

USDA/GIPSA Proficiency Program
Testing for the Presence of Biotechnology Events in Corn and Soybeans
April 2012 Sample Distribution Results

Purpose of USDA/GIPSA Proficiency Program

Through the USDA/GIPSA Proficiency Program, USDA seeks to improve the overall performance of testing for biotechnology-derived grains and oil seeds. The USDA/GIPSA Proficiency Program helps organizations identify areas of concern and take corrective actions to improve testing precision, capability and reliability.

Program Description and Assessment of Results

The USDA/GIPSA proficiency program report contains inter-laboratory comparisons for the purpose of proficiency testing (i.e. to determine the performance of individual laboratories' ability to detect and/or quantify transgenic traits in corn or soy and to monitor laboratories' continuing performance). It does not assess the effectiveness of different detection methods for biotechnology-derived traits nor does it determine the characteristics of fortified samples to a particular degree of accuracy, such as what is performed in the preparation of certified reference materials.

In this round of the USDA/GIPSA Proficiency Program sample distribution, one set of samples was used for both qualitative and quantitative analyses. The samples were fortified with various combinations and concentrations of transgenic traits, and participants had the choice of providing qualitative and/or quantitative results. Scoring of the participant's qualitative results was done by computing the "percentage of correctly reported transgenic traits" in the samples (Tables 1 through 41 and Figure 1 for DNA-based analysis and Tables 42 to 49 for protein-based analysis). The "percentage false positive" and "percentage false negative" were calculated by dividing the number of incorrectly reported results by the number of "provided negatives" or "provided positives" that were distributed to the participants. It should be noted that trait specific, DNA-based testing can discern between different traits that express the same protein, (e.g. Roundup Ready (RUR) and Roundup Ready II (RUR II)), whereas in most instances, construct-specific DNA-based testing or protein-based testing cannot.

Consensus mean values were calculated on the sets of quantitative data shown in Tables 48 to 65, with outliers excluded. Data sets were treated equally with this model, assuming no laboratory effect on outcomes, and are most likely idealistic. To assess accuracy of individual participant's submitted quantitative results, for a specified transgenic event, z-scores (based on: (reported value – consensus mean value) / standard deviation) were computed for each reported quantification result (Tables 50 to 69). Tests for outliers and z-scores assume a normal distribution. At the 0.0 or 0.1% fortification levels, and on tables with a limited number of results, the distributions are not likely normal and are probably skewed. A false positive on a 0.0% spike level is considered an outlier. At the 0.1% fortification level, outlier tests will likely declare more outliers than should be declared. Some judgment will be necessary when interpreting data at these low levels. For levels higher than 0.1%, outliers were not included in the standard deviation used to compute the z-scores. Z-scores that are > 2 should be scrutinized by the participating lab. Those that are > 3 are clearly suspect and action should be taken by the participating laboratory. Prior to computing the z-scores, outliers in the distribution of values were eliminated by use of the "Grubb's Test for Outliers." To evaluate the performance as a group (i.e., inter-laboratory variation), a summary table (Table 70) was prepared to show the

accuracy and precision of compiled quantification results at each fortification level for the various transgenic events.

Sample Preparation and Composition

GIPSA receives 100% genetically-engineered (GE) trait material from life science companies through materials transfer agreements. Specific GE trait materials are characterized at GIPSA and tested for the presence of all other available traits (also used in the program) by event-specific polymerase chain reaction (PCR) testing. Occasionally, stack-traits are identified. Seed purity and zygosity characteristics are not assessed by GIPSA. Commercially available and internationally recognized reference material are purchased through the Institute for Reference Materials and Measurements (IRMM) or the American Oil Chemists Society (AOCS) as finely ground flour, containing a certified percentage weight/weight (% w/w), level. GIPSA uses commercially available reference standards to characterize the composition of proficiency samples prior to disseminating to participants.

Transgene-free, Pioneer Negative Corn (PNC) is provided by Pioneer Hi-Bred International, Inc., and the maize is ground to the consistency of fine flour using a high speed rotor mill, "Pulverisette 14." A 50 gram aliquot of 100% event material (maize or soy) is ground in liquid nitrogen, in a highly controlled environment using a SPEX Certi Prep 6800 Freezer Mill. The 100% event sample is stored at -20 °C until further use. The 100% event material is blended gravimetrically with well characterized non-event PNC to a specified %w/w concentration. The sample sets are then analyzed by real-time PCR using in-house validated methods. GIPSA always characterizes one challenge sample batch that is not fortified with any maize/soy GE trait and this serves as a negative control sample.

The corn samples contained various combinations and concentrations of the following transgenic traits: T25, MON810, GA21, Bt176, Bt11, NK603, Herculex (TC1507), MON863, Herculex RW (DAS-59122-7), MIR 604 (Agrisure RWTM), Event 3272, MON 88017, MON 89034, MIR 162; or, no events (i.e., negative corn sample). The transgenic trait CBH351 (Starlink) was not fortified into any of the samples for this dissemination. The various transgenic concentration levels were produced on a %w/w basis. A calculated amount of ground transgenic corn was blended to homogeneity with a calculated amount of non-transgenic corn to produce concentrations ranging from 0.1 to 2.0% of a specified event. The soybean samples contained non-transgenic soybeans, or were fortified soybean samples containing 0.2 to 1.5% of the transgenic glyphosate-tolerant soybeans (Roundup Ready®), the glufosinate ammonium tolerant soybeans (A2704-12), and/or the transgenic glyphosate-tolerant soybeans (Roundup ReadyII®), or no events (i.e., negative soy sample). Each participant received six corn and four soybean samples. Individual samples contained approximately 10 to 15 grams of ground material.

Samples prepared at a particular %w/w fortification should in theory be concordant with consensus values as cited in the report. In many instances, however, the %w/w fortification value did not agree with analytical data generated by PCR when compared to commercially available reference standards and in-house validated methods. The trend of generating lower reported concentrations compared with gravimetric fortified values is possibly due to zygosity differences in the corn and soy samples compared with commercially available reference materials. For example, GIPSA in-house validated methods reflect composite averages for MON810 to be about half the %w/w fortified levels; conversely, Herculex RW composite averages were observed to be higher than the %w/w fortifications. GIPSA data are consistent

with historical data generated by GIPSA proficiency program participants. For this reason, consensus means are used for statistical evaluation in lieu of gravimetric fortification values.

Program Participants

Participants included organizations from Africa, Asia, Europe, North America, and South America. Each participant received a study description and a data report form by electronic mail, and included with the samples. Participants submitted results by electronic mail. No analytical methodologies were specified, and organizations used both DNA- and protein-based testing technologies. Sixty (60) organizations received samples in the April 2012 round of proficiency testing, and fifty-four (54) organizations submitted results to GIPSA.

- Fourteen (14) participants submitted **qualitative** results only (of these 14, three (3) participants performed a combination of DNA and protein based testing),
- Seven (7) submitted **quantitative** results only,
- Thirty-one (31) participants submitted a combination of **qualitative** and **quantitative** results (of these 31, one (1) participant performed a combination of DNA and protein based testing), and
- Two (2) participants submitted **protein** based results, using Lateral Flow Strip (LFS) qualitative and/or Enzyme-linked Immunosorbent Assay (ELISA) quantitative analyses.

In this report, participating organizations are identified by a confidential “Participant Identification Number.” Appendix I identifies those organizations who gave GIPSA permission to list them as participants in the USDA/GIPSA Proficiency Program; several listed organizations requested that their identity remain anonymous.

Data Summary Results

Data submitted by the participants is summarized in this report primarily in tables and figures. Participants reported their results on a qualitative basis, quantitative basis, or a combination of both qualitative and quantitative bases. Qualitative results were reported as the presence or absence of a particular event in each sample. Quantitative results were reported as the concentration (% w/w) of a particular event in the sample. Due to the complexity of the data, this report summarizes the data as follows:

Qualitative Data Summaries. This section summarizes qualitative sample analysis data:

DNA Based Testing

- Table 1: Qualitative results for corn fortified with 35S for all participants (DNA-based assays).
- Table 2: Percentages of correct results, false negatives, and false positives in qualitative reports for 35S for all participants.
- Table 3: Qualitative results for corn fortified with NOS for all participants (DNA-based assays).
- Table 4: Percentages of correct results, false negatives, and false positives in qualitative reports for NOS for all participants.
- Table 5: Qualitative results for corn fortified with T25 for all participants (DNA-based assays).

- Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports for T25 for all participants.
- Table 7: Qualitative results for corn fortified CBH351 with for all participants (DNA-based assays).
- Table 8: Percentages of correct results, false negatives, and false positives in qualitative reports for CBH351 for all participants.
- Table 9: Qualitative results for corn fortified with MON810 for all participants (DNA-based assays).
- Table 10: Percentages of correct results, false negatives, and false positives in qualitative reports for MON810 for all participants.
- Table 11: Qualitative results for corn fortified with GA21 for all participants (DNA-based assays).
- Table 12: Percentages of correct results, false negatives, and false positives in qualitative reports for GA21 for all participants.
- Table 13: Qualitative results for corn fortified with Bt176 for all participants (DNA-based assays).
- Table 14: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt176 for all participants.
- Table 15: Qualitative results for corn fortified with Bt11 for all participants (DNA-based assays).
- Table 16: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt11 for all participants.
- Table 17: Qualitative results for corn fortified with NK603 for all participants. (DNA-based assays).
- Table 18: Percentages of correct results, false negatives, and false positives in qualitative reports for NK603 for all participants.
- Table 19: Qualitative results for corn fortified with Herculex for all participants (DNA-based assays).
- Table 20: Percentages of correct results, false negatives, and false positives in qualitative reports for Herculex for all participants.
- Table 21: Qualitative results for corn fortified with MON863 for all participants (DNA-based assays).
- Table 22: Percentages of correct results, false negatives, and false positives in qualitative reports for MON863 for all participants.
- Table 23: Qualitative results for corn fortified with Herculex RW for all participants (DNA-based assays).
- Table 24: Percentages of correct results, false negatives, and false positives in qualitative reports for Herculex RW for all participants.
- Table 25: Qualitative results for corn fortified with MIR604 for all participants (DNA-based assays).
- Table 26: Percentages of correct results, false negatives, and false positives in qualitative reports for MIR604 for all participants.
- Table 27: Qualitative results for corn fortified with Event 3272 for all participants (DNA-based assays).
- Table 28: Percentages of correct results, false negatives, and false positives in qualitative reports for Event 3272 for all participants.
- Table 29: Qualitative results for corn fortified with MON 88017 for all participants (DNA-based assays).

- Table 30: Percentages of correct results, false negatives, and false positives in qualitative reports for MON 88017 for all participants.
- Table 31: Qualitative results for corn fortified with MON 89034 for all participants (DNA-based assays).
- Table 32: Percentages of correct results, false negatives, and false positives in qualitative reports for MON 89034 for all participants.
- Table 33: Qualitative results for corn fortified with MIR162 for all participants (DNA-based assays)
- Table 34: Percentages of correct results, false negatives and false positives in qualitative reports for MIR162 for all participants.
- Table 35: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays).
- Table 36: Percentages of correct results, false negatives, and false positives in qualitative reports for CP4 EPSPS for all participants.
- Table 37: Qualitative results for soybeans fortified with A2704-12 (Liberty Link) for all
- Table 38: Percentages of correct results, false negatives, and false positives in qualitative reports for A2704-12 for all participants.
- Table 39: Qualitative results for soybeans fortified with Roundup Ready II for all participants (DNA-based assays).
- Table 40: Percentages of correct results, false negatives, and false positives in qualitative reports for Roundup Ready II for all participants.
- Table 41: Composite percentages of correct results, false negatives, and false positives in qualitative reports for each transgenic event for all participants (DNA-based assays).
- Figure 1: Group average of percentage correct for Qualitative reports on each event (DNA-based assays).

Protein Based Data Summaries. This section summarizes protein based sample analysis data:

- Table 42: Lateral Flow Strip (LFS) testing (Protein-based testing) results for the detection of transgenic events in corn.
- Table 43: Percentage of correct results, false negatives, and false positives in qualitative reports for transgenic events in corn using Lateral Flow Strip (LFS) testing.
- Table 44: Results for soybeans fortified with CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) testing.
- Table 45: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) testing.
- Table 46: Results for the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).
- Table 47: Percentage of correct results in the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).
- Table 48: Results for soybeans fortified with CP4EPSPS using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).
- Table 49: Percentage of correct results in qualitative reports for CP4EPSPS using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing)

- **Quantitative Data Summaries.** This section summarizes quantitative sample analysis data: z-scores were purposefully left blank on non-fortified (0.0%) samples since a z-score assumes a normal distribution and its interpretation would be distorted.

DNA Based Testing

- Table 50: Quantitative results and z-scores for corn fortified with T25 for all participants (DNA-based assays).
- Table 51: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays).
- Table 52: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).
- Table 53: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).
- Table 54: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays).
- Table 55: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays).
- Table 56: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays).
- Table 57: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays).
- Table 58: Quantitative results and z-scores for corn fortified with MON863 for all participants (DNA-based assays).
- Table 59: Quantitative results and z-scores for corn fortified with Herculex RW for all participants (DNA-based assays).
- Table 60: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays).
- Table 61: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays).
- Table 62: Quantitative results and z-scores for corn fortified with MON 88017 for all participants (DNA-based assays).
- Table 63: Quantitative results and z-scores for corn fortified with MON 89034 for all participants (DNA-based assays).
- Table 64: Quantitative results and z-scores for corn fortified with MIR162 for all participants (DNA-based assays).
- Table 65: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays).
- Table 66: Quantitative results and z-scores for soybeans fortified with A2704-12 for all participants (DNA-based assays).
- Table 67: Quantitative results and z-scores for soybeans fortified with Roundup Ready II for all participants (DNA-based assays).
- Table 68: Quantitative results for 35S and NOS in corn (DNA based assay).
- Table 69: Results for 35S and NOS in soybeans (DNA based assay)
- Table 70: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays.
- Appendix I: List of organizations who wished to be identified as a participant in the GIPSA October 2011 Proficiency Program.

Table 1: Qualitative results for corn fortified with 35S for all participants (DNA-based assays)
(N = negative; P = positive; Incorrect results are shown in boldface).

35S	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	N	P	P	P	P	P
1754	N	P	P	P	P	P
1761	N	P	P	P	P	P
1764	P	P	P	P	P	P
1773	N	P	P	P	P	P
1788	N	P	P	P	P	P
1859	N	P	P	P	P	P
1862	N	P	P	P	P	P
1870	N	P	P	P	P	P
1875	N	P	P	P	P	P
1891	N	P	P	P	P	P
1892	N	P	P	P	P	P
1895	N	P	P	P	P	P
2005	N	P	P	P	P	P
2034	N	P	P	P	P	P
2039	N	P	P	P	P	P
2057	N	P	P	P	P	P
2076	N	P	P	P	P	P
2112	N	P	P	P	P	P
2113	N	P	P	P	P	P
2126	N	P	P	P	P	P
2560	N	P	P	P	P	P
2691	N	P	P	P	P	P
2694	N	P	P	P	P	P
2716	N	P	P	P	P	P
2822	N	P	P	P	P	P
2830	N	P	P	P	P	P
3095	N	P	P	P	P	P
3927	N	P	P	P	P	P
3928	N	P	P	P	P	P
3929	N	P	P	P	P	P
4901	N	P	P	P	P	P
4932	N	P	P	P	P	P
4934	N	P	P	P	P	P
4935	N	P	P	P	P	P
4936	N	P	P	P	P	P
4937	N	P	P	P	P	P
4945	N	P	P	P	P	P
4946	N	P	P	P	P	P
4947	N	P	P	P	P	P
N, Results	39	39	39	39	39	39
# Negative	38	0	0	0	0	0
# Positive	1	39	39	39	39	39
% Correct	97.4%	100.0%	100%	100.0%	100.0%	100%
% Incorrect	2.6%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 2: Percentages of correct results, false negatives, and false positives in qualitative reports for 35S for all participants

Total # Reported results	234
# Incorrect	1
% Correct	99.6%
# Provided Positives	195
# False Negative	0
% False Negative	0.0%
# Provided Negatives	39
# False Positive	1
% False Positive	2.6%

Table 3: Qualitative results for corn fortified with NOS for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

NOS	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	N	P	P	P	P	P
1754	N	P	P	P	P	P
1761	N	P	P	P	P	P
1764	N	P	P	P	P	P
1773	N	P	P	P	P	P
1783	N	P	P	P	P	P
1785	N	P	P	P	P	P
1788	N	P	P	P	P	P
1859	N	P	P	P	P	P
1862	N	P	P	P	P	P
1870	N	P	P	P	P	P
1875	N	P	P	P	P	P
1891	N	P	P	P	P	P
1892	N	P	P	P	P	P
1895	N	P	P	P	P	P
2005	N	P	P	P	P	P
2031	N	P	P	P	P	P
2034	N	P	P	P	P	P
2039	N	P	P	P	P	P
2057	N	P	P	P	P	P
2076	N	P	P	P	P	P
2112	N	P	P	P	P	P
2113	N	P	P	P	P	P
2126	N	P	P	P	P	P
2560	N	P	P	P	P	P
2691	N	P	P	P	P	P
2694	N	P	P	P	P	P
2716	N	P	P	P	P	P
2822	N	P	P	P	P	P
2830	N	P	P	P	P	P
3095	N	P	P	P	P	P
3927	N	P	P	P	P	P
3928	N	P	P	P	P	P
3929	N	P	P	P	P	P
4901	N	P	P	P	P	P
4932	N	P	P	P	P	P
4934	N	P	P	P	P	P
4935	N	P	P	P	P	P
4936	N	P	P	P	P	P
4937	N	P	P	P	P	P
4945	N	P	P	P	P	P
4946	N	P	P	P	P	P
4947	N	P	P	P	P	P
N, Results	42	42	42	42	42	42
# Negative	42	0	0	0	0	0
# Positive	0	42	42	42	42	42
% Correct	100.0%	100.0%	100.0%	100%	100%	100%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 4: Percentages of correct results, false negatives, and false positives in qualitative reports for NOS for all participants.

Total # Reported results	252
# Incorrect	0
% Correct	100.0%
# Provided Positives	210
# False Negative	0
% False Negative	0.0%
# Provided Negatives	42
# False Positive	0

Table 5: Qualitative results for corn fortified with T25 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

T25	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.4%	0.0%	0.0%	0.1%
1761	N	N	P	N	N	P
1773	N	N	P	N	N	P
1785	N	N	P	N	N	P
1788	N	N	P	N	P	P
1859	N	N	P	N	N	P
1862	N	N	P	N	N	P
1892	N	N	P	N	P	P
1895	N	P	P	N	P	P
2005	N	N	P	N	P	P
2034	N	N	P	N	P	P
2057	N	N	P	N	N	P
2060	N	N	P	N	P	N
2089	N	N	P	N	N	P
2113	N	N	P	N	N	P
2126	N	N	P	N	N	P
2560	N	N	P	N	N	P
2694	N	N	P	N	N	P
2822	N	N	P	N	N	P
2830	N	N	P	N	P	P
3929	N	N	P	N	N	P
4901	N	N	P	N	N	P
4932	N	N	P	N	N	P
4937	N	N	P	N	N	P
4945	N	N	P	N	N	P
4947	N	P	P	N	N	P
N, Results	25	25	25	25	25	25
# Negative	25	23	0	25	18	1
# Positive	0	2	25	0	7	24
% Correct	100.0%	92.0%	100.0%	100.0%	72.0%	96.0%
% Incorrect	0.0%	8.0%	0.0%	0.0%	28.0%	4.0%

Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports for T25 for all participants.

Total # Reported results	150
# Incorrect	10
% Correct	93.3%
# Provided Positives	50
# False Negative	1
% False Negative	2.0%
# Provided Negatives	100
# False Positive	9
% False Positive	9.00%

Table 7: Qualitative results for corn fortified CBH351 with for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

CBH351	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
1773	N	N	N	N	N	N
1785	N	N	N	N	N	N
1788	N	N	N	N	N	N
1859	N	N	N	N	N	N
1891	N	N	N	N	N	N
1892	N	N	N	N	N	N
2034	N	N	N	N	N	N
4932	N	N	N	N	N	N
N, Results	8	8	8	8	8	8
# Negative	8	8	8	8	8	8
# Positive	0	0	0	0	0	0
% Correct	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%
% Incorrect	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 8: Percentages of correct results, false negatives, and false positives in qualitative reports for CBH351 for all participants.

Total # Reported results	48
# Incorrect	0
% Correct	100.0%
# Provided Positives	0
# False Negative	0
% False Negative	0.0%
# Provided Negatives	48
# False Positive	0
% False Positive	0.0%

Table 9: Qualitative results for corn fortified with MON810 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

MON810	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.2%	0.1%	0.3%	0.1%	0.1%
1773	N	P	P	P	P	P
1859	N	P	P	P	P	P
1862	N	P	P	P	P	P
1891	N	P	P	P	P	P
1892	N	P	P	P	P	P
1895	N	P	P	P	P	P
2034	N	P	P	P	P	P
2039	N	P	P	P	P	P
2057	N	P	P	P	P	P
2060	N	P	P	P	P	P
2089	N	P	P	P	P	P
2113	N	P	N	P	P	P
2560	N	P	P	P	P	P
2691	N	P	P	P	P	P
2694	N	P	P	P	P	P
2822	N	P	P	P	P	P
2824	N	P	N*	P	N*	N*
2830	N	P	N	P	P	N
3929	N	P	P	P	P	P
4901	N	P	P	P	P	P
4937	N	P	P	P	P	P
4947	N	P	P	P	P	P
N, Results	22	22	22	22	22	22
# Negative	22	0	3	0	1	2
# Positive	0	22	19	22	21	20
% Correct	100.0%	100.0%	90.9%	100.0%	100.0%	95.5%
% Incorrect	0.0%	0.0%	9.1%	0.0%	0.0%	4.5%

* - Fortification level below participants' LOD, assessed as provided negative

Table 10: Percentages of correct results, false negatives, and false positives in qualitative reports for MON810 for all participants

Total # Reported results	132
# Incorrect	3
% Correct	97.7%
# Provided Positives	107
# False Negative	3
% False Negative	2.8%
# Provided Negatives	25
# False Positive	0
% False Positive	0.0%

Table 11: Qualitative results for corn fortified with GA21 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

GA21	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.1%	0.5%	0.6%	0.0%	0.0%
1773	N	P	P	P	N	N
1785	N	P	P	P	N	N
1788	N	P	P	P	N	N
1859	N	P	P	P	N	N
1862	N	P	P	P	N	N
1892	N	P	P	P	N	N
1895	N	P	P	P	N	N
2005	N	P	P	P	N	N
2034	N	P	P	P	N	N
2057	N	P	P	P	N	N
2060	N	P	P	P	N	N
2089	N	P	P	P	N	N
2113	N	P	P	P	N	N
2126	N	P	P	P	N	N
2560	N	P	P	P	N	N
2691	N	P	P	P	N	N
2721	N	P	P	P	N	N
2822	N	P	P	P	N	N
2824	N	P	P	P	N	N
2830	N	P	P	P	N	N
3929	N	P	P	P	N	N
4901	N	P	P	P	N	N
4936	N	P	P	P	N	N
4937	N	P	P	P	N	N
4947	N	P	P	P	N	N
N, Results						
	25	25	25	25	25	25
# Negative	25	0	0	0	25	25
# Positive	0	25	25	25	0	0
% Correct	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 12: Percentages of correct results, false negatives, and false positives in qualitative reports for GA21 for all participants

Total # Reported results	150
# Incorrect	0
% Correct	100.0%
# Provided Positives	75
# False Negative	0
% False Negative	0.0%
# Provided Negatives	75
# False Positive	0
% False Positive	0.0%

Table 13: Qualitative results for corn fortified with Bt176 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

Bt176	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.4%	0.1%	0.0%	0.0%	0.0%
1773	N	P	P	N	N	N
1785	N	P	P	N	N	N
1859	N	P	P	N	N	N
1862	N	P	P	N	N	N
1892	N	P	P	N	N	N
2034	N	P	P	N	N	N
2057	N	P	P	N	N	N
2060	N	P	P	N	N	N
2113	N	P	P	N	N	N
2126	N	P	P	N	N	N
2691	N	P	P	N	N	N
2721	N	P	P	N	N	N
2822	N	P	P	N	N	N
3095	N	P	P	N	N	N
3928	N	P	P	N	N	N
3929	N	P	P	N	N	N
4901	N	P	P	N	N	N
4935	N	P	P	N	N	N
4937	N	P	P	N	N	N
4947	N	P	P	N	N	N
N, Results	20	20	20	20	20	20
# Negative	20	0	0	20	20	20
# Positive	0	20	20	0	0	0
% Correct	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 14: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt176 for all participants.

Total # Reported results	120
# Incorrect	0
% Correct	100.0%
# Provided Positives	40
# False Negative	0
% False Negative	0.0%
# Provided Negatives	80
# False Positive	0
% False Positive	0.0%

Table 15: Qualitative results for corn fortified with Bt11 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface.)

Bt11	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.8%	1.2%	0.0%	0.6%	0.0%
1773	N	P	P	N	P	N
1785	N	P	P	N	P	N
1859	N	P	P	N	P	N
1862	N	P	P	N	P	N
1892	N	P	P	N	P	N
1895	N	P	P	N	P	N
2034	N	P	P	N	P	N
2057	N	P	P	N	P	N
2060	N	P	P	N	P	N
2089	N	P	P	N	P	N
2113	N	N	P	N	P	N
2560	N	P	P	N	P	N
2691	N	P	P	N	P	N
2822	N	P	P	N	P	N
2824	N	P	P	N	P	N
2830	N	P	P	N	P	N
3095	N	P	P	N	P	N
3929	N	P	P	N	P	N
4901	N	P	P	N	P	N
4936	N	P	P	N	P	N
4937	N	P	P	N	P	N
4947	N	P	N	N	P	N
N, Results	22	22	22	22	22	22
# Negative	22	1	1	22	0	22
# Positive	0	21	21	0	22	0
% Correct	100.0%	95.5%	95.5%	100.0%	100.0%	100.0%
% Incorrect	0.0%	4.5%	4.5%	0.0%	0.0%	0.0%

Table 16: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt11 for all participants.

Total # Reported results	132
# Incorrect	2
% Correct	98.5%
# Provided Positives	66
# False Negative	2
% False Negative	3.0%
# Provided Negatives	66
# False Positive	0
% False Positive	0.0%

Table 17: Qualitative results for corn fortified with NK603 for all participants. (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

NK603	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.0%	0.4%	0.0%	0.0%
1773	N	N	N	P	N	N
1785	N	N	N	P	N	N
1788	N	N	N	P	N	N
1859	N	N	N	P	N	N
1862	N	N	N	P	N	N
2005	N	N	N	P	N	N
2034	N	N	N	P	N	N
2057	N	N	N	P	N	N
2060	N	N	N	P	N	N
2089	N	N	N	P	N	N
2113	N	N	N	P	N	N
2126	N	N	N	P	N	N
2560	N	N	N	P	N	N
2691	N	N	N	P	N	N
2822	N	N	N	P	N	N
2830	N	P	N	P	NR*	N
3928	N	N	N	P	N	N
3929	N	N	N	P	N	N
4901	N	N	N	P	N	N
4936	N	N	N	P	N	N
4937	N	N	N	P	N	N
4947	N	N	N	P	N	N
N, Results	22	22	22	22	21	22
# Negative	22	21	22	0	21	22
# Positive	0	1	0	22	0	0
% Correct	100.0%	95.5%	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	4.5%	0.0%	0.0%	0.0%	0.0%

*NR- Not reported

Table 18: Percentages of correct results, false negatives, and false positives in qualitative reports for NK603 for all participants.

Total # Reported results	131
# Incorrect	1
% Correct	99.2%
# Provided Positives	22
# False Negative	0
% False Negative	0.0%
# Provided Negatives	109
# False Positive	1
% False Positive	0.9%

Table 19: Qualitative results for corn fortified with Herculex for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

Herculex	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.6%	0.0%	0.0%	0.6%
1773	N	N	P	N	N	P
1761	N	N	P	N	N	P
1785	N	N	P	N	N	P
1859	N	N	P	N	N	P
1862	N	N	P	N	N	P
1895	N	N	P	N	N	P
2005	N	N	P	N	N	P
2034	N	N	N	N	N	N
2057	N	N	P	N	N	P
2060	N	N	P	N	N	P
2089	N	N	P	N	N	P
2112	N	N	P	N	N	P
2113	N	N	P	N	N	P
2126	N	N	P	N	N	P
2560	N	N	P	N	N	P
2691	N	N	P	N	N	P
2694	N	N	P	N	N	P
2822	N	N	P	N	N	P
3929	N	N	P	N	N	P
4901	N	N	P	N	N	P
4936	N	N	P	N	N	P
4937	N	N	P	N	N	P
4947	N	N	P	N	N	P
N, Results	23	23	23	23	23	23
# Negative	23	23	1	23	23	1
# Positive	0	0	22	0	0	22
% Correct	100.0%	100.0%	95.7%	100.0%	100.0%	95.7%
% Incorrect	0.0%	0.0%	4.3%	0.0%	0.0%	4.3%

Table 20: Percentages of correct results, false negatives, and false positives in qualitative reports for Herculex for all participants.

Total # Reported results	138
# Incorrect	2
% Correct	98.6%
# Provided Positives	46
# False Negative	2
% False Negative	4.3%
# Provided Negatives	92
# False Positive	0
% False Positive	0.0%

Table 21: Qualitative results for corn fortified with MON863 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

MON863	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.6%	0.4%	1.3%	0.0%
1773	N	N	P	P	P	N
1785	N	N	P	P	P	N
1788	N	N	P	P	P	N
1859	N	N	P	P	P	N
1895	N	N	P	P	P	N
2005	N	N	P	P	P	N
2034	N	N	P	P	P	P
2039	N	N	P	P	P	N
2057	N	N	P	P	P	N
2060	N	N	P	P	P	N
2089	N	N	P	P	P	N
2113	N	N	P	P	N	N
2126	N	N	P	P	P	N
2560	N	N	P	P	P	N
2691	N	N	P	P	P	N
2694	N	N	P	P	P	N
2822	N	N	P	P	P	N
3929	N	N	P	P	P	N
4901	N	N	P	P	P	N
4932	N	N	P	P	P	N
4936	N	N	P	P	P	N
4937	N	N	P	P	P	N
4947	N	N	P	P	P	N
N, Results	23	23	23	23	23	23
# Negative	23	23	0	0	1	22
# Positive	0	0	23	23	22	1
% Correct	100.0%	100.0%	100.0%	100.0%	95.7%	95.7%
% Incorrect	0.0%	0.0%	0.0%	0.0%	4.3%	4.3%

Table 22: Percentages of correct results, false negatives, and false positives in qualitative reports for MON863 for all participants.

Total # Reported results	138
# Incorrect	2
% Correct	98.6%
# Provided Positives	69
# False Negative	1
% False Negative	1.4%
# Provided Negatives	69
# False Positive	1
% False Positive	1.4%

Table 23: Qualitative results for corn fortified with Herculex RW for all participants (DNA-based assays) (N = negative; P = positive).

Herculex RW	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.1%	0.0%	0.8%	0.0%
1761	N	N	N	N	N	P
1773	N	N	P	N	P	N
1785	N	N	P	N	P	N
1859	N	N	P	N	P	N
1862	N	N	P	N	P	N
1895	N	N	P	N	P	N
2005	N	N	P	N	P	N
2034	N	N	N *	N	P	N
2057	N	N	P	N	P	N
2060	N	N	P	N	P	N
2089	N	N	P	N	P	N
2113	N	N	P	N	P	P
2126	N	N	P	N	P	N
2560	N	N	P	N	P	N
2694	N	N	P	N	P	N
2822	N	N	P	N	P	N
3929	N	N	P	N	P	N
4901	N	N	P	N	P	N
4936	N	N	P	N	P	N
4937	N	N	P	N	P	N
4947	N	N	P	N	P	N
N, Results						
	21	21	21	21	21	21
# Negative						
	21	21	2	21	1	19
# Positive						
	0	0	19	0	20	2
% Correct						
	100.0%	100.0%	95.2%	100.0%	95.2%	90.5%
% Incorrect						
	0.0%	0.0%	4.8%	0.0%	4.8%	9.5%

* - Fortification level below participants' LOD, assessed as provided negative

Table 24: Percentages of correct results, false negatives, and false positives in qualitative reports for Herculex RW for all participants

Total # Reported results	126
# Incorrect	4
% Correct	96.8%
# Provided Positives	41
# False Negative	2
% False Negative	4.9%
# Provided Negatives	85
# False Positive	2
% False Positive	2.4%

Table 25: Qualitative results for corn fortified with MIR604 for all participants (DNA-based assays). (N = negative; P = positive; Incorrect results are shown in boldface).

MIR604	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.5%	0.0%	0.1%	0.0%	0.0%
1773	N	P	N	P	N	N
1785	N	P	N	P	N	N
1859	N	P	N	P	N	N
1895	N	P	N	N	N	N
2005	N	P	N	P	N	N
2034	N	N	P	P	N	N
2039	N	P	N	P	N	N
2057	N	P	N	P	N	N
2060	N	P	N	P	N	N
2089	N	P	N	P	N	N
2113	N	P	N	P	N	N
2126	N	P	N	P	N	N
2560	N	P	N	P	N	N
2691	N	P	N	P	N	N
2694	N	P	N	P	N	N
2822	N	P	N	P	N	N
2824	N	P	N	P	N	N
3929	N	P	N	P	N	N
4901	N	P	N	P	N	N
4932	N	P	N	P	N	N
4936	N	P	N	P	N	N
4937	N	P	N	P	N	N
4947	N	P	N	P	N	N
N, Results	23	23	23	23	23	23
# Negative	23	1	22	1	23	23
# Positive	0	22	1	22	0	0
% Correct	100.0%	95.7%	95.7%	95.7%	100.0%	100.0%
% Incorrect	0.0%	4.3%	4.3%	4.3%	0.0%	0.0%

Table 26: Percentages of correct results, false negatives, and false positives in qualitative reports for MIR604 for all participants.

# Reported results	138
# Incorrect	3
% Correct	97.8%
# Provided Positives	46
# False Negative	2
% False Negative	4.3%
# Provided Negatives	92
# False Positive	1
% False Positive	1.1%

Table 27: Qualitative results for corn fortified with Event 3272 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

Event 3272	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.2%	0.5%	0.0%	0.8%	0.0%
1773	N	P	P	N	P	N
1785	N	P	P	N	P	N
1859	N	P	P	N	P	N
2005	N	P	P	N	P	N
2034	N	P	P	N	P	N
2057	N	P	P	N	P	N
2113	N	P	P	N	P	N
2126	N	P	P	N	P	N
2716	N	P	P	N	P	N
2822	N	P	P	N	P	N
4901	N	P	P	N	P	N
4932	N	P	P	N	P	N
4937	N	P	P	N	P	N
N, Results	13	13	13	13	13	13
# Negative	13	0	0	13	0	13
# Positive	0	13	13	0	13	0
% Correct	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 28: Percentages of correct results, false negatives, and false positives in qualitative reports for Event 3272 for all participants.

# Reported results	78
# Incorrect	0
% Correct	100.0%
# Provided Positives	39
# False Negative	0
% False Negative	0.0%
# Provided Negatives	39
# False Positive	0
% False Positive	0.0%

Table 29: Qualitative results for Corn fortified with MON 88017 for all participants (DNA-based assays) (N = negative; P = positive).

MON 88017	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.0%	0.4%	0.9%	0.1%
1785	N	N	N	P	P	P
1859	N	N	N	P	P	P
1862	N	N	N	P	P	P
1875	N	N	N	P	P	P
1895	N	N	N	P	P	P
2005	N	N	N	P	P	P
2034	N	N	N	P	P	P
2039	N	N	N	P	P	P
2057	N	N	N	P	P	P
2060	N	N	N	P	P	N
2089	N	N	N	P	P	P
2113	N	N	N	P	P	P
2126	N	N	N	P	P	P
2560	N	N	N	P	P	NR*
2694	N	N	N	P	P	P
2716	N	N	N	P	P	P
2824	N	N	N	P	P	P
3929	N	N	N	P	P	P
4901	N	N	N	P	P	P
4932	N	N	N	P	P	P
4934	N	N	N	P	P	P
4936	N	N	N	P	P	P
4937	N	N	N	P	P	P
4945	N	N	N	P	P	P
4947	N	N	N	P	P	P
N, Results	25	25	25	25	25	24
# Negative	25	25	25	0	0	1
# Positive	0	0	0	25	25	23
% Correct	100%	100%	100%	100.0%	100.0%	95.8%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	4.2%

*NR- Not reported

Table 30: Percentages of correct results, false negatives, and false positives in qualitative reports for MON 88017 for all participants

# Reported results	149
# Incorrect	1
% Correct	99.3%
# Provided Positives	74
# False Negative	1
% False Negative	1.4%
# Provided Negatives	75
# False Positive	0
% False Positive	0.0%

Table 31: Qualitative results for corn fortified with MON 89034 for all participants (DNA-based assays) (N = negative; P = positive).

MON 89034	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.0%	0.6%	0.3%	0.8%
1785	N	N	N	P	P	P
1859	N	N	N	P	P	P
1862	N	N	N	P	P	P
1891	N	N	N	P	P	P
1895	N	N	N	P	P	P
2005	N	N	P	N	P	N
2034	N	N	N	N	P	P
2039	N	N	N	P	P	P
2057	N	N	N	P	P	P
2060	N	N	N	P	P	N
2089	N	N	N	P	P	P
2113	N	N	N	P	P	P
2126	N	N	N	P	P	P
2560	N	N	N	P	P	P
2694	N	N	N	P	P	P
4901	N	N	N	P	P	P
4932	N	N	N	P	P	P
4935	N	N	N	P	P	P
4936	N	N	N	P	P	P
4937	N	N	N	P	P	P
4947	N	N	N	P	P	P
N, Results	21	21	21	21	21	21
# Negative	21	21	20	2	0	2
# Positive	0	0	1	19	21	19
% Correct	100%	100%	95.2%	90.5%	100.0%	90.5%
% Incorrect	0.0%	0.0%	4.8%	9.5%	0.0%	9.5%

Table 32: Percentages of correct results, false negatives, and false positives in qualitative reports for MON 89034 for all participants

# Reported results	126
# Incorrect	5
% Correct	96.0%
# Provided Positives	63
# False Negative	4
% False Negative	6.3%
# Provided Negatives	63
# False Positive	1
% False Positive	1.6%

Table 33: Qualitative results for corn fortified with MIR 162 for all participants (DNA-based assays) (N = negative; P = positive).

MIR 162	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.0%	0.0%	0.0%	0.8%
1785	N	N	N	N	N	P
1859	N	N	N	N	N	P
1862	N	N	N	N	N	P
1870	N	N	N	N	N	P
1895	N	N	N	N	N	P
2039	N	N	N	N	N	P
2057	N	N	N	N	N	P
2126	N	N	N	N	N	P
2560	N	N	N	N	N	P
2694	N	N	N	N	N	P
2716	N	N	N	N	N	P
3928	N	N	N	N	N	P
4901	N	N	N	N	N	P
4947	N	N	N	N	N	P
N, Results	14	14	14	14	14	14
# Negative	14	14	14	14	14	0
# Positive	0	0	0	0	0	14
% Correct	100%	100%	100%	100.0%	100.0%	100%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 34: Percentages of correct results, false negatives, and false positives in qualitative reports for MIR 162 for all participants

# Reported results	84
# Incorrect	0
% Correct	100.0%
# Provided Positives	14
# False Negative	0
% False Negative	0.0%
# Provided Negatives	70
# False Positive	0
% False Positive	0.0%

Table 35: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

CP4 EPSPS (RUR I)	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	0.2%	0.5%	0.0%
1785	N	P	P	N
1859	N	P	P	N
1892	N	P	P	N
1895	N	P	P	N
2034	N	P	P	N
2057	N	P	P	N
2076	N	P	P	N
2113	N	P	P	N
2560	N	P	P	N
2691	N	P	P	N
2822	N	P	P	N
2830	N	P	P	N
4937	N	P	P	N
4947	N	P	P	N
N, Results	14	14	14	14
# Negative	14	0	0	14
# Positive	0	14	14	0
% Correct	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%

Table 36: Percentages of correct results, false negatives, and false positives in qualitative reports for CP4 EPSPS (Roundup Ready) for all participants

# Reported results	56
# Incorrect	0
% Correct	100.0%
# Provided Positives	28
# False Negative	0
% False Negative	0.0%
# Provided Negatives	28
# False Positive	0
% False Positive	0.0%

Table 37: Qualitative results for soybeans fortified with A2704-12 (Liberty Link Soy) for all participants (DNA-based assays) (N = negative; P = positive).

A2704-12	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	0.2%	0.0%	0.2%
1859	N	P	N	P
1875	N	P	N	P
1895	N	P	N	P
2034	N	P	N	P
2039	N	P	N	P
2057	N	P	N	P
2113	N	P	N	P
2560	N	P	N	P
2691	N	P	N	P
2716	N	P	N	P
3095	N	P	N	P
3928	N	P	N	P
4901	N	P	N	P
4932	N	P	N	P
4945	N	P	N	P
4947	N	P	N	P
N, Results	16	16	16	16
# Negative	16	0	16	0
# Positive	0	16	0	16
% Correct	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%

Table 38: Percentages of correct results, false negatives, and false positives in qualitative reports for A2704-12 (Liberty Link Soy) for all participants

Total # Reported results	64
# Incorrect	0
% Correct	100.0%
# Provided Positives	32
# False Negative	0
% False Negative	0.0%
# Provided Negatives	32
# False Positive	0
% False Positive	0.0%

Table 39: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready II) for all participants (DNA-based assays) (N = negative; P = positive)

RUR II	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	0.0%	0.3%	0.0%
1788	N	N	P	N
1859	N	N	P	N
1862	N	N	P	N
1875	N	N	P	N
1895	N	N	P	N
2039	N	N	P	N
2057	N	N	P	N
2560	N	N	P	N
2691	N	N	P	N
2716	N	N	P	N
2824	N	N	P	N
4932	N	N	P	N
4935	N	N	P	N
4937	N	N	P	N
4945	N	N	P	N
4947	N	N	P	N
N, Results	16	16	16	16
# Negative	16	16	0	16
# Positive	0	0	16	0
% Correct	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%

Table 40: Percentages of correct results, false negatives, and false positives in qualitative reports for CP4 EPSPS (Roundup Ready II) for all participants

Total # Reported results	64
# Incorrect	0
% Correct	100.0%
# Provided Positives	16
# False Negative	0
% False Negative	0.0%
# Provided Negatives	48
# False Positive	0
% False Positive	0.0%

Table 41: Composite percentages of correct results, false negatives, and false positives in qualitative reports for each transgenic event for all participants (DNA-based assays)

N = total number of results submitted for an event; % False Negative = [# False Negatives / # Provided Positives] x 100; % False Positives = [#False Positives / # Provided Negatives] x100.

Event	35S	NOS	T25	CBH351	MON810	GA21	Bt176
N, Results	234	252	150	48	132	150	120
Reported Incorrect	1	0	10	0	3	0	0
% Correct	99.6%	100.0%	93.3%	100.0%	97.7%	100.0%	100.0%
N, Provided Positives	195	210	50	0	107	75	40
N, False Negatives	0	0	1	0	3	0	0
% False Negative	0.0%	0.0%	2.0%	0.0%	2.8%	0.0%	0.0%
N, Provided Negatives	39	42	100	48	25	75	80
N, False Positives	1	0	9	0	0	0	0
% False Positives	2.6%	0.0%	9.0%	0.0%	0.0%	0.0%	0.0%

Event	Bt11	NK603	Herculex	MON863	HerculexRW	MIR604	EV3272
N, Results	132	131	138	138	126	138	78
Reported Incorrect	2	1	2	2	4	3	0
% Correct	98.5%	99.2%	98.6%	98.6%	96.8%	97.8%	100.0%
N, Provided Positives	66	22	46	69	41	46	39
N, False Negatives	2	0	2	1	2	2	0
% False Negative	3.0%	0.0%	4.3%	1.4%	4.9%	4.3%	0.0%
N, Provided Negatives	66	109	92	69	85	92	39
N, False Positives	0	1	0	1	2	1	0
% False Positives	0.0%	0.9%	0.0%	1.4%	2.4%	1.1%	0.0%

Event	MON88017	MON89034	MIR162	RUR	A2704-12	RUR II
N, Results	149	126	84	56	64	64
Reported Incorrect	1	5	0	0	0	0
% Correct	99.3%	96.0%	100.0%	100.0%	100.0%	100%
N, Provided Positives	74	63	14	28	32	16
N, False Negatives	1	4	0	0	0	0
% False Negative	1.4%	6.3%	0.0%	0.0%	0.0%	0.0%
N, Provided Negatives	75	63	70	28	32	48
N, False Positives	0	1	0	0	0	0
% False Positives	0.0%	1.6%	0.0%	0.0%	0.0%	0.0%

Figure 1: Group average of percentage correct for Qualitative reports on each event (DNA-based assays).

Embedded numbers represent the total number of reported results for that event. Data are shown on a composite basis (i.e., all participants results combined) extracted from the percentage correct scores in Table 41.

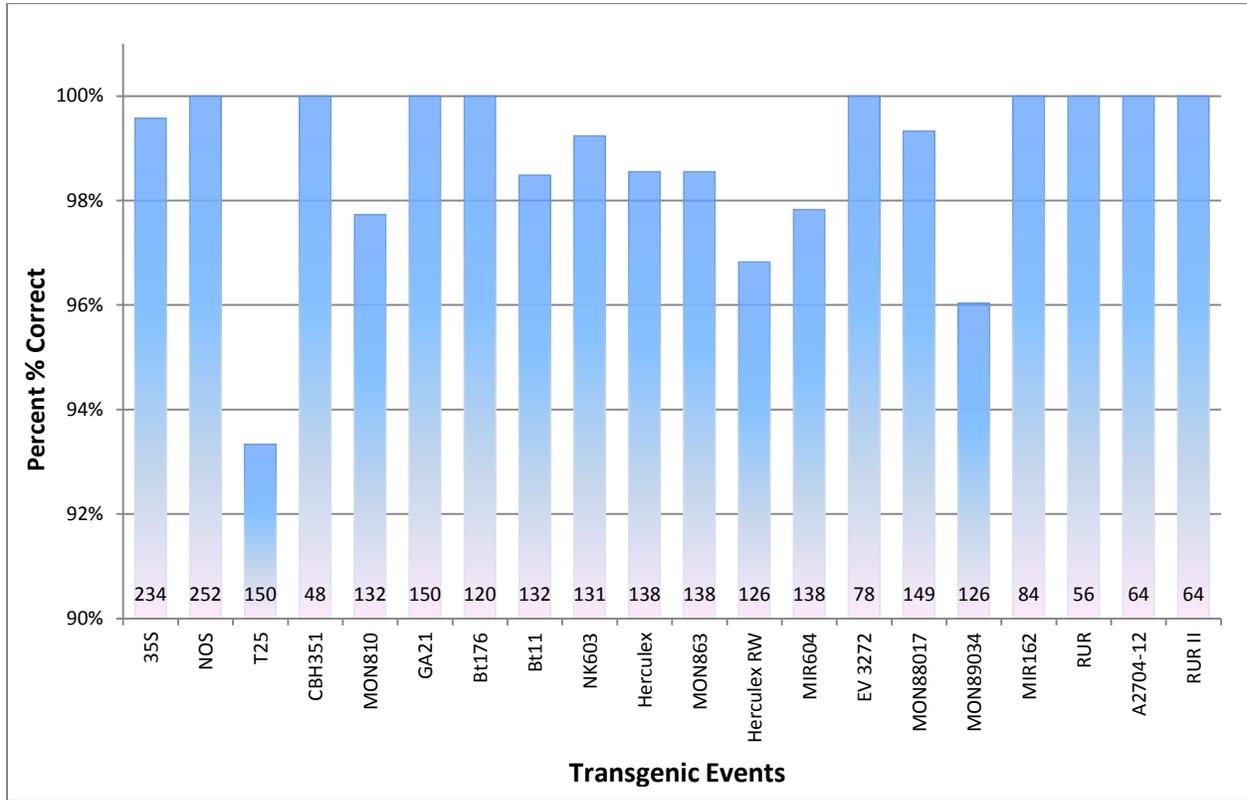


Table 42: Lateral Flow Strip (LFS) Testing (Protein-based testing) results for the detection of transgenic events in corn (N = negative; P = positive; NR = no result submitted; Incorrect results are shown in boldface).

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	LOD
T 25	0.0%	0.0%	0.4%	0.0%	0.0%	0.1%	
1843	N	N	N*	N	N	N*	0.5%
EPSPS (NK603/MON88017)	0.0%	0.0%	0.0%	0.7%	0.9%	0.1%	
1843	N	N	N	N	N	N*	0.5%
1895	N	P	P	P	P	P	0.1%
2824	N	N	N	P	P	P	0.2%
Cry1Ab (MON810/Bt11/Bt176)	0.0%	1.3%	1.4%	0.3%	0.7%	0.1%	
1843	N	P	N*	N*	P	N*	2.0%
1895	N	P	P	P	P	P	10.0%
Herculex	0.0%	0.0%	0.6%	0.0%	0.0%	0.6%	
1843	N	N	N	N	N	P	0.5%
1895	N	N	P	N	N	P	Not Provided
Cry3Bb1 (MON863/MON88017)	0.0%	0.0%	0.6%	0.7%	2.1%	0.1%	
1843	N	N	P	P	P	P	1.0%
1895	N	N	P	P	P	P	10.0%
2824	N	N	P	P	P	P	0.2%
Herculex RW	0.0%	0.0%	0.1%	0.0%	0.8%	0.0%	
1843	N	N	P	N	P	N	0.5%
1895	N	N	P	N	P	N	Not Provided
MIR 604	0.0%	0.5%	0.0%	0.1%	0.0%	0.0%	
1843	N	P	N	N*	N	N	2.0%
1895	N	P	N	N*	N	N	0.3%

* Fortification below LOD, assessed as a provided negative sample.

Table 43: Percentage of correct results, false negatives, and false positives in reports for transgenic events in corn using Lateral Flow Strip (LFS) Testing

Event	T25	EPSPS	Cry1Ab	Herculex	Cry3Bb1	Hclx RW	MIR 604
Total # Reported Results	6	18	12	12	18	12	12
# Incorrect	0	4	0	1	0	0	0
% Correct	100.0%	77.8%	100.0%	91.7%	100.0%	100.0%	100.0%
# Provided Positives	0	8	7	4	12	4	2
# False Negatives	0	2	0	1	0	0	0
% False Negatives	0.0%	12.5%	0.0%	25.0%	0.0%	0.0%	0.0%
# Provided Negatives	6	10	5	8	6	8	10
# False Positives	0	2	0	0	0	0	0
% False Positive	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 44: Results for soybeans fortified with CP4EPSPS (RUR) and A2704-12 (LL) for all participants using Lateral Flow Strip (LFS) Testing (N = negative; P = positive; (Incorrect results are shown in boldface).

CP4 EPSPS (RUR)	Sample 1	Sample 2	Sample 3	Sample 4	LOD
Participant Number	0.0%	0.2%	0.5%	0.0%	LOD
1782	N	P	P	N	Not Provided
1843	N	P	P	N	1.0%
1895	N	P	P	N	0.1%
2126	N	P	P	N	Not Provided

N, Results	4	4	4	4
# Negative	4	0	0	4
# Positive	0	4	4	0
% Correct	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%

A2704-12 (Liberty Link)	0.0%	0.0%	0.2%	0.2%	LOD
1843	N	N	N *	N*	0.5%

Table 45: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for all participants using Lateral Flow Strip (LFS) Testing

Event	RUR	LL
Total # Reported results	16	4
# Incorrect	0	0
% Correct	100.0%	100.0%
# Provided Positives	8	0
# False Negative	0	0
% False Negative	0.0%	0.0%
# Provided Negatives	8	4
# False Positive	0	0
% False Positive	0.0%	0.0%

Table 46: Results for the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing)

Participant	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	LOD
Herculex	0.0%	0.0%	0.6%	0.0%	0.0%	0.6%	
1895	N	N	P	N	N	P	0.10%
CBH 351	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
1754	N	N	N	N	N	N	0.10%
1895	N	N	N	N	N	N	0.01%
Cry3Bb1 (MON863/MON88017)	0.0%	0.0%	0.6%	0.7%	2.1%	0.1%	
1895	N	N	P	P	P	P	Not Provided

Table 47: Percentage of correct results in the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing)

Event	Herculex	CBH 351	Cry3Bb1
Total # Reported results	6	12	6
# Incorrect	0	0	0
% Correct	100.0%	100.0%	100.0%
# Provided Positives	2	0	4
# False Negative	0	0	0
% False Negative	0.0%	0.0%	0.0%
# Provided Negatives	4	12	2
# False Positive	0	0	0
% False Positive	0.0%	0.0%	0.0%

Table 48: Results for soybeans fortified with CP4EPSPS for participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

CP4 EPSPS (RUR & RURII)	Sample 1	Sample 2	Sample 3	Sample 4	LOD
Participant Number	0.0%	0.2%	0.8%	0.0%	LOD
1754	0.0	0.1	0.5	0.0	0.1%
1782	0.0	0.1	0.6	0.0	Not Provided
1843	0.0	0.3	1.0	0.0	0.1%

Table 49: Percentage of correct results in qualitative reports for CP4EPSPS for participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing)

Total # Reported results	12
# Incorrect	0
% Correct	100.0%
# Provided Positives	6
# False Negative	0
% False Negative	0.0%
# Provided Negatives	6
# False Positive	0
% False Positive	0.0%

Table 50: Quantitative results and z-scores for corn fortified with T25 for all participants (DNA-based assays). Value highlighted in yellow indicates a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier. Quantifications marked in red indicate values determined to be either: (1) an outlier by the “Grubb’s Test for Outliers”; (2) a negative value for a fortified sample (i.e. a false negative result); or (3) a positive value for a non-fortified sample (i.e. a false positive result).

Event: T-25								
%w/w Fortification Level	0.0%	0.0%	0.5%		0.0%	0.0%	0.1%	
Consensus Mean	0.0%	0.0%	0.36%		0.0%	0.0%	0.12%	
Participant Number	Result	Result	Result	z-score	Result	Result	Result	z-score
1754	0.00	0.00	0.40	0.25	0.00	0.00	<.05	
1764	0.40	0.30	0.70	2.29	1.00	0.00	1.00	10.86
1780	0.00	0.00	0.40	0.25	0.00	0.00	0.10	-0.28
1783	0.00	0.00	0.39	0.18	0.00	0.00	0.09	-0.41
1870	0.00	0.00	0.40	0.25	0.00	0.00	0.10	-0.28
1875	0.00	0.00	0.24	-0.85	0.00	0.00	0.05	-0.90
1891	0.00	0.00	0.36	-0.03	0.00	0.00	0.11	-0.16
2716	0.00	0.00	0.37	0.04	0.00	0.00	0.00	
2721	0.00	0.00	0.18	-1.25	0.00	0.00	0.11	-0.16
4946	0.00	0.00	0.20	-1.12	0.00	0.00	0.30	2.19

Table 51: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays). The value marked in red denotes a positive value for a non-fortified sample (i.e. a false positive result).

Event: CBH351						
%w/w Fortification Level	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Participant Number	Result	Result	Result	Result	Result	Result
1754	0.00	0.00	0.00	0.00	0.00	0.00
1764	0.00	0.00	0.10	0.00	0.00	0.00
1870	0.00	0.00	0.00	0.00	0.00	0.00
1875	0.00	0.00	0.00	0.00	0.00	0.00
1891	0.00	0.00	0.00	0.00	0.00	0.00
2005	0.00	0.00	0.00	0.00	0.00	0.00

Table 52: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays). Values highlighted in **yellow** indicates a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier. Quantifications marked in **red** indicate values determined to be either: (1) an outlier by the “Grubb’s Test for Outliers”; or (2) a negative value for a fortified sample (i.e. a false negative result).

Event: MON810											
%w/w Fortification Level	0.0%	0.5%		0.1%		0.5%		0.2%		0.1%	
Consensus Mean	0.0%	0.19%		0.06%		0.27%		0.13%		0.10%	
Participant Number	Result	Result	z-score								
1754	0.00	0.10	-1.23	0.00		0.20	-0.51	0.05	-1.54	0.10	-0.01
1761	0.00	0.15	-0.57	0.04	-0.28	0.20	-0.51	0.10	-0.36	0.04	-0.76
1764	0.00	0.30	1.40	0.60	7.39	0.00		0.00		0.10	-0.01
1780	0.00	0.20	0.09	0.04	-0.28	0.30	0.25	0.10	-0.36	0.06	-0.51
1783	0.00	0.17	-0.31	0.03	-0.42	0.36	0.71	0.19	1.77	0.04	-0.76
1785	0.00	0.13	-0.83	0.03	-0.42	0.20	-0.51	0.10	-0.36	0.03	-0.88
1788	0.00	0.21	0.22	0.00		0.25	-0.13	<0.1		<0.1	
1870	0.00	0.21	0.22	0.05	-0.14	0.20	-0.51	0.10	-0.36	0.03	-0.88
1875	0.00	0.20	0.09	0.03	-0.42	0.18	-0.67	0.10	-0.36	0.05	-0.63
1891	0.00	0.17	-0.31	<0.1		0.23	-0.28	<0.1		<0.1	
2005	0.00	0.23	0.48	<0.05		0.25	-0.13	0.12	0.11	0.10	-0.01
2112	0.00	0.34	1.86	0.08	0.27	0.38	0.82	0.18	1.41	0.10	-0.01
2708	0.00	0.04	-2.01	0.01	-0.75	0.04	-1.71	0.02	-2.25	0.02	-1.01
2716	0.00	0.40	2.71	0.10	0.54	0.45	1.39	0.18	1.53	0.20	1.23
2721	0.00	0.14	-0.70	0.29	3.15	0.57	2.31	0.13	0.35	0.25	1.85
3095	0.00	0.20	0.09	0.05	-0.14	0.25	-0.13	0.14	0.58	0.10	-0.01
3926	0.00	0.16	-0.44	0.02	-0.55	0.21	-0.44	0.08	-0.83	0.29	2.34
3928	0.00	0.16	-0.44	<0.1		0.23	-0.28	0.10	-0.36	<0.1	
3929	0.00	0.68	6.04	P*		0.58	2.38	0.36	5.78	P*	
4504	0.00	0.00		0.00		0.00		5.72	132.35	0.00	
4932	0.00	0.17	-0.31	0.02	-0.55	0.16	-0.82	0.16	1.06	0.07	-0.39
4934	0.00	0.20	0.09	0.01	-0.69	0.10	-1.28	0.08	-0.83	0.04	-0.76
4936	0.00	0.21	0.22	<0.1		0.32	0.40	0.12	0.11	<0.1	
4945	0.00	0.17	-0.31	0.00		0.18	-0.67	0.12	0.11	0.00	
4948	0.00	0.95	9.58	0.11	0.68	0.31	0.33	0.14	0.58	0.20	1.23

* Qualitative data only, see Qualitative Table #9

Table 53: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays). Z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ that are not considered an outlier, were not observed in this data set. Quantifications marked in **red** indicate values determined to be either: (1) an outlier by the “Grubb’s Test for Outliers”; (2) a negative value for a fortified sample (i.e. a false negative result); or (3) a positive value for a non-fortified sample (i.e. a false positive result).

Event: GA21									
%w/w Fortification Level	0.0%	0.2%		1.0%		0.8%		0.0%	0.0%
Consensus Mean	0.0%	0.14%		0.47%		0.62%		0.0%	0.0%
Participant Number	Result	Result	z-score	Result	z-score	Result	z-score	Result	Result
1754	0.00	0.10	-0.93	0.10	-1.57	0.40	-1.01	0.00	0.00
1761	0.00	0.21	1.54	0.90	1.84	0.90	1.32	0.00	0.00
1764	0.00	1.50	30.51	0.70	0.99	0.00		0.20	0.50
1780	0.00	0.20	1.32	0.60	0.56	0.60	-0.08	0.00	0.00
1783	0.00	0.17	0.64	0.32	-0.63	0.65	0.15	0.00	0.00
1870	0.00	0.14	-0.03	0.60	0.56	0.60	-0.08	0.00	0.00
1875	0.00	0.12	-0.48	0.33	-0.59	0.38	-1.10	0.00	0.00
1891	0.00	0.14	-0.03	0.63	0.69	0.64	0.11	0.00	0.00
2694	0.00	P < LQ		0.42	-0.21	0.52	-0.45	0.00	0.00
2708	0.00	0.05		0.16	-1.32	0.37	-1.15	0.00	0.00
3095	0.00	0.14	-0.03	0.28	-0.80	0.60	-0.08	0.00	0.00
3926	0.00	0.18	0.87	0.64	0.73	0.61	-0.03	0.00	0.00
3928	0.00	0.17	0.64	0.74	1.16	0.97	1.65	0.00	0.00
4504	0.00	0.00		0.00		0.00		0.00	0.00
4932	0.00	0.15	0.19	0.30	-0.72	0.55	-0.31	0.00	0.00
4934	0.00	0.08	-1.38	0.20	-1.14	0.27	-1.62	0.00	0.00
4945	0.00	0.13	-0.26	0.58	0.47	0.81	0.90	0.00	0.00
4946	0.00	0.00		0.00		1.00	1.79	0.00	0.00

Table 54: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays). Value highlighted in yellow indicates a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier. The quantifications marked in red indicate either (1) an outlier by the “Grubb’s Test for Outliers”; or (2) a negative value for a fortified sample (i.e. a false negative result).

Event: Bt176								
%w/w Fortification Level	0.0%	0.5%		0.1%		0.0%	0.0%	0.0%
Consensus Mean	0.0%	0.38%		0.10%		0.0%	0.0%	0.0%
Participant Number	Result	Result	Z-score	Result	Z-score	Result	Result	Result
1754	0.00	0.50	0.97	0.10	-0.03	0.00	0.00	0.00
1761	0.00	0.65	2.14	0.21	1.72	0.00	0.00	0.00
1764	0.00	0.50	0.97	0.50	6.33	0.00	0.00	0.00
1780	0.00	0.40	0.19	0.10	-0.03	0.00	0.00	0.00
1783	0.00	0.26	-0.90	0.07	-0.50	0.00	0.00	0.00
1788	0.00	0.38	0.03	<0.1		0.00	0.00	0.00
1870	0.00	0.40	0.19	0.10	-0.03	0.00	0.00	0.00
1875	0.00	0.27	-0.82	0.05	-0.82	0.00	0.00	0.00
1891	0.00	0.33	-0.36	<0.1		0.00	0.00	0.00
2005	0.00	<0.05		0.22	1.88	0.00	0.00	0.00
2694	0.00	0.26	-0.90	P <LQ		0.00	0.00	0.00
2708	0.00	0.13	-1.91	0.02	-1.30	0.00	0.00	0.00
2716	0.00	0.44	0.50	0.10	-0.03	0.00	0.00	0.00
2822	0.00	0.40	0.19	0.10	-0.03	0.00	0.00	0.00
3926	0.00	0.32	-0.43	0.02	-1.30	0.00	0.00	0.00
4932	0.00	0.51	1.05	0.13	0.45	0.00	0.00	0.00
4945	0.00	0.26	-0.90	<0.1		0.00	0.00	0.00
4946	0.00	0.00		0.90	12.69	0.00	0.00	0.00

Table 55: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate a negative value for a fortified sample (i.e. a false negative result).

Event: Bt11									
%w/w Fortification Level	0.0%	1.0%		2.0%		0.0%	0.5%		0.0%
Consensus Mean	0.0%	0.75%		1.22%		0.0%	0.55%		0.0%
Participant Number	Result	Result	z-score	Result	z-score	Result	Result	z-score	Result
1754	0.00	0.60	-0.47	1.30	0.18	0.00	0.40	-0.62	0.00
1761	0.00	0.30	-1.42	0.50	-1.48	0.00	0.20	-1.44	0.00
1764	0.00	0.00		0.70	-1.07	0.00	0.00		0.20
1780	0.00	0.80	0.16	1.70	1.01	0.00	0.80	1.02	0.00
1783	0.00	0.54	-0.66	1.06	-0.32	0.00	0.50	-0.21	0.00
1788	0.00	0.62	-0.41	0.87	-0.72	0.00	0.34	-0.87	0.00
1870	0.00	0.90	0.48	1.50	0.59	0.00	0.50	-0.21	0.00
1875	0.00	0.62	-0.41	1.42	0.43	0.00	0.53	-0.09	0.00
1891	0.00	0.63	-0.38	1.50	0.59	0.00	0.54	-0.05	0.00
2005	0.00	1.10	1.11	1.90	1.42	0.00	0.99	1.80	0.00
2694	0.00	0.90	0.48	1.64	0.88	0.00	0.92	1.51	0.00
2708	0.00	0.35	-1.28	0.02	-2.48	0.00	0.38	-0.70	0.00
2716	0.00	0.61	-0.44	1.46	0.51	0.00	0.45	-0.42	0.00
2721	0.00	0.93	0.57	1.40	0.38	0.00	0.60	0.20	0.00
2822	0.00	0.40	-1.11	1.00	-0.45	0.00	0.20	-1.44	0.00
3926	0.00	0.61	-0.44	1.34	0.26	0.00	0.48	-0.29	0.00
3928	0.00	1.45	2.22	1.80	1.21	0.00	0.78	0.94	0.00
4932	0.00	1.27	1.65	1.21	-0.01	0.00	0.93	1.55	0.00
4934	0.00	0.50	-0.79	0.56	-1.36	0.00	0.24	-1.28	0.00
4945	0.00	1.10	1.11	1.42	0.43	0.00	0.70	0.61	0.00

Table 56: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays). Value highlighted in yellow indicates a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate either (1) a negative value for a fortified sample (i.e. a false negative result); or (2) a positive value for a non-fortified sample (i.e. a false positive result).

Event: NK603							
%w/w Fortification Level	0.0%	0.0%	0.0%	0.5%		0.0%	0.0%
Consensus Mean	0.0%	0.0%	0.0%	0.35%		0.0%	0.0%
Participant Number	Result	Result	Result	Result	z-score	Result	Result
1754	0.00	0.00	0.00	0.20	-0.82	0.00	0.00
1764	0.00	1.50	0.70	0.00		0.20	1.00
1780	0.00	0.00	0.00	0.40	0.29	0.00	0.00
1783	0.00	0.00	0.00	0.15	-1.10	0.00	0.00
1870	0.00	0.00	0.00	0.34	-0.04	0.00	0.00
1875	0.00	0.00	0.00	0.68	1.85	0.89	0.09
1891	0.00	0.00	0.00	0.30	-0.27	0.00	0.00
2694	0.00	0.00	0.00	0.28	-0.38	0.00	0.00
2708	0.00	0.00	0.00	0.18	-0.95	0.00	0.00
2716	0.00	0.00	0.00	0.79	2.46	0.00	0.00
2721	0.00	0.00	0.00	0.38	0.18	0.00	0.00
2822	0.00	0.00	0.00	0.50	0.85	0.00	0.00
3926	0.00	0.00	0.00	0.25	-0.55	0.00	0.00
4504	0.00	0.00	0.00	0.00		0.00	0.00
4932	0.00	0.00	0.00	0.40	0.29	0.00	0.00
4934	0.00	0.00	0.00	0.24	-0.60	0.00	0.00
4945	0.00	0.00	0.00	0.15	-1.10	0.00	0.00
4946	0.00	0.00	0.00	0.45	0.57	0.00	0.00
4948	0.00	0.00	0.00	0.23	-0.66	0.00	0.00

Table 57: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ that are not considered outliers. Quantifications marked in red indicate either (1) an outlier by the “Grubb’s Test for Outliers”; or (2) a negative value for a fortified sample (i.e. a false negative result).

Event: Herculex								
%w/w Fortification Level	0.0%	0.0%	1.5%		0.0%	0.0%	0.8%	
Consensus Mean	0.0%	0.0%	0.64%		0.0%	0.0%	0.57%	
Participant Number	Result	Result	Result	z-score	Result	Result	Result	z-score
1754	0.00	0.00	0.40	-0.70	0.00	0.00	0.30	-0.84
1764	0.00	0.00	0.10	-1.60	0.00	0.00	0.00	
1780	0.00	0.00	0.60	-0.11	0.00	0.00	0.50	-0.21
1783	0.00	0.00	0.59	-0.14	0.00	0.00	0.63	0.20
1870	0.00	0.00	0.55	-0.26	0.00	0.00	0.40	-0.52
1875	0.00	0.00	0.42	-0.64	0.00	0.00	0.37	-0.62
1891	0.00	0.00	0.54	-0.29	0.00	0.00	0.51	-0.18
2708	0.00	0.00	0.32	-0.94	0.00	0.00	0.59	0.06
2716	0.00	0.00	0.86	0.66	0.00	0.00	1.41	2.63
2721	0.00	0.00	0.89	0.75	0.00	0.00	0.66	0.29
3095	0.00	0.00	1.50	2.57	0.00	0.00	0.00	
3928	0.00	0.00	1.01	1.11	0.00	0.00	0.81	0.76
4504	0.00	0.00	3.60	8.82	0.00	0.00	0.00	
4932	0.00	0.00	0.79	0.46	0.00	0.00	0.74	0.54
4934	0.00	0.00	0.45	-0.56	0.00	0.00	0.08	-1.52
4945	0.00	0.00	0.53	-0.32	0.00	0.00	0.38	-0.59

Table 58: Quantitative results and z-scores for corn fortified with MON863 for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate values determined to be either: (1) an outlier by the “Grubb’s Test for Outliers”; (2) a negative value for a fortified sample (i.e. a false negative result): or (3) a positive value for a non-fortified sample (i.e. a false positive result).

Event: MON863									
%w/w Fortification Level	0.0%	0.0%	0.8%		0.5%		1.5%		0.0%
Consensus Mean	0.0%	0.0%	0.61%		0.38%		1.25%		0.0%
Participant Number	Result	Result	Result	z-score	Result	z-score	Result	z-score	Result
1754	0.00	0.00	0.70	0.32	0.30	-0.63	1.30	0.12	0.00
1764	2.00	3.00	0.00		0.00		0.00		0.20
1780	0.00	0.00	0.60	-0.05	0.40	0.19	1.20	-0.10	0.00
1783	0.00	0.00	0.81	0.73	0.35	-0.22	1.80	1.22	0.00
1870	0.00	0.00	0.63	0.06	0.40	0.19	1.00	-0.54	0.00
1875	0.00	0.00	0.56	-0.20	0.28	-0.80	1.22	-0.06	0.00
1891	0.00	0.00	0.65	0.13	0.44	0.52	1.39	0.31	0.00
2694	0.00	0.00	0.54	-0.28	P*		0.96	-0.63	0.00
2708	0.00	0.00	0.40	-0.80	0.35	-0.23	0.82	-0.94	0.00
2716	0.00	0.00	0.60	-0.05	0.40	0.19	1.50	0.56	0.00
2721	0.00	0.00	1.36	2.79	0.50	1.01	2.21	2.12	0.00
2822	0.00	0.00	0.40	-0.80	0.60	1.83	1.10	-0.32	0.00
4945	0.00	0.00	0.24	-1.40	0.13	-2.03	0.47	-1.71	0.00
4946	0.00	0.00	0.50	-0.43	2.00	13.33	0.00		0.00

* Qualitative data only, see Qualitative Table #21

Table 59: Quantitative results and z-scores for corn fortified with Herculex RW for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate a negative value for a fortified sample (i.e. a false negative result).

Event: Herculex RW								
%w/w Fortification Level	0.0%	0.0%	0.1%		0.0%	0.5%		0.0%
Consensus Mean	0.0%	0.0%	0.11%		0.0%	0.79%		0.0%
Participant Number	Result	Result	Result	z-score	Result	Result	z-score	Result
1754	0.00	0.00	0.10	-0.19	0.00	0.90	0.38	0.00
1764	0.00	0.00	0.10	-0.19	0.00	0.00		0.00
1780	0.00	0.00	0.10	-0.19	0.00	0.80	0.03	0.00
1783	0.00	0.00	0.03	-1.40	0.00	0.41	-1.35	0.00
1870	0.00	0.00	0.13	0.33	0.00	0.70	-0.33	0.00
1875	0.00	0.00	0.20	1.54	0.00	0.92	0.45	0.00
1891	0.00	0.00	0.24	2.24	NR	1.46	2.36	0.00
2708	0.00	0.00	0.08	-0.54	0.00	0.61	-0.64	0.00
2716	0.00	0.00	0.10	-0.19	0.00	0.55	-0.86	0.00
4932	0.00	0.00	0.08	-0.54	0.00	0.78	-0.04	0.00
4945	0.00	0.00	0.10	-0.19	0.00	0.79	-0.01	0.00
4946	0.00	0.00	0.06	-0.88	0.00	0.00		0.00

Table 60: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays). Z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ were not observed in this data set. Quantifications marked in red indicate a negative value for a fortified sample (i.e. a false negative result).

Event: MIR604								
%w/w Fortification Level	0.0%	0.8%		0.0%	0.2%		0.0%	0.0%
Consensus Mean	0.0%	0.51%		0.0%	0.14%		0.0%	0.0%
Participant Number	Result	Result	z-score	Result	Result	z-score	Result	Result
1754	0.00	0.50	-0.11	0.00	0.10	-1.11	0.00	0.00
1764	0.00	0.00		0.00	0.00		0.00	0.00
1780	0.00	0.60	0.78	0.00	0.20	1.39	0.00	0.00
1870	0.00	0.44	-0.64	0.00	0.15	0.14	0.00	0.00
1875	0.00	0.45	-0.55	0.00	0.10	-1.11	0.00	0.00
1891	0.00	0.43	-0.73	0.00	0.13	-0.36	0.00	0.00
2708	0.00	0.38	-1.18	0.00	0.16	0.39	0.00	0.00
2716	0.00	0.72	1.85	0.00	0.20	1.39	0.00	0.00
2721	0.00	0.46	-0.46	0.00	0.10	-1.11	0.00	0.00
4945	0.00	0.63	1.05	0.00	0.16	0.39	0.00	0.00

Table 61: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays). Z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ were not observed in this data set. Quantifications marked in **red** indicate either (1) a negative value for a fortified sample (i.e. a false negative result); or (2) a positive value for a non-fortified sample (i.e. a false positive result).

Event: Event 3272									
%w/w Fortification Level	0.0%	0.2%		1.0%		0.0%	0.8%		0.0%
Target Value	0.0%	0.18%		0.54%		0.0%	0.80%		0.0%
Participant Number	Result	Result	z-score	Result	z-score	Result	Result	z-score	Result
1754	0.00	0.20	0.25	0.90	1.15	0.00	1.20	0.98	0.00
1764	0.00	0.30	1.50	0.10	-1.39	0.00	0.00		0.00
1780	0.00	0.20	0.25	0.80	0.83	0.00	1.20	0.98	0.00
1870	0.00	0.20	0.25	0.80	0.83	0.00	1.00	0.49	0.00
1875	0.00	0.08	-1.25	0.46	-0.25	0.00	0.53	-0.66	0.00
1891	0.00	<0.1		0.35	-0.60	0.00	0.60	-0.49	0.00
2721	0.00	0.21	0.37	0.74	0.64	0.00	0.97	0.42	0.00
4934	0.00	0.07	-1.37	0.15	-1.23	0.00	0.10	-1.72	0.00
4946	0.00	0.00		0.00		0.15	0.00		0.00

Table 62: Quantitative results and z-scores for corn fortified with MON 88017 for all participants (DNA-based assays). Z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ were not observed in this data set. Quantifications marked in **red** indicate either (1) a negative value for a fortified sample (i.e. a false negative result); or (2) a positive value for a non-fortified sample (i.e. a false positive result).

Event: MON 88017									
%w/w Fortification Level	0.0%	0.0%	0.0%	0.5%		1.0%		0.1%	
Consensus Mean	0.0%	0.0%	0.0%	0.36%		0.88%		0.10%	
Participant Number	Result	Result	Result	Result	z-score	Result	z-score	Result	z-score
1754	0.00	0.00	0.00	0.20	-0.76	0.40	-0.88	0.08	-0.39
1764	0.10	0.00	0.00	0.00		1.50	1.15	0.10	0.00
1773	0.00	0.00	0.00	0.40	0.18	0.80	-0.14	<0.1	
1780	0.00	0.00	0.00	0.50	0.65	0.80	-0.14	0.10	0.00
1783	0.00	0.00	0.00	0.70	1.59	1.83	1.75	0.11	0.19
1870	0.00	0.00	0.00	0.45	0.42	1.10	0.41	0.10	0.00
1891	0.00	0.00	0.00	0.52	0.75	1.22	0.63	0.13	0.58
2708	0.00	0.00	0.00	0.01	-1.68	0.02	-1.58	0.002	-1.90
2721	0.00	0.00	0.00	0.31	-0.24	0.61	-0.49	0.20	1.93
4948	0.00	0.00	0.00	0.17	-0.90	0.50	-0.70	0.08	-0.39

Table 63: Quantitative results and z-scores for corn fortified with MON 89034 for all participants (DNA-based assays). Value highlighted in yellow indicates a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate a negative value for a fortified sample (i.e. a false negative result).

Event: MON 89034									
%w/w Fortification Level	0.0%	0.0%	0.0%	1.0%		0.5%		2.0%	
Consensus Mean	0.0%	0.0%	0.0%	0.56%		0.28%		0.81%	
Participant Number	Result	Result	Result	Result	z-score	Result	z-score	Result	z-score
1754	0.00	0.00	0.00	0.40	-0.67	0.30	0.19	0.90	0.20
1764	0.00	0.00	0.00	0.90	1.40	0.00		1.00	0.42
1773	0.00	0.00	0.00	0.60	0.16	0.40	1.02	1.00	0.42
1780	0.00	0.00	0.00	0.50	-0.25	0.30	0.19	0.80	-0.01
1783	0.00	0.00	0.00	0.62	0.24	0.17	-0.89	0.77	-0.08
1870	0.00	0.00	0.00	0.62	0.24	0.30	0.19	1.30	1.07
2708	0.00	0.00	0.00	0.01	-2.29	0.004	-2.26	0.07	-1.59
2721	0.00	0.00	0.00	0.91	1.44	0.34	0.52	0.14	-1.44
4504	0.00	0.00	0.00	0.54	-0.09	0.37	0.77	0.54	-0.57
4945	0.00	0.00	0.00	0.58	0.08	0.31	0.27	1.54	1.59
4946	0.00	0.00	0.00	0.50	-0.25	0.00		0.00	

Table 64: Quantitative results and z-scores for corn fortified with MIR162 for all participants (DNA-based assays). Z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ were not observed in this data set. Quantifications marked in red indicate either (1) a negative value for a fortified sample (i.e. a false negative result); or (2) a positive value for a non-fortified sample (i.e. a false positive result).

Event: MIR 162							
%w/w Fortification Level	0.0%	0.0%	0.0%	0.0%	0.0%	0.8%	
Consensus Mean	0.0%	0.0%	0.0%	0.0%	0.0%	0.83%	
Participant Number	Result	Result	Result	Result	Result	Result	z-score
1754	0.00	0.00	0.00	0.00	0.00	1.10	0.99
1764	0.00	0.00	0.00	0.00	0.00	0.00	
1773	0.00	0.00	0.00	0.00	0.00	0.80	-0.11
1780	0.00	0.00	0.00	0.00	0.00	0.50	-1.21
1783	0.00	0.32	0.32	0.10	0.57	0.64	-0.70
4932	0.00	0.00	0.00	0.00	0.00	1.11	1.03

Table 65: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS (RUR) for all participants (DNA-based assays). Z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ that are not considered an outlier, were not observed in this data set. Quantifications marked in red indicate values determined to be either: (1) an outlier by the “Grubb’s Test for Outliers”; (2) a negative value for a fortified sample (i.e. a false negative result); or (3) a positive value for a non-fortified sample (i.e. a false positive result).

Event: RUR						
%w/w Fortification Level	0.0%	0.2%		0.8%		0.0%
Consensus Mean	0.0%	0.18%		0.51%		0.0%
Participant Number	Result	Result	z-score	Result	z-score	Result
1754	0.00	0.20	0.50	0.50	-0.09	0.00
1761	0.00	0.21	0.70	0.35	-1.47	0.01
1764	0.20	0.50	6.66	0.00		1.00
1773	0.00	0.20	0.50	0.60	0.83	<0.1
1780	0.00	0.20	0.50	0.60	0.83	0.00
1783	0.00	0.22	0.91	0.53	0.19	0.00
1785	0.00	P *		0.33	-1.65	0.00
1788	0.00	0.16	-0.33	0.52	0.09	<0.1
1870	0.00	0.20	0.50	0.50	-0.09	0.00
1875	0.00	0.11	-1.35	0.45	-0.55	0.00
1891	0.00	0.21	0.70	0.58	0.65	0.00
2005	0.00	0.10	-1.56	0.59	0.74	0.00
2031	0.00	0.18	0.08	0.55	0.37	0.00
2039	0.00	0.20	0.50	0.60	0.83	0.00
2060	0.00	0.15	-0.53	0.29	-2.02	0.00
2112	0.00	0.19	0.29	0.59	0.69	0.00
2691	0.00	0.15	-0.53	0.48	-0.27	0.00
2716	0.00	0.12	-1.15	2.11	14.72	0.00
2721	0.00	0.08	-1.97	0.63	1.11	0.00
3095	0.00	0.25	1.52	0.70	1.75	0.00
3928	0.00	0.16	-0.33	0.36	-1.38	0.00
4901	0.00	0.21	0.70	0.60	0.83	0.00
4932	0.00	0.26	1.73	0.46	-0.46	0.00
4934	0.00	0.50	6.66	1.84	12.24	0.00
4945	0.00	0.11	-1.35	0.41	-0.92	0.00
4946	0.00	3.78	74.06	8.63	74.72	0.00

* Qualitative data only, see Qualitative Table 35

Table 66: Quantitative results and z-scores for soybeans fortified with A2704-12 (Liberty Link) for all participants (DNA-based assays). Value highlighted in yellow indicates a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate a negative value for a fortified sample (i.e. a false negative result).

Event: A2704-12						
%w/w Fortification Level	0.0%	0.2%		0.0%	0.1%	
Consensus Mean	0.0%	0.24%		0.0%	0.15%	
Participant Number	Result	Result	z-score	Result	Result	z-score
1754	0.00	0.30	1.02	0.00	0.20	0.67
1761	0.00	0.30	1.02	0.00	0.20	0.67
1764	0.00	0.00		0.00	0.00	
1773	0.00	0.15	-1.48	0.00	0.10	-0.69
1780	0.00	0.20	-0.65	0.00	0.10	-0.69
1783	0.00	0.16	-1.32	0.00	0.07	-1.10
1785	0.00	0.00		0.00	0.06	-1.24
1870	0.00	0.23	-0.15	0.00	0.30	2.03
1891	0.00	0.26	0.35	0.00	0.18	0.39
2005	0.00	0.24	0.02	0.00	0.17	0.26
2721	0.00	0.31	1.19	0.00	0.13	-0.29
4934	0.00	0.00		0.00	0.00	
4946	0.00	0.00		0.00	0.00	

Table 67: Quantitative results and z-scores for soybeans fortified with Roundup Ready II (CP4 EPSPS) for all participants (DNA-based assays). Z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$, were not observed in this data set. Quantification marked in red indicates a value determined to be an outlier by the “Grubb’s Test for Outliers”.

Event: RUR II					
%w/w Fortification Level	0.0%	0.0%	0.5%	0.0%	
Consensus Mean	0.0%	0.0%	0.30%	0.0%	
Participant Number	Result	Result	Result	z-score	Result
1754	0.00	0.00	0.40	0.98	0.00
1761	0.00	0.00	0.20	-0.92	0.00
1764	0.00	0.00	0.00		0.00
1773	0.00	0.00	0.40	0.98	0.00
1780	0.00	0.00	0.40	0.98	0.00
1785	0.00	0.00	0.33	0.31	0.00
1870	0.00	0.00	0.42	1.17	0.00
1891	0.00	0.00	0.35	0.50	0.00
2005	0.00	0.00	0.30	0.03	0.00
2721	0.00	0.00	0.10	-1.87	0.00
3095	0.00	0.00	0.30	0.03	0.00
4901	0.00	0.00	0.32	0.22	0.00
4934	0.00	0.00	0.19	-1.02	0.00
4946	0.00	0.00	0.15	-1.40	0.00

Table 68: Quantitative results for 35S and NOS in corn (DNA based assay).

Value highlighted in **yellow** indicates a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$.

Event: 35S											
Consensus Mean	0.0%	1.6%		3.6%		1.8%		3.6%		2.1%	
Participant Number	Result	Result	z-score								
1785	0.00	1.50	-0.17	3.80	0.10	1.80	-0.01	3.60	0.02	1.20	-0.46
2031	0.00	0.90	-0.91	1.91	-1.07	2.00	0.31	2.84	-0.58	1.00	-0.56
2678	0.00	1.17	-0.58	2.96	-0.42	1.67	-0.22	4.51	0.73	1.35	-0.38
2708	0.00	2.35	0.87	4.81	0.72	2.68	1.41	4.29	0.56	6.26	2.23
2721	0.00	3.13	1.83	6.64	1.85	2.29	0.78	5.48	1.49	2.09	0.02
2830	0.00	1.42	-0.27	2.81	-0.51	1.48	-0.53	2.54	-0.81	1.34	-0.38
4948	0.00	1.01	-0.78	2.56	-0.67	0.74	-1.73	1.79	-1.40	1.19	-0.46
Event: NOS											
Consensus mean	0.0%	1.3%		3.1%		2.7%		2.1%		1.1%	
Participant Number	Result	Result	z-score								
2678	0.00	2.00	0.71	2.89	-0.71	3.91	0.71	2.26	0.71	1.44	0.71
2721	0.00	0.63	-0.71	3.30	0.71	1.43	-0.71	1.88	-0.71	0.70	-0.71

Note: Levels cited as Consensus Mean are averages of reported quantitative results of events containing these promoters and terminators. Assigning a more accurate quantification value is beyond the scope of this program.

Table 69: Results for 35S and NOS in soybeans (DNA based assay)

Event: 35S Soy				
Consensus Mean	0.0%	0.4%	0.5%	0.2%
Participant Number	Result	Result	Result	Result
1862	0.00	0.65	0.54	0.20
2830	0.00	0.61	0.52	0.09
4935	N	P	P	P
4945	N	P	P	P
Event: NOS Soy				
Consensus Mean	0.0%	0.2%	0.5%	0.0%
Participant Number	Result	Result	Result	Result
1862	N	P	P	N
2830	N	P	P	N
4935	N	P	P	N
4945	N	P	P	N

Note: As 35S accompanies both RUR and LL genetic modification events, its presence is estimated to be equivalent to the sum of the consensus mean of these events in the sample. The NOS trait serves as a terminator in RUR only in this list of events.

Table 70: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays. % Relative standard deviation (%RSD_R) = [standard deviation/mean value x 100]. Outliers were determined by the Grubb's Test for Outliers and **excluded** from calculations involving reported mean, standard deviation, and % relative deviation but were **included** in the range of results.

Transgenic Event	Reported Results (N)	Gravimetric Fortification (%w/w)	Consensus Mean	Standard Deviation	% Relative Standard Deviation	Range of Results (%)
T25	10	0.1	0.12	0.08	66.7	0.0- 1.00
T25	10	0.5	0.36	0.15	41.7	0.18- 0.70
CBH351	6	0.0	0.00	0.00	NA	NA
MON810	25	0.1	0.06	0.07	116.7	0.0- 0.60
MON810	25	0.1	0.10	0.08	80.0	0.0- 0.29
MON810	25	0.2	0.12	0.04	33.3	0.0- 5.72
MON810	25	0.5	0.19	0.08	42.1	0.0- 0.95
MON810	25	0.5	0.27	0.13	48.1	0.0- 0.58
GA21	18	0.2	0.14	0.04	28.6	0.0- 1.50
GA22	18	0.8	0.62	0.21	33.9	0.0- 1.00
GA21	18	1.0	0.47	0.23	48.9	0.0- 0.90
Bt176	18	0.1	0.10	0.06	60.0	0.02- 0.90
Bt176	18	0.5	0.38	0.13	34.2	0.0- 0.65
Bt11	20	0.5	0.55	0.24	43.6	0.0- 0.99
Bt11	20	1.0	0.75	0.32	42.7	0.0- 1.45
Bt11	20	2.0	1.22	0.48	39.3	0.02 -1.90
NK603	19	0.5	0.35	0.18	51.4	0.0- 0.79
Herculex	16	0.8	0.57	0.32	56.1	0.0- 1.41
Herculex	16	1.5	0.64	0.34	53.1	0.10- 3.60
MON863	14	0.5	0.38	0.12	31.6	0.0- 2.00
MON863	14	0.8	0.61	0.27	44.3	0.0- 1.36
MON863	14	1.5	1.25	0.45	36.0	0.0- 2.11
HerculexRW	12	0.1	0.11	0.06	54.5	0.07- 0.16
HerculexRW	12	0.5	0.79	0.28	35.4	0.30- 10.78
MIR604	10	0.2	0.14	0.04	28.6	0.10- 0.30
MIR604	10	0.8	0.51	0.11	21.6	0.29- 1.36

Transgenic Event	Reported Results (N)	Gravimetric Fortification (%w/w)	Consensus Mean	Standard Deviation	% Relative Standard Deviation	Range of Results (%)
EV3272	9	0.2	0.18	0.08	44.4	0.07- 0.47
EV3272	9	0.8	0.80	0.41	51.3	0.09- 0.59
EV3272	9	1.0	0.54	0.31	57.4	0.58- 4.66
MON88017	10	0.1	0.10	0.05	50.0	0.30- 0.90
MON88017	10	0.5	0.36	0.21	58.3	0.50- 1.30
MON88017	10	1.0	0.88	0.54	61.4	0.50- 1.31
MON89034	11	0.5	0.28	0.12	42.9	0.02- 0.46
MON89034	11	1.0	0.56	0.24	42.9	0.03- 0.60
MON89034	11	2.0	0.81	0.46	56.8	0.03- 0.61
MIR 162	6	0.8	0.83	0.27	32.5	0.0- 1.11
RUR	26	0.2	0.18	0.05	27.8	0.04- 0.96
RUR	26	0.8	0.51	0.11	21.6	0.19- 2.08
A2704-12	13	0.1	0.15	0.07	46.7	0.001- 0.30
A2704-12	13	0.2	0.24	0.06	25.0	0.001- 0.30
RUR II	14	0.5	0.30	0.11	36.7	0.05- 2.50

Summary of Findings

It is recognized that some organizations participate in this program to retain their ISO accreditation. Participation serves to provide a verification of current laboratory practices and/or aids in identifying areas for improvement. These factors should be taken into consideration when reviewing the following analyses.

- **Qualitative Sample Analysis**

DNA-based Testing. The typical method of DNA-based testing for the qualitative determination of events is by conventional PCR which generally has a sensitivity of 0.01% w/w transgenic event. This level is consistent with what has been reported by Lipp et al. and represents the lowest concentration of genetic material that can be reliably detected by qualitative PCR.

The lowest gravimetric fortification level in this round of proficiency testing was 0.1% w/w; therefore, if the event was present it should be detectable by a laboratory that employs conventional PCR. As evidenced by the summary of performance scores (**Table 41** and **Figure 1**), all of the twenty (20) transgenic events were correctly detected with greater than or equal to 93% reliability, and nineteen of the twenty (19/20) transgenic events were correctly detected with greater than or equal to 96% reliability. The event that tested with less than 96% reliability was T25. Seven of twenty-five (7/25) laboratories generated false positive results for sample 5. The reliability of detecting T25 might be affected by the presence of the phosphinothricin N-acetyltransferase (*pat*) trait, also produced in the events Bt11, Herculex, and Herculex RW. The Bt11 and Herculex RW events are present in sample 5, whereas the T25 event is not. Construct-specific DNA or protein-based testing for the *pat* gene/protein will not differentiate between these events. This could possibly explain the false positive results observed for T25. Trait specific, DNA-based testing should be able to discern between these traits, whereas construct-specific or protein-based testing would not.

Two participants submitted qualitative results for the 35S promoter and four for the NOS terminator in soybeans (**Table 69**). These data revealed no false positive and no false negative results for either 35S or NOS in soybeans (compared with one false positive result for 35S and no false positive results for NOS in corn, see **Tables 1** and **3**).

Protein-based Testing. The principle methods of protein-based testing were lateral flow strip (LFS) and enzyme-linked immunosorbent assay (ELISA). The LFS test has a sensitivity ranging between 0.125 – 1.0% w/w for corn events and 0.1% w/w for soybean event RUR according to some kit manufacturers. Generally, ELISA has a sensitivity of 0.1 - 1% w/w for corn and soy events (Ahmed, 2004) and laboratories demonstrated good proficiency when using protein-based methods to detect the presence of biotechnology-derived traits in maize and soybean that were fortified above their reported LOD's (see **Tables 42 through 49**). The test results for NK603/MON88017 were combined because both traits express the *CP4EPSPS* protein, and protein-based testing cannot distinguish between the two traits. The test results for MON863/MON88017 were combined because both traits express the C3Bb1 protein. MON810/Bt11/Bt176 were combined because these traits all express the same Cry1Ab protein, and protein-based testing cannot distinguish between traits that express the same protein. See the discussion in "Qualitative Sample Analysis."

- **Quantitative Sample Analysis**

DNA-based Testing. The typical method of DNA-based testing for the quantitative determination of transgenic events is by real-time quantitative PCR (qPCR). This analytical method has a limit of detection (LOD) of 0.01% w/w and a limit of quantification (LOQ) of approximately 0.1% w/w for a specified event (Ahmed, 2004; Lipp et al., 2005).

Composite Performance Assessment. These data combined the participants' reported quantifications and evaluated the group's performance by considering the mean value of "reported results" of all participants (**Table 67**). Because test samples were fortified ranging from 0.1 – 2.0% w/w of a particular event, it was expected that qPCR technologies would detect the traits in all of the fortified samples but not in non-fortified samples. Low instances of false positive results were observed when using qPCR to detect the presence of GE traits in these proficiency samples.

There were forty-nine (49) false negative results observed in this report. This compares to five (5) false negative results cited in October 2011, three (3) false negatives in April 2011, and thirteen (13) in October 2010. The majority of the false negatives were generated by a select group of participants, some of whom are new to the program.

Seven (7) participants submitted quantitative results for 35S, and two (2) participants submitted quantitative results for NOS in corn (**Table 68**). The target %w/w levels for these traits should be additive for all events containing either 35S or NOS fortified into the sample, but consensus mean values from the data set do not reflect this amount. Validated methods to quantify with a high degree of accuracy for the presence of 35S and NOS, in samples fortified with multiple traits, is beyond the scope of the program at this time.

Two laboratories submitted quantitative results using qPCR (DNA-based testing) for the 35S trait in Soy (**Table 69**). The ability to critically evaluate the usefulness of these data can be challenging and should be considered on an individual laboratory basis only.

Quantitative data from previous rounds of our proficiency sample distributions can be found at: http://www.gipsa.usda.gov/fgis/insp_weigh_proficprog.html

Individual Performance Assessment. The performance of each participating laboratory for quantifying transgenic events in the proficiency samples can be observed by inspecting Tables 50 through 68. To assess the accuracy of their reported quantifications z-scores were computed. Laboratories with z-scores above +2 or below -2 were noted and highlighted in yellow because their result was greater than two standard deviations from the target value. Interpretation of z-scores assumes that the data have a normal distribution. Data from samples with lower fortification levels (e.g., 0.1% w/w) and from tables with low numbers of results may not be normally distributed and caution should be used when interpreting their z-scores.

Monitoring and improving the performance of laboratories that use PCR technologies for the detection and/or quantification of transgenic events in corn and soybeans will improve the reliability of testing methods and the marketing of these commodities. The USDA/GIPSA

proficiency testing program should be a complement to other quality assurance measures that laboratories use to improve their analytical capabilities.

Note: The transgenic seed or grain used to prepare these samples was made available to GIPSA by the Life Science Organizations. Care was taken to ensure the transgenic material was either essentially 100% positive for the event, or adjusted accordingly. The fortified samples were prepared using a process that has been verified to produce homogenous mixes, and representative samples were analyzed to ensure proper fortification and homogeneity. Reference standards are now commercially available for all transgenic traits used in this proficiency program and GIPSA encourages the use of these reference materials when developing internal validated methods.

To obtain additional information on the USDA/GIPSA Proficiency Program, contact Dr. Tandace Scholdberg, USDA/GIPSA Proficiency Program Manager, at US 816-891-0459, or by e-mail at Tandace.A.Scholdberg@usda.gov.

References

<http://www.itl.nist.gov/div898/software/dataplot/refman1/auxillar/consmean.htm>

Ahmed, F.E. (editor.). 2004. Testing of genetically modified organisms in foods. The Haworth Press, Inc., Binghamton, NY, pp. 174-176.

Definition of minimum performance requirements for analytical methods in GMO testing. 13 October 2008. European Network of GMO Laboratories and the Joint Research Council. <http://gmo-crl.jrc.ec.europa.eu>

Lipp, M., Shillito, R., Giroux, R., Spiegelhalter, F., Charlton, S., Pinero, D. 2005. Polymerase chain reaction technology as an analytical tool in agricultural biotechnology. Journal of AOAC International, 88 (1), 136-154.

Trait check Bt corn grain lateral flow test kit user guide. November 2001. Strategic Diagnostics, Inc., Newark, DE, part no. 3099998.

Trait check RUR bulk grain lateral flow test kit user guide. November 2003. Strategic Diagnostics, Inc., Newark, DE, part no. 3099956.

Appendix I: List of organizations who wished to be identified as a participant in the GIPSA April 2011 Proficiency Program. Participant identification numbers are listed below with permission from the organization.

BioDiagnostics, Inc.
507 Highland Dr.
River Falls, WI 54022
USA
Attn: Ryan Johnson
Phone: 715-426-0246
Fax: 715-426-0251
ryan.johnson@biodiagnostics.net

Bolsa de Comercio de Rosario
Cordoba 1402-2 Pisa
Rosario S2000 AWV-Santa Fe
Argentina
Attn: Juan J. Giorda, Ariel Soso
Phone: 54-341-4213471 ext: 2397
Fax: 54-341-421 1000
asoso@bcr.com.ar; colsina@bcr.com.ar

CNTA-Laboratorio del Ebro
Carretera NA- 134 km 50
31570 San Adrian
Navarro
Spain
Attn: Javier Butron Ilundain
Phone: 00 34 948 670 159
Fax: 00 34 948 696 127
jbutron@cnta.es

DASCA -Maicerias Españolas S.A.
c/Barcelona, km 5.
C.P. 46132 Almacera, Valencia
Spain
Attn: Mary Carmen Vidal
Phone: +34 961850052
Fax: +34 961851017
mc.vidal@dasca.com

**Federal Office of Public Health
Consumer Protection Directorate**
Schwarzenburgstrasse 165
CH-3003 Bern
Switzerland
Attn: Dominik Moor
Phone: +41 31 324 93 78
Fax: +41 31 322 95 74
Dominik.Moor@bag.admin.ch

Food and Drug Administration, DOH, Taiwan
161-2 Kunyang Street, Nangang District
Nangang
Taipei
Attn: Dr. Hsu-Yang Lin PhD
Phone: 02-26531068
Fax: 02-26531268
michael@fda.gov.tw
1780

BIOTECON Diagnostics
Hermannswerder 17
14473 Potsdam
Germany
Attn: Dr. Christina Harzman
Phone: +49 172 2323 606
Fax: +49 331 2300-299
charzman@bc-diagnostics.com

**Bureau of Quality and Safety of Foods
Ministry of Public Health**
88/7 Tiwanon Road
Nonthaburi 11000, Bangkok
Thailand
Attn: Nittatya Phunbua
Phone: 662-9510000 ext. 99514-5
Fax: 662-9511021
nittaya.ph@dmsc.mail.go.th

CONGEN Biotechnologie GmbH
Robert-Rössle-Strasse 10
13125 Berlin
Germany
Attn: Dipl.-Ing. A. Palisch
Phone: 0049-030-9489 3504
Fax: 0049-030-9489 3510
a.palisch@congen.de

Eurofins Genescan, Inc.
2315 N. Causeway Blvd.,
Suite 200
Metairie, Louisiana 70001
USA
Attn: Dr. Frank Spiegelhalter, Gregory M. Ditta
Phone: 504-297-4330
Fax: 504-294-4335
gregoryditta@eurofinsus.com

**Food and Daily Use Objects Analysis Laboratory
Voivodship Sanitary &Epidemological Station in Poznam**
ul. Noskowskiego 23
61-705 Poznam
Poland
Attn: Bartosz Rogozinski M.Sc.
Phone: +48 061 8544 855
Fax: +48 061 8544 849
bartosz.rogozinski@vp.pl

GEN-IAL GmbH
Heuserweg 13-15
D-53842 Troisdorf
Germany
Attn: Dr. Gabriele Muecher
Phone: *49 2241 2522981
Fax: *49 2241 2522989
g.muecher@gen-ial.de

Germ Services

21, Chemin de Pau
64121 Montardon
France
Attn: Cedric Barbe-Barrailh/ Pilar Cambet
Phone: 05-59-12-67-61
Fax: 05-59-12-67-10
cedric.barbe@agpm.com

Indiana Crop Improvement Association

7700 Stockwell Rd

Lafayette, IN 47909

USA

Attn: Rachael Sondeno
Phone: 765-523-2535
Fax: 765-523-2536
sondeno@live.com

Instituto de Medicina Genómica, S.L.

University of Valencia Sciency Park
Catedrático Agustín Escardino, 9 Edif. 3 P2
E-46980 Paterna, (Valencia)
Spain

Attn: Dr. Carlos Ruiz Lafora or Angela Pérez Pérez
Phone: +34 96 321 23 40
Fax: +34 96 321 23 41
carlos.ruiz@imegen.es; angela.perez@imegen.es

4901

Instituto Nacional de Semillas – INASE

Venezuela 162
CP C1095AAD- Ciudad Autónoma de Buenos Aires
Argentina

Attn: Ana Vicario
Phone: 54 11 4349 2037
Fax: 51 11 4349 2394
alvicario@inase.gov.ar

**Laboratoire de la Santé des Végétaux – ANSES
Unité Bactériologie, Virologie OGM**

7 Rue Jean Dixmères
49044 Angers Cedex
France

Attn: Vincent Herau
Phone: +33 241207425
Fax: +33 241207430
vincent.herau@anses.fr

Laboratorio COOP Italia

Via del Lavoro 6/8
40033 Casalecchio di Reno
Bologna
Italy

Attn: Martino Barbanera
Phone: 0039-051-596172
Fax: 0039-051-596170
martino.barbanera@coopitalia.coop.it

LANAGRO-GO**Ministry of Agriculture, Livestock and Food Supply**

Rua da Divisa s/n Setor Jaó
Goiânia-GO CEP: 74674-025
Brazil

Attn: Regina Morello
Phone: 55 62 81385701
Fax: 55 62 3235503
regina.morello@agricultura.gov.br

Illinois Crop Improvement Association, Inc

3105 Research Road
PO Box 9013
Champaign, IL 61826
USA

Attn: Matt Raymond
Phone: 217-359-4053
Fax: 217-359-4075
mraymond@ilcrop.com

Institute of Agricultural and Food Biotechnology

36 Rakowiecka St.

02-532 Warsaw

Poland

Attn: Joanna Bucka
Phone: (48) 022 606 38 06
Fax: (48) 022 606 36 02
bucka@ibprs.pl

2822

Instituto Nacional de Ecología, Mexico

Av. San Rafael Atlixco #186
UAM Iztapalapa Edificio W
2° piso, Col. Vincentina, Delegación Iztapalapa
CP 09340m México, D.F.

Attn: Martha Graciela Rocha Munive
Phone: 52 55 54246400 ext. 13306
Fax: 52 55 56133821
mrocha@ine.gob.mx

2708

JenaGen GmbH

Loebstedter Strasse 80
D-07749, Jena
Germany

Attn: Dr. Reinhard Baier
Phone: +49-3641-628 52 50
Fax: +49-3641-628 52 51
r.baier@jenagen.de

Laboratorio Central de Veterinaria**Ministerio de Agricultura Alimentación y Medio Ambiente**

Carretera M106-Km14
28110- Algete, Madrid
Spain

Attn: Maria del Valle Perez Barbachano
Phone: 0034913474561
Fax: 0034913475601
mperezba@magrama.es

Laboratório de Análises Genéticas – AgroGenética

Av. Olivia de Castro Almeida 273-L1C
Barrio Clélia Bernardees, Viçosa-MG
CEP36570-000 Minas Gerais
Brazil

Attn: Wilton Marota de Souza
Phone: 55 (31) 3891-0817
Fax: 55 (31) 3891-1856
agrogenetica@agrogenetica.com.br

LANAGRO/RS**Laboratório Nacional Agropecuário no Rio Grande do Sul**

Estrada da Ponta Grossa 3036
Porto Alegre, RS, Postal Code: 91780-580
Brazil

Attn: Rodrigo Fortunato
Phone: 55 51 32482133
Fax: 55 51 32482133
rodrigo.fortunato@agricultura.gov.br

LANAGRO-MG**Laboratório Nacional Agropecuário - MG**

Avenida Romulo Joviano, s/n, Centro
Pedro Leopoldo
Minas Gerais 33600-000
Brazil
Attn: Nilson Cesar Castanheira Guimaraes
Phone: 55 31 3660 9730
Fax: 55 31 3660 9737
nilson.cesar@argricultura.gov.br

LUFASpeyer

Obere Langgasse 40
D-67346 Speyer
Germany
Attn: Dr.Sartorius-Neef
Phone: 06232-136291
Fax: 06232-136110
neef@lufa-speyer.de

Monsanto- Europe

Croix de Pardies
F-40305 Peyrehorade
France
Attn: Bruno Zacommer
Phone: +33 558 73 21 64
Fax: +33 558 73 09 29
bruno.zacommer@monsanto.com

Planton GmbH

Am Kiel-Kanal 44
D-24106 Kiel
Germany
Attn: Dr. Martin C. Weigel
Phone: +49 (0)431 38015 0
Fax: +49(0)431 38015 11
weigel@plnton.de

SGS Bulgaria Ltd - Laboratory Varna

1 William Froude Str.
Institute for Hydor and Aerodymanics, 7th floor
9003 Varna
Bulgaria
Attn: Veselka Pashova
Phone: +359(52)370988
Fax: +359(52)370979
veselka.pashova@sgs.com

**School of Lifescience and Biotechnology
Shanghai Jiao Tong University**

800 Dongchuan Road
Shanghai 200240
China
Attn: Litao Yang
Phone: 86-21-34207174
Fax: 86-21-34204869
yyltt@sjtu.edu.cn

Thionville Laboratories, Inc.

5440 Pepsi St.
Harahan, LA 70123
USA
Attn: Boyce Butler
Phone: 504-733-9603
Fax: 504-733-6457
lab@thionvillenola.com

Landesamt fuer Verbraucherschutz Sachsen-Anhalt

Freimfelder Str. 68
D-061112 Halle
Germany
Attn: Dr. Dietrich Maede
Phone: +49 345 5643 313
Fax: +49 345 5643 439
dietrich.maede@lav.ms.sachsen-anhalt.de
1870

Microbac Laboratories

505 E. Broadway Ave.
Maryville, TN 37804
USA
Attn: Robert Brooks
Phone: 865-911-1200 x 1229
Fax: 865-984-8616
robert.brooks@microbac.com

**Nippon Yuryo Kentei Kyokai Yokohoma Laboratory
(Japan Oil Stuff Inspectors Corporation)**

Nagataminami 1-2-34
Minami-Ku, Yokohama 232-0073
Japan
Attn: Kumi Goto
Phone: 045-722-3605
Fax: 045-722-3639
goto3045@nykk.or.jp

SENASICA, México

Centro Nacional de Referencia en Detección de Organismos
km 37.5 Carretera Federal México-Pachuca
Col. Centro, Tecámac Estado de Mexico C.P. 55740
Mexico
Attn: Maria Guadalupe Barrera Andrade
Phone: 52 55 59041000 ext. 53039
Fax:
maria.barrera@sensasica.gob.mx
4936

SGS do Brasil Ltda

Av. Vereador Alfredo das Neves
480 – CEP: 11095-510
Santos/Sao Paulo
Brazil
Attn: Mara Rubia Camolesi
Phone: +55 13 2105-9558
Fax: +55 13 3296-2921
mara.camolesi@sgs.com

Sistemas Genomicos

Parque Tecnológico de Valencia
Ronda G. Marconi, 6
46980 Paterna, Valencia
Spain
Attn: Amparo Girós Pérez
Phone: 902 364 669
Fax:
amparo.giros@sistemasgenomicos.com

**Voivodship Sanitary & Epidemiological station in Bialystok
Genetically Modified Food Section**

ul. Legionowa 8
15-099 Bialystok
Poland
Attn: Grazyna Ostrowska
Phone: +48 508859709
Fax: +48 85 7404899
dl@wsse.bialystok.pl