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Comparative Testing Report on the Detection and Quantification of GM Events in Compound Feedstuff

Comparative testing round: ILC-EURL-GMFF-CT-02/12

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Executive Summary

The European Union Reference Laboratory for Genetically Modified Food and Feed (EU-RL GMFF, Regulation (EC) No 1829/2003[1]) that is also mandated as EU-RL by Regulation (EC) 882/2004[2] organised a comparative testing round for National Reference Laboratories (NRLs) nominated under Regulation (EC) No 882/2004[2]. Participation was open and free of charge for any official control laboratory. In addition, participation was mandatory for NRLs nominated under 882/2004 and highly recommended for NRLs nominated under Regulation 1981/2006.

The EU-RL GMFF is accredited under ISO 17043 ('General requirements for proficiency testing'[4]) and this comparative testing round met this ISO Standard[4].

The test items were produced in-house from dried leaves of MON 88017 (MON-88Ø17-3) and seeds of soybean event 40-3-2 (MON-Ø4Ø32-6) provided by Monsanto, by spiking a compound feedstuff provided by a Belgian NRL. Participants were required to screen two test items (feedstuff Levels 1 and 2) for the presence of maize events Maize MON 88017, MON 89034 and soybean events 356043, 40-3-2 and MON 89788. Any event detected then had to be quantified.

Participants could report the results in mass/mass % or copy/copy % and the EU-RL GMFF calculated the robust means (μ_R) of Level 1 and 2 test items accordingly. In addition, "target" values (μ) were assigned by the EU-RL GMFF on the basis of its homogeneity study[8] for m/m % data. These values were included in the uncertainty budget.

The target standard deviation for CT $\hat{\sigma}$ was fixed by the Advisory Board for Comparative Testing at 0.15 ($\log_{10}$ value) for soybean event 40-3-2 and at 0.20 for maize event MON 88017 based on experience from previous CT rounds. This target standard deviation was used to derive z-scores for the participants' results.

Ninety laboratories from 43 countries registered for this CT round of which 82 from 35 countries returned at least qualitative test results.

The results of the qualitative evaluation of the GM content indicated that most of the laboratories correctly detected soybean event 40-3-2 and maize event MON 88017 thus resulting in a very good performance overall.

The results of the quantitative evaluation of GM content were found to be satisfactory overall for both events, with 94% of the laboratories submitting results in mass/mass % with a z-score, estimated on the basis of the robust mean, lying within the range of -2 to +2. This percentage decreased to 79% for results expressed in copy/copy %. When asked to repeat experimental work, most of the underperforming laboratories obtained satisfactory results.

Only ~57% of participants provided information on measurement uncertainty in a complete and consistent manner, it is apparent therefore that despite the overall satisfactory outcome of this CT round, there is still improvement needed in this crucial area.

Content

1. Introduction 6
2. Test items 8
2.1 Characterisation of base materials 8
2.2 Preparation and characterization of test items 8
2.2.1 Homogeneity of test items 9
2.2.2 Stability of test items 10
2.2.3 Assigned values 10
3. Tasks to be performed by participants 11
4. Results 12
4.1 Qualitative results 14
4.1.1 Soybean event 356043 14
4.1.2 Soybean event 40-3-2 15
4.1.3 Soybean event MON 89788 16
4.1.4 Maize event MON 88017 17
4.1.5 Maize event MON 89034 18
4.1.6 Conclusions on qualitative screening 18
4.2 Quantitative results 20
4.2.1 Consensus values from participants 20
4.2.2 Participants' results 21
5. Discussion of laboratories' performance 42
5.1 Overall performance 42
5.2 Underperforming laboratories 45
5.3 Repetition of the experimental work 47
6. Conclusions 49
References 50
Questionnaire data 52
Annex 1: Invitation letter 76
Annex 2: Accompanying letter to shipment of samples 78
Annex 3: Confirmation of shipment 80
Annex 4: Acknowledgement of receipt 81

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1. Introduction

The Joint Research Centre (JRC) of the European Commission was established as European Union Reference Laboratory for GM Food and Feed by Regulation (EC) No 1829/2003[(1)]. The EU-RL GMFF is also mandated by Regulation (EC) No 882/2004[(2)].

Article 32 of Regulation (EC) No 882/2004 tasks the EU-RL GMFF with the organisation of comparative testing for NRLs (nominated under Reg 882/2004) and an appropriate follow-up of such testing. The aim of this activity is 'to contribute to a high quality and uniformity of analytical results'[(2)]. Moreover, Article 12 of the said Regulation requires that the nominated NRLs should be accredited under ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' and 17025-accredited laboratories must prove their competence by taking part in proficiency testing. As the EU-RL GMFF is accreditied under ISO 17043, successful participation in CT rounds organised by it meets this requirement.

Regulations (EC) No 1829/2003 and 619/2011 establish a threshold for labelling of food and feed products (0.9%) and minimum method performance (0.1% m/m) for detecting low level presence of GMO in feed. These values are used by the Member States of the European Union in the official control of food and feed. Hence, an accurate and harmonised determination of the GM content is of paramount importance.

In December 2012, a total of 160 laboratories were invited to participate in this CT round of the EU-RL GMFF (ILC-EURL-GMFF-CT-02/12) and 90 laboratories from 43 countries registered for it. Test items were prepared by the EU-RL and shipped to registered participants at the beginning of February 2013 in plastic containers containing approximately 5 g of flour. The EU-RL GMFF managed the on-line registration and submission of results and was responsible for their evaluation. It was supported by the Advisory Board for CT.

Eighty-two laboratories from 35 countries returned at least qualitative results (see Figures 1 and 2). These laboratories fell into the following groups:

1. 2 were NRLs nominated only under Regulation (EC) No 882/2004 (group 1),
2. 26 were NRLs nominated only under Regulation (EC) No 1981/2006 (group 2),
3. 29 were NRLs nominated under both Regulations (group 3),
4. 4 were ENGL members but did not belong to group 1, 2 or 3 (group 4),
5. 9 were official control laboratories from EU Member States but not ENGL members (group 5),
6. 12 were official control laboratories from third countries (group 6).

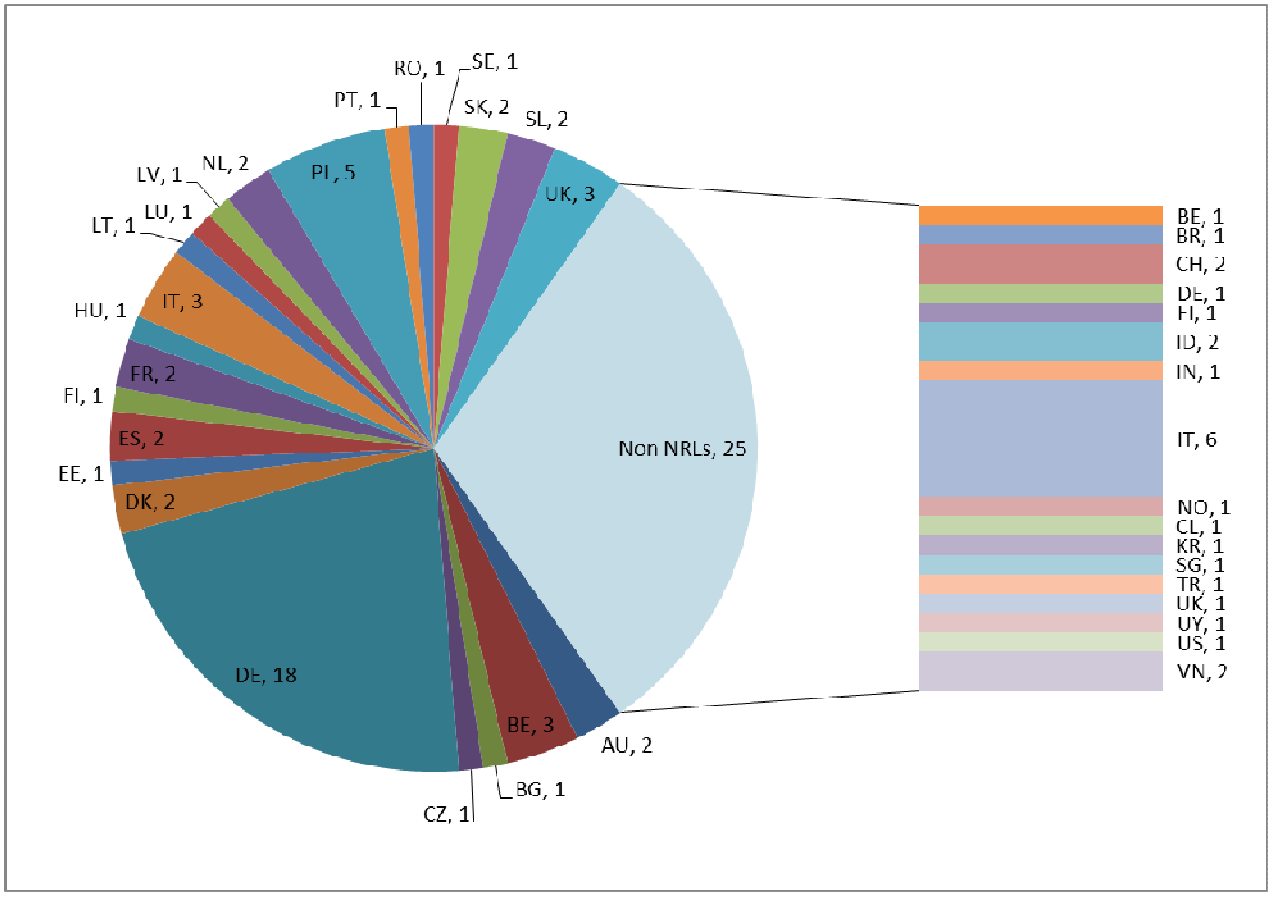


Figure 1. Overview of laboratories submitting at least qualitative results.

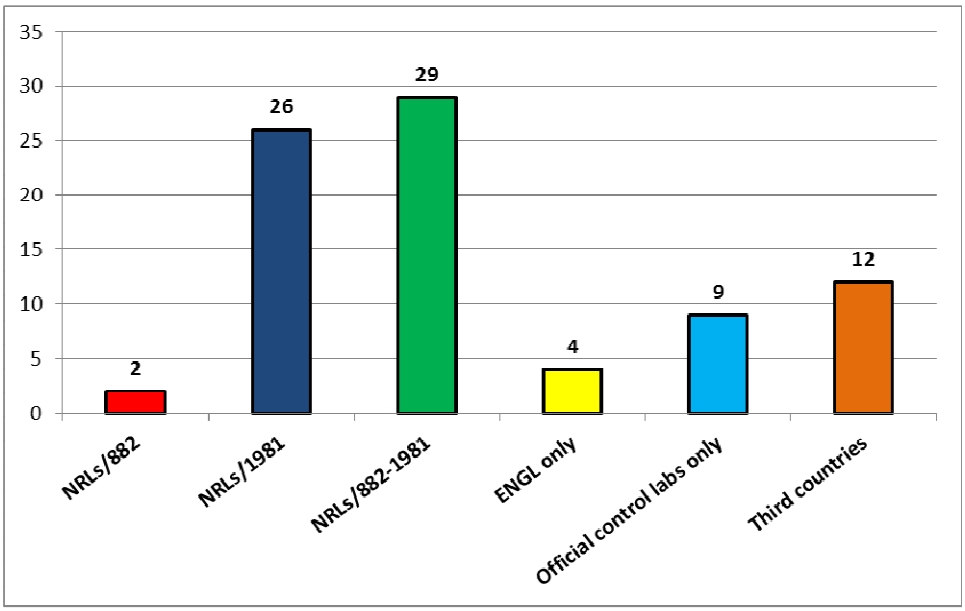


Figure 2. Laboratories submitting at least qualitative results, divided by group

2. Test items

The test items were produced in-house from dried leaves of maize event MON 88017 (MON-88Ø17-3) and seeds of soybean event 40-3-2 (MON-Ø4Ø32-6) provided by Monsanto, by spiking a compound feedstuff.

2.1 Characterisation of base materials

Base materials consisted of:

- 1400 g of non-GM maize (in grains)
- 1400 g of non-GM soybean (in grains)
- 365 g of GM maize MON 88017 and 365 g of GM soybean 40-3-2 provided by Monsanto
- 1500 g of feedstuff including wheat (31%), wheatbran (20.7%), soya hulls (7.5%), sunflowerseed meal (6.5%), palmkernel meal (5%), soybean meal (3%), barley (1%) and other components, provided by a NRL from Belgium

Base materials were ground using an Ultra Centrifugal Mill ZM200 (Retsch GmbH, DE). The oven-drying method was used for determining the water content in the powders. In order to determine the extractability of DNA from the GM and non-GM base materials, DNA was extracted from each of the powders in up to 10 replicates using a validated CTAB DNA extraction method. Extracted DNA was quantified with Picogreen in a VersaFluor Fluorometer. The water content of the powdery base materials was taken into consideration when estimating DNA extractability.

The purity of the non-GM and GM powdery base material was assessed: four DNA samples were analysed. Inhibition analysis confirmed the absence of inhibitors in DNA samples. The DNA samples were also assessed for the presence of GM-event(s) or species-specific DNA other than those relevant to the present comparative testing round, using ABI pre-spotted plates[9] GM event 40-3-2 was identified in DNA extracted from the feedstuff material: this was quantified and is reflected in the final GM concentration of the relevant test items.

2.2 Preparation and characterization of test items

Test items were prepared by the EU-RL GMFF in accordance with ISO Guide 34[10] ('General requirements for the competence of reference material producers'), as follows:

- Two different mass fractions (mixtures) of GM materials, representing two different GM levels, were produced by mixing pure non GM with pure GM powder base materials.
- After separate manual mixing of this powder base material and the powder feedstuff base material for 10 minutes, the required masses of the powders, corrected for the water content, were combined in a container.
- The mixtures were then thoroughly mixed for at least 60 min in a Turbula T10B mixer to produce test items GM Level 1 and 2.

Two levels of compound feedstuff (Level 1 and 2) test items were prepared to nominal concentration values of 1.5 m/m % and 0.2 m/m % GM of 40-3-2; 0.7 m/m % and

1.4 m/m % GM of MON 88017, respectively. Concerning soybean event 40-3-2 however, the final concentrations for this GM test item were 1.78% (± 0.14) m/m and 0.21% (± 0.03) m/m respectively (see Table 1).

From each of these two powder test materials, 300 test items of up to 5g were prepared in 30ml-bottles using a sample divider (Retsch GmbH, Haan, DE). Bottles were labelled according to the GM level of the test items and stored at 4 °C.

2.2.1 Homogeneity of test items

The assessment of the homogeneity[11] was performed by the EU-RL GMFF after the test items had been packed in their final form and before distribution to participants in line with the following consideration:

Samples are considered to be adequately homogeneous if:

$$s_s \leq 0.3\hat{\sigma} \qquad (1)$$

Where s_s is the between-test item standard deviation as determined by a 1-way random effects ANOVA[12] and $\hat{\sigma}$ is the standard deviation for comparative testing.

If this criterion is met, the between-test item standard deviation contributes no more than about 10 % to the standard deviation for comparative testing.

The repeatability of the test method is the square root of mean sum of squares within-test item MS_{within}. The relative between-test item standard deviation $s_{s,rel}$ is given by

$$s_{s,rel} = \frac{\sqrt{\frac{MS_{between} - MS_{within}}{n}}}{\bar{y}} \times 100\% \qquad (2)$$

where: $MS_{between}$ is the mean sum of squares between test items

MS_{within} is the mean sum of squares within test items

n is the number of replicates

$\bar{y}$ is the mean of the homogeneity data

If $MS_{within} > MS_{between}$, then:

$$s_{s,rel} = u^*_{bb} = \frac{\frac{repeatability}{\sqrt{n}}\sqrt[4]{\frac{2}{N(n-1)}}}{\bar{y}} \times 100\% \qquad (3)$$

where: u^*_{bb} is the maximum uncertainty contribution that can be obtained by the hidden heterogeneity of the material.

For each group of test items 10 bottles were randomly selected and analysed in five-fold replicates (n = 5). The criterion described in formula (1) was fulfilled in all cases, indicating that all groups of test items were homogeneous. The data from the homogeneity study were also used for the estimation of the assigned values and for the estimation of the uncertainty contribution related to the level of homogeneity of test items (see Table 1).

2.2.2 Stability of test items

An isochronous short term stability study involving two Level 1 test items (N = 2, n = 3), was conducted over one, two and four weeks at +4ºC and +18ºC[13]. The results did not reveal an influence of time or temperature on the stability of test items, which were thus shipped at ambient temperature.

An isochronous long term stability study involving two Level 1 test items (N = 2, n = 3) was conducted over two, four and six months at +4ºC[13]. No trends were detected in the GM concentration level for any of the test items analysed at the 5% significance level, thus indicating that test items can be stored over a prolonged period at +4 ºC.

2.2.3 Assigned values

Assigned values μ were estimated by the EU-RL GMFF on the basis of the data from the homogeneity study for m/m % content.

Table 1 shows the estimated assigned values, together with the related measurement uncertainties. The assigned value for soybean event 40-3-2 Level 1 test item is different from the nominal concentration (1.78% m/m ± 0.14 vs 1.50% m/m). However, since homogeneity of that group of test items was found to be adequate, the assigned value (1.78% m/m) was retained.

Table 1. Assigned values (μ) on the original scale and expanded uncertainties of Level 1 and 2 test items. [1] Relative standard uncertainty relating to the characterisation, [2] Relative standard uncertainty resulting from the homogeneity assessment, [3] Relative standard uncertainty resulting from the long-term stability assessment.

μ [m/m %]		*Expanded uncertainty* ($U = 2 * u_c$)		*Relative standard uncertainty contributions [%]*		
		U_{abs} [m/m %]	U_{rel} [%]	($u_{char, rel}$)[1]	($u_{bb, rel}$)[2]	($u_{lts, rel}$)[3]
Soybean 40-3-2						
Level 1	*1.78*	0.14	7.68	2.6759	2.7557	0.2090
Level 2	*0.21*	0.03	13.74	5.2168	4.4623	0.2090
Maize MON 88017						
Level 1	*0.68*	0.07	9.78	4.2320	2.4508	0.0480
Level 2	*1.42*	0.12	8.26	3.4285	2.3058	0.0480

The expanded uncertainty (U) comprises standard uncertainty contributions from the characterisation of the material (u_{char}), the between-test item homogeneity (u_{bb}) and the long-term stability of the material (u_{lts})[15], and is estimated according to:

$$U = k\sqrt{u_{char}^2 + u_{bb}^2 + u_{lts}^2} \qquad (4)$$

A coverage factor of 2 was used to calculate the expanded uncertainty corresponding to a 95 % level of confidence[16]. The standard uncertainty (u_{char}) of the characterisation is calculated using the formula:

$$u_{char} = \frac{\sigma}{\sqrt{N}} \qquad (5)$$

where: σ = Relative Standard Deviation of the assigned value expressed in m/m %

N = number of data points.

The assigned values of Level 1 and 2 test items are traceable to the International System of Units (SI). The traceability chain is based on the use of calibrated balances and a thorough control of the weighing procedure.

3. Tasks to be performed by participants

Participants in this CT round were required to screen the two test items (Level 1 and 2) for the presence of maize events Maize MON 88017 and MON 89034, and soybean events 356043, 40-3-2 and MON 89788. Any event detected had to be quantified. Participants could report the quantitative results in m/m % or DNA cp/cp %.

Participants were instructed to apply the formulas described below when reporting their results:

$$\text{m/m \%} = \frac{\text{mass GM event [g]}}{\text{Total mass species [g]}} \times 100\ \% \qquad (6)$$

$$\text{cp/cp \%} = \frac{\text{GM event DNA copy numbers [cp]}}{\text{Target taxon-specific DNA copy numbers [cp]}} \times 100\ \% \qquad (7)$$

4. Results

A total of 82 laboratories from 35 countries submitted at least qualitative results, and of these 79 from 33 countries also submitted quantitative results for at least one of the two GM events involved. Table 2 lists deviations from the reporting of quantitative results.

Table 2. Observed deviations in quantitative result reporting

LabCode	Event	Deviation
L26	Soybean 40-3-2	Results for both Level 1 and 2 were reported in both m/m % and cp/cp %
L29	Soybean 40-3-2	Only results for Level 1 reported (in m/m %)
L55, L57	Soybean 40-3-2	No results submitted
L34	Maize MON 88017	Only results for Level 1 reported (in cp/cp %)
L11, L22, L25, L29, L41, L45, L75,L89	Maize MON 88017	No results submitted
L43	Maize MON 88017	Only results for Level 2 reported (in cp/cp %)

Most laboratories (≈ 78%) reported the GM content of all test items in m/m %, whereas a minority of laboratories expressed their results only or additionally in cp/cp % (Figure 3).

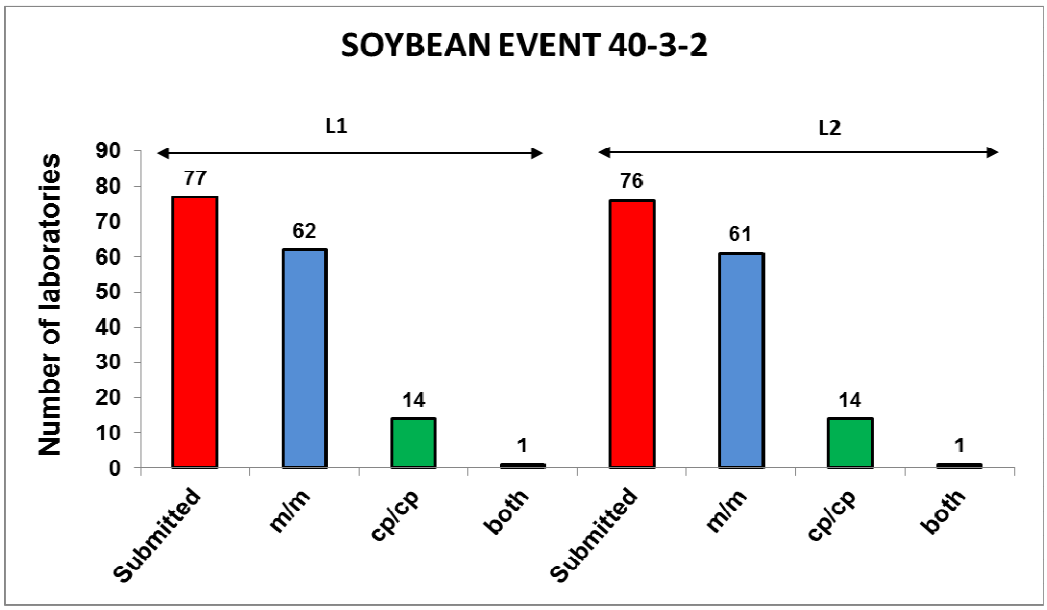
A large majority of the participating laboratories used Certified Reference Material (CRM) from IRMM[1] or AOCS[2] as calibrant, or a commercial kit, and only few used plasmid calibrants. It is worth noting that the CRM are certified in m/m, only.

To facilitate the comparison between the laboratory groups defined on page 6, the qualitative and quantitative results reported hereunder are stratified according to the three following categories:

- Category (a)
    - NRLs appointed only under Regulation (EC) No 882/2004 and appointed under both Regulations (groups 1 and 3),
- Category (b)
    - NRLs appointed only under Regulation (EC) No 1981/2006 (group 2)
- Category (c)
    - ENGL members (not in group 1, 2, or 3), non-ENGL EU and third countries official control laboratories (groups 4, 5, and 6).

[1] Institute for Reference Materials and Methods, JRC, European Commission. http://irmm.jrc.ec.europa.eu/
[2] AOCS = American Oil Chemists' Society. http://www.aocs.org/

(a)



(b)

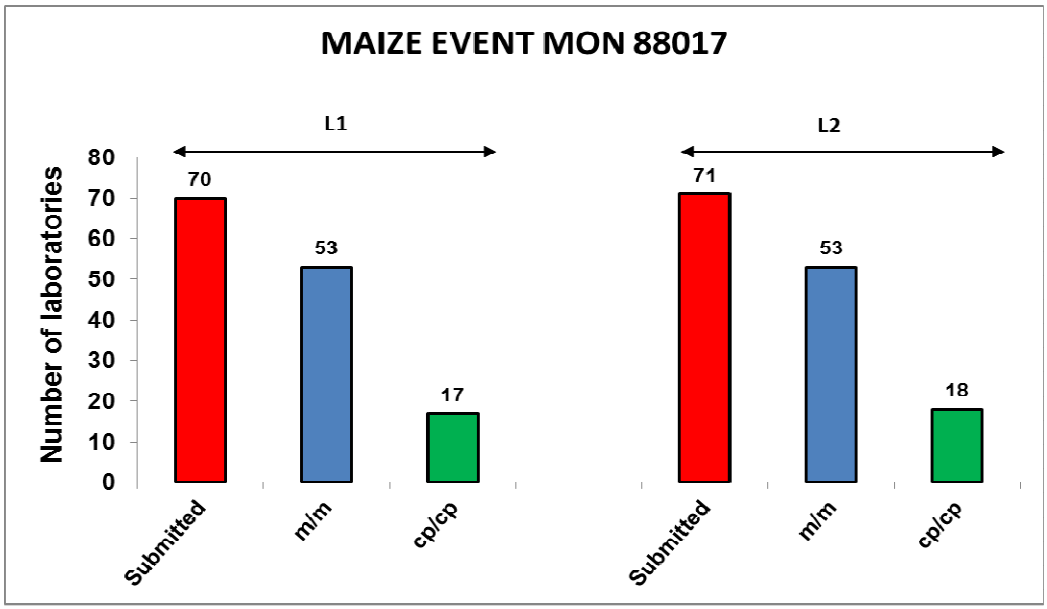


Figure 3. Overview of quantitative results grouped by GM event and measurement unit. m/m = results submitted in mass/mass %, cp/cp = results submitted in copy/copy %, both = results submitted in both measurement units, L1 = Level 1, L2 = Level 2.

4.1 Qualitative results

4.1.1 Soybean event 356043

Overall, results for the screening of this event were satisfactory, and it was correctly not detected by a large majority of laboratories (see Table 3a-c). One NRL appointed under both regulations 882/2004 and 1981/2006 did not screen for it, whereas one appointed only under 1981/2006 returned a result that did not agree with consensus and one did not screen for it. Amongst the non-NRLs laboratories, 11 did not screen for the event.

Table 3. Results of qualitative analysis for soybean event 356043 by laboratory category; NC = No agreement with consensus (calculated only on laboratories that screened for the event), NS = Not screened.

(a)

LabCode	Group	Level 1	Level 2
L37	1	Not Detected	Not Detected
L63	1	Not Detected	Not Detected
L01	3	Not Detected	Not Detected
L04	3	Not Detected	Not Detected
L05	3	Not Detected	Not Detected
L06	3	Not Detected	Not Detected
L12	3	Not Detected	Not Detected
L20	3	Not Detected	Not Detected
L23	3	Not Detected	Not Detected
L28	3	Not Detected	Not Detected
L30	3	Not Detected	Not Detected
L32	3	Not Detected	Not Detected
L33	3	Not Detected	Not Detected
L34	3	Not Detected	Not Detected
L40	3	Not Detected	Not Detected
L46	3	Not Detected	Not Detected
L49	3	Not Detected	Not Detected
L54	3	Not Detected	Not Detected
L58	3	Not Detected	Not Detected
L59	3	Not Detected	Not Detected
L60	3	Not Detected	Not Detected
L68	3	Not Detected	Not Detected
L69	3	Not Detected	Not Detected
L71	3	**Not Screened**	**Not Screened**
L72	3	Not Detected	Not Detected
L77	3	Not Detected	Not Detected
L82	3	Not Detected	Not Detected
L84	3	Not Detected	Not Detected
L85	3	Not Detected	Not Detected
L86	3	Not Detected	Not Detected
L88	3	Not Detected	Not Detected

NC = 0 %; NS = 3 %

(b)

LabCode	Group	Level 1	Level 2
L02	2	**Detected**	**Detected**
L08	2	Not Detected	Not Detected
L11	2	Not Detected	Not Detected
L13	2	Not Detected	Not Detected
L14	2	Not Detected	Not Detected
L15	2	Not Detected	Not Detected
L16	2	Not Detected	Not Detected
L17	2	**Not Screened**	**Not Screened**
L18	2	Not Detected	Not Detected
L21	2	Not Detected	Not Detected
L24	2	Not Detected	Not Detected
L35	2	Not Detected	Not Detected
L36	2	Not Detected	Not Detected
L39	2	Not Detected	Not Detected
L43	2	Not Detected	Not Detected
L48	2	Not Detected	Not Detected
L51	2	Not Detected	Not Detected
L53	2	Not Detected	Not Detected
L61	2	Not Detected	Not Detected
L62	2	Not Detected	Not Detected
L64	2	Not Detected	Not Detected
L66	2	Not Detected	Not Detected
L74	2	Not Detected	Not Detected
L78	2	Not Detected	Not Detected
L79	2	Not Detected	Not Detected
L90	2	Not Detected	Not Detected

NC = 4 %; NS = 4 %

(c)

LabCode	Group	Level 1	Level 2
L03	4	Not Detected	Not Detected
L25	4	**Not Screened**	**Not Screened**
L42	4	Not Detected	Not Detected
L52	4	Not Detected	Not Detected
L65	4	Not Detected	Not Detected
L07	5	**Not Screened**	**Not Screened**
L22	5	Not Detected	Not Detected
L26	5	**Not Screened**	**Not Screened**
L29	5	**Not Screened**	**Not Screened**
L70	5	Not Detected	Not Detected
L75	5	**Not Screened**	**Not Screened**
L83	5	Not Detected	Not Detected
L87	5	Not Detected	Not Detected
L09	6	Not Detected	Not Detected
L19	6	**Not Screened**	**Not Screened**
L27	6	**Not Screened**	**Not Screened**
L31	6	Not Detected	Not Detected
L41	6	**Not Screened**	**Not Screened**
L45	6	Not Detected	Not Detected
L50	6	**Not Screened**	**Not Screened**
L55	6	Not Detected	Not Detected
L56	6	**Not Screened**	**Not Screened**
L57	6	Not Detected	Not Detected
L76	6	Not Detected	Not Detected
L89	6	**Not Screened**	**Not Screened**

NC = 0 %; NS = 44 %

4.1.2 Soybean event 40-3-2

Results for this event were very satisfactory, with an overall detection rate of 100%, for the laboratories in categories (a) and (b). Only two laboratories in category (c) reported a false negative for Level 2 test item. One of these laboratories is a member of the ENGL whilst the other one is an official control laboratory (see Table 4a-c for details).

Table 4. Results of qualitative screening for soybean event 40-3-2, by laboratory category: (a) results of NRLs appointed under regulation 882/2004 (group 1 and 3, see page 6), (b) results of NRLs appointed under regulation 1981/2006 only (group 2), (c) results of ENGL members only, official control and third countries laboratories (group 4, 5 and 6); NC = No agreement with consensus (calculated only on laboratories that screened for the event), NS = Not screened. % of deviation from consensus is calculated on the basis of the number of results (e.g. in Table 4c, 25 laboratories x 2 Levels = 50) rather than just on the basis of the number of laboratories.

(a)

LabCode	Group	Level 1	Level 2
L37	1	Detected	Detected
L63	1	Detected	Detected
L01	3	Detected	Detected
L04	3	Detected	Detected
L05	3	Detected	Detected
L06	3	Detected	Detected
L12	3	Detected	Detected
L20	3	Detected	Detected
L23	3	Detected	Detected
L28	3	Detected	Detected
L30	3	Detected	Detected
L32	3	Detected	Detected
L33	3	Detected	Detected
L34	3	Detected	Detected
L40	3	Detected	Detected
L46	3	Detected	Detected
L49	3	Detected	Detected
L54	3	Detected	Detected
L58	3	Detected	Detected
L59	3	Detected	Detected
L60	3	Detected	Detected
L68	3	Detected	Detected
L69	3	Detected	Detected
L71	3	Detected	Detected
L72	3	Detected	Detected
L77	3	Detected	Detected
L82	3	Detected	Detected
L84	3	Detected	Detected
L85	3	Detected	Detected
L86	3	Detected	Detected
L88	3	Detected	Detected

NC = 0 %; NS = 0 %

(b)

LabCode	Group	Level 1	Level 2
L02	2	Detected	Detected
L08	2	Detected	Detected
L11	2	Detected	Detected
L13	2	Detected	Detected
L14	2	Detected	Detected
L15	2	Detected	Detected
L16	2	Detected	Detected
L17	2	Detected	Detected
L18	2	Detected	Detected
L21	2	Detected	Detected
L24	2	Detected	Detected
L35	2	Detected	Detected
L36	2	Detected	Detected
L39	2	Detected	Detected
L43	2	Detected	Detected
L48	2	Detected	Detected
L51	2	Detected	Detected
L53	2	Detected	Detected
L61	2	Detected	Detected
L62	2	Detected	Detected
L64	2	Detected	Detected
L66	2	Detected	Detected
L74	2	Detected	Detected
L78	2	Detected	Detected
L79	2	Detected	Detected
L90	2	Detected	Detected

NC = 0 %; NS = 0 %

(c)

LabCode	Group	Level 1	Level 2
L03	4	Detected	Detected
L25	4	Detected	**Not Detected**
L42	4	Detected	Detected
L52	4	Detected	Detected
L65	4	Detected	Detected
L07	5	Detected	Detected
L22	5	Detected	Detected
L26	5	Detected	Detected
L29	5	Detected	**Not Detected**
L70	5	Detected	Detected
L75	5	Detected	Detected
L83	5	Detected	Detected
L87	5	Detected	Detected
L09	6	Detected	Detected
L19	6	Detected	Detected
L27	6	Detected	Detected
L31	6	Detected	Detected
L41	6	Detected	Detected
L45	6	Detected	Detected
L50	6	Detected	Detected
L55	6	Detected	Detected
L56	6	Detected	Detected
L57	6	Detected	Detected
L76	6	Detected	Detected
L89	6	Detected	Detected

NC = 4 %; NS = 0 %

4.1.3 Soybean event MON 89788

All of the NRLs that screend for this event did not detect it, which was the correct result, whereas two of them did not screen for it. Additionally, 5 non-NRL laboratories did not screen for it, whereas 3 laboratories from third countries detected it in both Level 1 and 2 test items (see Table 5a-c).

Table 5. Results of qualitative screening for soybean event MON 87988, by laboratory category; NC = No agreement with consensus (calculated only on laboratories that screened for the event), NS = Not Screened.

(a)

LabCode	Group	Level 1	Level 2
L37	1	Not Detected	Not Detected
L63	1	Not Detected	Not Detected
L01	3	Not Detected	Not Detected
L04	3	Not Detected	Not Detected
L05	3	Not Detected	Not Detected
L06	3	Not Detected	Not Detected
L12	3	Not Detected	Not Detected
L20	3	Not Detected	Not Detected
L23	3	Not Detected	Not Detected
L28	3	Not Detected	Not Detected
L30	3	Not Detected	Not Detected
L32	3	Not Detected	Not Detected
L33	3	Not Detected	Not Detected
L34	3	Not Detected	Not Detected
L40	3	Not Detected	Not Detected
L46	3	Not Detected	Not Detected
L49	3	Not Detected	Not Detected
L54	3	Not Detected	Not Detected
L58	3	Not Detected	Not Detected
L59	3	Not Detected	Not Detected
L60	3	Not Detected	Not Detected
L68	3	Not Detected	Not Detected
L69	3	Not Detected	Not Detected
L71	3	**Not Screened**	**Not Screened**
L72	3	Not Detected	Not Detected
L77	3	Not Detected	Not Detected
L82	3	Not Detected	Not Detected
L84	3	Not Detected	Not Detected
L85	3	Not Detected	Not Detected
L86	3	Not Detected	Not Detected
L88	3	Not Detected	Not Detected

NC = 0 %; NS = 3 %

(b)

LabCode	Group	Level 1	Level 2
L02	2	Not Detected	Not Detected
L08	2	Not Detected	Not Detected
L11	2	Not Detected	Not Detected
L13	2	Not Detected	Not Detected
L14	2	Not Detected	Not Detected
L15	2	Not Detected	Not Detected
L16	2	Not Detected	Not Detected
L17	2	**Not Screened**	**Not Screened**
L18	2	Not Detected	Not Detected
L21	2	Not Detected	Not Detected
L24	2	Not Detected	Not Detected
L35	2	Not Detected	Not Detected
L36	2	Not Detected	Not Detected
L39	2	Not Detected	Not Detected
L43	2	Not Detected	Not Detected
L48	2	Not Detected	Not Detected
L51	2	Not Detected	Not Detected
L53	2	Not Detected	Not Detected
L61	2	Not Detected	Not Detected
L62	2	Not Detected	Not Detected
L64	2	Not Detected	Not Detected
L66	2	Not Detected	Not Detected
L74	2	Not Detected	Not Detected
L78	2	Not Detected	Not Detected
L79	2	Not Detected	Not Detected
L90	2	Not Detected	Not Detected

NC = 0 %; NS = 4 %

(c)

LabCode	Group	Level 1	Level 2
L03	4	Not Detected	Not Detected
L25	4	**Not Screened**	**Not Screened**
L42	4	Not Detected	Not Detected
L52	4	Not Detected	Not Detected
L65	4	Not Detected	Not Detected
L07	5	Not Detected	Not Detected
L22	5	**Not Screened**	**Not Screened**
L26	5	Not Detected	Not Detected
L29	5	**Not Screened**	**Not Screened**
L70	5	Not Detected	Not Detected
L75	5	Not Detected	Not Detected
L83	5	Not Detected	Not Detected
L87	5	Not Detected	Not Detected
L09	6	Not Detected	Not Detected
L19	6	Not Detected	Not Detected
L27	6	**Detected**	**Detected**
L31	6	Not Detected	Not Detected
L41	6	**Not Screened**	**Not Screened**
L45	6	Not Detected	Not Detected
L50	6	Not Detected	Not Detected
L55	6	**Detected**	**Detected**
L56	6	**Detected**	**Detected**
L57	6	Not Detected	Not Detected
L76	6	Not Detected	Not Detected
L89	6	**Not Screened**	**Not Screened**

NC = 15 %; NS = 20 %

4.1.4 Maize event MON 88017

All the NRL appointed at least under Regulation 882/2004 correctly detected this event on both Level 1 and 2 test items (detection rate = 100 %), whereas there was one false negative, for level 1, in the group of NRLs appointed only under Regulation 1981/2006. Among the non-NRLs, 8 laboratories (1 ENGL, 3 official control from EU and 4 from third countries) did not screen for this event (see Table 6a-c).

Table 6. Results of qualitative screening for maize event MON 88017, by laboratory category; NC = No agreement with consensus (calculated only on laboratories that screened for the event), NS = Not Screened.

(a)

LabCode	Group	Level 1	Level 2
L37	1	Detected	Detected
L63	1	Detected	Detected
L01	3	Detected	Detected
L04	3	Detected	Detected
L05	3	Detected	Detected
L06	3	Detected	Detected
L12	3	Detected	Detected
L20	3	Detected	Detected
L23	3	Detected	Detected
L28	3	Detected	Detected
L30	3	Detected	Detected
L32	3	Detected	Detected
L33	3	Detected	Detected
L34	3	Detected	Detected
L40	3	Detected	Detected
L46	3	Detected	Detected
L49	3	Detected	Detected
L54	3	Detected	Detected
L58	3	Detected	Detected
L59	3	Detected	Detected
L60	3	Detected	Detected
L68	3	Detected	Detected
L69	3	Detected	Detected
L71	3	Detected	Detected
L72	3	Detected	Detected
L77	3	Detected	Detected
L82	3	Detected	Detected
L84	3	Detected	Detected
L85	3	Detected	Detected
L86	3	Detected	Detected
L88	3	Detected	Detected

NC = 0 %; NS = 0 %

(b)

LabCode	Group	Level 1	Level 2
L02	2	Detected	Detected
L08	2	Detected	Detected
L11	2	Detected	Detected
L13	2	Detected	Detected
L14	2	Detected	Detected
L15	2	Detected	Detected
L16	2	Detected	Detected
L17	2	Detected	Detected
L18	2	Detected	Detected
L21	2	Detected	Detected
L24	2	Detected	Detected
L35	2	Detected	Detected
L36	2	Detected	Detected
L39	2	Detected	Detected
L43	2	**Not Detected**	Detected
L48	2	Detected	Detected
L51	2	Detected	Detected
L53	2	Detected	Detected
L61	2	Detected	Detected
L62	2	Detected	Detected
L64	2	Detected	Detected
L66	2	Detected	Detected
L74	2	Detected	Detected
L78	2	Detected	Detected
L79	2	Detected	Detected
L90	2	Detected	Detected

NC = 4 %; NS = 0 %

(c)

LabCode	Group	Level 1	Level 2
L03	4	Detected	Detected
L25	4	**Not Screened**	**Not Screened**
L42	4	Detected	Detected
L52	4	Detected	Detected
L65	4	Detected	Detected
L07	5	Detected	Detected
L22	5	**Not Screened**	**Not Screened**
L26	5	Detected	Detected
L29	5	**Not Screened**	**Not Screened**
L70	5	Detected	Detected
L75	5	**Not Screened**	**Not Screened**
L83	5	Detected	Detected
L87	5	Detected	Detected
L09	6	Detected	Detected
L19	6	**Not Screened**	**Not Screened**
L27	6	Detected	Detected
L31	6	Detected	Detected
L41	6	**Not Screened**	**Not Screened**
L45	6	Detected	Detected
L50	6	Detected	Detected
L55	6	Detected	Detected
L56	6	**Not Screened**	**Not Screened**
L57	6	Detected	Detected
L76	6	Detected	Detected
L89	6	**Not Screened**	**Not Screened**

NC = 0 %; NS = 32 %

4.1.5 Maize event MON 89034

Among NRLs appointed under Regulation 882/2004, all those that screened for this event (i.e. all laboratories except one) did not detect it. Of the NRLs belonging to group 2 (appointed under Regulation 1981/2006) one returned a result that did not agree with consensus for both Level 1 and 2 test items, and three did not screen for the event. Notably, this is the same lab that reported a false negative for maize event 88017 Level 1 test item. Moreover, four laboratories from third countries reported a result that did not agree with consensus (see Table 7a-c) and eight did not screen for the event.

Table 7. Results of qualitative screening for maize event MON 89034, distributed by laboratory category; NC = No agreement with consensus (calculated only on laboratories that screened for the event), NS = Not Screened.

(a)

LabCode	Group	Level 1	Level 2
L37	1	Not Detected	Not Detected
L63	1	Not Detected	Not Detected
L01	3	Not Detected	Not Detected
L04	3	Not Detected	Not Detected
L05	3	Not Detected	Not Detected
L06	3	Not Detected	Not Detected
L12	3	Not Detected	Not Detected
L20	3	Not Detected	Not Detected
L23	3	Not Detected	Not Detected
L28	3	Not Detected	Not Detected
L30	3	Not Detected	Not Detected
L32	3	Not Detected	Not Detected
L33	3	Not Detected	Not Detected
L34	3	Not Detected	Not Detected
L40	3	Not Detected	Not Detected
L46	3	Not Detected	Not Detected
L49	3	Not Detected	Not Detected
L54	3	Not Detected	Not Detected
L58	3	Not Detected	Not Detected
L59	3	Not Detected	Not Detected
L60	3	Not Detected	Not Detected
L68	3	Not Detected	Not Detected
L69	3	Not Detected	Not Detected
L71	3	**Not Screened**	**Not Screened**
L72	3	Not Detected	Not Detected
L77	3	Not Detected	Not Detected
L82	3	Not Detected	Not Detected
L84	3	Not Detected	Not Detected
L85	3	Not Detected	Not Detected
L86	3	Not Detected	Not Detected
L88	3	Not Detected	Not Detected

NC = 0 %; NS = 3 %

(b)

LabCode	Group	Level 1	Level 2
L02	2	Not Detected	Not Detected
L08	2	Not Detected	Not Detected
L11	2	Not Detected	Not Detected
L13	2	Not Detected	Not Detected
L14	2	Not Detected	Not Detected
L15	2	Not Detected	Not Detected
L16	2	Not Detected	Not Detected
L17	2	**Not Screened**	**Not Screened**
L18	2	Not Detected	Not Detected
L21	2	Not Detected	Not Detected
L24	2	Not Detected	Not Detected
L35	2	**Not Screened**	**Not Screened**
L36	2	Not Detected	Not Detected
L39	2	Not Detected	Not Detected
L43	2	**Detected**	**Detected**
L48	2	**Not Screened**	**Not Screened**
L51	2	Not Detected	Not Detected
L53	2	Not Detected	Not Detected
L61	2	Not Detected	Not Detected
L62	2	Not Detected	Not Detected
L64	2	Not Detected	Not Detected
L66	2	Not Detected	Not Detected
L74	2	Not Detected	Not Detected
L78	2	Not Detected	Not Detected
L79	2	Not Detected	Not Detected
L90	2	Not Detected	Not Detected

NC = 4 %; NS = 12 %

(c)

LabCode	Group	Level 1	Level 2
L03	4	Not Detected	Not Detected
L25	4	**Not Screened**	**Not Screened**
L42	4	Not Detected	Not Detected
L52	4	**Not Screened**	**Not Screened**
L65	4	Not Detected	Not Detected
L07	5	**Not Screened**	**Not Screened**
L22	5	**Not Screened**	**Not Screened**
L26	5	Not Detected	Not Detected
L29	5	**Not Screened**	**Not Screened**
L70	5	Not Detected	Not Detected
L75	5	**Not Screened**	**Not Screened**
L83	5	Not Detected	Not Detected
L87	5	Not Detected	Not Detected
L09	6	Not Detected	Not Detected
L19	6	**Detected**	**Detected**
L27	6	Not Detected	Not Detected
L31	6	Not Detected	Not Detected
L41	6	Not Screened	Not Screened
L45	6	Not Detected	Not Detected
L50	6	Not Detected	Not Detected
L55	6	**Detected**	**Detected**
L56	6	**Detected**	**Detected**
L57	6	**Detected**	**Detected**
L76	6	Not Detected	Not Detected
L89	6	**Not Screened**	**Not Screened**

NC = 24 %; NS = 32 %

4.1.6 Conclusions on qualitative screening

Overall, the performance of laboratories in the qualitative PCR screening task of this CT round was satisfactory. Very few laboratories returned results that did not agree with the consensus: for soybean event 40-3-2 and maize event MON 88017 there were only two and one false negative results respectively (see Tables 3(c) and 5(b)). On average, 2 % of laboratories in category (a) did not screen for the specified GM events, and of those who screened 0 % showed a deviation from consensus, whereas in category (b) these

percentages were respectively 4 % and 2 %. Both categories (a) and (b) performed better than category (c), which included all non-NRL laboratories: of this category 26% did not screen for the specified events, and of those 18 that did screen, 9 deviated from the consensus. Notably, the large majority of deviations from consensus or lack of screening occurred in category (c), however it was not possible to determine the reasons why these laboratories did not carry out the requested task of screening for certain or all events. Results for all events, regardless of laboratory groups, are summarized in Figures 4a-b. For both test items, the majority of laboratories provided results that agreed with consensus (Detected for soybean 40-3-2 and maize MON 88017, Not Detected for other events).

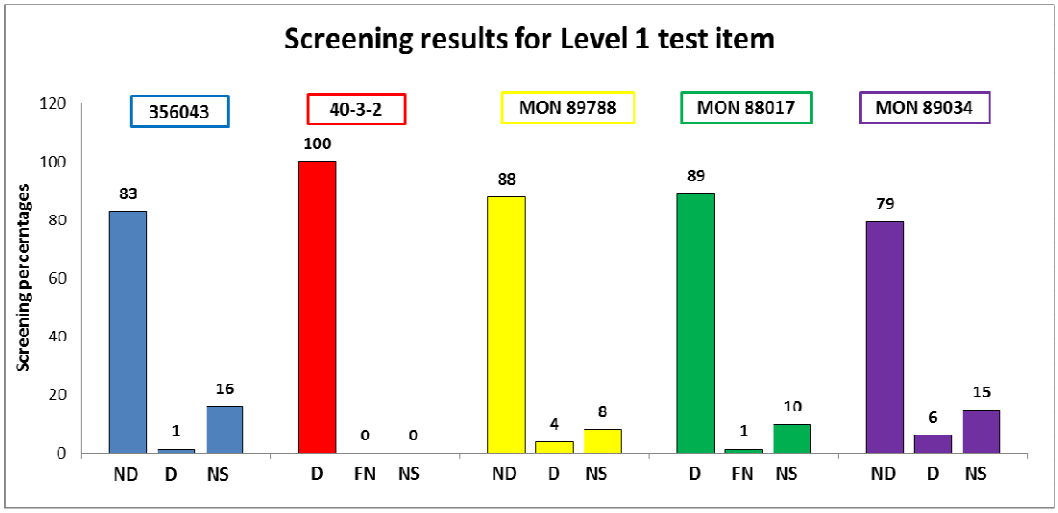


Figure 4a. Overview of screening data (in %) for Level 1 test item. D = Detected, FN = False Negative, NS = Not Screened, ND = Not Detected.

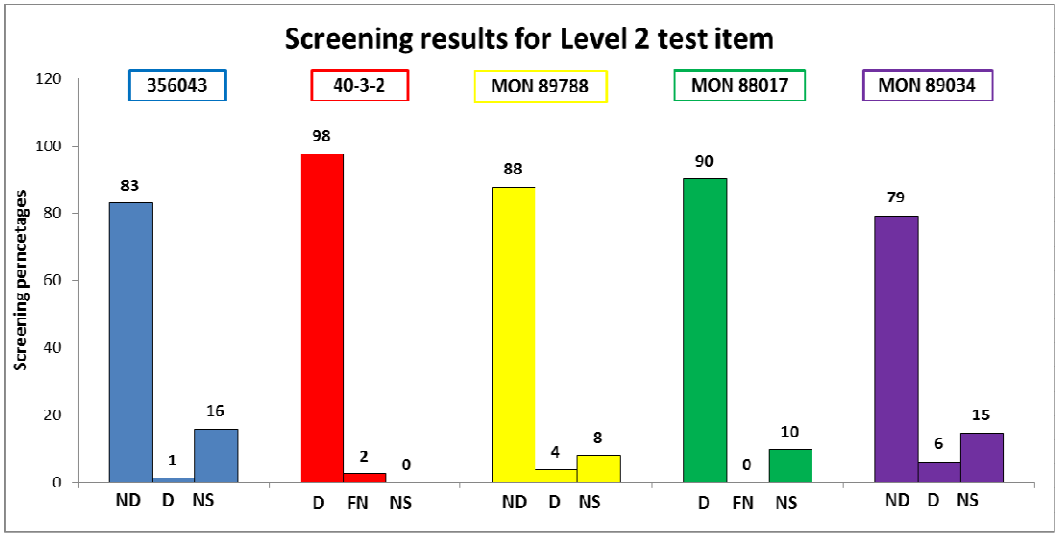


Figure 4b. Overview of screening data (in %) for Level 2 test item. D = Detected, FN = False Negative, NS = Not Screened, ND = Not Detected.

4.2 Quantitative results

The aim of a performance statistic is to provide participants with a meaningful result that can be easily interpreted. The procedure followed for the evaluation of participants' performance was agreed by the Members of the Advisory Board and relies on the calculation of z-scores from log10-transformed data[6] based on the assigned values[8] (μ) and the robust means[17] (μ_R) of the participants' results.

The EU-RL GMFF calculated the concensus values from participants taking the robust means (μ_R) for Level 1 and 2 test items in m/m % and cp/cp % on both original and log10-transformed scale. The assigned values were established on the basis of the homogeneity assessment of the EU-RL GMFF and are indicated in Table 1.

The value of $\hat{\sigma}$, the target standard deviation for comparative testing, was defined by the Members of the Advisory Board on the basis of the experience acquired with previous CT rounds, and set to 0.15 for soybean event 40-3-2 and to 0.2 for maize event MON 88017[18].

The z-scores (z_i) for participant i reporting measurement result x_i are thus calculated in comparison to the assigned value (only for m/m data) as

$$z_i = \left(\log_{10} x_i - \log_{10} \mu \right) \Big/ \hat{\sigma} \qquad (8)$$

or in comparison to the robust mean as

$$z_i = \left(\log_{10} x_i - \log_{10} \mu_R \right) \Big/ \hat{\sigma} \qquad (9)$$

Additionally, laboratories were asked to report the estimated measurement uncertainty as an absolute value, and the practical LOD and LOQ in the appropriate measurement unit.

4.2.1 Consensus values from participants

The consensus value (μ_R) from participants in the CT round was calculated using robust statistics[17]. This approach minimises the influence of outlying values. Robust means (μ_R) were calculated on the basis of the measurements reported both in m/m% and cp/cp%.

The expanded uncertainty (U) comprises standard uncertainty contributions from the characterisation, the between-test item homogeneity, and the stability[15] (Formula 4).

The robust means (μ_R) for data on the non-transformed scale, as determined by the EU-RL GMFF, are reported in Table 8.

Table 8. Overview of robust means (μ_R) and expanded uncertainties for Level 1 and 2 test items.

μ_R [m/m %]		*Expanded uncertainty* ($U = 2 * u_c$)		*Relative standard uncertainty contributions [%]*		
		U_{abs} [m/m %]	U_{rel} [%]	$(u_{char, rel})^1$	$(u_{bb, rel})^2$	$(u_{lts, rel})^3$
Soybean 40-3-2						
Level 1	*1.86 (N = 62)*	0.13	6.96	2.12	2.76	0.209
Level 2	*0.25 (N = 61)*	0.03	12.06	4.05	4.46	0.209
Maize MON 88017						
Level 1	*0.59 (N = 51)*	0.08	12.76	4.77	4.23	0.048
Level 2	*1.05 (N = 51)*	0.10	9.25	4.01	2.31	0.048
μ_R [cp/cp %]		*Expanded uncertainty* ($U = 2 * u_c$)		*Relative standard uncertainty contributions [%]*		
		U_{abs} [cp/cp %]	U_{rel} [%]	$(u_{char, rel})^1$	$(u_{bb, rel})^2$	$(u_{lts, rel})^3$
Soybean 40-3-2						
Level 1	*1.77 (N = 15)*	0.18	10.24	4.31	2.76	0.209
Level 2	*0.26 (N = 14)*	0.07	28.81	13.70	4.46	0.209
Maize MON 88017						
Level 1	*0.44 (N = 17)*	0.16	36.02	17.51	4.23	0.048
Level 2	*0.86 (N = 18)*	0.31	36.06	17.88	2.31	0.048

4.2.2 Participants' results

The z-scores were calculated for both events and for both Level 1 and 2 test items on the basis of the assigned values (for m/m % data only) and on the basis of the robust means for both m/m % and cp/cp % data. Results are reported by laboratory in Tables 9 to 16. For matters of consistency, all decimal numbers have been rounded to two digits. The information is given by laboratory category and, for indicative purposes, by laboratory group (see page 6). "Value" refers to the reported value and uncertainty as calculated and reported by the laboratory. Also "LOD" (limit of detection) and "LOQ" (limit of quantification) are values calculated and provided by the laboratories and referring to the methods they used. The z-scores, measurement uncertainty (MU; % of incorrectly reported MU is estimated only using data from laboratories which reported a value), mean LOD (μ_{lod}) and mean LOQ (μ_{loq}) as well as their standard deviation are calculated by the EU-RL GMFF. As an indicator for the overall performance the fraction of laboratories outside the acceptable range of the z-score is given and corresponding data are highlighted as bold.

Table 9 (a), (b), (c). z-scores for soybean event 40-3-2 **Level 1 test item** for results reported in m/m %, laboratory category: (a) , (b), or (c) . - = not reported, * = no z-score attributed, (1) Uncertainty (*U*) and/or coverage factor *k* was reported in an inconsistent manner, (2) *U* was reported in an incomplete manner, (3) U seems to be a relative value.

(a)

Laboratory Number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 1.86	z-score based on μ = 1.78
L37	1	1.88	0.21	0.02	0.04	0.05	0.17
L04	3	1.62	0.38	0.03	0.10	-0.37	-0.26
L05	3	2.04	(1) 0.82	<0.10	0.09	0.29	0.41
L06	3	1.55	0.51	0.02	0.15	-0.50	-0.39
L12	3	1.88	0.73	-	-	0.06	0.17
L20	3	1.79	0.25	0.04	0.07	-0.08	0.03
L23	3	1.88	(1) 0.30	0.07	0.10	0.06	0.17
L28	3	2.50	(1) 1.35	(%) -1	(%) 1	0.88	1.00
L32	3	2.18	(2) 0.65	-	0.10	0.49	0.60
L33	3	1.71	(1) 0.18	0.01	0.10	-0.22	-0.10
L34	3	2.11	0.36	0.01	0.10	0.39	0.51
L40	3	2.26	0.81	0.01	0.10	0.59	0.71
L46	3	1.46	0.48	0.03	0.07	-0.67	-0.56
L49	3	1.71	(3) 30.00	0.02	0.06	-0.22	-0.10
L54	3	1.83	0.55	0.01	0.12	-0.02	0.09
L58	3	1.90	0.62	0.02	0.10	0.09	0.20
L59	3	1.67	0.65	-	-	-0.29	-0.17
L68	3	1.85	(1) 0.56	-	0.04	0.01	0.13
L69	3	1.30	0.50	<0.05	0.05	-1.01	-0.90
L71	3	2.01	0.71	(%) <0.10	-	0.25	0.37
L72	3	1.85	(3) 22.90	-	-	0.01	0.13
L77	3	1.91	(2) 0.43	0.05	0.10	0.10	0.22
L82	**3**	**4.20**	**(1) 0.80**	**0.03**	**0.10**	**2.39**	**2.50**
L84	3	1.70	0.22	0.10	0.50	-0.23	-0.12
L88	3	2.14	0.76	0.07	0.26	0.43	0.55

% Incorrect MU	μ_{LOD} = 0.04	μ_{LOQ} = 0.12	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
40%	σ_{LOD} = 0.03	σ_{LOQ} = 0.10	4%	4%

(b)

Laboratory Number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 1.86	z-score based on μ = 1.78
L02	**2**	**21.17**	**(3) 33.69**	**0.01**	**0.02**	**7.07**	**7.18**
L08	2	2.14	0.56	0.01	0.05	0.43	0.55
L11	2	2.03	(3) 38.72	0.02	0.10	0.28	0.39
L13	2	1.89	0.39	0.01	0.05	0.07	0.19
L14	2	< 0.10	-	-	-	*	*
L16	2	1.71	0.05	-	-	-0.22	-0.10
L18	2	1.94	0.11	0.01	0.03	0.15	0.26
L21	2	1.59	0.66	0.01	0.06	-0.43	-0.31
L24	2	1.70	0.30	0.04	0.10	-0.23	-0.12
L35	2	1.91	0.12	0.02	0.08	0.10	0.22
L36	2	2.20	0.72	17.00	24.00	0.51	0.63
L39	2	1.83	0.30	0.01	0.10	-0.02	0.09
L48	2	1.38	(1) 0.01	-	-	-0.84	-0.72
L51	2	1.45	0.44	0.02	0.10	-0.69	-0.58
L53	2	2.02	0.29	0.04	0.07	0.27	0.38
L61	2	1.90	(1) 0.30	0.02	0.03	0.09	0.20
L62	2	1.55	(1) 0.10	0.01	0.01	-0.50	-0.39
L64	2	1.50	0.30	0.03	0.10	-0.60	-0.48
L66	2	1.71	0.28	0.01	0.10	-0.22	-0.10
L74	2	1.45	0.25	-	-	-0.69	-0.58
L78	2	1.80	0.40	-	0.10	-0.07	0.05
L79	2	1.63	0.05	0.03	0.10	-0.36	-0.24
L90	2	2.01	-	0.05	0.10	0.25	0.37
			% Incorrect MU	μ_{LOD} = 0.02	μ_{LOQ} = 0.07	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
			24%	σ_{LOD} = 0.01	σ_{LOQ} = 0.03	5%	5%

(c)

Laboratory Number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 1.86	z-score based on μ = 1.78
L03	4	1.77	1.13	0.03	0.12	-0.12	0.00
L42	4	1.70	(1) 0.16	0.00	0.02	-0.23	-0.12
L65	4	1.77	(1) 0.72	0.08	0.10	-0.12	0.00
L07	5	2.29	1.06	0.06	0.06	0.63	0.74
L22	5	1.75	(1) 0.50	0.05	0.10	-0.15	-0.04
L26	5	3.31	0.93	-	-	1.70	1.81
L29	5	2.61	0.30	0.04	0.08	1.01	1.12
L70	**5**	**0.08**	**(2) 0.03**	**0.05**	**0.09**	**-9.08**	**-8.97**
L75	5	1.71	0.25	-	-	-0.22	-0.10
L76	5	3.00	(2) (3) 10.00	0.05	0.10	1.41	1.53
L83	5	1.98	0.15	0.01	0.10	0.21	0.32
L87	5	2.24	(1) 1.42	-	0.05	0.57	0.68
L41	6	1.57	(1) 0.84	0.10	0.10	-0.46	-0.34
L50	6	1.23	-	-	-	-1.17	-1.06
L89	6	1.89	-	0.03	0.10	0.07	0.19
			% Incorrect MU	μ_{LOD} = 0.05	μ_{LOQ} = 0.09	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
			54%	σ_{LOD} = 0.03	σ_{LOQ} = 0.03	7%	7%

Table 10 (a), (b), (c). z-scores for soybean event 40-3-2 **Level 2 test item** for results reported in m/m %, laboratory category: (a), (b), or (c). - = not reported, * = no z-score attributed, (1) Uncertainty (*U*) and/or coverage factor *k* was reported in an inconsistent manner, (2) *U* was reported in an incomplete manner, (3) U seems to be a relative value.

(a)

Laboratory Number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 0.25	z-score based on μ = 0.21
L37	1	0.15	0.05	0.02	0.04	-1.36	-0.90
L04	3	0.22	0.07	0.03	0.10	-0.29	0.17
L05	3	0.35	(1) 0.14	<0.10	0.09	1.06	1.52
L06	3	0.23	0.10	0.02	0.17	-0.16	0.30
L12	3	0.22	0.11	-	-	-0.29	0.17
L20	3	0.19	0.03	0.04	0.07	-0.71	-0.25
L23	3	0.26	(1) 0.04	0.07	0.10	0.20	0.66
L28	3	0.19	(1) 0.06	(%) -1	(%) 1	-0.68	-0.22
L32	3	0.24	(2) 0.07	-	0.10	-0.03	0.43
L33	3	0.36	(1) 0.08	0.01	0.10	1.14	1.60
L34	3	0.20	0.05	0.01	0.10	-0.56	-0.10
L40	**3**	**0.53**	**0.20**	**0.01**	**0.10**	**2.26**	**2.72**
L46	3	0.33	0.11	0.03	0.07	0.89	1.35
L49	3	0.26	(3) 30.00	0.02	0.06	0.20	0.66
L54	3	0.35	0.16	0.01	0.12	1.06	1.52
L58	3	0.31	0.10	0.02	0.10	0.71	1.17
L59	3	0.25	0.13	-	-	0.08	0.55
L68	3	0.21	(1) 0.06	-	0.04	-0.42	0.04
L69	3	0.23	0.10	<0.05	0.05	-0.16	0.30
L71	3	0.29	0.15	(%) <0.10	-	0.51	0.97
L72	3	0.24	(3) 46.46	-	-	-0.03	0.43
L77	3	0.26	(2) 0.14	0.05	0.10	0.20	0.66
L82	**3**	**0.86**	**(1) 0.20**	**0.03**	**0.10**	**3.66**	**4.12**
L84	3	0.20	0.07	0.10	0.50	-0.56	-0.10
L88	3	0.28	0.10	0.07	0.26	0.41	0.87

% Incorrect MU	μ_{LOD} = 0.04	μ_{LOQ} = 0.12	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
40%	σ_{LOD} = 0.03	σ_{LOQ} = 0.1	8%	8%

(b)

Laboratory Number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 0.25	z-score based on μ = 0.21
L02	**2**	**6.30**	**(3) 96.57**	**0.01**	**0.02**	**9.43**	**9.89**
L08	2	0.25	0.06	0.01	0.05	0.08	0.55
L11	2	0.22	(3) 33.90	0.02	0.10	-0.29	0.17
L13	2	0.23	0.10	0.01	0.05	-0.16	0.30
L14	2	< 0.10	-	-	-	*	*
L16	2	0.26	0.10	-	-	0.20	0.66
L18	2	0.22	0.03	0.01	0.03	-0.29	0.17
L21	2	0.14	0.08	0.01	0.06	-1.59	-1.13
L24	2	0.30	0.10	0.05	0.10	0.61	1.07
L35	2	0.19	0.05	0.02	0.08	-0.71	-0.25
L36	2	0.20	0.09	17.00	24.00	-0.56	-0.10
L39	2	0.29	0.08	0.01	0.10	0.51	0.97
L48	**2**	**0.04**	**(1) 0.01**	**-**	**-**	**-5.37**	**-4.91**
L51	2	0.30	0.08	0.02	0.10	0.61	1.07
L53	2	0.19	0.04	0.04	0.07	-0.71	-0.25
L61	2	0.20	(1) 0.02	0.02	0.03	-0.56	-0.10
L62	2	0.20	(1) 0.04	0.01	0.01	-0.56	-0.10
L64	2	0.20	0.10	0.03	0.10	-0.56	-0.10
L66	2	0.25	0.06	0.01	0.10	0.08	0.55
L74	2	0.16	0.18	-	-	-1.21	-0.75
L78	2	0.20	0.05	-	0.10	-0.56	-0.10
L79	2	0.28	0.02	0.03	0.10	0.41	0.87
L90	2	0.22	-	0.05	0.10	-0.29	0.17
			% Incorrect MU	μ_{LOD} = 0.02	μ_{LOQ} = 0.07	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
			24%	σ_{LOD} = 0.01	σ_{LOQ} = 0.03	9%	9%

(c)

Laboratory Number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 0.25	z-score based on μ = 0.21
L03	4	0.30	0.21	0.03	0.12	0.61	1.07
L42	4	0.17	(1) 0.04	0.00	0.02	-1.07	-0.61
L65	4	0.46	(1) 0.19	0.08	0.10	1.85	2.31
L07	5	0.40	0.30	0.06	0.06	1.45	1.91
L22	5	0.35	(1) 0.15	0.05	0.10	1.06	1.52
L26	5	0.21	0.06	-	-	-0.42	0.04
L70	**5**	**2.24**	**(2) 0.37**	**0.05**	**0.09**	**6.43**	**6.89**
L75	5	0.18	0.25	-	-	-0.87	-0.41
L83	5	0.17	0.02	0.01	0.10	-1.03	-0.57
L87	5	0.21	(1) 0.16	-	0.05	-0.42	0.04
L41	**6**	**0.66**	**(1) 0.35**	**0.10**	**0.10**	**2.89**	**3.35**
L50	6	0.15	-	-	-	-1.39	-0.93
L76	6	0.30	(2) (3) 10.00	0.05	0.10	0.61	1.07
L89	6	0.13	-	0.03	0.10	-1.81	-1.35
			% Incorrect MU	μ_{LOD} = 0.05	μ_{LOQ} = 0.09	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
			54%	σ_{LOD} = 0.03	σ_{LOQ} = 0.03	14%	14%

Table 11 (a), (b), (c). z-scores for soybean event 40-3-2 Level 1 test item for results reported in **cp/cp %,** laboratory category: (a), (b), and (c). - = not reported, * = no z-score attributed, (1) Uncertainty (*U*) and/or coverage factor *k* was reported in an inconsistent manner, (2) *U* was reported in an incomplete manner, (3) U seems to be a relative value, (4) LOD and/or LOQ reported inconsistenly (with respect to unit of measurement).

(a)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 1.77
L63	1	1.86	0.20	(4) 0.04	(4) 0.08	0.16
L01	3	1.62	(1) 0.01	0.05	0.10	-0.24
L30	3	1.91	0.73	0.01	0.10	0.24
L60	3	1.90	0.28	-	-	0.22
L85	3	1.81	0.36	0.05	0.10	0.08
L86	3	1.44	(3) 48	0.10	0.10	-0.58

% Incorrect MU	μ_{LOD} = 0.05	μ_{LOQ} = 0.10	% $Z_{\mu R}$ outside (-2, +2)
33%	σ_{LOD} = 0.03	σ_{LOQ} = 0.01	0%

(b)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 1.77
L15	2	1.59	(3) 5.30	0.05	0.01	-0.29
L17	2	1.60	-	-	-	-0.27
L43	2	1.57	0.63	0.09	0.19	-0.33

% Incorrect MU	μ_{LOD} = 0.07	μ_{LOQ} = 0.10	% $Z_{\mu R}$ outside (-2, +2)
50%	σ_{LOD} = 0.03	σ_{LOQ} = 0.13	0%

(c)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 1.77
L25	4	1.56	(1) 0.64	0.10	0.10	-0.35
L52	4	2.00	(1) (2) 0.8	0.00	0.01	0.37
L26	5	2.59	-	-	-	1.12
L09	6	1.93	-	0.10	-	0.27
L31	**6**	**0.80**	**-**	**-**	**-**	**-2.28**
L45	6	2.88	(1) 0.48	(%) 0.10	(%) 0.10	1.43

% Incorrect MU	μ_{LOD} = 0.08	μ_{LOQ} = 0.07	% $Z_{\mu R}$ outside (-2, +2)
100%	σ_{LOD} = 0.05	σ_{LOQ} = 0.05	17%

Table 12 (a), (b), (c). z-scores for soybean event 40-3-2 Level 2 test item for results reported in **cp/cp %,** laboratory category: (a), (b), and (c). - = not reported, * = no z-score attributed, (1) Uncertainty (*U*) and/or coverage factor *k* was reported in an inconsistent manner, (2) *U* was reported in an incomplete manner, (3) U seems to be a relative value, (4) LOD and/or LOQ reported inconsistenly (with respect to unit of measurement).

(a)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 0.26
L63	1	0.26	0.03	(4) 0.04	(4) 0.08	0.14
L01	3	0.49	(1) 0.15	0.05	0.10	1.97
L30	3	0.32	0.04	0.01	0.10	0.74
L60	3	0.21	0.02	-	-	-0.48
L85	3	0.28	0.36	0.05	0.10	0.35
L86	3	0.23	(3) 48.00	0.10	0.10	-0.22
			% Incorrect MU	μ_{LOD} = 0.05	μ_{LOQ} = 0.10	% $Z_{\mu R}$ outside (-2, +2)
			33%	σ_{LOD} = 0.03	σ_{LOQ} = 0.01	0%

(b)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 0.26
L15	2	0.16	(3) 20.10	0.05	0.01	-1.27
L17	2	0.20	-	-	-	-0.62
L43	2	0.14	0.28	0.09	0.19	-1.66
			% Incorrect MU	μ_{LOD} = 0.07	μ_{LOQ} = 0.10	% $Z_{\mu R}$ outside (-2, +2)
			50%	σ_{LOD} = 0.03	σ_{LOQ} = 0.13	0%

(c)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 0.26
L25	4	< 0.10	-	0.10	0.10	*
L52	**4**	**0.50**	**(1) (2) 0.20**	**0.00**	**0.01**	**2.03**
L26	5	0.21	-	-	-	-0.48
L09	6	0.21	-	0.10	-	-0.48
L31	**6**	**0.10**	**-**	**-**	**-**	**-2.63**
L45	**6**	**0.54**	**(1) 0.48**	**(%) 0.10**	**(%) 0.10**	**2.25**
			% Incorrect MU	μ_{LOD} = 0.08	μ_{LOQ} = 0.07	% $Z_{\mu R}$ outside (-2, +2)
			100%	σ_{LOD} = 0.05	σ_{LOQ} = 0.05	60%

Table 13 (a), (b), (c). z-scores for **maize event MON 88017 Level 1 test item** for results reported in **m/m %,** laboratory category: (a), (b), and (c).- = not reported, * = no z-score attributed, (1) Uncertainty (*U*) and/or coverage factor *k* was reported in an inconsistent manner, (2) *U* was reported in an incomplete manner, (3) U seems to be a relative value.

(a)

Laboratory number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 0.59	z-score based on μ = 0.68
L37	1	0.91	0.17	0.03	0.34	1.00	0.66
L04	3	0.49	0.15	0.03	0.10	-0.34	-0.68
L05	3	0.37	-	-	-	-0.95	-1.29
L06	3	0.50	0.23	0.05	0.22	-0.29	-0.64
L12	3	0.50	0.22	-	-	-0.29	-0.64
L20	3	0.45	0.10	0.04	0.07	-0.52	-0.86
L23	3	0.48	(1) 0.08	0.05	0.10	-0.38	-0.72
L28	3	0.57	(1) 0.17	(%) - 1	(%) - 1	-0.01	-0.36
L33	3	0.80	(1) 0.07	0.01	0.10	0.73	0.38
L40	**3**	**1.60**	**0.56**	**0.01**	**0.10**	**2.23**	**1.89**
L46	3	0.46	0.13	0.01	0.10	-0.47	-0.82
L49	3	0.43	(3) 30.00	0.04	0.12	-0.62	-0.96
L54	3	0.83	0.24	0.02	0.55	0.81	0.46
L58	3	0.55	0.18	0.03	0.10	-0.08	-0.43
L59	3	0.39	0.29	-	-	-0.83	-1.18
L68	3	0.52	(1) 0.16	-	0.17	-0.21	-0.55
L69	3	0.32	0.10	0.05	0.10	-1.26	-1.60
L71	3	0.62	0.28	<0.10%		0.18	-0.17
L72	3	1.11	(3) 64.01	-	-	1.44	1.10
L77	3	0.42	-	0.10	0.10	-0.67	-1.01
L82	3	0.79	(1) 0.20	0.05	0.10	0.70	0.36
L84	3	0.37	0.04	0.10	0.30	-0.95	-1.29
L86	3	0.48	(3) 32.00	0.10	0.10	-0.38	-0.72
L88	3	0.59	0.26	0.13	0.33	0.07	-0.28

% Incorrect MU	μ_{LOD} = 0.05	μ_{LOQ} = 0.17	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
36%	σ_{LOD} = 0.04	σ_{LOQ} = 0.13	4%	0%

(b)

Laboratory number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 0.59	z-score based on μ = 0.68
L02	2	0.58	(3) 19.08	0.06	0.18	0.03	-0.31
L08	2	0.50	0.10	0.03	0.10	-0.29	-0.64
L13	2	0.78	0.32	0.02	0.07	0.67	0.33
L14	2	> 0.10	-	-	-	*	*
L16	2	0.39	0.17	-	-	-0.83	-1.18
L18	2	0.50	0.06	0.04	0.18	-0.29	-0.64
L21	2	0.33	0.20	0.05	0.10	-1.19	-1.54
L24	2	> 0.01	-	0.05	0.09	*	*
L35	2	0.54	0.03	0.02	0.08	-0.12	-0.47
L36	2	0.50	0.16	-	-	-0.29	-0.64
L39	2	0.66	0.23	0.02	0.20	0.31	-0.03
L51	2	0.99	0.18	0.05	0.10	1.19	0.85
L53	2	0.53	0.14	0.12	0.24	-0.17	-0.51
L61	2	0.90	(1) 0.30	0.00	0.10	0.98	0.64
L62	**2**	**0.18**	**(1) 0.04**	**0.01**	**0.09**	**-2.51**	**-2.85**
L64	2	0.70	0.30	0.03	0.10	0.44	0.09
L66	2	0.53	0.16	0.01	0.10	-0.17	-0.51
L74	2	0.73	0.17	-	-	0.53	0.19
L78	2	0.50	-	-	-	-0.29	-0.64
L79	2	1.21	0.24	0.03	0.10	1.63	1.28
L90	2	0.73	-	0.05	0.10	0.53	0.19

% Incorrect MU	μ_{LOD} = 0.04	μ_{LOQ} = 0.12	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
18%	σ_{LOD} = 0.03	σ_{LOQ} = 0.05	5%	5%

(c)

Laboratory number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 0.59	z-score based on μ = 0.68
L03	4	0.55	0.27	0.03	0.12	-0.08	-0.43
L42	4	0.55	(1) 0.15	-	-	-0.10	-0.44
L65	4	1.02	(1) 0.47	0.04	0.10	1.26	0.91
L07	5	0.46	-	-	-	-0.47	-0.82
L70	5	0.89	(2) 0.18	0.50	0.98	0.96	0.62
L83	5	0.61	0.01	0.01	0.10	0.14	-0.20
L87	5	0.50	(1) 0.24	-	0.05	-0.29	-0.64
L76	6	0.60	(3) 36.00	0.05	0.10	0.10	-0.24
			% Incorrect MU	μ_{LOD} = 0.13	μ_{LOQ} = 0.24	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
			71%	σ_{LOD} = 0.21	σ_{LOQ} = 0.36	0%	0%

Table 14 (a), (b), (c). z-scores for maize event MON 88017 Level 2 test item for results reported in **m/m %**, divided by laboratory group: (a), (b), and (c). - = not reported, * = no z-score attributed, (1) Uncertainty (*U*) and/or coverage factor *k* was reported in an inconsistent manner, (2) *U* was reported in an incomplete manner, (3) U seems to be a relative value.

(a)

Laboratory number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 1.05	z-score based on μ = 1.42
L37	1	1.21	0.25	0.03	0.32	0.35	-0.33
L04	3	1.14	0.36	0.03	0.10	0.22	-0.46
L05	3	0.67	-	-	-	-0.94	-1.62
L06	3	1.07	0.48	0.05	0.02	0.08	-0.60
L12	3	0.90	0.33	-	-	-0.29	-0.98
L20	3	0.88	0.14	0.04	0.07	-0.34	-1.02
L23	3	0.79	(1) 0.12	0.05	0.10	-0.58	-1.26
L28	3	1.02	(1) 1.27	(%) - 1	(%) - 1	-0.02	-0.70
L33	3	1.43	(1) 0.03	0.01	0.10	0.71	0.03
L40	3	1.59	0.57	0.01	0.10	0.94	0.26
L46	3	0.96	0.28	0.01	0.10	-0.15	-0.84
L49	3	0.90	(3) 30.00	0.04	0.12	-0.29	-0.98
L54	3	1.31	0.39	0.02	0.55	0.52	-0.16
L58	3	1.19	0.39	0.03	0.10	0.31	-0.37
L59	3	1.21	0.62	-	-	0.35	-0.33
L68	3	1.15	(1) 0.35	-	0.17	0.24	-0.44
L69	3	0.64	0.40	0.05	0.10	-1.04	-1.72
L71	3	1.03	0.33	<0.10%	-	0.00	-0.68
L72	3	1.59	(3) 27.74	-	-	0.94	0.26
L77	3	0.84	-	0.10	0.10	-0.44	-1.12
L82	3	1.28	(1) 0.30	0.05	0.10	0.47	-0.21
L84	3	0.78	0.13	0.10	0.30	-0.61	-1.29
L86	3	1.08	(3) 32.00	0.10	0.10	0.10	-0.58
L88	3	1.12	0.46	0.13	0.33	0.18	-0.50

% Incorrect MU	μ_{LOD} = 0.05	μ_{LOQ} = 0.16	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
36%	σ_{LOD} = 0.04	σ_{LOQ} = 0.13	0%	0%

(b)

Laboratory number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 1.05	z-score based on μ = 1.42
L02	2	0.93	(3) 58.44	0.06	0.18	-0.22	-0.90
L08	2	0.73	0.18	0.03	0.10	-0.75	-1.43
L13	2	1.44	0.32	0.02	0.07	0.73	0.05
L14	2	> 0.10	-	-	-	*	*
L16	2	0.84	0.19	-	-	-0.44	-1.12
L18	2	0.92	0.07	0.04	0.18	-0.25	-0.93
L21	**2**	**0.50**	**0.23**	**0.05**	**0.10**	**-1.57**	**-2.25**
L24	2	> 0.01	-	0.05	0.09	*	*
L35	2	1.09	0.02	0.02	0.08	0.12	-0.56
L36	2	1.10	0.36	-	-	0.14	-0.54
L39	2	1.30	0.43	0.02	0.20	0.50	-0.18
L51	2	1.60	0.36	0.05	0.10	0.95	0.27
L53	2	0.98	0.18	0.12	0.24	-0.11	-0.79
L61	2	1.60	(1) 0.30	0.00	0.10	0.95	0.27
L62	**2**	**0.33**	**(1) 0.04**	**0.01**	**0.09**	**-2.47**	**-3.15**
L64	2	1.30	0.40	0.03	0.10	0.50	-0.18
L66	2	0.81	0.14	0.01	0.10	-0.52	-1.20
L74	2	1.25	0.68	-	-	0.42	-0.26
L78	2	1.00	-	-	-	-0.07	-0.75
L79	2	1.88	0.15	0.03	0.10	1.30	0.62
L90	2	1.02	-	0.05	0.10	-0.02	-0.70

% Incorrect MU	μ_{LOD} = 0.04	μ_{LOQ} = 0.12	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
18%	σ_{LOD} = 0.03	σ_{LOQ} = 0.05	5%	11%

(c)

Laboratory number	Group	Value	Uncertainty	LOD m/m	LOQ m/m	z-score based on μ_R = 1.05	z-score based on μ = 1.42
L03	4	0.86	0.42	0.03	0.12	-0.39	-1.07
L42	4	1.18	(1) 0.25	-	-	0.29	-0.39
L65	4	1.45	(1) 0.67	0.04	0.10	0.74	0.06
L07	5	0.72	-	-	-	-0.78	-1.46
L70	**5**	**0.08**	**(2) 0.02**	**0.50**	**0.98**	**-5.55**	**-6.23**
L83	5	1.14	0.25	0.01	0.10	0.22	-0.46
L87	5	0.88	(1) 0.43	-	0.05	-0.34	-1.02
L76	6	0.80	(3) 36.00	0.05	0.10	-0.55	-1.23
			% Incorrect MU	μ_{LOD} = 0.13	μ_{LOQ} = 0.24	% $Z_{\mu R}$ outside (-2, +2)	% Z_{μ} outside (-2, +2)
			71%	σ_{LOD} = 0.21	σ_{LOQ} = 0.36	13%	13%

Table 15. z-scores for maize event MON 88017 Level 1 test item for results reported in **cp/cp %,** divided by laboratory group: (a), (b), (c).- = not reported, (1) Uncertainty (*U*) and/or coverage factor *k* was reported in an inconsistent manner, (2) *U* was reported in an incomplete manner, (3) U seems to be a relative value.

(a)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 0.44
L63	1	0.24	0.06	-	0.03	-1.00
L01	3	0.80	(1) 0.07	0.05	0.10	1.62
L30	3	0.41	0.06	0.03	0.10	0.17
L32	3	0.57	(2) 0.17	-	-	0.88
L34	3	0.26	0.10	0.01	0.10	-0.82
L60	3	0.29	0.14	-	-	-0.59
L85	**3**	**0.08**	**0.17**	**0.01**	**0.05**	**-3.38**

% Incorrect MU	μ_{LOD} = 0.02	μ_{LOQ} = 0.08	% $Z_{\mu R}$ outside (-2, +2)
29%	σ_{LOD} = 0.02	σ_{LOQ} = 0.04	14%

(b)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 0.44
L15	2	0.25	(3) 45.30	0.05	0.01	-0.91
L17	2	0.30	-	-	-	-0.51
L48	**2**	**2.59**	**(3) (1) 77.50**	**31.00**	**63.00**	**4.17**

% Incorrect MU	μ_{LOD} = NE	μ_{LOQ} = NE	% $Z_{\mu R}$ outside (-2, +2)
100%	σ_{LOD} = NE	σ_{LOQ} = NE	33%

(c)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 0.44
L52	4	0.34	(1) (2) 0.14	0.01	0.04	-0.24
L26	5	0.64	-	-	-	1.13
L09	6	0.21	-	0.10	-	-1.29
L31	6	0.82	-	-	-	1.67
L50	6	0.36	-	-	-	-0.12
L55	**6**	**67.09**	**-**	**-**	**-**	**11.24**
L57	**6**	**0.06**	**(1) (2) 0.05**	**0.01**	**0.01**	**-3.90**

% Incorrect MU	μ_{LOD} = 0.04	μ_{LOQ} = 0.03	% $Z_{\mu R}$ outside (-2, +2)
100%	σ_{LOD} = 0.05	σ_{LOQ} = 0.02	29%

Table 16. z-scores for maize event MON 88017 Level 2 test item for results reported in **cp/cp %**, divided by laboratory group: (a), (b), (c). - = not reported, (1) Uncertainty (*U*) and/or coverage factor *k* was reported in an inconsistent manner, (2) *U* was reported in an incomplete manner, (3) U seems to be a relative value.

(a)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 0.86
L63	1	0.38	0.05	-	0.03	-1.46
L01	3	1.43	(1) 0.13	0.05	0.10	1.41
L30	3	0.73	0.08	0.03	0.10	-0.05
L32	3	1.36	(2) 0.40	-	-	1.31
L34	3	0.57	0.12	0.01	0.10	-0.58
L60	3	0.72	0.29	-	-	-0.08
L85	**3**	**0.16**	**0.17**	**0.01**	**0.05**	**-3.34**

% Incorrect MU	μ_{LOD} = 0.02	μ_{LOQ} = 0.08	% $Z_{\mu R}$ outside (-2, +2)
29%	σ_{LOD} = 0.02	σ_{LOQ} = 0.04	14%

(b)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 0.86
L15	2	0.53	(3) 53.40	0.05	0.01	-0.74
L17	2	0.60	-	-	-	-0.47
L43	2	0.69	0.31	0.11	0.23	-0.17
L48	**2**	**3.56**	**(1) (3) 532.00**	**31.00**	**63.00**	**3.40**

% Incorrect MU	μ_{LOD} = 0.08	μ_{LOQ} = 0.12	% $Z_{\mu R}$ outside (-2, +2)
67%	σ_{LOD} = 0.04	σ_{LOQ} = 0.16	25%

(c)

Laboratory number	Group	Value	Uncertainty	LOD cp/cp	LOQ cp/cp	z-score based on μ_R = 0.44
L52	4	0.50	(1) (2) 0.20	0.01	0.04	-0.87
L26	5	1.30	-	-	-	1.21
L09	**6**	**0.28**	**-**	**0.10**	**-**	**-2.13**
L31	**6**	**2.64**	**-**	**-**	**-**	**2.75**
L50	6	0.70	-	-	-	-0.14
L55	**6**	**16.65**	**-**	**-**	**-**	**6.75**
L57	**6**	**0.08**	**(1) (2) 0.05**	**0.01**	**0.01**	**-4.96**

% Incorrect MU	μ_{LOD} = 0.04	μ_{LOQ} = 0.03	% $Z_{\mu R}$ outside (-2, +2)
100%	σ_{LOD} = 0.05	σ_{LOQ} = 0.02	57%

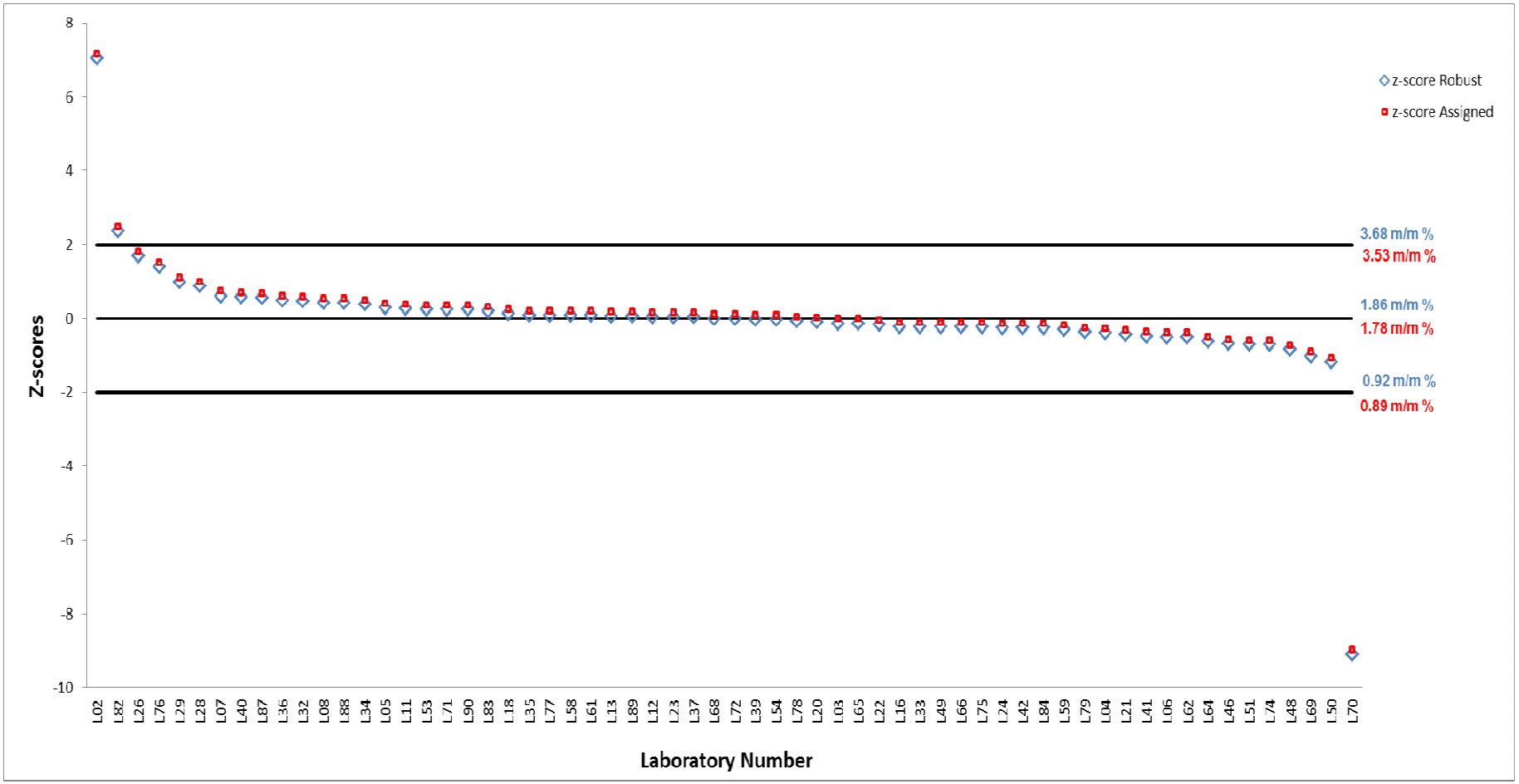


Figure 5. z-scores for soybean event 40-3-2 Level 1 test item on the basis of an assigned value of 1.78 m/m % (□) and a robust mean of 1.86 m/m % (◊).

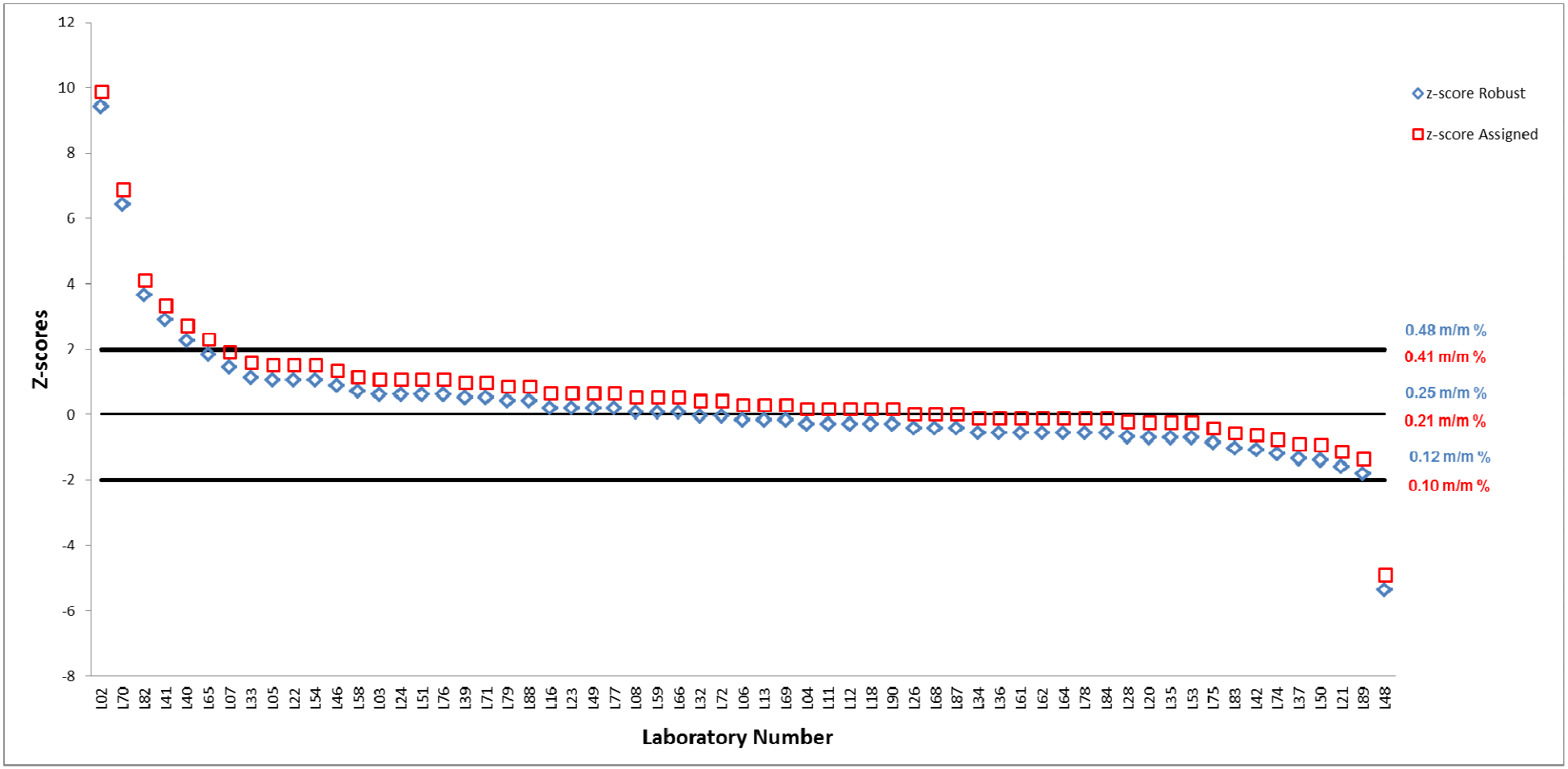


Figure 6. z-scores for soybean event 40-3-2 Level 2 test item on the basis of an assigned value of 0.21 m/m % (□) and a robust mean of 0.25 m/m % (◊).

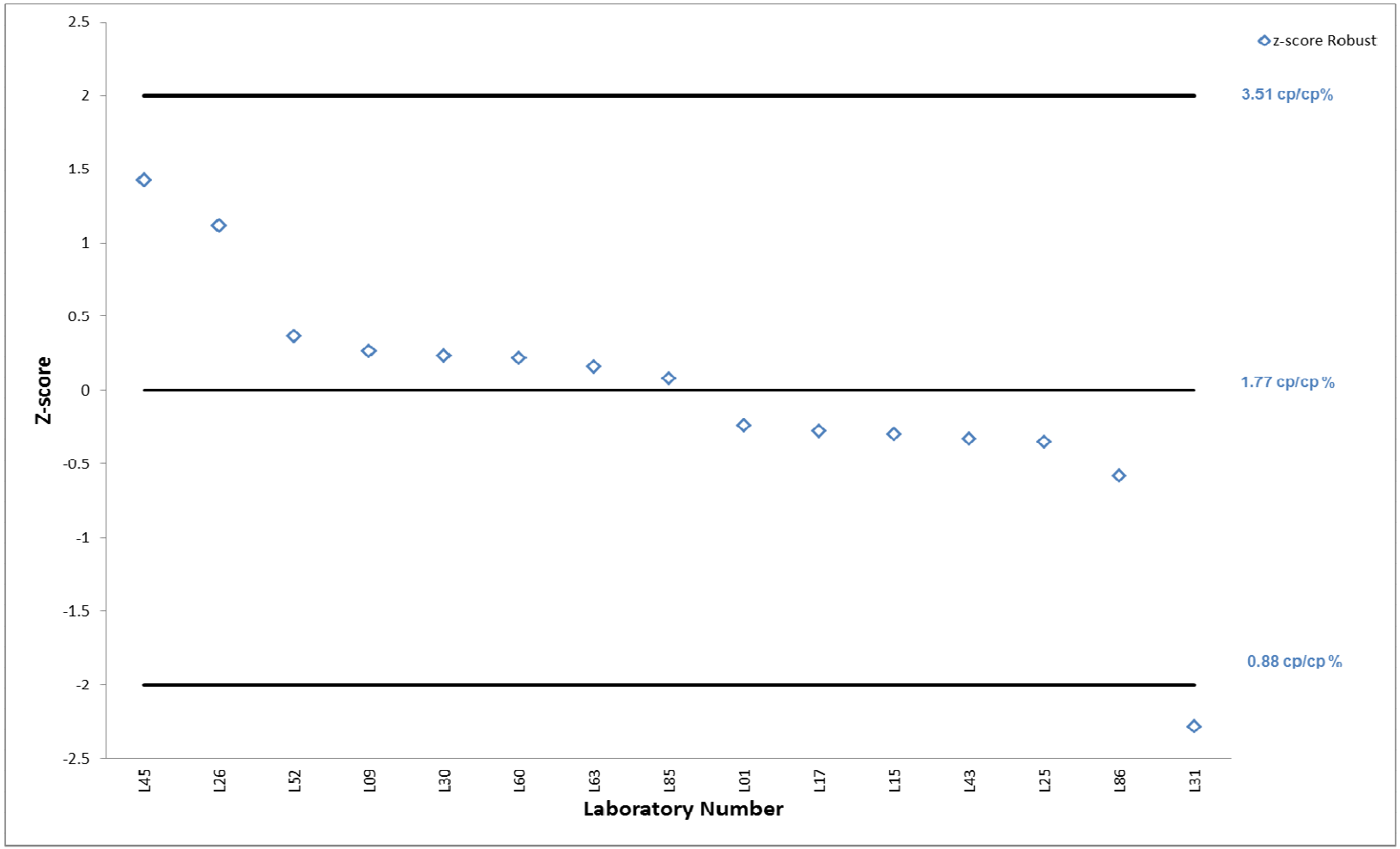


Figure 7. z-scores for soybean event 40-3-2 Level 1 test item on the basis of a robust mean of 1.77 cp/cp % (◊).

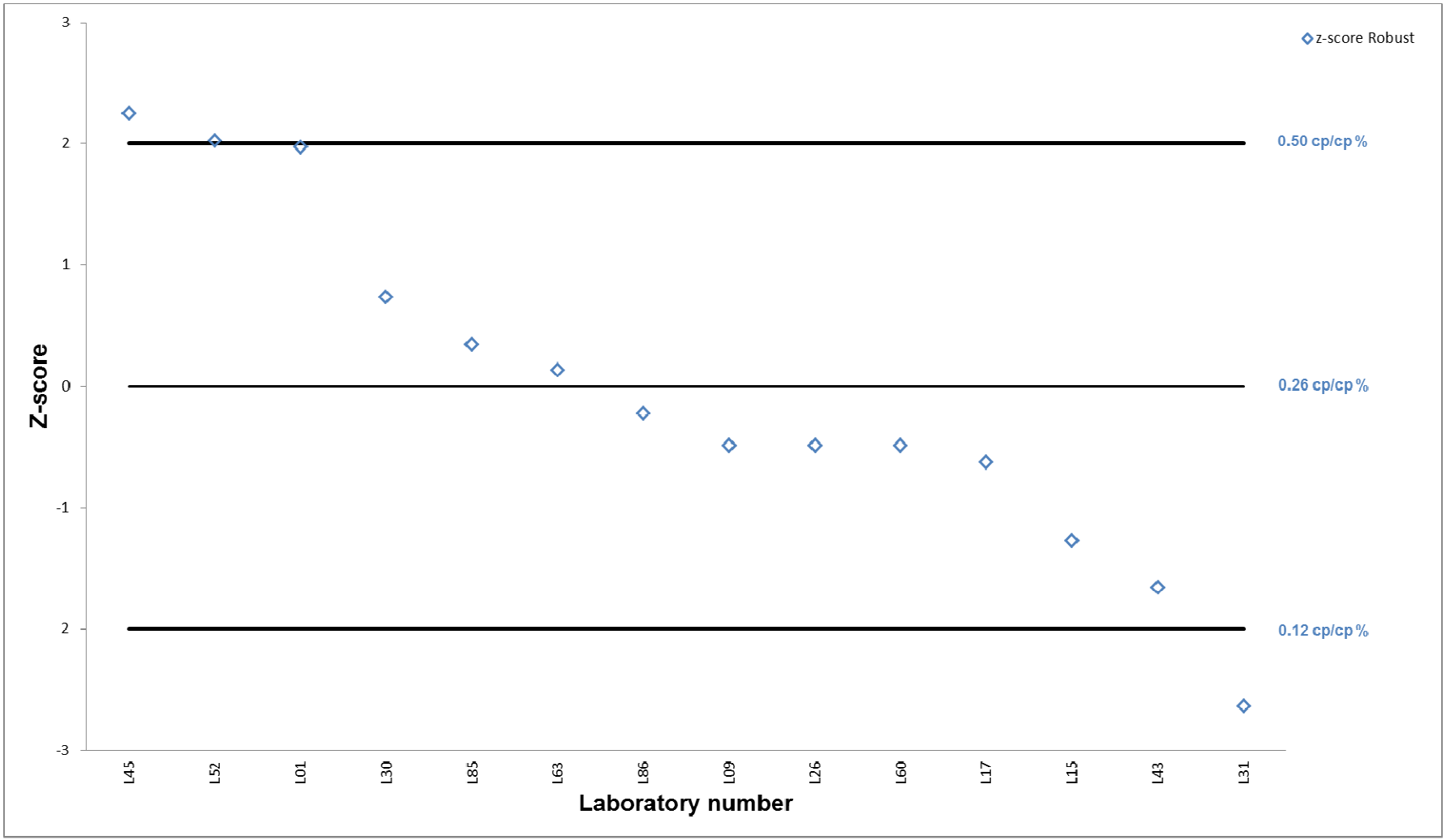


Figure 8. z-scores for soybean event 40-3-2 Level 2 test item on the basis of a robust mean of 0.26 cp/cp % (◊).

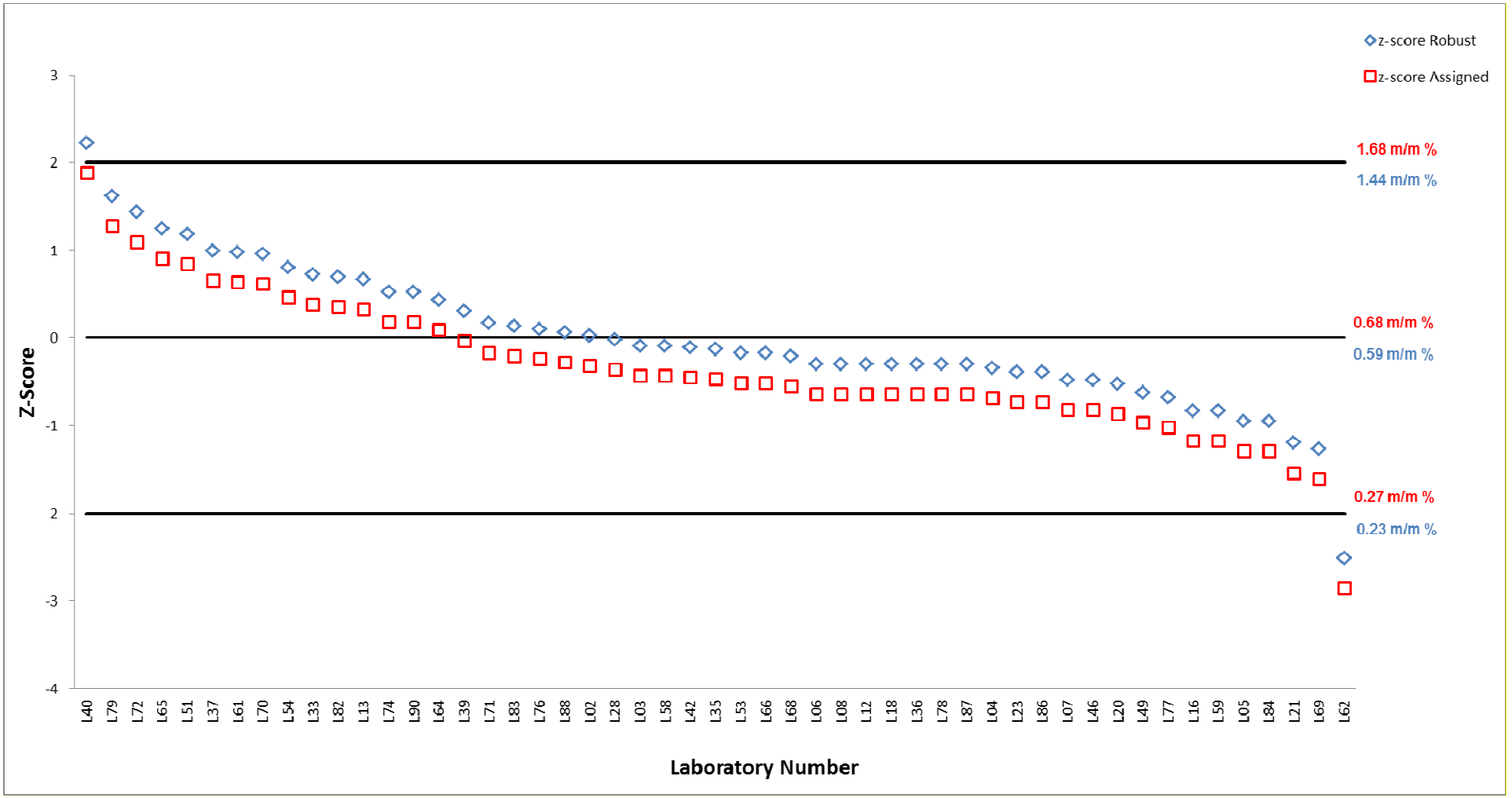


Figure 9. z-scores for maize event MON 88017 Level 1 test item on the basis of an assigned value of 0.68 m/m % (□) and a robust mean of 0.59 m/m % (◊).

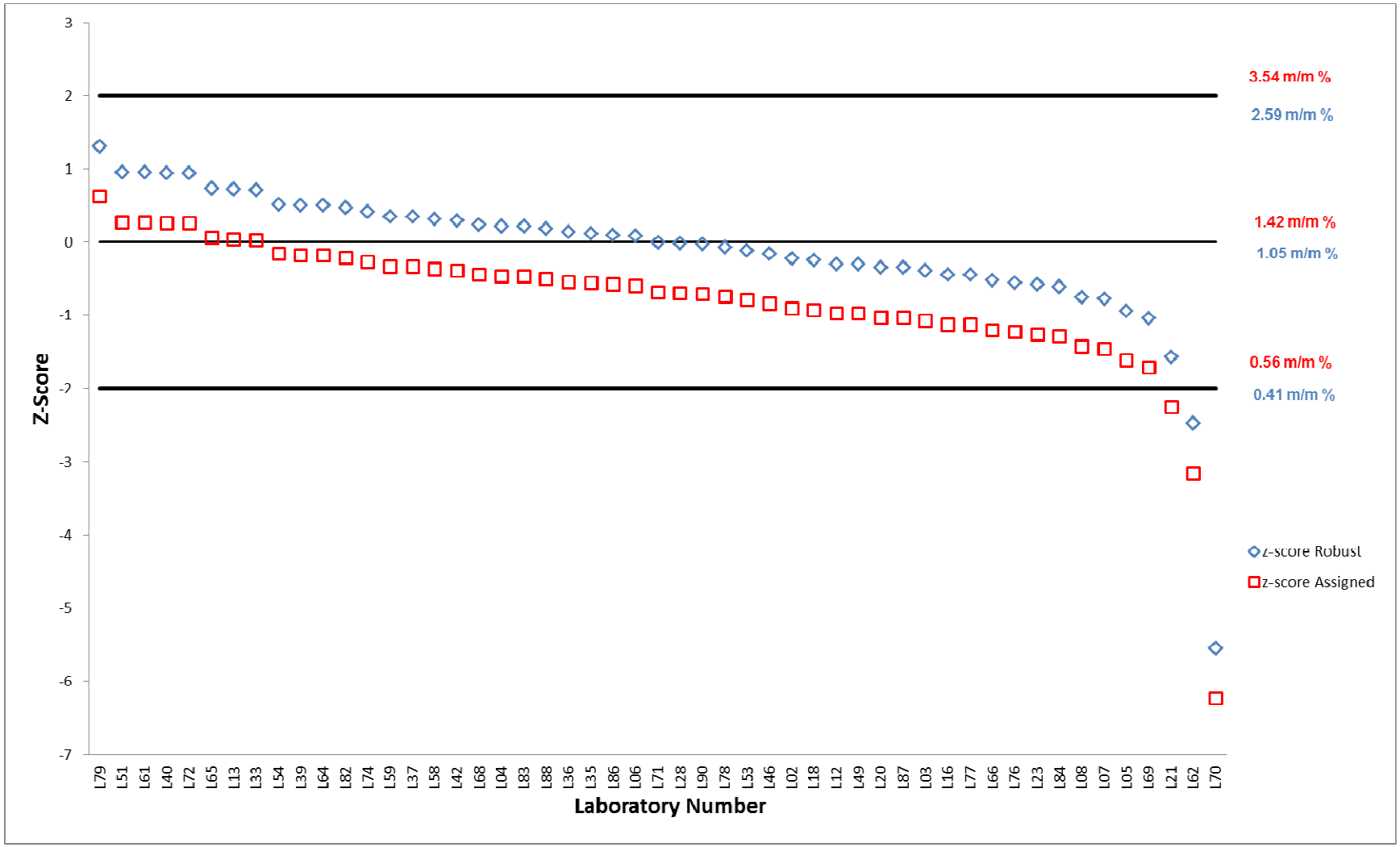


Figure 10. z-scores for maize event MON 88017 Level 2 test item on the basis of an assigned value of 1.42 m/m % (□) and a robust mean of 1.05 m/m % (◊).

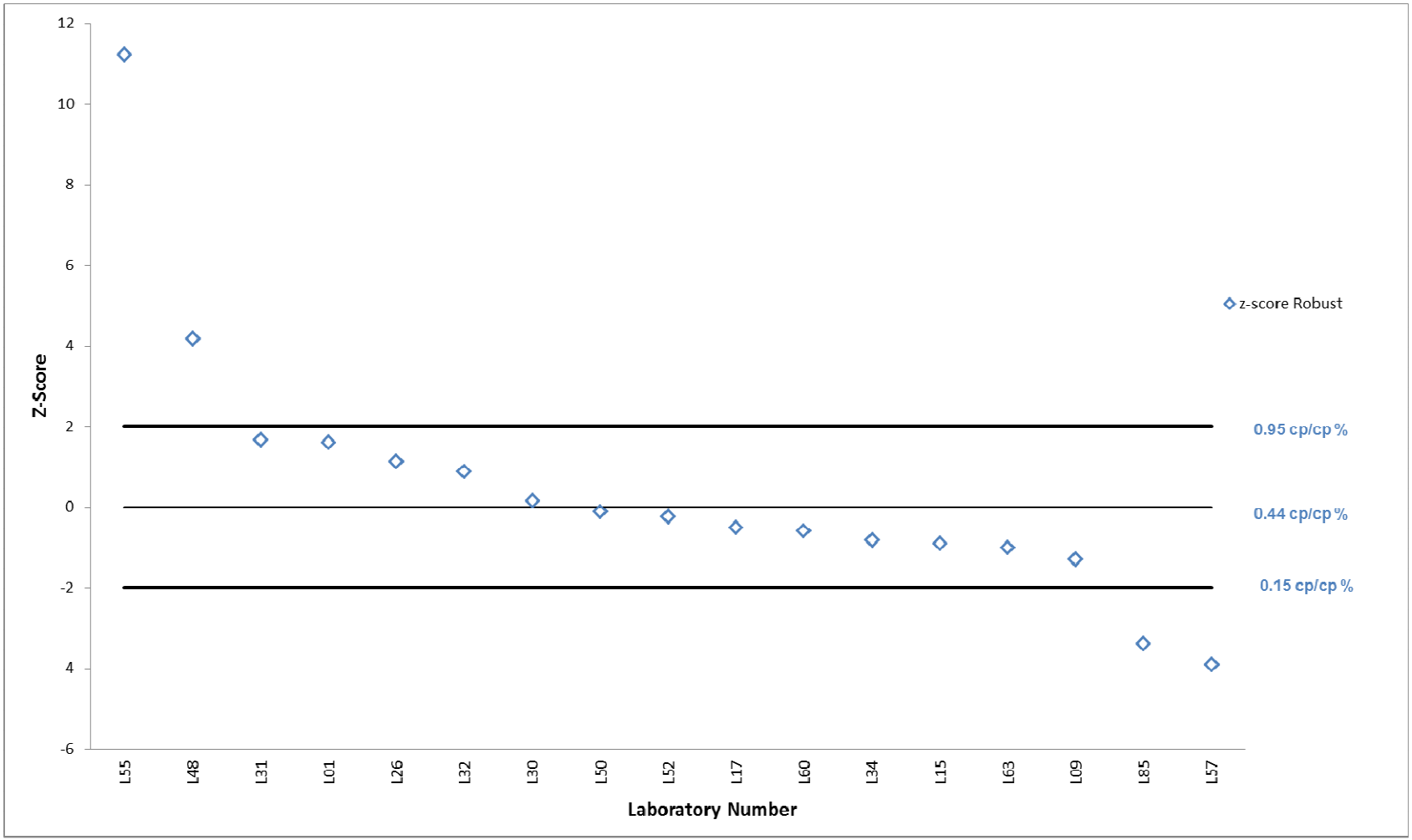


Figure 11. z-scores for maize event MON 88017 Level 1 test item on the basis of a robust mean of 0.44 cp/cp % (◊).

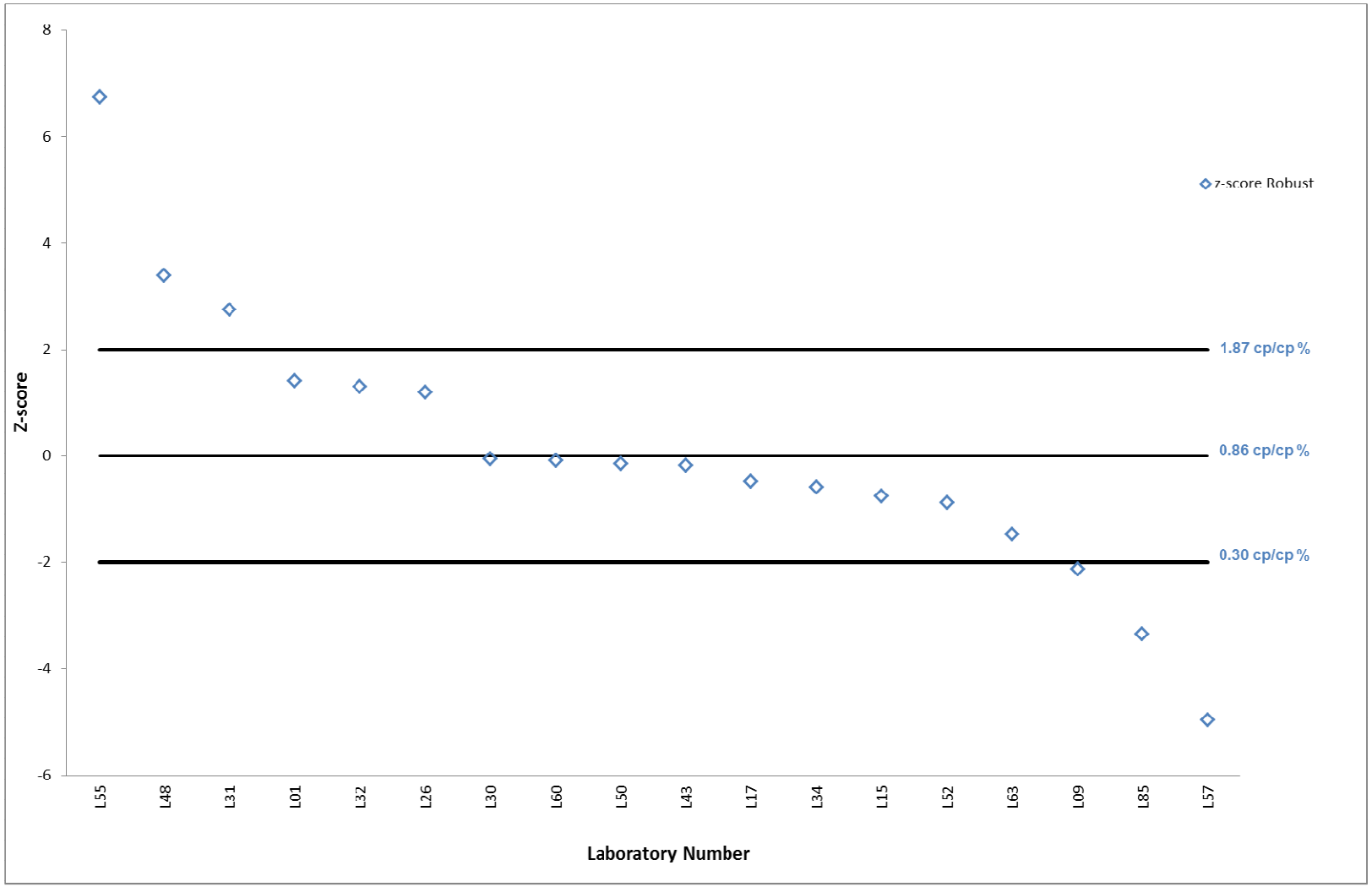


Figure 12. z-scores for maize event MON 88017 Level 2 test item on the basis of a robust mean of 0.86 cp/cp % (◊).

5. Discussion of laboratories' performance

5.1 Overall performance

In this sixth comparative testing round, qualitative screening of five different GM events was characterised by a satisfactory percentage of laboratories reporting results in agreement with consensus, with very low percentages of false negatives results. According to the categories introduced in section 4, laboratories in (a) and (b) (i.e. NRLs) showed similar performances, generally better than those in category (c).

In terms of quantification, the results expressed in m/m % were characterised by a higher percentage of z-scores lying within the working range of -2 to +2 than results expressed in cp/cp % (mean 94 % versus 79 %, only z-scores calculated on the basis of the robust means), a result which is consistent with what has been seen in previous CT rounds. The differences in the percentages of z-scores within the working range between m/m % and cp/cp % results for maize event MON88017 (mean 96 % versus 72 %) appear more relevant than that for soybean event 40-3-2 (mean 93 % versus 86 % for m/m % and cp/cp % respectively). These differences in performances between measurement units could possibly be due to the material used for calibration, as well as to what such a material was certitied for. That is, a CRM certified for m/m % should not be used as a calibrant for quantifying in cp/cp %.

When considering the different laboratory categories (a), (b) and (c), it can be seen (see Tables 17a-b) that for both measurement units the laboratory category (c) shows the largest proportion of underperforming laboratories. Differences in the proportions of acceptable z-scores between categories, however, are not statistically significant at a 5 % level, with the exception of the comparison between (a) and (c) for soybean 40-3-2 Level 2 test item on cp/cp % data (p-value = 0.03, with the Normal approximation test). It should be noted that this lack of statistical significance could be due do the small sample size of some categories, which reduces the statistical power of the tests. Overall, differences between category (a) and (b) appear extremely moderate, whereas those between (c) and the former (a and b) seem to be relevant, thus suggesting a greater need of improvement for these laboratories.

Table 17a. Number and % of laboratories with z-scores calculated on the basis of the robust mean falling within the working range of -2 to +2, m/m % data. Categories are those described in section 4.

	m/m %							
	SOYBEAN 40-3-2				**Maize MON 88017**			
	Level 1		***Level 2***		***Level 1***		***Level 2***	
	n	***%***	***n***	***%***	***n***	***%***	***n***	***%***
(a)	24	96%	23	92%	22	96%	24	100%
(b)	21	95%	20	91%	18	95%	18	95%
(c)	14	93%	12	86%	8	100%	8	87%

Table 17b. Number and % of laboratories with zscores calculated on the basis of the robust mean falling within the working range of -2 to +2, cp/cp % data. Categories are those described in section 4.

	cp/cp %							
	SOYBEAN 40-3-2				Maize MON 88017			
	Level 1		*Level 2*		*Level 1*		*Level 2*	
	n	*%*	*n*	*%*	*n*	*%*	*n*	*%*
(a)	6	100%	6	100%	7	86%	6	86%
(b)	3	100%	3	100%	2	67%	3	75%
(c)	6	83%	6	40%	5	71%	3	43%

Soybean event 40-3-2

For soybean event 40-3-2 the assigned values derived from the homogeneity study conducted at the EU-RL GMFF were close to the robust means expressed in m/m % (1.78 ± 0.14 vs 1.86 ± 0.13 for Level 1 and 0.21 ± 0.03 vs 0.25 ± 0.03 for Level 2), see Figure 13a. That is, though the expanded uncertainty of the assigned values included the robust mean only for Level 1, the expanded uncertainties of assigned value and robust mean overlapped for both levels.

No such comparison could be performed for cp/cp % measurements, since there was no assigned value. However, by comparison of the results with the nominal concentration level, it was found that expanded uncertainties did not include these values for soybean event 40-3-2 for Level 1 (1.77 ± 0.18) but did include them for Level 2 (0.26 ± 0.07), see Figure 13b.

For this event (40-3-2), most of the underperformances occurred for Level 2, with 7 out of 62 and 3 out 15 laboratories reporting, respectively, in m/m % and cp/cp % showing a z-score outside the working range of -2 to +2. This is likely to be due to the fact that concentration of this event for Level 2 test item is quite close to the average value of LOQ reported by laboratories (see Tables 10 and 12).

Maize event MON 88017

For maize event MON 88017, the assigned values (for m/m %, only) and the robust means were consistent only for Level 1, whereas the expanded uncertainties for Level 2 did not overlap (0.68 ± 0.07 vs 0.59 ± 0.08 for Level 1 and 1.42 ± 0.12 vs 1.05 ± 0.10 for Level 2), with a robust mean that substantially under-estimated the concentration level. Additionally, 43 out of 51 laboratories (i.e. 84 %) reported a value lower than the concentration level of 1.4.

When considering cp/cp % data, the expanded uncertainties around the robust means did not include the nominal concentration levels of 0.7 for Level 1 (μ_R = 0.44 ± 0.16) and of 1.4 for Level 2(μ_R = 0.86 ± 0.31). Additionally, 6 laboratories out of 18 (i.e. ≈ 33%) that reported in cp/cp % for Level 2 of maize event MON 88017 showed an underperforming z-score, suggesting that issues arise when dealing with cp/cp %, and that improvements need to be made in the analysis of GM concentrations using this measurement unit.

a)

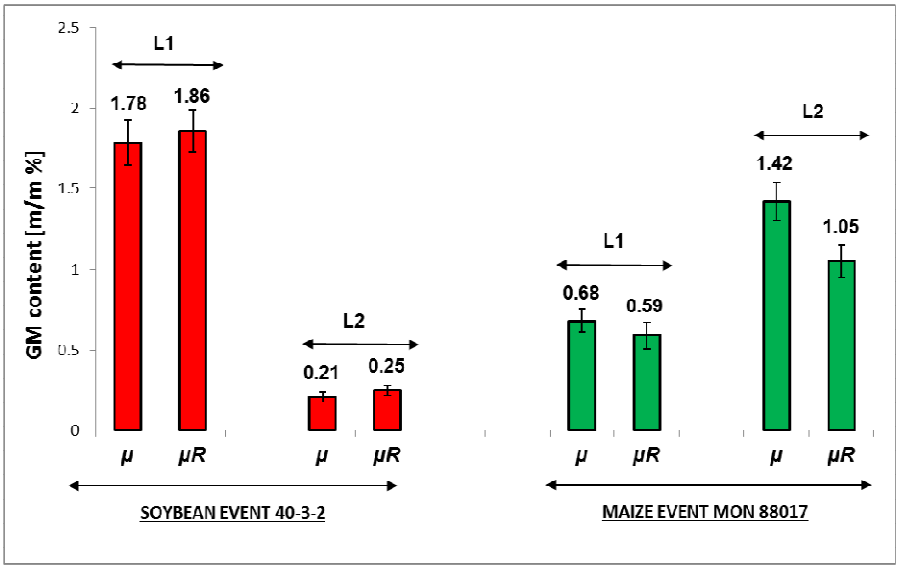


Figure 13a. Comparison of assigned values (μ) and robust means (μ_R) of Level 1 and 2 test items in m/m %. The error bars represent the expanded uncertainties.

b)

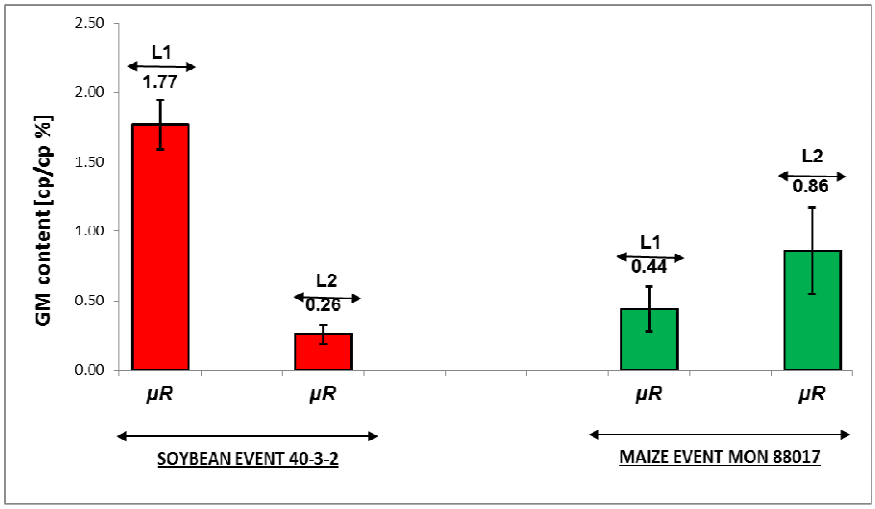


Figure 13b. Robust means (μ_R) of Level 1 and 2 test items in cp/cp %. The error bars represent the expanded uncertainties.

Measurement uncertainty

It is worth underling that on average across all events and test items, only 57% of 79 laboratories reported a complete and consistent estimate of measurement uncertainty (MU), a result which is only slightly better from what was obtained in the previous CT round. In particular:

- 20% of laboratories answered the questions related to MU inconsistently
- 6% did not answer all the questions relating to MU
- 11% did not provide an estimate of the MU

- 9% reported a relative estimate, even though on the questionnaire it was explicitly stated that an absolute value had to be reported for the MU

As an additional general remark, it is important to note that the correct use of CRM as calibrant is of paramount importance. That is, CRMs that have been certified for the m/m % content should not be used for reporting results in cp/cp %, which might be an important part of the explanation for the performance when assessed against the cp/cp % data.

5.2 Underperforming laboratories

An overview of the laboratories having obtained outlying z-scores is provided in Table 18a (m/m %) and table 18b (cp/cp %), calculated on the basis of the robust mean.

Table 18a. Laboratories with outlying z-scores on the basis of the assigned value and the robust mean for Level 1 and 2 test items in m/m %. - = no quantitative results submitted, [r] = outlying z-scores based on robust mean, [a] = outlying z-score based on assigned value.

			Outlying z-scores [m/m %]			
Laboratory number	Category	Group	Soybean 40-3-2		Maize MON 88017	
			Level 1	Level 2	Level 1	Level 2
L40	(a)	3		X [r,a]	X [r]	
L82	(a)	3	X [r,a]	X [r,a]		
L02	(b)	2	X [r,a]	X [r,a]		
L21	(b)	2				X [a]
L48	(b)	2		X [r,a]	-	-
L62	(b)	2			X [r,a]	X [r,a]
L65	(c)	4		X [a]		
L70	(c)	5	X [r,a]	X [r,a]		X [r,a]
L41	(c)	6		X [r,a]	-	-

Table 18b. Overview of laboratories with outlying z-scores on the basis of the robust mean for Level 1 and 2 test items in cp/cp %. - = no quantitative results submitted.

			Outlying z-scores [cp/cp %]			
Laboratory number	Category	Group	Soybean 40-3-2		Maize MON 88017	
			Level 1	Level 2	Level 1	Level 2
L85	(a)	3			X	X
L48	(b)	2	-	-	X	X
L52	(c)	4		X		
L09	(c)	6				X
L31	(c)	6	X	X		X
L45	(c)	6		X	-	-
L55	(c)	6	-	-	X	X
L57	(c)	6	-	-	X	X

As described above, a higher proportion of laboratories obtained a z-score outside the range of -2 to +2 for the results expressed in cp/cp %. Out of 16 underperfoming laboratories, 3 were NRLs appointed under both Regulations 882/2004 and 1981/2006, 4 were NRLs appointed under Regulation 1981/2006 only, 2 were ENGL members only, 1 was an official control laboratory and the remaining 6 were laboratories from third countries.

Follow-up

All the underperforming laboratories were asked to submit their raw data, and possible causes for underperformance were identified as follows:

- 'Technical problems', included problems encountered with the real-time PCR equipment or with the consumables.
- 'Ct values outside working range', meaning that the Ct values of the unknown samples fell beyond the linear working range of the calibration curve. Since it is not known if the calibration curve shows a linear pattern beyond its working range, it is unacceptable to extrapolate the quantification of unknown samples beyond the working range of the calibration curve.
- 'R^2 outside range', i.e. poor coefficient of determination (R^2) compared to the acceptable value ($R^2 \geq 0.98$) outlined in the ENGL guidance document[19].
- 'Slope outside range', i.e. poor slope of the calibration curve compared to the acceptable values ($-3.6 \leq$ slope ≤ -3.1) outlined in the ENGL guidance[19].
- 'Great DNA amount analysed', meaning that, in all probability, the participant used a sample intake above 200 ng for a reaction volume of 50 µL in real-time PCR. The Advisory Board for comparative testing recommends that such great sample intakes should be avoided because it may reduce PCR efficiency and therefore could cause an underestimation of the actual GM content.
- 'Swapped results', meaning that the participant has swapped the results reported for the Level 1 and 2 test items.
- 'Possible reporting error' indicates that those participants should have reported their results in cp/cp % instead of m/m % or that the final digits of reported results were swapped.
- 'Possible calculation mistake' refers to simple calculation errors such as wrong multiplication factors (e.g. % calculated by multiplying by 10 rather than by 100)
- 'No quantification of endogenous target' means that the endogenous target was not quantified by real-time PCR.

A summary of the reasons for underperformance for each laboratory is given in Table 19. All of these laboratories received individual e-mails containing suggestions on how to improve their performances, and asking them to repeat the experimental work.

Table 19. Overview of the possible reasons for outlying z-scores. Ct value = cycle threshold value, R^2 = coefficient of determination.

Laboratory Number	Category	Group	Technical problems	Ct values outside working range	R^2 outside range	Slope outside range	Great DNA amount analysed	Swapped results	Possible reporting error	Possible calculation mistake	No quantification of endogenous target
L40	(a)	3		X		X	X				
L82	(a)	3	X								
L85	(a)	3		X						X	
L02	(b)	2				X					
L21	(b)	2							X		
L48	(b)	2		X	X	X					X
L62	(b)	2		X							
L52	(c)	4								X	
L65	(c)	4								X	
L70	(c)	5		X	X			X			
L09	(c)	6		X	X	X					
L31	(c)	6	-	-	-	-	-	-	-	-	-
L41	(c)	6							X		
L45	(c)	6	X								
L55	(c)	6	X	X		X					
L57	(c)	6	X								

5.3 Repetition of the experimental work

Of the sixteen laboratories that were asked to repeat experimental work, 2 non-NRLs were unable to perform the analysis because of issues with the shipment of the repetiton samples, and one NRL could not do repeat the analysis due to reduced availability of personnel.

One laboratory from a third country that was not able to submit results in due time during the CT round because of sample shipment problems, was invited to submit them in this phase.

All results from this phase have been summarized, separately per GM events and measurements units, in Tables 20a-b (for soybean event 40-3-2) and in Tables 21a-b (for maize event MON 88017).

Table 20a. Results for the repetition of experimental work for soybean event 40-3-2, m/m % data. μ_R = robust mean from participants results, μ = assigned value as derived by the EURL-GMFF. Results were rounded to two digits and underperforming laboratories were highlighted with bold character.

Level 1	Category	Group	Value	Corrected value	Uncertainty	z-score based on μ_R = 1.84 m/m %	z-score based on μ = 1.78 m/m %
L40	(a)	3	2.26	1.34	0.50	-0.90	-0.81
L82	(a)	3	4.20	2.98	0.57	1.42	1.51
L02	(b)	2	21.17	2.70	0.39	1.13	1.22
L65	(c)	5	1.43	1.55	0.64	-0.48	-0.39
L70	(c)	5	0.08	1.57	-	-0.44	-0.35
L41	(c)	6	1.57	1.52	0.81	-0.53	-0.44
L44	(c)	6	1.60	-	0.44	-0.39	-0.29
Level 2	**Category**	**Group**	**Value**	**Corrected value**	**Uncertainty**	**z-score based on μ_R = 0.24 m/m %**	**z-score based on μ = 0.21 m/m %**
L40	(a)	3	0.53	0.22	0.08	-0.23	0.17
L82	**(a)**	**3**	**0.86**	**0.47**	**0.09**	**1.97**	**2.37**
L02	**(b)**	**2**	**6.30**	**0.46**	**0.83**	**1.91**	**2.31**
L65	(c)	5	0.39	0.35	0.14	1.12	1.52
L70	(c)	5	2.24	< 0.05	-	-	-
L41	(c)	6	0.66	0.22	0.13	-0.23	0.17
L44	(c)	6	0.28	-	0.06	0.47	0.87

Table 20b. Results for the repetition of experimental work for soybean event 40-3-2, cp/cp % data. μ_R = robust mean from participants results, μ = assigned value as derived by the EURL-GMFF. Results were rounded to two digits and underperforming laboratories were highlighted with bold character.

Level 1	Category	Group	Value	Corrected value	Uncertainty	z-score based on μ_R = 1.79 cp/cp %
L31	**(c)**	**6**	**0.80**	**4.19**	**-**	**2.55**
L45	(c)	6	2.88	1.22	0.16	-1.03
L52	(c)	4	2.00	2.20	0.50	0.71
Level 2	**Category**	**Group**	**Value**	**Corrected value**	**Uncertainty**	**z-score based on μ_R = 0.24 cp/cp %**
L31	(c)	6	0.10	0.22	-	-0.20
L45	(c)	6	0.54	0.40	0.01	1.53
L52	(c)	4	0.50	0.23	0.06	-0.07

Table 21a. Results for the repetition of experimental work for maize event MON 88017, m/m % data. μ_R = robust mean from participants results, μ = assigned value as derived by the EURL-GMFF. Results were rounded to two digits and underperforming laboratories were highlighted with bold character.

Level 1	Category	Group	Value	Corrected value	Uncertainty	z-score based on μ_R = 0.58 m/m %	z-score based on μ = 0.68 m/m %
L40	(a)	3	1.60	0.53	0.20	-0.13	-0.51
L21	(b)	2	0.33	0.73	0.02	0.57	0.19
L62	**(b)**	**2**	**0.18**	**0.12**	**0.02**	**-3.35**	**-3.73**
L70	(c)	5	0.89	0.64	0.13	0.28	-0.10
L44	**(c)**	**6**	**0.24**	**-**	**0.08**	**-1.85**	**-2.23**
Level 2	**Category**	**Group**	**Value**	**Corrected value**	**Uncertainty**	**z-score based on μ_R = 1.05 m/m %**	**z-score based on μ = 1.42 m/m %**
L40	(a)	3	1.59	1.08	0.41	0.10	-0.58
L21	(b)	2	0.50	1.30	0.12	0.50	-0.18
L62	**(b)**	**2**	**0.33**	**0.22**	**0.02**	**-3.36**	**-4.03**
L70	(c)	5	0.08	0.82	0.16	-0.50	-1.18
L44	**(c)**	**6**	**0.36**	**-**	**0.12**	**-2.29**	**-2.96**

Table 21b. Results for the repetition of experimental work for maize event MON 88017, cp/cp % data. μ_R = robust mean from participants results, μ = assigned value as derived by the EURL-GMFF. Results were rounded to two digits and underperforming laboratories were highlighted with bold character.

Level 1	Category	Group	Value	Corrected value	Uncertainty	z-score based on μ_R = 0.37 cp/cp %
L85	(a)	3	0.08	0.26	0.14	-0.65
L31	(c)	6	0.82	0.53	-	0.90
L57	**(c)**	**6**	**0.06**	**0.00**	**0.00**	**-10.00**
Level 2	**Category**	**Group**	**Value**	**Corrected value**	**Uncertainty**	**z-score based on μ_R = 0.72 cp/cp %**
L85	(a)	3	0.16	0.43	0.10	-0.98
L31	(c)	6	2.64	0.93	-	0.69
L57	**(c)**	**6**	**0.08**	**0.01**	**0.00**	**-9.92**

Overall, of the 16 laboratories that were invited to repete the experimental work, 13 did so, and 62% reached a satisfactory performance (2 NRLs appointed under Regulation 882/2004, 1 NRL appointed under Regulation 1981/2006, 1 ENGL member, 2 official control and 2 third country laboratories). The remaining 5 laboratories (1 NRL appointed under Regulation 1981/2006, 2 NRLs appointed under Regulation 882/2004 and 2 third country laboratories) had at least one z-score lying outside the working range of -2 to +2. Notably, the proportion of still underperforming laboratories was similar between those who reported in m/m % and those who reported in cp/cp %.

6. Conclusions

In this sixth comparative testing round participants were asked to screen (qualitative) for 5 GM events (356043, 40-3-2, MON 89788, MON 88017, MON 89034) and to quantify the detected events in two blinded test items containing soybean event 40-3-2 and maize event MON 88017 in different concentrations. Both test items were produced by the EU-RL GMFF.

The results of the qualitative screening of the test items indicated that the large majority of the 82 laboratories correctly detected soybean event 40-3-2 and maize event MON 88017, with only 2 and 1 false negatives, respectively. However, it should be noted that, for event MON 88017, 8 out of 25 non-NRL laboratories did not screen for this event at all. NRLs appointed under Regulation 882/2004 performed excellently, with no false negatives and the correct detection of soybean events 356043 and MON 89788 and maize event MON 89034.

Performance in the quantification of the GM events detected was also satisfactory, with some slight differences between soybean event 40-3-2 and maize event MON 88017 in terms of z-scores (90 % vs 84 % within the working range of -2 to +2 respectively, on the basis of the robust mean). Laboratories submitting their results in cp/cp % had slightly poorer performance, in particular for maize event MON 88017, with a larger proportion of underperforming z-scores.

Of the 16 underperforming laboratories, 6 also underperformed in the previous CT round (1 NRL appointed under both 882/2004 and 1981/2006 Regulations, 1 ENGL member and 4 official control laboratories) and of these, 3 also underperformed in CT round ILC-EURL-GMFF-CT-02/11 (1 NRL appointed under both 882/2004 and 1981/2006 Regulations, 1 ENGL member and 1 official control laboratory).

When asked to repeat the experimental work, most of the underperforming laboratories obtained a satisfactory result, with only 5 still having z-scores outside the working range (1 NRL appointed under Regulation 882/2004, 2 NRLs appointed under Regulation 1981/2006 and 2 third country laboratories).

Overall, NRLs appointed under Regulation 882/2004 showed a slightly better performance throughout all tasks when compared to the NRLs appointed under Regulation 1981/2006 alone and to non-NRLs laboratories.

The reporting of uncertainty, on average across GM events and concentration levels, was complete and consistent in about 57% of laboratories, a result which is similar to the one obtained for the previous CT round. Thus, given the importance of a correct estimation of measurement uncertainty, it is apparent that there is still a need to provide laboratories with guidance and training to harmonise the MU reported in the field of GMO detection.

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Questionnaire data

1. DNA extraction method?	No. of laboratories
a) ISO/CEN published method	37
b) EURL validated method	3
c) National reference method	1
d) International literature	4
e) In-house developed and optimised	11
f) Other	26
Other of which	Answers referred to used kits, see Q4

1.3. Was the DNA extraction method used within the scope of your ISO/IEC 17025 accreditation?	No. of laboratories
a) Yes	67
b) No	15

2. Number of replicate DNA extractions from test materials:	No. of laboratories
a) 1	1
b) 2	61
c) 3	5
d) 4	9
e) Other	6
Other of which:	
5	3
6	2
10	1

3. Sample intake (in g) for the DNA extraction:	No. of laboratories
a) < 0.1	1
b) 0.1 - 0.2	49
c) > 0.2	19
d) Other	13
Other of which:	
0.5	1
1	8
2	4

4. DNA extraction method/kit used:	No. of laboratories
a) CTAB	32
b) CTAB-derived	15
c) Biotecon	2
d) GeneScan GENESpin	4
e) Guanidine HC1 with proteinase K	4
f) Macherey-Nagel Nucleospin	10
g) Promega Wizard	5
h) Qiagen Dneasy plant mini kit	3
i) TEPNEL kit	0
j) In-house developed and optimised	1
k) Other	6
Other of which:	
GeneScan kit	1
ZR Plant/Seed DNA Mini Prep Kit	1
Qiagen DNeasy plant maxi kit	1
Genetic ID (Europe) AG: Fast ID Genomic DNA Extraction Kit	1
Geneaid Genomic DNA Mini Kit.	1
Extraction Kit: DNA Extraction kit (GMO and Allergen) NEOGEN	1

5. How was the clean-up of the DNA performed?	No. of laboratories
a) No DNA clean-up	44
b) Ethanol precipitation	11
c) Amersham MicroSpin S300	0
d) Promega Wizard DNA clean-up resin	8
e) Qiagen QIAQuick	8
f) Qiagen Genomic-Tip 20/G	0
g) Silica	2
h) Other	9
Other of which:	
method based on Maxwell 16 LEV Blood DNA Kit (Promega)	1
JET QUICK Genomed	1
Eurofins DNA Extractor Cleaning coloumn	1
Geneaid GD coloumn	1
QIAamp DNA Mini Kit	1
Isopropanol	1
Promega Wizard SV Genomic DNA purification system (in house modified)	1
Invisorb DNA Clean up	1
Cleaning Columns Eurofins/GeneScan	1

6. How have you quantified the DNA?	No. of laboratories
a) Gel	1
b) UV spectrophotometer	54
c) Fluorometer	14
d) Other	6
e) Not applicable (i.e. DNA was not quantified)	7
Other of which:	
QPCR	1
Nanodrop	3
Estimation was made based on qPCR results.	1
Nanodrop Spectrophotometer	1

7. Dilution buffer?	No. of laboratories
a) TE (10 mM Tris-HC1, 1 mM EDTA)	14
b) TE 0.1X (10 mM Tris-HC1, 0.1 mM EDTA)	9
c) TE low (1 mM Tris, 0.01 mM EDTA)	4
d) Water	45
e) Other	10
Other of which	
TE 0.2X	1
TE 0.2x (2mM tris, 0.2mM EDTA)	1
Dilution buffer from Maxwell 16 LEV Blood DNA Kit (Promega)	1
No dilution applied	1
TE (10 mM TrisHCl, 0,2 mM EDTA)	1
TE x0.2 (Tris-HCl 2mM,PH 7.5, EDTA 0.2 mM)	1
Provided in the Qiagen DNeasy Plant Mini Kit	1
buffer AE (TE)	1
TE 0.5X	1

Q8. Compound feedstuff level 1: test for presence/absence of GM event	No. of laboratories per event				
	356043	40-3-2	MON 89788	MON 88017	MON 89034
Present	1	82	3	73	5
Absent	68	0	72	1	65
NA	13	0	7	8	12

Q9. Compound feedstuff level 2: test for presence/absence of GM event	No. of laboratories per event				
	356043	40-3-2	MON 89788	MON 88017	MON 89034
Present	1	82	3	74	5
Absent	68	0	72	0	65
Not Tested	13	0	7	8	12

10. Screening method used for GM detection	No. of laboratories
a) Combinatory SYBR® Green qPCR Screening (COSYPS)	0
b) In-house developed and optimised	1
c) International literature	4
d) ISO/CEN published method	9
e) National reference method	8
f) Pre-spotted plate	4
g) Qualitative PCR	7
h) Real-time PCR	40
i) SYBR® Green qPCR screening	0
j) Other	9
Other of which:	
Genescan Screen 35S/NOST	1
Screening Not Done	1
In case of poor PCR results, the QPCR methods were used: MON88017-QT-EVE-ZM-016; MON89788-QT-EVE-GM-006; 356043-QT-EVE-GM-009; QT-EVE-GM-005	1
none	1
no screening performed	1
We used the event specific methods directly as qualitative methods	1
in house monitoring run	1
pFMV : in house (Debode et al. 2013)	1
no screening, all possible events were tested	1

10.3 Screening method used within the scope of your ISO/IEC 17025 accreditation?	No. of laboratories
a) Yes	65
b) No	17

11. Principle of PCR product detection used for screening?	**No. of laboratories**
a) Gel	7
b) Taqman probe	68
c) Hybridisation probe	0
d) SYBR® Green	2
e) Other	5
Other of which:	
Screening Not Done	1
Gel or/and TaqMan probe	1
TaqMan-based method for MON89034 and SYBR green for MON88017	1
No screening performed	1
No screening, all possible events were tested	1

12. Screening method used for GM detection:	**No. of laboratories**
a) Multiplex PCR	14
b) Singleplex PCR	68

13. Elements / targets used for screening (P = promoter, T = terminator):	**No. of laboratories**
a) CP4 EPSPS	25
b) P35S	45
c) T-nos	42
d) Other	54
Other of which:	
event-specific	17
bar, 35S-pat	3
pFMV	4
bar	2
No screening	3
P35S;TNOS;PAT;NPTII;CP4EPSPS;CTP-CP4EPSPS	1
Soybean Events/Lectin: Multiplex Event-specific PCR	1
pat, bar, etc, whole screening strategy not applied in this ring trial	1
Events on pre-spotted plate	1
screening with event specific primers and probes by qualitative real time PCR (as in 10.1)	1
P34S	1
CTP-CP4EPSPS, PAT	1
Multiplex: P35S / Tnos; Singleplex: bar, CTP2-CP4EPSPS, 35S-pat	1

event-specific methods were used, for 40-3-2 construct-specific method, no screenings	1
GTS40-3-2	1
MON 88017: 5'-flanking region/insert or insert/3'-flanking region; MON 89034: MON 89788: 5'flanking region/(P4-FMV/Tsf1) or 5'-flanking region/insert; DP-356043-5: 5'-flanking region/insert; GTS-40-3-2: CaMV 35S/CTP	1
none	1
356043, GTS 40-3-2, MON 89788, MON 88017, MON 89034	1
targets DP356043, GTS40-3-2, MON89788, MON 88017, MON89034	1
CAMV35S-pat, bar, FMV	1
P-nos, PFMV, Bar, Pat, npt II, P35S-npt II, SPEC-T-nos	1
qualitative real time PCR methods for detection of maize events MON88017, MON 89034, soybean events 356043,40-3-2, MON89788	1
We used the event specific methods directly as qualitative methods	1
"Real-Time PCR based ready-to-use multi-target analytcial system for the detection of EU authorised and unathorised GM events"	1
PAT, NPTII, CTP2-CP4EPSPS	1
Events used in one plate for which requested to screen for.	1
EU-RL-Event-specific Methods	1
Primer/ Probes for trait specific Transgenes, i.e 356043, 40-3-2, MON89788, MON88017, MON89034	1
pFMV- Method § 64 LFGB (in preparation)	1

14. Real-time PCR quantification method(s)/ end-point digital PCR methods	**No. of laboratories**
a) EU-RL validated method(s)	66
b) In-house developed and optimised	3
c) International literature	0
d) ISO/CEN published method(s)	20
e) National reference method(s)	2
f) Other	5
Other of which:	
Quantification of soybean line 40-3-2 by ISO 21570:2003 modified	1
Not applicable	1
Pietsch, K; Waiblinger, H.U.(2001): Quantification of Genetically Modified Soybeans in Food with the lightcycler system. and konstruct specific detection of genetically modified maize based on informations of P. Brodmann	1
GeneScan GMO Quant RoundupReady Soy, GMO Quant Event MON88017 Corn	1

14.3. Real-time PCR quantification method /end-point digital PCR method used within the scope of your ISO/IEC 17025 accreditation?	**No. of laboratories**
a) Yes	62
b) No	9
Not reported	11

15. Real-time PCR quantification method(s) / end-point digital PCR method(s):	**No. of laboratories**
a) Multiplex PCR	6
b) Singleplex PCR	76
Not reported	1

16. Real-time PCR instrument / end-point digital PCR instrument:	**No. of laboratories**
a) ABI 7000	1
b) ABI 7300	3
c) ABI 7500	28
d) ABI 7700	2
e) ABI 7900 HT	22
f) ABI StepOne & StepOne Plus real-time PCR system	2
g) BioRad icycler	3
h) Corbett Rotor-Gene 6000	1
i) Roche LightCycler 480	5
j) Roche Light Cycler 2.0	2
k) Stratagene Mx 3000/Mx 3005	9
l) Stratagene Mx4000	0
m) BioRad digital droplet PCR	0
n) Life Technologies digital PCR	0
o) Fluidigm BioMark	0
p) other	9
Other of which:	
BioRad CFX96	4
ABI ViiA7	2
Qiagen Rotor-Gene	1
Qiagen Rotor-Gene Q	1
Not applicable	1

17. Real-time PCR Master Mix:	**No. of laboratories**
a) ABI TaqMan® Universal PCR master mix	44
b) ABI TaqMan® Universal PCR master mix, no AmpErase® UNG	6
c) ABI TaqMan® Fast Universal PCR master mix	1
d) ABI TaqMan® Gold with Buffer A	5
e) Eurogentec: qPCR MasterMix	4
f) Eurogentec MESA GREEN qPCR MasterMix Plus for SYBR® Assay	0
g) Eurogentec qPCR MasterMix for SYBR® Green	0
h) Sigma JumpstartTM Taq ReadyMixTM	1
i) Qiagen: QuantiTect SYBR® Green PCR Kit	1
j) Qiagen: QuantiTect Probe PCR Kit	5
k) Roche: FastStart TaqMan® Probe Master (Rox)	0
l) Roche: FastStart Universal Probe Master (Rox)	4
m) Diagenode: Universal Mastermix	2
n) Fermentas: MaximaTM Probe/ROX qPCR Master Mix	1
o) Fermentas: MaximaTM SYBR Green/ROX qPCR Master Mix	0
p) Ampliqon: RealQ PCR 2 x Master Mix	0
q) Takara: SYBR® Premix Ex TaqTM	0
r) Takara: Premix Ex TaqTM	0
s) Other	18
Missing	1
Other of which:	
in-house made master mix	1
Roche: LightCycler 480 Probes Master	1
QIAGEN QUANTIFAST MULTIPLEX PCR KIT; BIORAD SUPERMIX	1
QIAGEN Quantitect Multiplex real-time PCR Kit	1
Brilliant II QPCR Master mix	1
Not applicable	1
BioConnect : 5x HOTFirePoI Probe qPCR Mix Plus (No ROX)	1
Roche: Light Cycler 480 Probes Master	1
Novazym: AmpliQ Real-time PCR Opti-probe KIT	1
ABI TaqMan PCR Core Kit	1
KAPA:SYBR MASTER MIX	1
Kapa Probe Fast QPCR Master Mix Universal	1
GeneScan mastermix endogenus gene and GM-trait gene	1
BioRad iQ Supermix	1
5 PRIME MasterMix1	1
for hmg (MON88017 no Universal Master Mix - dNTPs, primer, probe+ AmpliTaqGold, Mg2Cl and buffer	1
Eurogentec: qPCR Core Kit - no Rox	1
Quanta Biosciences Perfecta qPCR Fastmix, UNG	1

17.2. Number of reagents (i.e. DNA, primers, probe, water, …) involved?	**No. of laboratories**
a) 5	41
b) 6	33
c) 7	3
d) 8	3
e) other	6
Missing	1
Other of which:	
0	1
2	1
4	1
9	1
12	2

Q18.1. Sample intake (in ng) per real-time PCR	**No. of laboratories**
a) 0-50	7
b) 50-100	19
c) 100-200	39
d) > 200	7
e) DNA amount not quantified	6

Q18.2. Sample intake (in ng) per real-time PCR	**No. of laboratories**
a) 0-50	3
b) 50-100	1
c) 100-200	15
d) > 200	1
e) DNA amount not quantified	2

Q18.3. Sample intake (in ng) per real-time PCR	**No. of laboratories**
a) 0-50	1
b) 50-100	1
c) 100-200	8
d) > 200	2
e) DNA amount not quantified	2

Q18.4. Sample intake (in ng) per real-time PCR	**No. of laboratories**
a) 0-50	1
b) 50-100	0
c) 100-200	8
d) > 200	1
e) DNA amount not quantified	2

Q18.5. Sample intake (in ng) per real-time PCR	No. of laboratories
a) 0-50	1
b) 50-100	0
c) 100-200	7
d) > 200	1
e) DNA amount not quantified	2

19. Number of PCR replicates per test item (compound feedstuff level 1 and level 2):	No. of laboratories
a) 1	0
b) 2	15
c) 3	25
d) 4	18
e) 5	2
f) 6	9
g) other	12
Missing	1
Other of which:	
8	5
10	3
12	3
20	1

20. Real time detection method(s) / end-point digital PCR method(s) for quantification:	No. of laboratories
a) MGB	4
b) Roche probe	1
c) Taqman probe	76
d) SYBR® Green	2
e) Other	2
Missing	1
Other of which:	
Not applicable	1
TaqMan-based method for MON89034 and SYBR green for MON88017	1

21. Real-time PCR quantification method(s) / end-point digital PCR method(s) used?	**No. of laboratories**
a) DNA copy number standard curve using a dilution series	27
b) Mass/mass standard curve using a dilution series	51
c) Delta Ct method	8
d) Absolute quantification (end-point digital PCR)	1
e) Other	1
Missing	1
Other of which	
Not applicable	1

Q22. Real-time PCR quantification method(s) /end-point digital PCR method(s): slope(s) endogenous gene	**No. of laboratories per GM event**				
	356043	**40-3-2**	**MON 89788**	**MON 88017**	**MON 89034**
-4.1 ≤ slope < -3.6	1	8	3	2	1
-3.6 ≤ slope ≤ -3.1	11	62	7	62	8
-3.1 < slope < -2.6	1	1	1	1	1
Other	0	2	0	1	0
Not Applicable	39	5	42	9	43

Q23. Real-time PCR quantification method(s) /end-point digital PCR method(s): slope(s) GM trait gene	**No. of laboratories per GM event**				
	356043	**40-3-2**	**MON 89788**	**MON 88017**	**MON 89034**
-4.1 ≤ slope < -3.6	0	4	6	2	1
-3.6 ≤ slope ≤ -3.1	9	66	2	61	6
-3.1 < slope < -2.6	2	1	2	2	1
Other	1	4	0	2	1
Not Applicable	39	3	42	9	43

Q24. Real-time PCR quantification method(s) /end-point digital PCR method(s): R^2 coefficient(s) endogenous gene	No. of laboratories per GM event				
	356043	**40-3-2**	**MON 89788**	**MON 88017**	**MON 89034**
$0.97 \leq R^2 < 0.98$	0	0	0	3	1
$0.98 \leq R^2 < 0.99$	1	17	1	8	1
$0.99 \leq R^2 \leq 1.00$	12	54	10	56	8
Other	0	1	0	0	0
Not applicable	35	3	38	8	39

Q25. Real-time PCR quantification method(s) /end-point digital PCR method(s): R^2 coefficient(s) GM trait gene	No. of laboratories per GM event				
	356043	**40-3-2**	**MON 89788**	**MON 88017**	**MON 89034**
$0.97 \leq R^2 < 0.98$	1	1	1	0	1
$0.98 \leq R^2 < 0.99$	3	19	0	12	2
$0.99 \leq R^2 \leq 1.00$	8	52	8	53	6
Other	1	2	1	1	0
Not applicable	35	2	38	8	39

Q26. Real-time PCR quantification method(s) /end-point digital PCR method(s): endogenous target DNA sequence(s)	No. of laboratories per event				
	356043	**40-3-2**	**MON 89788**	**MON 88017**	**MON 89034**
Adh	0	0	0	10	3
Hmg	0	0	0	54	10
Invertase	0	0	0	2	1
Zein	0	1	1	1	1
ZSSIIb	0	0	0	2	1
Lectin	19	78	20	1	1
Other	0	0	0	0	0

Q27. Real-time PCR quantification method(s) /end-point digital PCR method(s): GM trait target DNA sequence(s)	**No. of laboratories per event**				
	356043	**40-3-2**	**MON 89788**	**MON 88017**	**MON 89034**
P35S	0	4	1	4	3
CP4 EPSPS	0	1	2	3	1
T-nos	0	4	1	3	3
356043 event-specific	15	0	0	0	0
40-3-2 event specific	0	67	1	0	1
MON 88017 event specific	0	1	2	63	0
MON 89034 event-specific	0	0	0	3	13
MON 89788 event-specific	0	0	14	0	2
Other	0	10	0	1	0
Of which:		*83 bp (40-3-2 con.* *74* *35S to CTP, 172 bp* *121, RRS construct* *74, P35S-CTP* *CTP-P35S; 83 bp* *74* *260* *p35S/petu, 83* *85 modification35S-*		*maize genome to*	

28. Which reference material(s) was (were) used for calibration?	**No. of laboratories**
a) ERM-BF410 series	28
b) ERM-BF410k series	45
c) ERM-BF425 series	20
d) AOCS 0406-A	22
e) AOCS 0406-D	56
f) AOCS 0906-A	11
g) AOCS 0906-B	19
h) AOCS 0906-E	16
i) Non-modified maize leaf tissue DNA AOCS 0306-C2	0
j) Non-modified soybean leaf tissue DNA AOCS 0707-A3	0
k) Single-target plasmid(s)	4
l) Multiple target plasmid(s)	1
n) Eurofins GeneScan	1
o) Other	10
Other of which:	
Not applicable	1
ERM-BF410b, ERM-BF410c, ERM-BF410d, ERM-BF410e, ERM-BF410f	1
BF 411a	1
100% 40-3-2 leaf material	1
USDA GIPSA Proficiency Study material for MON88017	1
calibration standards made of plasmids with a 1:1 ratio GMO/species	1
ERM-BF410f ; Non-Modified maize seeds and 100% MON88017 maize seeds from Monsanto.	1
Diagenode plasmids for Roundup Ready construct test	1

NB: Most laboratories used several reference materials

29. Which reference material(s) was (were) used for quality control?	**No. of laboratories**
a) ERM-BF410 series	35
b) ERM-BF410k series	40
c) ERM-BF425 series	26
d) AOCS 0406-A	24
e) AOCS 0406-D	49
f) AOCS 0906-A	15
g) AOCS 0906-B	25
h) AOCS 0906-E	20
i) Non-modified maize leaf tissue DNA AOCS 0306-C2	0
j) Non-modified soybean leaf tissue DNA AOCS 0707-A3	0
k) Single-target plasmid(s)	9
l) Multiple target plasmid(s)	0
n) Eurofins GeneScan	2
o) Other	9
Other of which:	
Not applicable	1
ERM-BF410b, ERM-BF410c, ERM-BF410d, ERM-BF410e, ERM-BF410f	1
USDA PROFICIENCY PROGRAM SAMPLE	1
Samples with known GMO content (2.5% GTS 40-3-2 and1.8% MON 88017)	1
USDA GIPSA Proficiency Study material for MON88017	1
ISTA PT material	1
ERM-BF410f ; Non-Modified maize seeds and 100% MON88017 maize seeds from Monsanto.	1
MON 88017 : mix AOCS 0406D / organic maize (10%; 1% and 0.1%)	1
ERM BF427 series	1

NB: Most laboratories used several reference materials

Q30a. Practical LOD and LOQ (in %) of the GM content determination in mass/mass or DNA copy number ratio?	No. of laboratories - event 356043			
	LOD (m/m)	LOQ (m/m)	LOD (cp/cp)	LOQ (cp/cp)
0.001			1	
0.01	6		2	2
0.02	1			
0.025	1			
0.03	3	1		
0.04	3			
0.045	1			
<0.05	1			
0.05	5	3		
0.07	1	2		
0.09		1		
0.1	3	15	1	1
0.23		1		
0.5		1		
63*			1	
250*				1
Not applicable	4	3	4	4
Not reported	61	63	81	82

* Seems to be absolute values of DNA copies (reported by L48)

Q30b. Practical LOD and LOQ (in %) of the GM content determination in mass/mass or DNA copy number ratio?	No. of laboratories - event 40-3-2			
	LOD (m/m)	LOQ (m/m)	LOD (cp/cp)	LOQ (cp/cp)
0.001			1	
0.003	1			
0.005	1			
0.01	11	1	1	2
0.012	1			
0.018	2			
0.02	7	1		
0.023		1		
0.025	1			
0.03	6	2	1	
0.035		1		
0.04	4	1		
0.045	1		1	
< 0.05	1			
0.05	5	4	2	
0.06	1	2		
0.061		1		
0.07	2	3		
0.08	1	3		
0.09		2	1	
< 0.1	2			
0.1	3	25	4	7
0.12		2		
0.15		1		
0.17		1		
0.19				1
0.26		1		
0.5		1		
17*	1			
24*		1		
63*			1	
250*				1
Not applicable	2	2	3	3
Not reported	38	35	75	76

* Seems to be absolute values of DNA copies

* 63 and 250 reported by L48, 17 and 24 reported by L36

Q30c. Practical LOD and LOQ (in %) of the GM content determination in mass/mass or DNA copy number ratio?	No. of laboratories - event MON 89788			
	LOD (m/m)	LOQ (m/m)	LOD (cp/cp)	LOQ (cp/cp)
0.001			1	
0.01	6		3	2
0.02	1			
0.025	1			
0.03	3	1		1
0.04	1			
0.045	1			
< 0.05	1			
0.05	4	3		
0.06	1			
0.07	1	1		
0.1	3	13	1	1
0.11		1		
0.23		1		
0.5		1		
63*			1	
250*				1
Not applicable	4	3	4	4
Not reported	63	66	80	81

* Seems to be absolute values of DNA copies (reported by L48)

Q30d. Practical LOD and LOQ (in %) of the GM content determination in mass/mass or DNA copy number ratio?	No. of laboratories - event MON 88017			
	LOD (m/m)	LOQ (m/m)	LOD (cp/cp)	LOQ (cp/cp)
0.001	1			
0.005			1	
0.01	6		3	2
0.02	4			
0.021		1		
0.025	1			1
0.03	5		1	
0.034	1			
0.04	4			1
0.045	1		1	
0.05	8	1	1	1
0.06	1			
0.07		2		
0.08		1		
0.09		2		
<0.1	2			
0.1	3	22	1	3
0.11			1	
0.12	1	2		
0.13	1			
0.17		1		
0.18		2		
0.2		1		
0.22		1		
0.23				1
0.24		1		
0.3		1		
0.33		1		
0.342		1		
0.5	1			
0.55		1		
0.98		1		
31*			1	
63*				1
Not applicable	3	3	4	4
Not reported	47	46	76	76

* Seems to be absolute values of DNA copies (reported by L48)

Q30e. Practical LOD and LOQ (in %) of the GM content determination in mass/mass or DNA copy number ratio?	No. of laboratories - event MON 89034			
	LOD (m/m)	LOQ (m/m)	LOD (cp/cp)	LOQ (cp/cp)
0.001	1			
0.01	3		2	1
0.02	1			
0.025	1			
0.03	3		1	
0.04	1			
0.045	1			
0.05	5	1		
0.07	1	1		
0.1	3	13	1	2
0.2		1		
0.23		1		
0.3		1		
0.7	1			
1.53		1		
31*			1	
63*				1
Not applicable	4	3	4	4
Not reported	65	68	81	82

* Seems to be absolute values of DNA copies (reported by L48)

31.1. Does the uncertainty correspond to a repeatability standard deviation?	No. of laboratories
a) Yes	46
b) No	12
c) Not applicable	13
d) Not reported	11

31.2. Does the uncertainty correspond to a within-laboratory reproducibility standard deviation?	No. of laboratories
a) Yes	32
b) No	24
c) Not applicable	15
d) Not reported	11

31.3. Does the uncertainty include a contribution from the DNA extraction step?	**No. of laboratories**
a) Yes	37
b) No	27
c) Not applicable	10
d) Not reported	8

31.5. Did you report an expanded uncertainty including a coverage factor?	**No. of laboratories**
a) Yes	61
b) No	4
c) Not applicable	8
d) Not reported	9

31.6. If applicable, please specify the coverage factor used (k = 1 for a 66.67% confidence level, k= 2 for a 95% confidence level, k = 3 for a 99% confidence level):	**No. of laboratories**
a) k = 1	0
b) k = 2	61
c) k = 3	1
d) Other	5
Other of which:	
2.57	1
The coverage factor depend on the number of measurements (n=5 factor 2.57, n=11 factor 2.23, n=12 factor 2.20)	1
t-value (Excel TINV)	1
NA	1
Coverage factors are given in "Results" section and vary from 2.23 to 2.26 depending on degrees of freedom	1

Acknowledgements

With respect to the raw material(s) used in this study we kindly acknowledge Monsanto Company Corporation for providing the raw materials used in this study: soybean event 40-3-2 and the maize event MON 88017. We sincerely thank Marko Maras, Adam Niedzwiecki, Matteo Maretti, Angelo Collotta Fabrizia Scabini, Roberta Brustio, Stéphane Cordeil, Steven Price and Lorella Vidmar, of the MBG Unit and EU-RL GMFF for their invaluable contributions to this sixth comparative testing round. A special thanks to Diana Charels for her thorough work on this CT round and for all the efforts in coordinating the comparative testing activities.

The CT-Advisory Board members (Bernard China, Philippe Corbisier, Hez Hird, Lotte Hougs, Martin Sandberg, Manuela Schulze and Isabel Taverniers) have provided invaluable input for the planning and analysis of the CT round and intensively revised and agreed to this report. Their constructive contribution is highly appreciated.

The laboratories listed below are kindly acknowledged for their participation in this exercise

[1] Laboratory appointed under Regulation (EC) No 882/2004, [2] Laboratory appointed under Regulation (EC) No 1981/2006, [3] ENGL member only, [4] Laboratory from third country, [5] Official control laboratory only

Organisation	Department	Country	Status
Agenzia provinciale per l'ambiente di Bolzano	Laboratorio analisi alimenti	IT	4
AGES - Austrian Agency for Health and Food Safety		AU	1+2
AGRICULTURAL GENETICS INSTITUTE	MOLECULAR BIOLOGY	VN	5
Agricultural Institute of Slovenia		SL	2
Agri-Food & Veterinary Authority of Singapore	Laboratory Department	SG	5
Agroscope Liebefeld-Posieux ALP	Analytics	CH	4
Bavarian Health and Food Safety Authority		DE	2
BfR	Food Saftey	DE	2
BioGEVES		FR	1+2
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit		DE	1
Central Control and Testing Institute in Agriculture	Dptm. of Molecular Biology NRL	SK	1+2
CENTRO NACIONAL DE ALIMENTACIÓN (AGENCIA ESPAÑOLA DE SEGURIDAD ALIMENTARIA Y NUTRICION)	BIOTECHNOLOGY UNIT	ES	1+2
Chemisches und Veterinäruntersuchungsamt Ostwestfalen-Lipppe (CVUA-OWL)		DE	2
CRA-W - Centre wallon de Recherches agronomiques	Valorisation des productions	BE	1+2
Crop Research Institute - Reference Laboratory for GMO Detection and DNA fingerprinting		CZ	1+2
CVUA Freiburg	GMO	DE	2
Danish Veterinary and Food Administration	Section for Plant Diagnostics	DK	1+2
ERSA	Servizio fitosanitario chimico	IT	4
Federaal Laboratorium voor de Voedselveiligheid		BE	5
Federal Office of Public Health FOPH	Food Safety	CH	3
Fera		UK	1+2
Finnish Customs Laboratory	ET2	FI	1+2
Finnish Food Safety Authority Evira		FI	4
Hessian State Laboratory		DE	2
IDAH	Molecular Biology and GMO	RO	1
INRAN - ENSE	Laboratorio Analisi Sementi	IT	2
Institut für Hygiene und Umwelt	Gentechnik	DE	2
Institute for Agricultural and Fisheries Research (ILVO)	Unit Technology and Food - PI	BE	1+2
Institute for Animal Health, Food Safety and Environment	Virology	LV	1+2
Institute of Biochemistry and Biophysics PAS		PL	2
Instituto Nacional de Investigação Agrária e Veterinária	UEIS-SAFSV	PT	2
Instytut Zootechniki PIB	KLP Pracownia w Szczecinie	PL	1+2
Istituto Superiore di Sanità (ISS)	DSPVSA	IT	2
Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta	S.C. Biotecnologie	IT	4
Istituto Zooprofilattico Sperimentale della Lombardia ed Emilia Romagna	Reparto Genomica	IT	4
ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELLA SARDEGNA	IGIENE ALIMENTI	IT	4
ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELL'UMBRIA E DELLE MARCHE	LABORATORIO OGM	IT	4
ISTITUTO ZOOPROFILATTICO SPERIMENTALE LAZIO E TOSCANA	BIOTECNOLOGY UNIT	IT	1+2
Kyung Hee University	Food Science and	KR	5

	Biotechnology		
Laboratoire national de Santé	food control	LU	1+2
Laboratoire SCL de Strasbourg		FR	1+2
Laboratorio Arbitral Agroalimentario - MAGRAMA	OGM	ES	1+2
Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei M-V	Dez. 200/PCR-Labor	DE	2
Landesamt für Verbraucherschutz Sachsen-Anhalt	Fachbereich 3	DE	2
Landeslabor Berlin-Brandenburg	Fachbereich I-6	DE	2
Landeslabor Schleswig-Holstein		DE	2
Landesuntersuchungsamt	Institut f. Lebensmittelchemie	DE	2
Landesuntersuchungsanstalt für das Gesundheits- und Veterinärwesen Sachsen (LUA)	Amtliche Lebensmitteluntersuchung	DE	2
LAV Saarbrücken	Molekularbiologie	DE	2
LAVES-LVI Braunschweig/Hannover	FB 120	DE	2
LGC		UK	1+2
LTZ Augustenberg		DE	2
Ministry of Agriculture Livestock and Food Supply	National Laboratory in Goiás	BR	5
National Bureau of Plant Genetic Resources, New Delhi	NRC on DNA Fingerprinting	IN	5
National Center of Public Helath and Anlyses	GMO unit	BG	1+2
National Food Agency	Science Department	SE	1+2
National food and veterinary risk assessment institute	Molecular biology and GMO	LT	1+2
National Food Institute, Technical University of Denmark	Toxicology and Risk Assessment	DK	1+2
National Food Reference Laboratory	Biotechnology and GMO Unit	TR	5
National Institute of Biology		SL	1+2
National Veterinary Research Institute	Department of Hygiene of Feed	PL	1+2
Netherlands Food and Consumer Product Safety Authority		NL	2
NFCSO, FFSD	Food Microbiological NRL, GMO	HU	1+2
Nowegian Veterinary Institute	Bacteriology-Feed and GMO	NO	3
Plant Breeding and Acclimatization Institute – National Research Institute	GMO Controlling Laboratory	PL	2
Quatest 3 (Quality assurance and testing center 3)	Microbiology - GMO testing lab	VN	5
Regional Laboratory of Genetically Modified Food		PL	1+2
RIKILT Wageningen UR	NFA	NL	1+2
Scientific Institute of Public Health	Platform Biotech & Mol Biol	BE	1+2
Scottish Government	SASA	UK	2
Servicio Agricola y Ganadero	Laboratorios y Estaciones Cuar	RC	5
Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft	Geschäftsbereich 6, FB 63	DE	2
State Veterinary and Food Institute Dolny Kubin		SK	1+2
Tallinn University of Technology	Gene Technology	EE	2
Thüringer Landesamt für Verbraucherschutz	Lab for detection of GMO/foods	DE	2
Thüringer Landesanstalt für Landwirtschaft	Untersuchungswesen	DE	3
Umweltbundesamt	Landuse and Biosafety	AU	1+2
USDA- GIPSA	Technical Services Division	US	4
National Quality Control Laboratory of Drug and Food	Biotechnology laboratory	ID	5
INASE (Instituto Nacional de Semillas)	Lab. Técnicas Moleculares	AR	5
ICABIOGRAD (BB-Biogen)	Molecular Biology	ID	5
Worcestershire Scientific Services		UK	3

Annex 1: Invitation letter

Ref. Ares(2012)1526339 - 19/12/2012

EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Molecular Biology and Genomics

EURL
European Union Reference Laboratory
for GM Food & Feed

Ispra, 19 December 2012
JRC.DG.I.3/MBG/JK/DC/ld/ARES(2012)

NOTE FOR THE ATTENTION OF

I. **All National Reference Laboratories nominated under COMMISSION REGULATION (EC) No 882/2004**
II. **All National Reference Laboratories nominated under COMMISSION REGULATION (EC) No 1981/2006**
III. **All members of the European Network of GMO Laboratories**
IV. **Official control laboratories**
V. **Interested parties from third countries**

Subject: Invitation to participate in the comparative test ILC-EURL-GMFF-CT-02/12

Pursuing Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004, the European Union Reference Laboratory for GM Food and Feed (EU-RL GMFF) has the obligation to organise comparative testing rounds and to ensure an appropriate follow-up of the results obtained.

Hereby, I would like to invite you to participate in the sixth round of comparative testing ILC-EURL-GMFF-CT-02/12. This comparative testing round will include two test materials of an organic feed stuff. Participants will need to screen for 5 GM events namely:

1. Soybean 356043 (unique identifier DP-356Ø43-5),
2. RoundUp Ready soybean (GTS 40-3-2, unique identifier MON-Ø4Ø32-6),
3. MON 89788 soybean (unique identifier MON-89788-1),
4. Maize MON 88017 (unique identifier MON-88Ø17-3),
5. Maize MON 89034 (unique identifier MON-89Ø34-3).

Detected GM events will subsequently need to be quantified in each test material.

Your participation is free of charge. Participants in the comparative testing rounds need to dispose over equipment for qualitative and quantitative Polymerase Chain Reaction (PCR).

I would like to remind you that participation in comparative testing is mandatory for all National Reference Laboratories nominated under Regulation (EC) No 882/2004. The participation of National Reference Laboratories nominated under Regulation (EC) No

ISO 9001:2008 certified by

Joint Research Centre · I-21027 Ispra (VA), Italy · TP 331
Telephone: direct line (+39)0332/786735, · Telefax: (+39)0332/785483
E-mail: Joachim.kreysa@ec.europa.eu
http://ihcp.jrc.ec.europa.eu

CERMET SINCERT

1981/2006 is not mandatory though highly recommended. The laboratory codes assigned to each participant in this comparative testing round are confidential. However, the EU-RL GMFF will disclose details of the National Reference Laboratories that have been appointed under Regulation (EC) No 882/2004 and Regulation (EC) No 1981/2006 to DG SANCO for the purpose of an assessment of their performance.

Registration for the sixth round of comparative testing and submission of results will be handled by the EU-RL GMFF. Please register electronically for the sixth comparative testing round using the following link:

https://web.jrc.ec.europa.eu/ilcRegistrationWeb/registration/registration.do?selComparison=1000

Please be aware that each laboratory can only register once for this comparative testing round. Hence it will no longer be possible to submit your results in both measurement units (i.e. mass/mass % and cp/cp %) for the same set of test items.

The deadline for registration is **17 January 2013 24.00 h CET**. On **18 January 2013** the EU-RL GMFF will send an E-mail to all participants who have successfully registered. Please contact the functional mailbox mbg-comparative-testing@jrc.ec.europa.eu in case you do not receive any confirmation of registration.

Samples should be shipped during the week of **4 to 8 February 2013**. The provisional deadline for submission of results is **22 March 2013**.

Please contact the functional mailbox mbg-comparative-testing@jrc.ec.europa.eu for all issues related to this comparative testing round: difficulties with your on-line registration, communications and questions related to the content of the comparative testing round.

The EU-RL GMFF is looking forward to your participation.

Yours sincerely,

Joachim Kreysa
Head of Molecular Biology and Genomics Unit

Annex 2: Accompanying letter to shipment of samples

EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Molecular Biology and Genomics

EURL
European Union Reference Laboratory
for GM Food & Feed

Ispra, 29 January 2013
JRC.DG.I.3/MBG/JK/dc/lv

NOTE FOR THE ATTENTION OF

All Laboratories registered for the comparative test ILC-EURL-GMFF-CT-02/12

<<Address>>

Subject: **Participation in ILC-EURL-GMFF-CT-02/12, a comparative testing round to determine the GM content in two test materials of an organic feed stuff.**

Dear <<Name>> <<Surname>>,

Thank you for participating in the ILC-EURL-GMFF-CT-02/12 comparative testing round containing two test materials of an organic feed stuff.

The parcel contains:

1. Two plastic containers each containing approximately 5 g of test item
2. An "Acknowledgement of Reception" form
3. This accompanying letter

Please check whether the plastic containers containing the test item remained undamaged during transport and return the "Acknowledgement of Reception" form by fax (+39 0332 786159). You should store the samples in a dark and cold place (not exceeding 18 °C).

This round of comparative testing will include two test materials of organic feed stuff. Participants will need to screen for 5 GM events namely:

1. Soybean 356043 (unique identifier DP-356Ø43-5),
2. RoundUp Ready soybean (GTS 40-3-2, unique identifier MON-Ø4Ø32-6),
3. MON 89788 soybean (unique identifier MON-89788-1),
4. Maize MON 88017 (unique identifier MON-88Ø17-3),
5. Maize MON 89034 (unique identifier MON-89Ø34-3).

Detected GM events will subsequently need to be quantified in each test material.
The procedures used for detection/quantification of the detected GM events should resemble as closely as possible the ones that you use in routine sample analyses.

The results can be reported in mass/mass % or copy/copy % as outlined below:

ISO 9001:2008 certified by

Joint Research Centre · I-21027 Ispra (VA), Italy · TP 331
Telephone: direct line (+39)0332/786735, · Telefax: (+39)0332/786159
E-mail: Joachim.kreysa@ec.europa.eu
http://ihcp.jrc.ec.europa.eu

CERMET SINCERT

$$\text{mass/mass \%} = \frac{\text{mass GM [g]}}{\text{Total mass [g]}} \times 100\ \%$$

$$\text{copy/copy \%} = \frac{\text{GM DNA copy numbers [cp]}}{\text{Target taxon-specific DNA copy numbers [cp]}} \times 100\ \%$$

You can find the reporting website at https://web.jrc.ec.europa.eu/ilcReportingWeb . You need a personal password to access this webpage which is **«GRIV1165103».** The system will guide you through the reporting procedure.

Please be aware that you are not allowed to report results both in mass/mass % and copy/copy %. The results of participants having submitted results in both measurement units will be discarded.

After entering all results, please complete the questionnaire. In the questionnaire, items bearing a question mark icon on the right-hand side contain additional information for the participant. In the reporting website clicking on the icon will give access to this information. Do not forget to save, submit and confirm when required to do so.

The pdf file of the questionnaire that you will or have already received by E-mail is intended as an aid in the laboratory. In this pdf file, items with the word '(number)' indicate that a numerical value should be provided. Pdf files of questionnaires bearing hand-written answers will not be accepted for reporting.

Only results and answers to the questionnaire that are reported on-line on the reporting website https://web.jrc.ec.europa.eu/ilcReportingWeb **will be accepted.**

Directly after submitting your results and the questionnaire information on-line, you will be prompted to print the completed report form. Please sign the printed report form and return it to the EU-RL GMFF by fax (+39 0332 78 61 59) or E-mail (mbg-comparative-testing@jrc.ec.europa.eu). Check your results carefully before submission, since this is your final confirmation.

The deadline for submission of results is **22 March 2013**. It will not be possible to submit your results after the deadline.

Please contact the functional mailbox mbg-comparative-testing@jrc.ec.europa.eu for all issues related to this comparative testing round.

We thank you very much for the collaboration in this comparative testing round.

Yours sincerely,

bo

Joachim Kreysa
Head of Unit

Annex 3: Confirmation of shipment

Dear participant,

All test parcels related to the sixth comparative testing round ILC-EURL-GMFF-CT-02/12 have left our premises today by TNT courier.
For your convenience, please find herewith the corresponding tracking number you could refer to in order to track the relevant materials on the Web:

56427 3527

The parcel with test items that you will or have already received should contain:

- Two plastic containers each containing approximately 5 g of test item
- An "acknowledgement of reception" form, that should be returned to the **EU-RL GMFF** by **fax (+39 0332 786159).**
- An accompanying letter entitled '**Participation in ILC-EURL-GMFF-CT-02/12'**

The accompanying letter contains your **personal password** for on-line submission of your results to the reporting website https://web.jrc.ec.europa.eu/ilcReportingWeb.

Please find herewith a pdf file of the questionnaire. This pdf file is intended as an aid in the laboratory. In the questionnaire, items with the indication (number) behind the answer box indicate that a numerical value should be given. Items bearing a question mark icon on the right-hand side contain valuable and important information for the participant. In the reporting website clicking on the icon will give access to this information. Pdf files of questionnaires bearing hand-written answers **will not be accepted**.
Only results and answers to the questionnaire reported on-line to the reporting website https://web.jrc.ec.europa.eu/ilcReportingWeb will be accepted.

The deadline for submission of your results is **22 March 2012**.

Please contact the functional mailbox mbg-comparative-testing@jrc.ec.europa.eu for **all issues** related to this comparative testing round

Thank you for your collaboration in this comparative testing round.

Fabrizia SCABINI
On behalf of Comparative Testing Staff

European Commission

DG - Joint Research Centre
Institute for Health and Consumer Protection
Unit I.3 – Molecular Biology and Genomics

Via E.fermi, 2749
I-21027 Ispra (VA)/Italy

fabrizia.scabini@jrc.ec.europa.eu

Annex 4: Acknowledgement of receipt

DG JRC I3	FAX - Record for Quality System	EURL
R71GP6/EURL Date: 19/07/2011 Revision. 4	**Acknowledgement of reception**	Page 1/1

From :

Lab Code:

To : Molecular Biology and Genomics Unit **fax: +39 0 332 78 6159**
Method Validation / EURL-GMFF
European Commission - Joint Research Centre - IHCP
21027 ISPRA (VA) Italy

File nb EURL-CT-02/12

We have received the following samples **In good condition** **Yes** ☐ **No** ☐

No information regarding the sample(s) received and results of related testing may be disclosed to any third party.

Comments:

Date:..... Visa:.....

By signing this document the participant agrees with the clause of non disclosure of information on samples and results

Please, send this document via FAX to:
+39 0332 78 6159 the day of reception

This document is not a recognition of the quantity and/or quality of samples and reagents provided. This document will be used by EURL-GMFF only to confirm the reception of goods provided to participating laboratories in its Quality System. EURL-GMFF thanks you very much for your participation.

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European Commission
EUR 26417 EN – Joint Research Centre – Institute for Institute for Health and Consumer Protection

Title: Comparative Testing Report on the Detection and Quantification of GM Events in Compound Feedstuff: ILC-EURL-GMFF-CT-02/12

Author(s): Niccolo Bassani, Adam Niedzwiecki, Angelo Collotta, Matteo Maretti, Marco Mazzara, Joachim Kreysa

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Abstract

In the frame of Regulation (EC) No 882/2004, the European Union Reference Laboratory for Genetically Modified Food and Feed has the duty to organise comparative testing rounds and to ensure an appropriate follow-up of these activities. This report describes the outcome of the fifth comparative testing round ILC-EURL-GMFF-CT-01/12. Participants had to determine the content of oilseed rape event GT73 and maize event 59122 in two test items denoted genomic DNA levels 1 and 2, containing different GM percentages of both GM events.

This comparative testing round was organised in collaboration with the Food Safety and Quality Unit of the Institute for Reference Materials and Measurements (Geel, BE). The test items were produced in-house. The Food Safety and Quality Unit managed the on-line registration and submission of results.

A total of 160 laboratories were invited to participate in ILC-EURL-GMFF-CT-01/12. Eighty laboratories from 36 countries returned results, of which 59 were National Reference Laboratories, six were only members of the European Network of GMO Laboratories, three were only Official control laboratories and 12 were laboratories from third countries. Five laboratories including one National Reference Laboratory and four laboratories from third countries did not submit results.

In this fifth comparative testing round 92 % to 98 % of participants gained a satisfactory z-score in the range of -2 to +2 for the results expressed in mass/mass % depending on the GM content and the GM event. However, a lower percentage (38 – 93 %) of z-scores within the working range of -2 to +2 was calculated for those participants that expressed the results in copy/copy %.

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