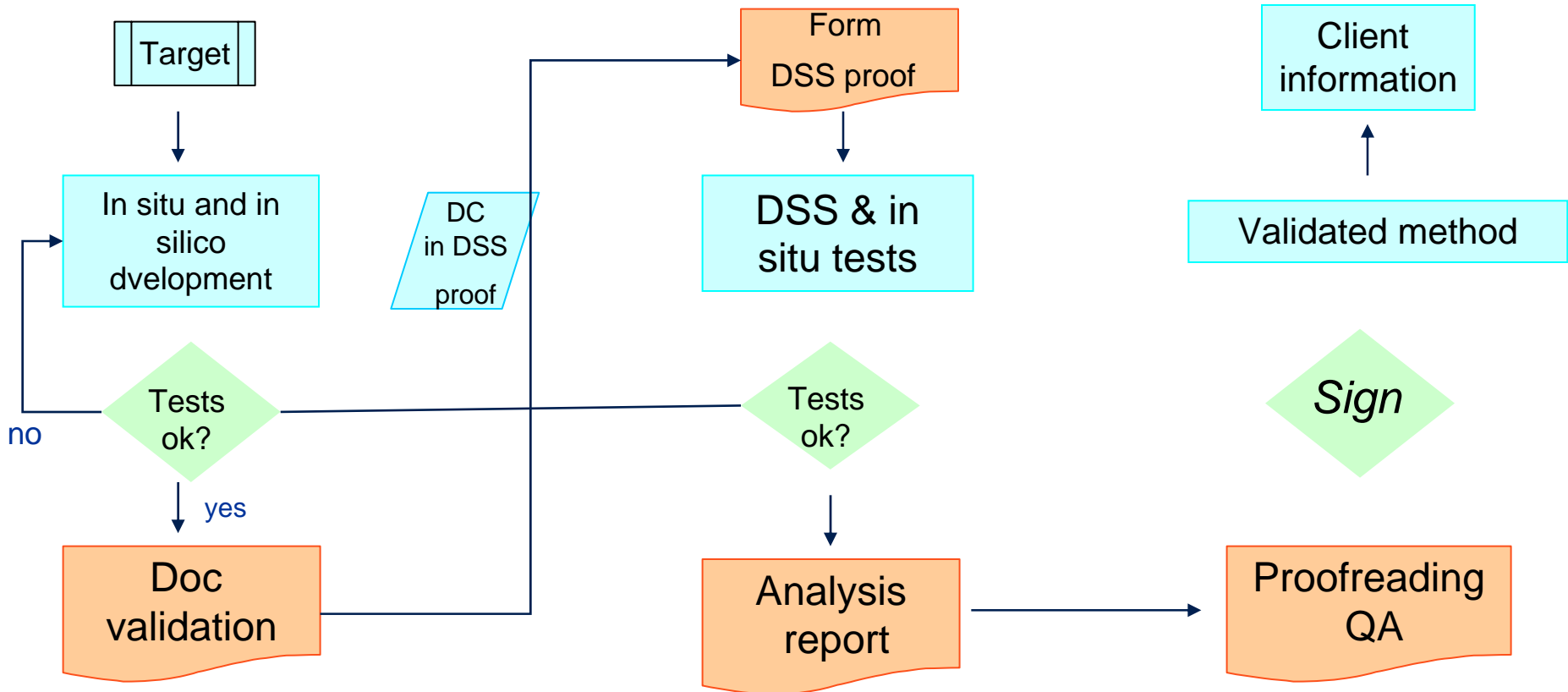
**CRL methods**

**Quantification**  
TAQMAN



**QPCR methods are validated CRL methods or in house validated methods (according to ISO 7525)**

**Flexible scope for validation of Methods**



## **General outlay of GMO activities for enforcement**

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- **Proficiency 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...)



## General Proficiency 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 your results should be returned.
- Some instructions may be included with the analysis to allow results to be compared but no specific methods which must 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 your 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)
- **JRC-IHCP/IRMM** (EU) (powders)
- **GIPSA** (US) (powders, DNA)

## INTERPRETATION of PT outcome

Key evaluator: z-score (acceptable between  $\pm 2$ )

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

- what if falling 'out of scope'

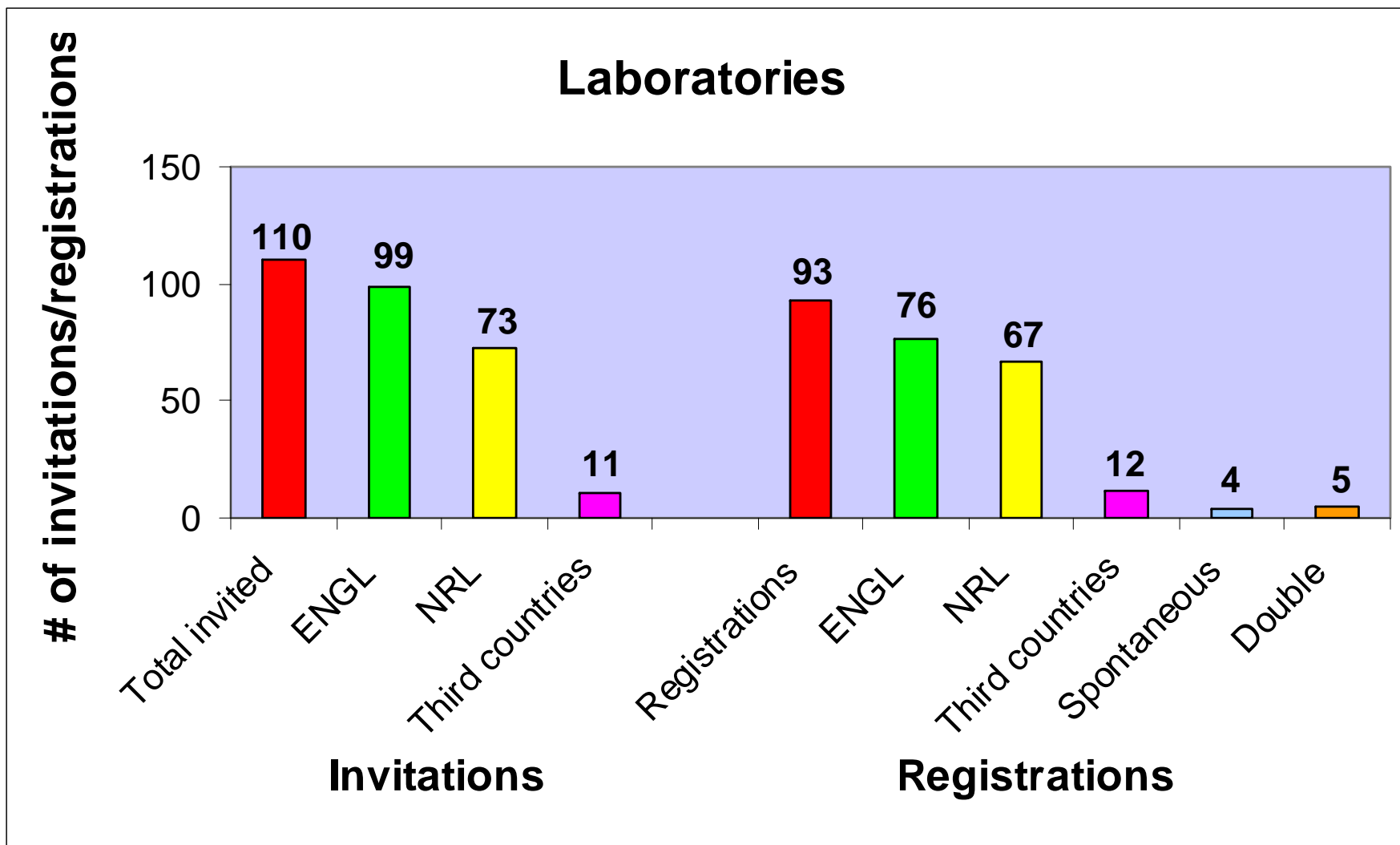
  - compare with other failing labs (similar methods, equipment ...)

  - call on 'Non Conformity': repeat analysis

**NEW: input from PT provider**

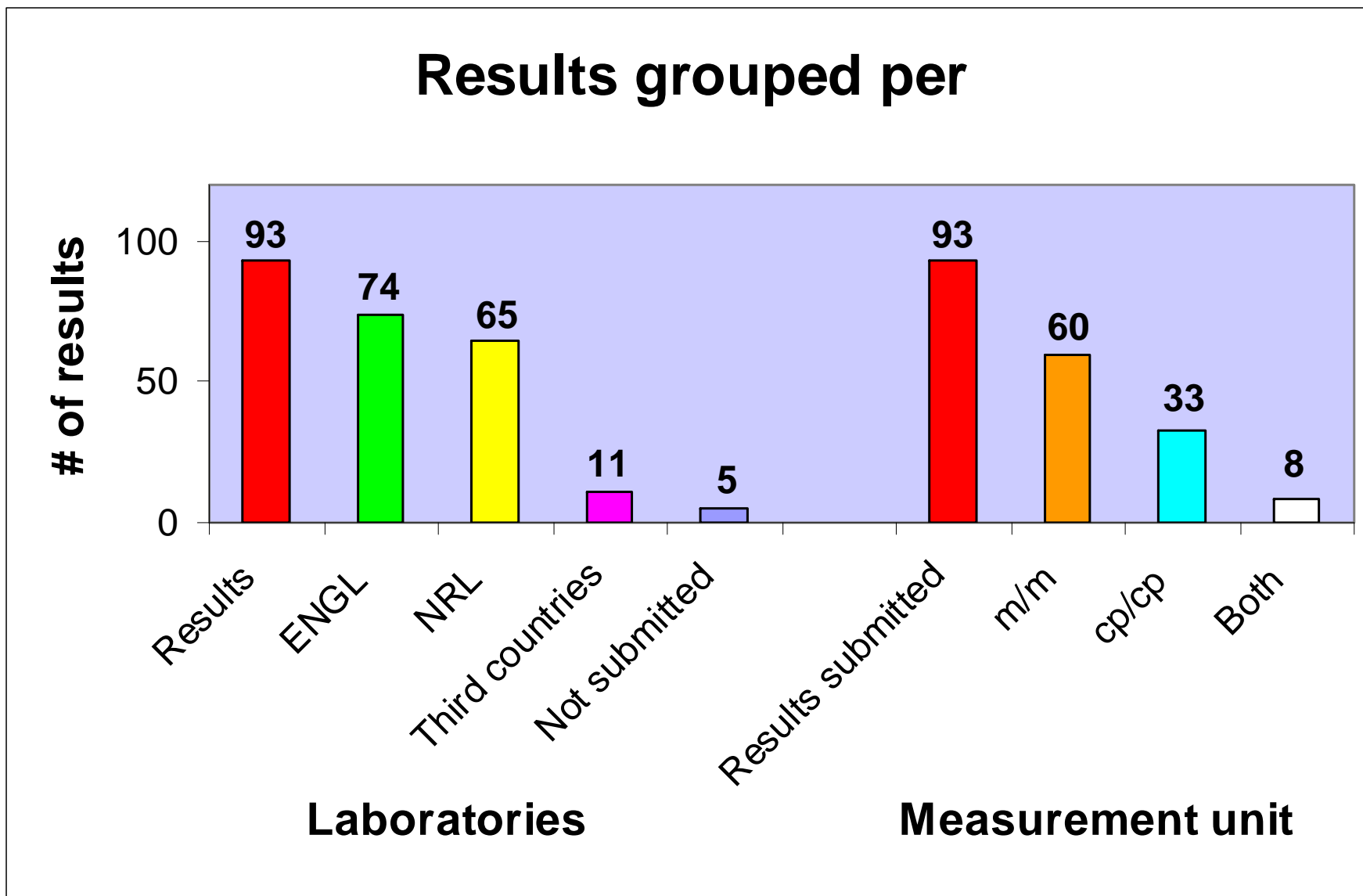
## JRC-IHCP Proficiency Test 1 (D. Charels, M. Maras, T. Weber)

GM level 1	m/m [%]	cp/cp [%]
Assigned value	0.1	-
Robust mean	0.12	0.102
<hr/>		
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**





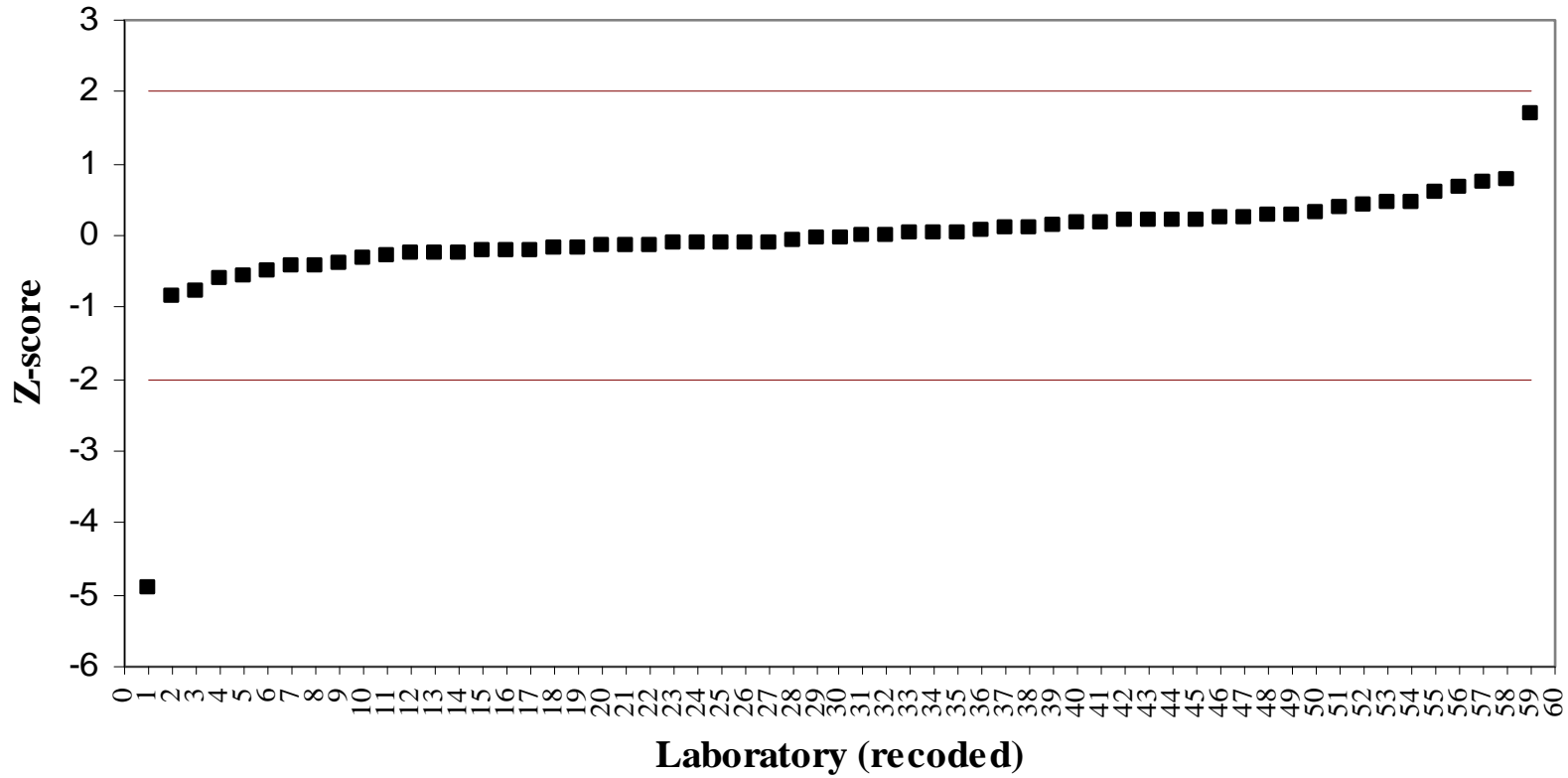
## **Data analysis : Z-scores using data from:**

- **NRLs**
- **All participants**
- **Calculation of z-scores on the basis of:**
  - **Assigned reference value**
  - **Robust mean**

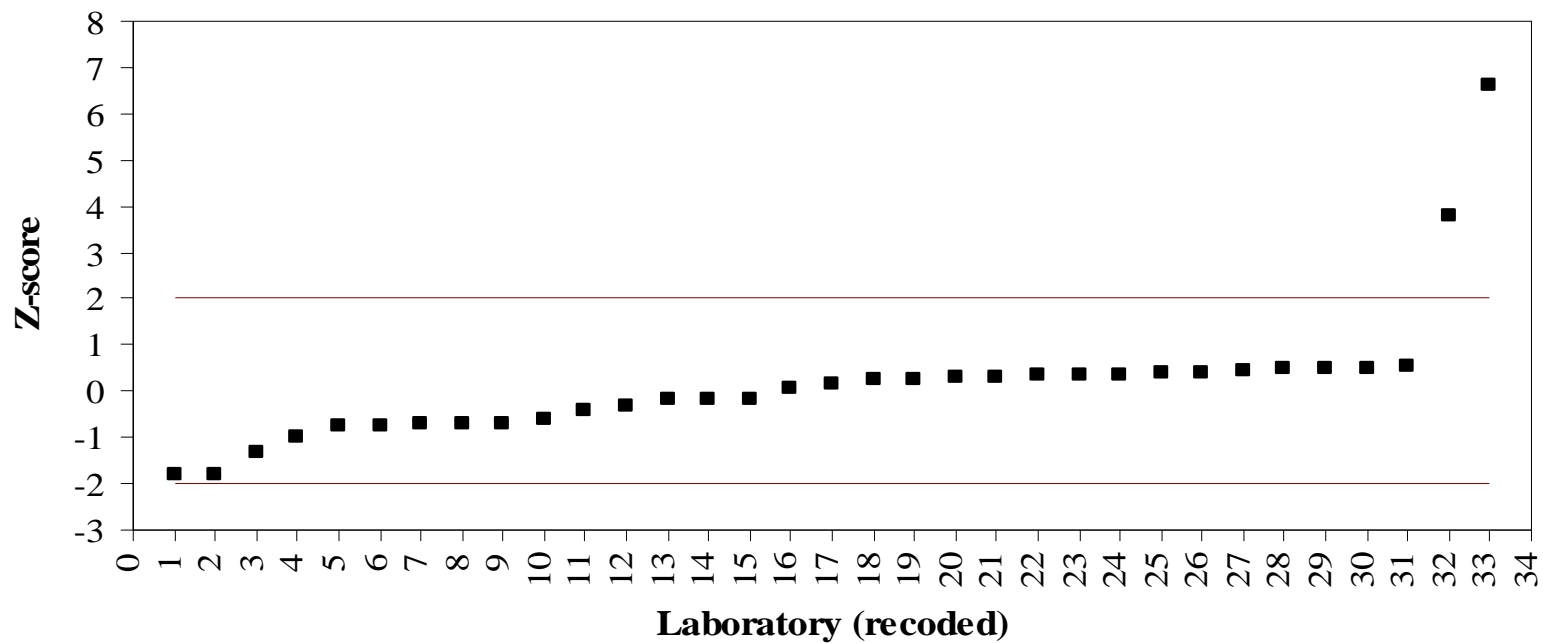
## **Statistical analysis:**

- Aim: Look for parameters that may influence GM quantification e.g. instrumentation, DNA extraction method, real-time PCR method,...
- Multivariate analyses, ANOVA
- Principal components analysis
- Partial least squares regression

**m/m level 2**  
**reference value =1.69**



**cp/cp level 2**  
**robust mean = 1.52**



## **EXPERIENCE from IPH (Be) PT testing**

About 100 GEMMA & ISTA tests (rule: one PT/method/year)

GEMMA: - GM maize : zygosity

- rare GM: low amounts of DNA

ISTA: - GM canola : zygosity/copy number

- GM cotton: reference material

Qualitative screening (CoSYPS): all favourable

Quantitative analysis:

a) GEMMA: all favourable

b) cotton/canola deviations

**Thank you for your attention**