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USDA/GIPSA Proficiency Program
Testing for the Presence of Biotechnology Events in Corn and Soybeans
October 2015
Sample Distribution Results

Purpose of USDA/GIPSA Proficiency Program

Through the USDA/GIPSA Corn and Soy 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 as well as to monitor laboratories' continuing performance). The program 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.

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. Qualitative results were scored by computing the "percentage of correctly reported transgenic traits" in the samples (Tables 1 to 39 and Figure 1 for DNA-based analysis, and Tables 40 to 47 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 64, 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 48 to 64). 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 identify more outliers than should be declared. Some judgment will be necessary when interpreting data at these low levels. Absolute values for z-scores that are > 2 should be scrutinized by the participating lab. Those that are > 3, or classified as outliers, 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 65) 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 (corn 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 ^{o}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 GIPSA 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: GA21, MON810, Herculex® (TC1507), MON863, Herculex® RW (DAS-59122-7), MIR604, Event 3272, MON 88017, MON 89034, and MIR 162. The transgenic trait CBH351 (Starlink™) is no longer included in the program. The soybean samples contained various combinations and concentrations of the following transgenic traits: the transgenic glyphosate-tolerant soybeans (Roundup Ready™), the glufosinate ammonium tolerant soybeans (A2704-12), the transgenic glyphosate-tolerant soybeans (Roundup Ready™ II), and high oleic acid soybeans (DP305423). The various transgenic concentration levels were produced on a %w/w basis. A calculated amount of ground transgenic corn or soybeans was blended to homogeneity with a calculated amount of ground non-transgenic corn or soybeans to produce concentrations ranging from 0.2 to 2.0% of a specified event. Each participant received four corn and two soybean samples. Individual samples contained approximately 5 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 using in-house validated methods. The trend of generating lower reported concentrations compared with gravimetric fortified values can have several possible explanations, including that of differences in trait zygosity between material used in the corn and soybean samples compared with the commercially available reference materials. For example, GIPSA in-house validated methods yield 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. Ninety-three (93) organizations received samples in the October 2015 round of proficiency testing, and ninety-one (91) organizations submitted results to GIPSA.

- Forty-four (44) participants submitted **qualitative** results only (of these 44, five (5) participants performed a combination of DNA and protein based testing),
- Three (3) submitted **quantitative** results only (of these 3, one (1) participant performed a combination of DNA and protein based testing),
- Forty-four (44) participants submitted a combination of **qualitative** and **quantitative** results (of these 44, one (1) participant performed a combination of DNA and protein based testing), and
- Ten (10) participants submitted **protein** based results, using Lateral Flow Strip (LFS) and/or Enzyme-linked Immunosorbent Assay (ELISA) qualitative analyses (of these 10, one (1) participant performed Enzyme-linked Immunosorbent Assay (ELISA) quantitative analysis.

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 either positive (presence) or negative (absence) for 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:

- Table 1: Qualitative results of corn fortified with 35S for all participants (DNA-based assays).
- Table 2: Percentages of correct results, false negatives, and false positives in qualitative reports of 35S for all participants.
- Table 3: Qualitative results of corn fortified with NOS for all participants (DNA-based assays).
- Table 4: Percentages of correct results, false negatives, and false positives in qualitative reports of NOS for all participants.
- Table 5: Qualitative results of corn fortified with GA21 for all participants (DNA-based assays).
- Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports of GA21 for all participants.

- Table 7: Qualitative results of corn fortified MON810 with for all participants (DNA-based assays).
- Table 8: Percentages of correct results, false negatives, and false positives in qualitative reports of MON810 for all participants.
- Table 9: Qualitative results of corn fortified with Herculex® for all participants (DNA-based assays).
- Table 10: Percentages of correct results, false negatives, and false positives in qualitative reports of Herculex® for all participants.
- Table 11: Qualitative results of corn fortified with MON863 for all participants (DNA-based assays).
- Table 12: Percentages of correct results, false negatives, and false positives in qualitative reports of MON863 for all participants.
- Table 13: Qualitative results of corn fortified with Herculex® RW for all participants (DNA-based assays).
- Table 14: Percentages of correct results, false negatives, and false positives in qualitative reports of Herculex® RW for all participants.
- Table 15: Qualitative results of corn fortified with MIR604 for all participants (DNA-based assays).
- Table 16: Percentages of correct results, false negatives, and false positives in qualitative reports of MIR604 for all participants.
- Table 17: Qualitative results of corn fortified with Event 3272 for all participants (DNA-based assays).
- Table 18: Percentages of correct results, false negatives, and false positives in qualitative reports of Event 3272 for all participants.
- Table 19: Qualitative results of corn fortified with MON 88017 for all participants (DNA-based assays).
- Table 20: Percentages of correct results, false negatives, and false positives in qualitative reports of MON 88017 for all participants.
- Table 21: Qualitative results of corn fortified with MON 89034 for all participants (DNA-based assays).
- Table 22: Percentages of correct results, false negatives, and false positives in qualitative reports of MON 89034 for all participants.
- Table 23: Qualitative results of corn fortified with MIR162 for all participants (DNA-based assays)
- Table 24: Percentages of correct results, false negatives and false positives in qualitative reports of MIR162 for all participants.
- Table 25: Qualitative results of soybeans fortified with CP4 EPSPS (Roundup Ready™) for all participants (DNA-based assays).
- Table 26: Percentages of correct results, false negatives, and false positives in qualitative reports of CP4 EPSPS for all participants.
- Table 27: Qualitative results of soybeans fortified with A2704-12 (Liberty Link®) for all participants (DNA-based assays).
- Table 28: Percentages of correct results, false negatives, and false positives in qualitative reports of A2704-12 for all participants.
- Table 29: Qualitative results of soybeans fortified with CP4 EPSPS (Roundup Ready™ II) for all participants (DNA-based assays).
- Table 30: Percentages of correct results, false negatives, and false positives in qualitative reports of CP4 EPSPS (Roundup Ready™ II) for all participants.

- Table 31: Qualitative results of soybeans fortified with DP305423 for all participants (DNA-based assays).
- Table 32: Percentages of correct results, false negatives, and false positives in qualitative reports of DP305423 for all participants.
- Table 33: Qualitative results for soybeans fortified with 35S for all participants (DNA-based assays).
- Table 34: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy 35S for all participants.
- Table 35: Qualitative results for soybeans fortified with NOS for all participants (DNA-based assays).
- Table 36: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy NOS for all participants.
- Table 37: Qualitative results of soybeans fortified with FMV for all participants (DNA-based assays).
- Table 38: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy FMV for all participants.
- Table 39: 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 40: Lateral Flow Strip (LFS) testing results for the detection of transgenic events in corn.
- Table 41: Percentage of correct results, false negatives, and false positives in qualitative reports for transgenic events in corn using Lateral Flow Strip (LFS) testing.
- Table 42: Results for soybeans fortified with CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) testing.
- Table 43: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) testing.
- Table 44: Results for the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA).
- Table 45: Percentage of correct results in the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA).
- Table 46: Results for soybeans fortified with CP4EPSPS and A2704-12 using Enzyme-Linked Immunosorbent Assay (ELISA).
- Table 47: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 using Enzyme-Linked Immunosorbent Assay (ELISA).

Quantitative Data Summaries. This section summarizes DNA based 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.

- Table 48: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).

- Table 49: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).
- Table 50: Quantitative results and z-scores for corn fortified with Herculex® for all participants (DNA-based assays).
- Table 51: Quantitative results and z-scores for corn fortified with MON863 for all participants (DNA-based assays).
- Table 52: Quantitative results and z-scores for corn fortified with Herculex® RW for all participants (DNA-based assays).
- Table 53: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays).
- Table 54: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays).
- Table 55: Quantitative results and z-scores for corn fortified with MON 88017 for all participants (DNA-based assays).
- Table 56: Quantitative results and z-scores for corn fortified with MON 89034 for all participants (DNA-based assays).
- Table 57: Quantitative results and z-scores for corn fortified with MIR162 for all participants (DNA-based assays).
- Table 58: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS in Roundup Ready™ for all participants (DNA-based assays).
- Table 59: Quantitative results and z-scores for soybeans fortified with A2704-12 for all participants (DNA-based assays).
- Table 60: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS in Roundup Ready™ II for all participants (DNA-based assays).
- Table 61: Quantitative results and z-scores for soybeans fortified with DP305423 for all participants (DNA-based assays).
- Table 62: Quantitative results for 35S and NOS in corn (DNA-based assays).
- Table 63: Quantitative results for 35S, NOS, and FMV in soybeans (DNA-based assays).
- Table 64: Quantitative results for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)
- Table 65: 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 USDA-GIPSA October 2015 Proficiency Program.

Table 1: Qualitative results of corn fortified with 35S for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

35S	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	**N**	**P**	**P**	**P**
1752	N	P	P	P
1754	N	P	P	P
1761	N	P	P	P
1764	N	P	P	P
1770	N	P	P	P
1788	N	P	P	P
1847	N	P	P	P
1854	**P**	P	P	**N**
1859	N	P	P	P
1862	N	P	P	P
1870	N	P	P	P
1875	N	P	P	P
1892	N	P	P	P
1893	N	P	P	P
1895	N	P	P	P
1897	N	P	P	P
2005	N	P	P	P
2034	N	P	P	P
2057	N	P	P	P
2076	N	P	P	P
2126	N	P	P	P
2560	N	P	P	P
2716	N	P	P	P
2717	NR	P	P	P
2721	N	P	P	P
2831	**P**	P	P	P
3928	N	P	P	P
3929	N	P	P	P
4502	N	P	P	P
4504	**P**	**N**	P	P
4932	N	P	P	P
4933	N	P	P	P
4934	N	P	P	P
4935	N	P	P	P
4937	N	P	P	P
4939	N	P	P	P
4942	N	P	P	P
4945	N	P	P	P
4950	N	P	P	P
4951	N	P	P	P
4952	N	P	P	P
4956	N	P	P	P
4957	**P**	P	P	P
4960	N	P	P	P
4962	N	P	P	P
4966	N	P	P	P
4974	N	P	P	P

35S	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	**N**	**P**	**P**	**P**
4975	N	P	P	P
4976	N	P	P	P
4977	N	P	P	P
4980	N	P	P	P
4982	N	P	P	P
4983	N	**N**	**N**	P
4984	**P**	P	P	**N**
4987	**P**	P	P	P
4990	N	P	P	P
7002	N	P	P	P
7003	N	P	P	P
7005	N	P	P	P
7006	**P**	P	P	P
7007	N	P	P	P
7008	N	P	P	P
7009	**P**	P	P	P
7010	N	P	P	P
7011	**P**	P	P	P
7013	N	P	P	P
N, Results	65	66	66	66
# Negative	56	2	1	2
# Positive	9	64	65	64
% Correct	86.2%	97.0%	98.5%	97.0%
% Incorrect	13.8%	3.0%	1.5%	3.0%

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

Total # Reported Results	263
# Incorrect	14
% Correct	94.7%
# Provided Positives	198
# False Negative	5
% False Negative	2.5%
# Provided Negatives	65
# False Positive	9
% False Positive	13.8%

Table 3: Qualitative results of 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
Participant Number	P	P	P	P
1752	P	P	P	P
1754	P	P	P	P
1761	P	P	P	P
1764	P	P	P	P
1770	P	P	P	P
1785	P	P	P	P
1788	P	P	P	P
1847	P	P	P	P
1854	P	P	P	**N**
1859	P	P	P	P
1862	P	P	P	P
1870	P	P	P	P
1875	P	P	P	P
1892	P	P	P	P
1893	P	P	P	P
1895	P	P	P	P
1897	P	P	P	P
2005	P	P	P	P
2034	P	P	P	P
2057	P	P	P	P
2076	P	P	P	P
2126	P	P	P	P
2560	P	P	P	P
2716	P	P	P	P
2717	P	P	P	P
2721	P	P	P	P
2831	P	P	P	P
3928	P	P	P	P
3929	P	P	P	P
4502	P	P	P	P
4504	P	**N**	P	P
4932	P	P	P	P
4933	P	P	P	P
4934	P	P	P	P
4935	P	P	P	P
4936	P	P	P	P
4937	P	P	P	P
4939	P	P	P	P
4942	P	P	P	P
4945	P	P	P	P
4950	P	P	P	P
4951	P	P	P	P
4952	P	P	P	P
4956	P	P	P	P
4957	P	P	P	P
4960	P	P	P	P
4962	P	P	P	P

NOS	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	**P**	**P**	**P**	**P**
4966	P	P	P	P
4974	P	P	P	P
4976	**N**	P	P	P
4977	P	P	P	P
4980	P	P	P	P
4982	P	P	P	P
4983	**N**	**N**	**N**	**N**
4984	P	P	P	**N**
4987	P	P	P	P
4990	P	P	P	P
7002	**N**	P	P	P
7003	P	P	P	P
7005	P	P	P	P
7006	P	P	P	P
7008	P	P	P	P
7009	P	P	P	P
7010	P	P	P	P
7011	P	P	P	P
7013	P	P	P	P
N, Results	66	66	66	66
# Negative	3	2	1	3
# Positive	63	64	65	63
% Correct	95.5%	97.0%	98.5%	95.5%
% Incorrect	4.5%	3.0%	1.5%	4.5%

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

Total # Reported Results	264
# Incorrect	9
% Correct	96.6%
# Provided Positives	264
# False Negative	9
% False Negative	3.4%
# Provided Negatives	0
# False Positive	0
% False Positive	0.0%

Table 5: Qualitative results of corn fortified with GA21 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

GA21	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	1.0%	0.2%	0.0%	0.0%
1783	P	P	N	N
1785	P	P	N	N
1788	P	P	N	N
1859	P	P	N	N
1862	P	P	N	N
1875	P	P	N	N
1892	P	P	N	N
1893	P	P	N	N
1895	P	P	N	N
1895	P	P	N	N
2034	P	P	N	N
2060	P	P	N	N
2089	P	P	N	N
2113	P	P	N	N
2126	P	P	N	N
2560	P	P	N	N
2569	P	P	N	N
2720	P	P	N	N
2721	P	**N**	**P**	N
2831	P	P	N	N
3929	P	P	N	N
4937	P	P	N	N
4942	P	P	N	N
4950	P	P	N	N
4957	P	P	N	N
4960	P	P	N	N
4962	P	P	N	N
4964	**N**	**N**	**P**	**P**
4966	P	P	N	N
4973	P	P	N	N
4974	P	P	N	N
4977	P	P	N	N
4983	**N**	**N**	N	N
7007	P	P	N	N
7011	**N**	**N**	N	N
7013	P	P	N	N
N, Results	36	36	36	36
# Negative	3	4	34	35
# Positive	33	32	2	1
% Correct	94.4%	91.7%	94.4%	97.2%
% Incorrect	5.6%	8.3%	5.6%	2.8%

Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports of GA21 for all participants

Total # Reported Results	144
# Incorrect	10
% Correct	93.1%
# Provided Positives	72
# False Negative	7
% False Negative	9.7%
# Provided Negatives	72
# False Positive	3
% False Positive	4.2%

Table 7: Qualitative results of corn fortified with MON810 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

MON810	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**
Participant Number	**0.0%**	**2.0%**	**0.5%**	**0.2%**
1752	N	P	P	P
1761	N	P	P	P
1764	N	P	P	P
1783	N	P	P	P
1785	N	P	P	P
1854	N	P	P	**N**
1859	N	P	P	P
1862	N	P	P	P
1892	N	P	P	P
1893	N	P	P	P
1895	N	P	P	P
1897	N	P	P	P
2034	N	P	P	P
2060	N	P	P	P
2089	N	P	P	P
2113	N	P	P	P
2126	N	P	P	P
2560	N	P	P	P
2569	N	P	P	P
2720	N	P	P	P
2721	N	P	P	P
4502	N	P	P	P
4504	N	**N**	P	P
4937	N	P	P	P
4945	NR	P	P	P
4950	N	P	P	**N**
4960	N	P	P	P
4964	**P**	P	**N**	P
4966	N	P	P	P
4973	N	P	P	P
4975	N	P	P	P

MON810	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	**0.0%**	**2.0%**	**0.5%**	**0.2%**
4976	N	P	P	P
4977	N	P	P	P
4984	N	P	P	**N**
4987	**P**	P	P	P
7007	N	P	P	P
N, Results	35	36	36	36
# Negative	33	1	1	3
# Positive	2	35	35	33
% Correct	97.1%	100.0%	100.0%	94.4%
% Incorrect	5.7%	0.0%	2.8%	8.3%

Table 8: Percentages of correct results, false negatives, and false positives in qualitative reports of MON810 for all participants

Total # Reported Results	143
# Incorrect	7
% Correct	95.1%
# Provided Positives	108
# False Negative	5
% False Negative	4.6%
# Provided Negatives	35
# False Positive	2
% False Positive	5.7%

Table 9: Qualitative results of corn fortified with Herculex® for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Herculex®	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	1.0%	0.0%	0.0%
1752	N	P	N	N
1761	N	P	N	N
1764	N	P	N	N
1783	N	P	N	N
1785	N	P	N	N
1854	N	**N**	**P**	N
1859	N	P	N	N
1862	N	P	N	N
1893	N	P	N	N
1895	N	P	N	N
1897	N	P	N	N
2005	N	P	N	N
2034	N	P	N	N
2060	N	P	N	N
2089	N	P	N	N
2113	N	P	N	N
2126	N	P	N	N
2560	N	P	N	N
2569	N	P	N	N
2720	N	P	N	N
2721	N	**N**	**P**	N
2831	N	P	N	N
3929	N	P	N	N
4504	**P**	**N**	**P**	**P**
4937	N	P	N	N
4942	N	P	N	N
4945	**P**	**N**	N	N
4960	N	P	N	N
4964	N	**N**	N	**P**
4966	N	P	N	N
4973	N	P	N	N
4976	N	P	N	N
N, Results	32	32	32	32
# Negative	30	5	29	30
# Positive	2	27	3	2
% Correct	93.8%	84.4%	90.6%	93.8%
% Incorrect	6.3%	15.6%	9.4%	6.3%

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

Total # Reported Results	128
# Incorrect	12
% Correct	90.6%
# Provided Positives	32
# False Negative	5
% False Negative	15.6%
# Provided Negatives	96
# False Positive	7
% False Positive	7.3%

Table 11: Qualitative results of corn fortified with MON863 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

MON863	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**
Participant Number	**0.0%**	**0.0%**	**1.0%**	**0.0%**
1761	N	N	P	N
1764	N	N	P	N
1785	N	N	P	N
1788	N	N	P	N
1859	N	N	P	N
1862	N	N	P	N
1892	N	N	P	N
1893	N	N	P	N
1895	N	N	P	N
1897	N	N	P	N
2005	N	N	P	N
2034	N	N	P	N
2060	N	N	P	N
2089	N	N	P	N
2113	N	N	P	N
2126	N	N	P	N
2560	N	N	P	N
2569	N	N	P	N
2720	N	N	P	N
2721	N	**P**	**N**	N
2831	**P**	**P**	P	**P**
3929	N	N	P	N
4504	N	N	P	N
4937	N	N	P	N
4942	N	N	P	N
4945	NR	N	P	N
4950	**P**	**P**	P	N
4956	N	N	P	N
4957	N	N	P	N
4964	N	**P**	**N**	N
4966	N	N	P	N
4973	N	N	P	N

MON863	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	0.0%	1.0%	0.0%
4975	N	N	P	N
4976	N	N	P	N
7011	**P**	**P**	P	**P**
7013	N	**P**	P	N
N, Results	35	36	36	36
# Negative	32	30	2	34
# Positive	3	6	34	2
% Correct	91.4%	83.3%	94.4%	94.4%
% Incorrect	8.6%	16.7%	5.6%	5.6%

Table 12: Percentages of correct results, false negatives, and false positives in qualitative reports of MON863 for all participants

Total # Reported Results	143
# Incorrect	13
% Correct	90.9%
# Provided Positives	36
# False Negative	2
% False Negative	5.6%
# Provided Negatives	107
# False Positive	11
% False Positive	10.3%

Table 13: Qualitative results of corn fortified with Herculex® RW for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in bold face)

Herculex® RW	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	0.0%	0.5%	0.2%
1752	N	N	P	P
1761	N	N	P	P
1764	N	N	P	P
1783	N	N	P	P
1785	N	N	P	P
1854	N	N	**N**	P
1859	N	N	P	P
1862	N	N	P	P
1892	N	N	P	P
1893	N	N	P	P
1895	N	N	P	P
2005	N	N	P	P
2034	N	N	P	P

Herculex® RW	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	0.0%	0.5%	0.2%
2060	N	N	P	P
2089	N	N	P	P
2113	N	N	P	P
2126	N	N	P	P
2560	N	N	P	P
2569	N	N	P	P
2721	N	**P**	**N**	P
2831	N	N	P	P
3929	N	N	P	P
4502	N	N	P	P
4937	N	N	P	P
4942	N	N	P	P
4945	NR	N	P	P
4950	N	N	P	P
4957	N	N	P	P
4964	**P**	**P**	**N**	**N**
4966	N	N	P	P
4973	N	N	P	P
4975	N	N	P	P
N, Results	31	32	32	32
# Negative	30	30	3	1
# Positive	1	2	29	31
% Correct	3.2%	93.8%	9.4%	96.9%
% Incorrect	96.8%	6.3%	90.6%	3.1%

Table 14: Percentages of correct results, false negatives, and false positives in qualitative reports of Herculex® RW for all participants

Total # Reported Results	127
# Incorrect	7
% Correct	94.5%
# Provided Positives	64
# False Negative	4
% False Negative	6.3%
# Provided Negatives	63
# False Positive	3
% False Positive	4.8%

Table 15: Qualitative results of corn fortified with MIR604 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

MIR604	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.2%	0.0%	0.0%	0.0%
1783	P	N	N	N
1785	P	N	N	N
1859	P	N	N	N
1862	P	N	N	N
1892	P	N	N	N
1893	P	N	N	N
1895	P	N	N	N
1897	P	N	N	N
2005	P	N	N	N
2034	P	N	N	N
2060	P	N	N	N
2089	P	N	N	N
2113	P	N	N	N
2126	P	N	N	N
2560	P	N	N	N
2569	P	N	N	N
2721	P	N	N	N
2831	P	N	N	N
3928	P	N	N	N
3929	P	N	N	N
4937	P	N	N	N
4942	P	N	N	N
4950	P	N	N	N
4952	**N**	N	N	N
4957	P	N	N	N
4960	P	N	N	N
4962	P	N	N	N
4964	**N**	N	**P**	N
4966	P	N	N	N
4973	P	N	N	N
4974	P	N	N	N
4975	P	N	N	N
4976	P	N	N	N
4977	P	N	N	N
7007	P	N	N	N
7013	P	N	N	N
N, Results	36	36	36	36
# Negative	2	36	35	36
# Positive	34	0	1	0
% Correct	94.4%	100.0%	97.2%	100.0%
% Incorrect	5.6%	0.0%	2.8%	0.0%

Table 16: Percentages of correct results, false negatives, and false positives in qualitative reports of MIR604 for all participants

Total # Reported Results	144
# Incorrect	3
% Correct	97.9%
# Provided Positives	36
# False Negative	2
% False Negative	5.6%
# Provided Negatives	108
# False Positive	1
% False Positive	0.9%

Table 17: Qualitative results of corn fortified with Event 3272 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Event 3272	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**
Participant Number	**0.5%**	**0.0%**	**1.0%**	**0.2%**
1761	P	N	P	P
1785	P	N	P	P
1854	P	N	**N**	**N**
1859	P	N	P	P
1893	P	N	P	P
2005	P	N	P	P
2034	P	N	P	P
2113	P	N	P	P
2126	P	N	P	P
2721	P	**P**	**N**	P
2831	P	N	P	P
3928	P	N	P	P
4502	P	N	P	P
4936	P	N	P	P
4937	P	N	P	P
4942	P	N	P	P
4945	P	N	P	P
4950	P	N	P	P
4952	P	N	P	P
4957	P	N	P	P
4960	P	N	P	P
4964	P	**P**	P	**N**
4966	P	N	P	P
4974	P	N	P	P
4975	P	N	P	P
4987	P	N	P	P

Event 3272	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	**0.5%**	**0.0%**	**1.0%**	**0.2%**
7007	P	N	P	P
7013	P	N	P	P
N, Results	28	28	28	28
# Negative	0	26	2	2
# Positive	28	2	26	26
% Correct	100.0%	92.9%	92.9%	92.9%
% Incorrect	0.0%	7.1%	7.1%	7.1%

Table 18: Percentages of correct results, false negatives, and false positives in qualitative reports of Event 3272 for all participants

Total # Reported Results	112
# Incorrect	6
% Correct	94.6%
# Provided Positives	84
# False Negative	0
% False Negative	0.0%
# Provided Negatives	84
# False Positive	4
% False Positive	4.8%

Table 19: Qualitative results of Corn fortified with MON88017 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

MON 88017	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	0.5%	0.2%	0.0%
1761	N	P	P	N
1783	N	P	P	N
1785	N	P	P	N
1854	**P**	**N**	P	N
1859	N	P	P	N
1862	N	P	P	N
1875	N	P	P	N
1893	N	P	P	N
1895	N	P	P	N
1897	N	P	P	N
2034	N	P	P	N
2060	N	P	P	N
2089	N	P	P	N
2113	N	P	P	N
2126	N	P	P	N
2560	N	P	P	N
2569	N	P	P	N
2720	N	P	P	N
2721	N	P	P	N
2831	N	P	P	N
3928	N	P	P	N
3929	N	P	P	N
4937	N	P	P	N
4942	N	P	P	N
4945	NR	P	P	N
4950	N	P	P	N
4964	N	P	**N**	**P**
4966	N	P	P	N
4973	N	P	P	N
4975	N	P	P	N
4976	N	P	P	N
4983	N	**N**	**N**	N
4987	N	P	P	**P**
7013	N	P	P	N
N, Results	33	34	34	34
# Negative	32	2	2	32
# Positive	1	32	32	2
% Correct	97.0%	94.1%	94.1%	94.1%
% Incorrect	3.0%	5.9%	5.9%	5.9%

Table 20: Percentages of correct results, false negatives, and false positives in qualitative reports of MON88017 for all participants

Total # Reported Results	135
# Incorrect	7
% Correct	94.8%
# Provided Positives	68
# False Negative	4
% False Negative	5.9%
# Provided Negatives	67
# False Positive	3
% False Positive	4.5%

Table 21: Qualitative results of corn fortified with MON89034 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in bold face)

MON 89034	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**
Participant Number	**0.0%**	**0.0%**	**0.5%**	**1.0%**
1785	N	N	P	P
1859	N	N	P	P
1862	N	N	P	P
1875	N	N	P	P
1893	N	N	P	P
1895	N	N	P	P
1897	N	N	P	P
2005	N	N	P	P
2034	N	N	P	P
2060	N	N	P	P
2089	N	N	P	P
2113	N	N	P	P
2126	N	N	P	P
2560	N	N	P	P
2569	N	N	P	P
2569	N	N	P	P
2720	N	N	P	P
2721	N	**P**	**N**	P
2831	N	N	P	P
3928	N	N	P	P
3929	N	N	P	P
4502	N	N	P	P
4937	N	N	P	P
4942	N	N	P	P
4945	NR	N	P	P
4950	N	N	P	P
4957	N	N	P	P

MON 89034	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	**0.0%**	**0.0%**	**0.5%**	**1.0%**
4964	**P**	**P**	**N**	**N**
4966	N	N	P	P
4973	N	N	P	P
4975	N	N	P	P
4983	N	**P**	**N**	**N**
7011	N	N	**N**	**N**
7013	N	N	P	P
N, Results	33	34	34	34
# Negative	32	31	4	3
# Positive	1	3	30	31
% Correct	97%	91%	88%	91%
% Incorrect	3.0%	8.8%	11.8%	8.8%

Table 22: Percentages of correct results, false negatives, and false positives in qualitative reports of MON89034 for all participants

Total # Reported Results	135
# Incorrect	11
% Correct	91.9%
# Provided Positives	68
# False Negative	7
% False Negative	10.3%
# Provided Negatives	67
# False Positive	4
% False Positive	6.0%

Table 23: Qualitative results of corn fortified with MIR162 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

MIR 162	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.2%	1.0%	0.0%	0.8%
1785	P	P	N	P
1859	P	P	N	P
1862	P	P	N	P
1893	P	P	N	P
1895	P	P	N	P
1897	P	P	N	P
2005	P	P	N	P
2034	P	P	N	P
2060	P	P	N	P
2089	P	P	N	P
2113	P	P	N	P
2126	P	P	N	P
2560	P	P	N	P
2569	P	P	N	P
2720	P	P	N	P
2721	P	**N**	**P**	P
2831	P	P	N	P
3928	P	P	N	P
3929	P	P	N	P
4502	P	P	N	P
4504	P	**N**	N	P
4937	P	P	N	P
4942	P	P	N	P
4950	P	P	**P**	P
4960	P	P	N	P
4964	P	**N**	**P**	P
4966	P	P	N	P
4973	P	P	N	P
4974	P	P	N	P
4975	P	P	N	P
4977	P	P	N	P
4987	P	P	N	P
7013	P	P	N	P
N, Results	33	33	33	33
# Negative	0	3	30	0
# Positive	33	30	3	33
% Correct	100%	91%	90.9%	100%
% Incorrect	0.0%	9.1%	9.1%	0.0%

Table 24: Percentages of correct results, false negatives, and false positives in qualitative reports of MIR162 for all participants

Total # Reported Results	132
# Incorrect	6
% Correct	95.5%
# Provided Positives	66
# False Negative	0
% False Negative	0.0%
# Provided Negatives	33
# False Positive	3
% False Positive	9.1%

Table 25: Qualitative results of 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)	**Sample 1**	**Sample 2**
Participant Number	**0.0%**	**0.5%**
1752	N	P
1783	N	P
1847	N	P
1854	**P**	P
1859	N	P
1862	N	P
1892	N	P
1895	**P**	P
1897	N	P
2034	N	P
2089	N	P
2560	N	P
2569	N	P
2732	NR	P
4937	N	P
4945	N	P
4950	N	P
4956	N	P
4964	N	P
4966	N	P
4973	N	P
4974	N	P
4975	N	P
4976	N	P
4977	N	P
4984	N	P
4987	N	P

CP4 EPSPS (RUR)	Sample 1	Sample 2
Participant Number	0.0%	0.5%
N, Results	26	27
# Negative	24	0
# Positive	2	27
% Correct	92.3%	100.0%
% Incorrect	7.7%	0.0%

Table 26: Percentages of correct results, false negatives, and false positives in qualitative reports of CP4 EPSPS (Roundup Ready™) for all participants

Total # Reported Results	53
# Incorrect	2
% Correct	96.2%
# Provided Positives	27
# False Negative	0
% False Negative	0.0%
# Provided Negatives	26
# False Positive	2
% False Positive	7.7%

Table 27: Qualitative results of soybeans fortified with A2704-12 (Liberty Link®) for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface)

LL	Sample 1	Sample 2
Participant Number	1.0%	0.5%
1785	P	P
1847	P	P
1859	P	P
1862	P	P
1875	P	P
1893	P	P
1895	P	P
2034	P	P
2089	P	P
2560	P	P
2692	P	P
4504	P	P
4934	P	P
4936	P	P
4937	P	P
4942	P	P

LL	Sample 1	Sample 2
Participant Number	**1.0%**	**0.5%**
4945	P	P
4950	P	P
4957	P	P
4964	P	P
4966	P	P
4975	P	P
4976	P	P
4977	P	P
N, Results	24	24
# Negative	0	0
# Positive	24	24
% Correct	100.0%	100.0%
% Incorrect	0.0%	0.0%

Table 28: Percentages of correct results, false negatives, and false positives in qualitative reports of A2704-12 (Liberty Link®) for all participants

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

Table 29: Qualitative results of soybeans fortified with CP4 EPSPS (Roundup Ready™ II) for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

RUR II	Sample 1	Sample 2
Participant Number	**0.2%**	**0.0%**
1752	P	N
1783	P	N
1785	P	N
1788	P	N
1847	P	N
1854	P	**P**
1859	P	N
1862	P	N
1875	P	N
1892	P	N
1895	P	N
2034	P	N
2089	P	N
2560	P	N
2569	P	N
2692	P	N
2824	P	N
3928	P	N
4502	P	N
4504	P	N
4937	P	N
4945	P	N
4950	P	N
4957	P	N
4964	P	N
4966	P	N
4973	P	N
4975	P	N
4976	P	N
4987	P	N
N, Results	30	30
# Negative	0	29
# Positive	30	1
% Correct	100.0%	96.7%
% Incorrect	0.0%	3.3%

Table 30: Percentages of correct results, false negatives, and false positives in qualitative reports of CP4 EPSPS (Roundup Ready™ II) for all participants

Total # Reported Results	60
# Incorrect	1
% Correct	98.3%
# Provided Positives	30
# False Negative	0
% False Negative	0.0%
# Provided Negatives	30
# False Positive	1
% False Positive	3.3%

Table 31: Qualitative results of soybeans fortified with DP305423 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in bold face)

DP 305423	Sample 1	Sample 2
Participant Number	**0.0%**	**0.5%**
1754	N	P
1761	N	P
1785	N	P
1847	N	P
1859	N	P
1893	N	P
1897	N	P
2005	N	P
2034	N	P
2692	N	P
2824	N	P
2831	N	P
4502	N	P
4934	N	P
4937	N	P
4942	N	P
4945	N	P
4950	N	P
4956	N	P
4960	N	P
4962	N	P
4964	N	P
4966	N	P
4974	N	P
4975	N	P
4976	N	P
4977	N	P

DP 305423	Sample 1	Sample 2
Participant Number	0.0%	0.5%
4987	N	P
N, Results	28	28
# Negative	28	0
# Positive	0	28
% Correct	100.0%	100.0%
% Incorrect	0.0%	0.0%

Table 32: Percentages of correct results, false negatives, and false positives in qualitative reports of DP305423 for all participants

Total # 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 33: Qualitative results for soybeans fortified with 35S for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in bold face)

Event: 35S Soy		
Event: 35S Soy	Sample 1	Sample 2
Participant Number	P	P
1752	P	P
1754	P	P
1764	P	P
1770	P	P
1785	P	P
1859	P	P
1870	P	P
1875	P	P
1892	P	P
1893	**P**	P
1895	P	P
1897	P	P
2005	P	P
2034	P	P
2057	P	P
2076	P	P
2560	P	P

Event: 35S Soy		
Event: 35S Soy	**Sample 1**	**Sample 2**
Participant Number	**P**	**P**
2692	P	P
2716	P	P
2717	P	P
2720	P	P
2831	P	P
3928	P	P
4502	P	P
4504	P	P
4932	P	P
4933	P	P
4934	P	P
4935	P	P
4937	P	P
4939	P	P
4942	P	P
4945	P	P
4950	P	P
4951	P	P
4952	P	P
4956	P	P
4957	P	P
4960	P	P
4962	P	P
4964	P	P
4966	P	P
4974	P	P
4975	P	P
4976	P	P
4980	P	P
4983	**N**	**N**
4984	**N**	P
4987	P	P
4990	P	P
7002	**N**	P
7003	P	P
7005	P	P
7006	**N**	P
7007	P	P
7008	P	P
7009	**N**	**N**
7011	P	P
7013	P	P

N, Results	59	59
# Negative	5	2
# Positive	52	55
% Correct	88.1%	93.2%
% Incorrect	8.5%	3.4%

Table 34: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy 35S for all participants

Total # Reported Results	118
# Incorrect	7
% Correct	94.1%
# Provided Positives	118
# False Negative	7
% False Negative	5.9%
# Provided Negatives	0
# False Positive	0
% False Positive	0.0%

Table 35: Qualitative results of soybeans fortified with NOS for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in bold face)

Event: NOS Soy		
Event: NOS Soy	**Sample 1**	**Sample 2**
Participant Number	**N**	**P**
1752	N	**N**
1754	N	P
1764	N	P
1770	N	P
1785	N	P
1854	**P**	P
1859	N	P
1862	N	P
1870	N	P
1875	N	P
1892	N	P
1893	N	P
1895	**P**	P
1897	N	P
2005	N	P
2034	N	P
2057	N	P
2076	N	P
2560	N	P
2692	N	P
2716	N	P
2717	N	P
2831	N	P
3928	N	P
4502	N	P
4504	**P**	P
4932	N	P
4933	N	P

Event: NOS Soy		
Event: NOS Soy	**Sample 1**	**Sample 2**
Participant Number	**N**	**P**
4934	N	P
4935	N	P
4936	N	P
4937	N	P
4939	N	P
4942	N	P
4945	N	P
4950	N	P
4951	N	P
4952	N	P
4956	N	P
4957	**P**	P
4960	N	P
4962	N	P
4964	N	P
4966	N	P
4974	N	P
4975	N	P
4976	N	P
4977	N	P
4980	N	P
4983	N	**N**
4984	N	P
4987	N	P
4990	N	P
7002	N	P
7003	N	P
7005	N	P
7006	N	P
7008	N	P
7009	**P**	**N**
7011	**P**	P
7013	N	P

N, Results	61	61
# Negative	55	3
# Positive	6	58
% Correct	90.2%	95.1%
% Incorrect	9.8%	4.9%

Note: The NOS trait serves as a terminator in RUR and DP305423 in this list of events.

Table 36: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy NOS for all participants

Total # Reported Results	122
# Incorrect	9
% Correct	92.6%
# Provided Positives	61
# False Negative	3
% False Negative	4.9%
# Provided Negatives	61
# False Positive	6
% False Positive	9.8%

Table 37: Qualitative results of soybeans fortified with FMV for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in bold face)

Event: FMV Soy		
Event: FMV Soy	**Sample 1**	**Sample 2**
Participant Number	**P**	**N**
1754	P	N
1785	P	N
1859	P	N
1870	P	N
1875	P	N
1892	P	N
1895	P	N
2005	P	N
2057	P	N
2716	P	N
2717	P	N
3928	P	N
4932	P	N
4934	**N**	N
4935	P	N
4936	P	N
4945	P	N
4950	P	N
4951	P	N
4952	P	N
4957	P	N
4960	P	N
4964	P	N
4966	P	N

Event: FMV Soy		
Event: FMV Soy	Sample 1	Sample 2
Participant Number	P	N
4974	P	N
4975	P	N
4976	P	N
4977	P	N
4987	P	N
4990	P	N
7002	N	N
7013	P	N

N, Results	32	32
# Negative	2	32
# Positive	30	0
% Correct	93.8%	100.0%
% Incorrect	6.3%	0.0%

Note: The FMV trait is a promoter in RURII in this list of events.

Table 38: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy FMV for all participants

Total # Reported Results	64
# Incorrect	2
% Correct	96.9%
# Provided Positives	32
# False Negative	2
% False Negative	6.3%
# Provided Negatives	32
# False Positive	0
% False Positive	0.0%

Table 39: 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	GA21	MON810	Herculex®
N, Results	263	264	144	143	128
Reported Incorrect	14	9	10	7	12
% Correct	94.7%	96.6%	93.1%	95.1%	90.6%
# Provided Positives	198	264	72	108	32
N, False Negatives	5	9	7	5	5
% False Negative	2.5%	3.4%	9.7%	4.6%	15.6%
# Provided Negatives	65	0	72	35	96
N, False Positives	9	0	3	2	7
% False Positives	13.8%	0.0%	4.2%	5.7%	7.3%

Event	MON863	Herculex® RW	MIR604	EV3272	MON88017
N, Results	143	127	144	112	135
Reported Incorrect	13	7	3	6	7
% Correct	90.9%	94.5%	97.9%	94.6%	94.8%
# Provided Positives	36	64	36	84	68
N, False Negatives	2	4	2	0	4
% False Negative	5.6%	6.3%	5.6%	0.0%	5.9%
# Provided Negatives	107	63	108	84	67
N, False Positives	11	3	1	4	3
% False Positives	10.3%	4.8%	0.9%	4.8%	4.5%

Event	MON89034	MIR162	RUR	LL	RUR II
N, Results	135	132	53	48	60
Reported Incorrect	11	6	2	0	1
% Correct	91.9%	95.5%	96.2%	100.0%	98.3%
# Provided Positives	68	66	27	48	30
N, False Negatives	7	0	0	0	0
% False Negative	10.3%	0.0%	0.0%	0.0%	0.0%
# Provided Negatives	67	33	26	0	30
N, False Positives	4	3	2	0	1
% False Positives	6.0%	9.1%	7.7%	0.0%	3.3%

Event	DP305423	Soy 35S	Soy NOS	Soy FMV
N, Results	56	118	122	64
Reported Incorrect	0	7	9	2
% Correct	100.0%	94.1%	92.6%	96.9%
# Provided Positives	28	118	61	32
N, False Negatives	0	7	3	2
% False Negative	0.0%	5.9%	4.9%	6.3%
# Provided Negatives	28	0	61	32
N, False Positives	0	0	6	0
% False Positives	0.0%	0.0%	9.8%	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.

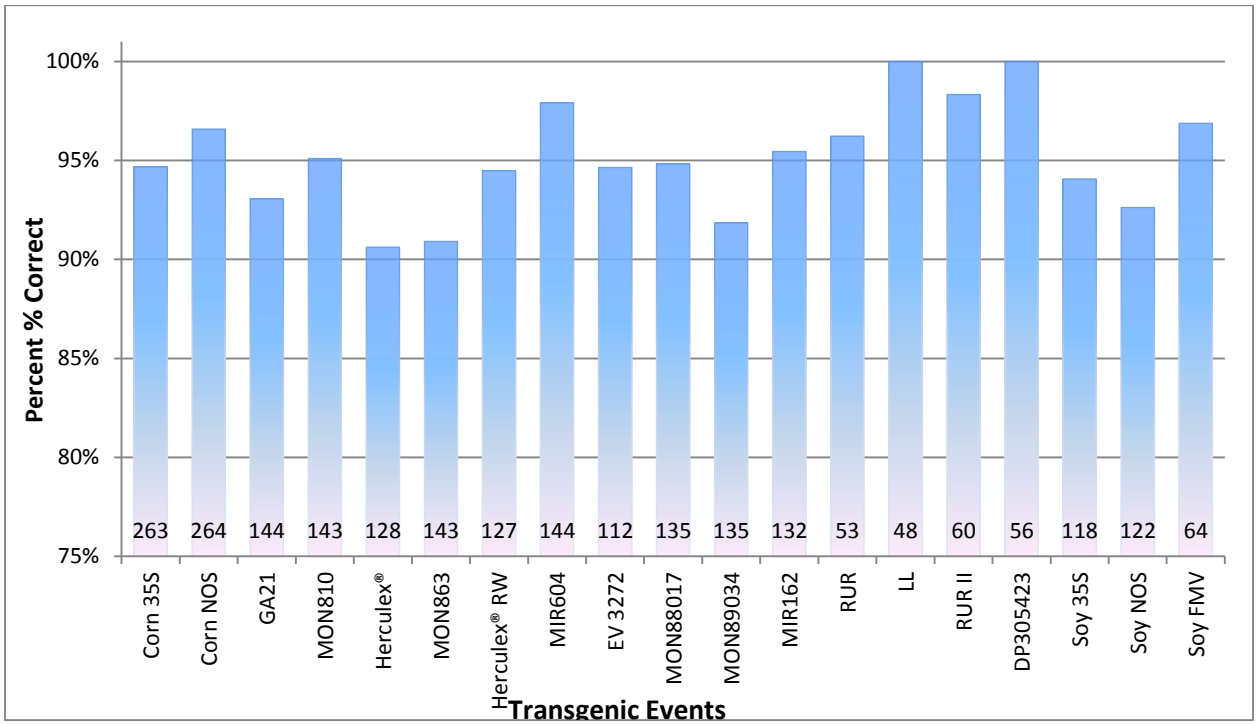

Table 40: Protein Based Lateral Flow Strip (LFS) Testing results for the detection of transgenic events in corn (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4	
Cry1Ab (MON810)	**0.00%**	**1.65%**	**0.38%**	**0.17%**	**LOD**
1843	N	P	P	P	1.0%
1895	N	**N**	N*	N*	0.8%
2815	N	**N**	**N**	**N**	Not Provided
3931	N	P	N*	N*	0.8%
4902	N	**N**	**N**	**N**	Not Provided
Herculex	**0.0%**	**0.45%**	**0.0%**	**0.0%**	
1843	N	N*	N	N	0.5%
1895	N	N*	N	N	0.5%
2815	N	**N**	N	N	Not Provided
3931	N	N*	**P**	**P**	0.5%
4902	N	**N**	N	N	0.5%
Cry3Bb1 (MON863/MON88017)	**0.00%**	**0.62%**	**1.29%**	**0.00%**	
1843	N	**N**	P	N	0.5%
1895	N	P	P	N	0.5%
2815	N	**N**	P	N	Not Provided
Hclx RW	**0.00%**	**0.00%**	**1.01%**	**0.46%**	
1843	N	N	**N**	N*	0.5%
1895	N	N	P	N*	0.5%
2815	N	N	P	P	Not Provided
MIR 604	**0.17%**	**0.00%**	**0.00%**	**0.00%**	
1843	N*	N	N	N	0.5%
1895	N*	N	N	N	0.5%
2815	**N**	N	N	N	Not Provided
MON89034	**0.00%**	**0.00%**	**0.42%**	**0.86%**	
1843	N	N	N*	P	0.5%
MIR 162	**0.43%**	**1.90%**	**0.00%**	**1.45%**	
1843	N*	P	N	P	0.5%
1895	P	P	N	P	0.5%

* - Fortification level/Consensus Mean below Participants' LOD, assessed as Provided Negative

Table 41: Percentage of correct results, false negatives, and false positives in reports for transgenic events in corn using Protein Based Lateral Flow Strip (LFS) Testing

Event	Cry1Ab	Herculex	Cry3Bb1	Hclx RW
Total # Reported Results	20	20	12	12
# Incorrect	7	4	2	1
% Correct	65.0%	80.0%	83.3%	91.7%
# Provided Positives	11	2	6	4
# False Negatives	7	2	2	1
% False Negatives	63.6%	100.0%	33.3%	25.0%
# Provided Negatives	9	18	6	8
# False Positives	0	2	0	0
% False Positive	0.0%	11.1%	0.0%	0.0%

Event	MIR 604	MON89034	MIR 162
Total # Reported Results	12	4	8
# Incorrect	1	0	0
% Correct	91.7%	100.0%	100.0%
# Provided Positives	1	1	5
# False Negatives	1	0	0
% False Negatives	100.0%	0.0%	0.0%
# Provided Negatives	11	3	3
# False Positives	0	0	0
% False Positive	0.0%	0.0%	0.0%

Table 42: Results for soybeans fortified with CP4EPSPS (RUR/RURII) and A2704-12 for all participants using Protein Based Lateral Flow Strip (LFS) Testing (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

CP4 EPSPS (RUR & RURII)	Sample 1	Sample 2	
Participant Number	0.17%	0.47%	LOD
1782	**N**	P	0.1%
1843	P	P	0.1%
1895	P	P	0.10%
2126	P	P	Not Provided
2815	P	P	0.1%
3931	P	P	0.1%
4902	P	P	Not Provided
A2704-12 (LL)	0.75%	0.36%	LOD
1782	**N**	N*	0.5%
1843	P	P	0.5%
1895	P	P	0.1%
2815	P	P	0.1%

* - Fortification level/Consensus Mean below Participants' LOD, assessed as Provided Negative

Table 43: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for all participants using Protein Based Lateral Flow Strip (LFS) Testing

Event	RUR/RURII	LL
Total # Reported results	14	8
# Incorrect	1	1
% Correct	92.9%	87.5%
# Provided Positives	14	7
# False Negative	1	1
% False Negative	7.1%	14.3%
# Provided Negatives	0	1
# False Positive	0	0
% False Positive	0.0%	0.0%

Table 44: Results for the detection of transgenic events in corn using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

Participant	Sample 1	Sample 2	Sample 3	Sample 4	
Cry1Ab (MON810)	**0.0%**	**1.65%**	**0.38%**	**0.17%**	**LOD**
1895	N	**N**	**N**	**N**	Not Provided
Herculex	**0.00%**	**0.45%**	**0.00%**	**0.00%**	
1895	N	P	N	N	Not Provided
MON863	**0.00%**	**0.00%**	**1.06%**	**0.00%**	
1895	N	**P**	P	N	Not Provided

Table 45: Percentage of correct results in the detection of transgenic events in corn using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

Event	Cry1Ab	Herculex	MON863
Total # Reported results	4	4	4
# Incorrect	3	0	1
% Correct	25.0%	100.0%	75.0%
# Provided Positives	3	1	1
# False Negative	3	0	0
% False Negative	100.0%	0.0%	0.0%
# Provided Negatives	1	3	3
# False Positive	0	0	1
% False Positive	0.0%	0.0%	33.3%

Table 46: Results for soybeans fortified with CP4EPSPS and A2704-12 for participants using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

CP4 EPSPS (RUR & RURII)	Sample 1	Sample 2	
Participant Number	**0.2%**	**0.5%**	**LOD**
2126	P	P	Not Provided
2817	N*	P	0.3%
4961	N*	P	0.3%
4975	P	P	Not Provided

A2704-12 (LL)	0.7%	0.4%	LOD
4975	P	P	Not Provided

* - Fortification level/Consensus Mean below Participants' LOD, assessed as Provided Negative

Table 47: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for participants using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

Event	RUR/RURII	LL
Total # Reported results	8	2
# Incorrect	0	0
% Correct	100.0%	100.0%
# Provided Positives	6	2
# False Negative	0	0
% False Negative	0.0%	0.0%
# Provided Negatives	2	0
# False Positive	0	0
% False Positive	0.0%	0.0%

Table 48: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays). Values highlighted in yellow indicate a z-score outside of the expected range, i.e., z > +2 or z < -2 that is not considered an outlier.

Event: GA21						
%w/w Fortification Level	1.0%		0.2%		0.0%	0.0%
Consensus Mean	1.18%		0.23%		0.0%	0.0%
Participant Number	Result	z-score	Result	z-score	Result	Result
1752	0.79	-0.69	0.14	-0.83	0.00	0.00
1754	1.00	-0.32	0.20	-0.25	0.00	0.00
1761	1.87	1.21	0.40	1.70	0.00	0.00
1764	1.17	-0.02	0.21	-0.15	0.00	0.00
1770	0.80	-0.67	0.10	-1.22	0.00	0.00
1844	0.76	-0.74	0.16	-0.64	0.00	0.00
1870	0.80	-0.67	0.20	-0.25	0.00	0.00
1875	0.90	-0.49	0.20	-0.25	0.00	0.00
2005	1.16	-0.04	0.32	0.92	0.00	0.00
2057	1.40	0.38	0.24	0.14	0.00	0.00
2694	0.70	-0.84	<0.2		0.00	0.00
2716	0.52	-1.16	0.12	-1.03	0.00	0.00
3928	0.94	-0.42	0.11	-1.12	0.00	0.00
4932	1.15	-0.05	0.15	-0.73	0.00	0.00
4934	2.30	1.96	0.40	1.70	0.00	0.00
4936	0.92	-0.46	0.18	-0.44	0.00	0.00
4945	1.76	1.02	<0.1		0.00	0.00
4952	1.00	-0.32	0.20	-0.25	0.00	0.00
4953	2.16	1.72	0.45	2.19	0.00	0.00
4990	2.30	1.96	0.30	0.73	0.00	0.00
7010	0.40	-1.37	0.20	-0.25	0.00	0.00

Table 49: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays). Quantifications marked in red indicate values determined to be either: (1) a positive value for a non-fortified sample (i.e. a false positive result); or (2) a negative value for a fortified sample (i.e. a false negative result); or (3) an outlier determined by the "Grubb's Test for Outliers". Values highlighted in yellow indicate a z-score outside of the expected range, i.e., z > +2 or z < -2 that is not considered an outlier.

Event: MON810							
%w/w Fortification Level	**0.0%**	**2.0%**		**0.5%**		**0.2%**	
Consensus Mean	**0.0%**	**1.65%**		**0.38%**		**0.17%**	
Participant Number	**Result**	**Result**	**z-score**	**Result**	**z-score**	**Result**	**z-score**
1754	0.00	1.00	-1.23	0.30	-0.60	0.20	0.44
1770	0.00	1.20	-0.85	0.40	0.11	0.20	0.44
1788	0.00	1.70	0.10	0.42	0.25	0.25	1.31
1844	0.00	1.41	-0.45	0.17	-1.52	0.11	-1.12
1870	0.00	2.50	1.61	0.70	2.24	0.30	2.18
1875	0.00	1.50	-0.28	0.30	-0.60	0.10	-1.30
2005	0.00	1.81	0.31	0.37	-0.10	0.13	-0.78
2057	0.00	1.93	0.53	0.40	0.11	0.28	1.84
2716	0.00	0.58	-2.02	0.28	-0.74	0.10	-1.30
2732	0.00	2.02	0.70	P		0.16	-0.25
2831	0.00	1.96	0.59	0.43	0.32	0.14	-0.60
3928	0.00	1.33	-0.60	0.30	-0.60	0.12	-0.95
3929	0.00	1.51	-0.26	0.39	0.04	0.17	-0.08
4934	0.00	2.13	0.91	0.55	1.18	0.20	0.44
4936	0.00	1.69	0.08	0.34	-0.32	0.19	0.27
4942	0.00	2.32	1.27	0.64	1.81	0.25	1.31
4952	0.00	P		1.00		0.20	0.44
4953	0.00	1.96	0.59	0.48	0.68	0.17	-0.08
4957	0.00	1.40	-0.47	0.30	-0.60	0.15	-0.43
4990	0.00	2.15	0.95	0.44	0.39	0.16	-0.25
7010	0.00	0.50	-2.17	0.10	-2.02	0.10	-1.30
7013	0.00	2.02	0.70	0.38	-0.03	0.16	-0.25

P - Qualitative data only

Table 50: Quantitative results and z-scores for corn fortified with Herculex® 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.

Event: Herculex®					
%w/w Fortification Level	**0.0%**	**1.0%**		**0.0%**	**0.0%**
Consensus Mean	**0.0%**	**0.45%**		**0.0%**	**0.0%**
Participant Number	**Result**	**Result**	**z-score**	**Result**	**Result**
1754	0.00	0.40	-0.26	0.00	0.00
1844	0.00	0.32	-0.68	0.00	0.00
1870	0.00	0.60	0.79	0.00	0.00
1875	0.00	0.50	0.26	0.00	0.00
2057	0.00	0.47	0.11	0.00	0.00
2716	0.00	0.10	-1.84	0.00	0.00
2732	0.00	0.35	-0.53	0.00	0.00
3928	0.00	0.68	1.21	0.00	0.00
4502	0.00	0.98±0.12		0.00	0.00
4932	0.00	0.66	1.10	0.00	0.00
4934	0.00	0.61	0.84	0.00	0.00
4936	0.00	0.26	-1.00	0.00	0.00
4952	0.00	0.20	-1.31	0.00	0.00
4953	0.00	0.58	0.68	0.00	0.00
4957	0.00	0.41	-0.21	0.00	0.00
4990	0.00	0.82	1.94	0.00	0.00
7010	0.00	0.30	-0.79	0.00	0.00
7013	0.00	0.39	-0.32	0.00	0.00

Table 51: 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.

Event: MON863					
%w/w Fortification Level	**0.0%**	**0.0%**	**1.0%**		**0.0%**
Consensus Mean	**0.0%**	**0.0%**	**1.06%**		**0.0%**
Participant Number	**Result**	**Result**	**Result**	**z-score**	**Result**
1754	0.00	0.00	1.30	0.80	0.00
1844	0.00	0.00	1.09	0.11	0.00
1870	0.00	0.00	1.00	-0.19	0.00
1875	0.00	0.00	1.10	0.14	0.00
2057	0.00	0.00	1.30	0.80	0.00
2716	0.00	0.00	0.22	-2.76	0.00
2732	NR	NR	1.07	0.04	NR
3928	0.00	0.00	0.74	-1.05	0.00
4502	0.00	0.00	1.04±0.34		0.00
4932	0.00	0.00	1.09	0.11	0.00
4934	0.00	0.00	1.29	0.77	0.00
4936	0.00	0.00	0.94	-0.39	0.00
4952	0.00	0.00	0.80	-0.85	0.00
4953	NR	NR	1.47	1.36	NR
4960	0.00	0.00	1.10	0.14	0.00
4990	0.00	0.00	1.35	0.96	0.00
7010	0.00	0.00	0.80	-0.85	0.00

NR – Not Reported

Table 52: Quantitative results and z-scores for corn fortified with Herculex® RW for all participants (DNA-based assays). Quantifications marked in red indicate values determined to be either: (1) a positive value for a non-fortified sample (i.e. a false positive result); or (2) a negative value for a fortified sample (i.e. a false negative result); or (3) an outlier determined by the "Grubb's Test for Outliers".

Event: Herculex RW						
%w/w Fortification Level	**0.0%**	**0.0%**	**0.5%**		**0.2%**	
Consensus Mean	**0.0%**	**0.0%**	**1.01%**		**0.46%**	
Participant Number	**Result**	**Result**	**Result**	**z-score**	**Result**	**z-score**
1754	0.00	0.00	1.20	0.54	0.40	-0.25
1844	0.00	0.00	0.96	-0.14	0.27	-0.79
1870	0.00	0.00	1.20	0.54	0.60	0.59
1875	0.00	0.00	1.00	-0.03	0.40	-0.25
2057	0.00	0.00	0.88	-0.37	0.46	0.01
2716	0.00	0.00	2.92		1.22	3.20
3928	0.00	0.00	1.23	0.63	0.33	-0.54
4504	0.00	0.00	0.44	-1.63	N*	
4932	0.00	0.00	1.07	0.17	0.37	-0.37
4936	0.00	0.00	0.84	-0.48	0.31	-0.62
4952	0.00	0.00	1.50	1.40	0.50	0.17
4953	0.00	0.00	1.30	0.83	0.52	0.26
4990	0.00	0.00	0.61	-1.14	0.34	-0.50
7010	0.00	0.00	0.40	-1.74	0.30	-0.67
7013	0.00	0.00	1.50	1.40	0.40	-0.25

N* - Fortification level/Consensus Mean below Participants' LOD, assessed as Provided Negative

Table 53: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays). Values highlighted in yellow indicate a z-score outside of the expected range, i.e., z > +2 or z < -2 that is not considered an outlier.

Event: MIR604					
%w/w Fortification Level	**0.2%**		**0.0%**	**0.0%**	**0.0%**
Consensus Mean	**0.17%**		**0.0%**	**0.0%**	**0.0%**
Participant Number	**Result**	**z-score**	**Result**	**Result**	**Result**
1752	0.20	0.31	0.00	0.00	0.00
1754	0.10	-0.90	0.00	0.00	0.00
1761	0.14	-0.41	0.00	0.00	0.00
1764	0.11	-0.78	0.00	0.00	0.00
1844	0.32	1.76	0.00	0.00	0.00
1870	0.10	-0.90	0.00	0.00	0.00
1875	0.10	-0.90	0.00	0.00	0.00
2057	0.13	-0.54	0.00	0.00	0.00
2694	<0.2		0.00	0.00	0.00
2716	0.14	-0.41	0.00	0.00	0.00
4502	0.11±0.06		0.00	0.00	0.00
4504	0.23	0.65	0.00	0.00	0.00
4932	0.14	-0.41	0.00	0.00	0.00
4936	0.13	-0.54	0.00	0.00	0.00
4945	<0.1		0.00	0.00	0.00
4951	0.35	2.13	0.00	0.00	0.00
4953	0.22	0.55	0.00	0.00	0.00
4990	0.28	1.28	0.00	0.00	0.00
7010	0.10	-0.90	0.00	0.00	0.00

Table 54: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays). Values highlighted in yellow indicate a z-score outside of the expected range, i.e., z > +2 or z < -2 that is not considered an outlier. Quantification marked in red indicates a value determined to be an outlier determined by the "Grubb's Test for Outliers".

%w/w Fortification Level	0.5%		0.0%	1.0%		0.2%	
Consensus Mean	0.62%		0.0%	1.02%		0.26%	
Participant Number	Result	z-score	Result	Result	z-score	Result	z-score
1754	0.70	0.42	0.00	1.20	0.41	0.40	1.42
1764	0.78	0.82	0.00	1.39	0.85	0.32	0.61
1844	0.75	0.67	0.00	1.45	0.99	0.23	-0.29
1870	0.70	0.42	0.00	1.30	0.64	0.30	0.41
1875	0.50	-0.60	0.00	0.70	-0.75	0.10	-1.60
2057	0.73	0.57	0.00	1.59	1.31	0.26	0.01
2716	0.21	-2.08	0.00	0.57	-1.05	0.10	-1.60
4504	0.76	0.72	0.00	0.12	-2.09	0.82	
4934	1.77		0.00	0.88	-0.33	0.38	1.22
4953	0.63	0.06	0.00	1.21	0.43	0.24	-0.19
4990	0.74	0.62	0.00	1.17	0.34	0.32	0.61
7010	0.30	-1.62	0.00	0.70	-0.75	0.20	-0.59

Table 55: Quantitative results and z-scores for corn fortified with MON 88017 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. Quantification marked in red indicates a value determined to be an outlier determined by the "Grubb's Test for Outliers".

Event: MON 88017						
%w/w Fortification Level	0.0%	0.5%		0.2%		0.0%
Consensus Mean	0.0%	0.62%		0.23%		0.0%
Participant Number	Result	Result	z-score	Result	z-score	Result
1752	0.00	0.37	-0.99	0.14	-0.78	0.00
1754	0.00	0.60	-0.08	0.20	-0.28	0.00
1764	0.00	0.77	0.60	0.15	-0.70	0.00
1844	0.00	0.67	0.20	0.17	-0.53	0.00
1870	0.00	0.50	-0.48	0.20	-0.28	0.00
2005	0.00	0.67	0.20	0.24	0.06	0.00
2057	0.00	0.96	1.36	0.33	0.81	0.00
2716	0.00	0.19	-1.71	0.10	-1.11	0.00
4502	0.00	0.43±0.13		0.18±0.05		0.00
4934	0.00	0.93	1.24	0.55	2.65	0.00
4936	0.00	0.45	-0.67	0.17	-0.53	0.00
4952	0.00	0.30	-1.27	0.20	-0.28	0.00
4953	0.00	0.78	0.64	0.31	0.64	0.00
4957	0.00	0.61	-0.04	0.26	0.22	0.00
4960	0.00	0.80	0.72	0.38	1.23	0.00
4990	0.00	1.01	1.56	0.70		0.00
7010	0.00	0.30	-1.27	0.10	-1.11	0.00

Table 56: 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 that is not considered an outlier.

Event: MON 89034						
%w/w Fortification Level	**0.0%**	**0.0%**	**0.5%**		**1.0%**	
Consensus Mean	**0.0%**	**0.0%**	**0.42%**		**0.86%**	
Participant Number	**Result**	**Result**	**Result**	**z-score**	**Result**	**z-score**
1752	0.00	0.00	0.22	-1.29	0.59	-0.90
1754	0.00	0.00	0.40	-0.11	0.80	-0.21
1761	0.00	0.00	0.65	1.53	1.12	0.84
1764	0.00	0.00	0.48	0.42	1.04	0.58
1844	0.00	0.00	0.63	1.40	1.22	1.17
1870	0.00	0.00	0.50	0.55	1.40	1.76
2057	0.00	0.00	0.38	-0.24	0.80	-0.21
2716	0.00	0.00	0.10	-2.07	0.36	-1.65
4504	0.00	0.00	0.43	0.09	0.98	0.38
4936	0.00	0.00	0.27	-0.96	0.59	-0.90
4952	0.00	0.00	0.50	0.55	0.60	-0.86
4953	0.00	0.00	0.47	0.35	1.09	0.75
4990	0.00	0.00	0.50	0.55	0.99	0.42
7010	0.00	0.00	0.30	-0.76	0.50	-1.19

Table 57: Quantitative results and z-scores for corn fortified with MIR162 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.

Event: MIR 162							
%w/w Fortification Level	**0.2%**		**1.0%**		**0.0%**	**0.8%**	
Consensus Mean	**0.43%**		**1.90%**		**0.0%**	**1.45%**	
Participant Number	**Result**	**z-score**	**Result**	**z-score**	**Result**	**Result**	**z-score**
1754	0.40	-0.20	1.70	-0.30	0.00	1.10	-0.58
1761	0.70	1.86	2.58	1.00	0.00	1.96	0.85
1764	0.30	-0.88	2.03	0.19	0.00	1.86	0.68
1844	0.37	-0.40	2.24	0.50	0.00	1.54	0.15
1870	0.20	-1.57	0.50	-2.06	0.00	0.45	-1.66
2057	0.49	0.42	2.51	0.90	0.00	2.29	1.40
2716	0.53	0.70	1.54	-0.53	0.00	1.16	-0.48
4936	0.30	-0.88	1.36	-0.80	0.00	1.14	-0.51
4952	0.50	0.49	2.30	0.59	0.00	1.00	-0.75
4953	0.43	0.01	2.09	0.28	0.00	1.65	0.33
4957	0.47	0.28	1.92	0.03	0.00	1.29	-0.26
4962	0.49	0.42	2.38	0.71	0.00	1.69	0.40
4990	0.62	1.31	2.76	1.27	0.00	2.55	1.83
7010	0.20	-1.57	0.70	-1.77	0.00	0.60	-1.41

Table 58: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) 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 is not considered an outlier.

Event: RUR			
%w/w Fortification Level	**0.0%**	**0.5%**	
Consensus Mean	**0.0%**	**0.47%**	
Participant Number	**Result**	**Result**	**z-score**
1754	0.00	0.40	-0.36
1761	0.00	0.59	0.65
1764	0.00	0.68	1.13
1770	0.00	0.40	-0.36
1785	0.00	0.68	1.13
1788	0.00	0.44	-0.14
1844	0.00	0.42	-0.25
1870	0.00	0.36	-0.57
1875	0.00	0.40	-0.36
1893	0.00	0.20	-1.42
2005	0.00	0.44	-0.14
2057	0.00	0.29	-0.94
2060	0.00	1.00	2.84
2067	0.00	0.26	-1.10
2692	0.00	0.42±0.08	
2716	0.00	0.41	-0.30
2831	0.00	0.74	1.45
3928	0.00	0.51	0.23
4502	0.00	0.43±0.06	
4504	0.00	0.50	0.18
4932	0.00	0.51	0.23
4934	0.00	0.49	0.12
4935	0.00	0.20	-1.42
4936	0.00	0.37	-0.52
4942	0.00	0.47	0.02
4952	0.00	0.50	0.18
4953	0.00	0.40	-0.36
4957	0.00	0.37	-0.52
4960	0.00	0.40	-0.36
4990	0.00	0.50	0.18
7007	0.00	0.95	2.59
7012	0.00	0.21	-1.37
7013	0.00	0.38	-0.46

Table 59: Quantitative results and z-scores for soybeans fortified with A2704-12 (Liberty Link®) for all participants (DNA-based assays). Quantification marked in red indicates a value determined to be an outlier determined by the "Grubb's Test for Outliers".

Event: LL				
%w/w Fortification Level	1.0%		0.5%	
Consensus Mean	0.75%		0.36%	
Participant Number	Result	z-score	Result	z-score
1754	0.70	-0.16	0.40	0.30
1761	0.94	0.64	0.54	1.24
1764	2.10		0.49	0.90
1770	1.30	1.84	0.40	0.30
1844	0.61	-0.46	0.23	-0.85
1870	0.88	0.44	0.47	0.77
2005	1.03	0.94	0.50	0.97
2057	0.41	-1.12	0.21	-0.99
2067	0.91	0.54	0.50	0.97
2716	0.19	-1.86	0.10	-1.73
2831	0.48	-0.89	P	
3928	1.14	1.30	0.54	1.24
4502	0.52±0..10		0.22±0.03	
4932	1.27	1.74	0.58	1.51
4951	0.46	-0.96	0.23	-0.85
4952	0.70	-0.16	0.20	-1.06
4953	0.71	-0.13	0.32	-0.25
4960	0.82	0.24	0.20	-1.06
4990	0.63	-0.39	0.39	0.23
7012	0.56	-0.62	0.26	-0.65
7013	0.47	-0.92	0.21	-0.99

Table 60: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS as Roundup Ready™ II (RUR II) 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 is not considered an outlier.

Event: RUR II			
%w/w Fortification Level	0.2%		0.0%
Consensus Mean	0.17%		0.0%
Participant Number	Result	z-score	Result
1754	0.10	-0.85	0.00
1761	0.15	-0.23	0.00
1764	0.26	1.14	0.00
1770	0.20	0.40	0.00
1844	0.10	-0.85	0.00
1870	0.23	0.77	0.00
1893	0.10	-0.85	0.00
2005	0.10	-0.85	0.00
2057	0.07	-1.22	0.00
2067	0.13	-0.48	0.00
2716	0.24	0.90	0.00
2732	0.15	-0.23	0.00
2831	0.25	1.02	0.00
4932	0.16	-0.10	0.00
4934	0.07	-1.22	0.00
4935	0.10	-0.85	0.00
4936	<0.1		0.00
4952	0.40	2.89	0.00
4953	0.15	-0.23	0.00
4960	0.26	1.14	0.00
4990	0.19	0.27	0.00
7012	0.17	0.02	0.00
7013	0.12	-0.60	0.00

Table 61: Quantitative results and z-scores for soybeans fortified with DP305423 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 is not considered an outlier.

Event: DP 305423			
%w/w Fortification Level	0.0%	0.5%	
Consensus Mean	0.0%	0.45%	
Participant Number	Result	Result	z-score
1764	0.00	0.44	-0.05
1844	0.00	0.58	0.63
1870	0.00	0.32	-0.64
1875	0.00	0.20	-1.22
2057	0.00	0.43	-0.10
2067	0.00	0.96	2.48
2716	0.00	0.51	0.29
2732	0.00	0.39	-0.30
3928	0.00	0.50	0.24
4504	0.00	0.86	2.00
4932	0.00	0.40	-0.25
4936	0.00	0.38	-0.34
4952	0.00	0.30	-0.73
4953	0.00	0.42	-0.15
4990	0.00	0.35	-0.49
7012	0.00	0.14	-1.51
7013	0.00	0.48	0.14

Table 62: Quantitative results and z-scores for 35S and NOS in corn for all participants (DNA based assay). Z-scores outside of the expected range, i.e., z > +2 or z < -2 were not observed in these data sets.

Event: 35S							
Consensus Mean	0.0%	1.7%		1.8%		1.0%	
Participant Number	Result	Result	z-score	Result	z-score	Result	z-score
1785	0.00	1.00	-1.52	1.20	-0.49	0.45	-1.64
1844	0.00	1.76	0.08	2.51	0.65	0.95	-0.23
2720	0.00	2.26	1.13	2.56	0.69	1.29	0.74
4936	0.00	2.00	0.58	2.56	0.69	1.16	0.37
4964	0.60	1.60	-0.26	0.00	-1.54	1.30	0.76

Event: NOS								
Consensus mean	2.2%		1.7%		2.2%		1.7%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1844	3.63	1.00	2.65	1.06	3.94	1.15	2.82	1.13
2720	2.15	-0.01	1.55	-0.13	1.30	-0.58	1.30	-0.37
4964	0.70	-1.00	0.80	-0.93	1.30	-0.58	0.90	-0.76

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 at this time.

Table 63: Quantitative results and z-scores for 35S, NOS, and FMV in soybean for all participants (DNA based assay). The sample size for event FMV soybean are too small to be statistically significant.

Event: 35S Soy				
Consensus mean	1.5%		1.1%	
Participant Number	Result	z-score	Result	z-score
1844	1.83	0.84	1.18	0.93
1862	1.10	-1.09	0.99	-0.61
4936	1.28	-0.61	0.93	-1.09
4977	1.84	0.86	1.16	0.77

Event: NOS Soy			
Consensus mean	0.0%	1.1%	
Participant Number	Result	Result	z-score
2031	0.0	0.75	-0.71
2723	0.0	1.5	0.71

Event: FMV Soy		
Event: FMV Soy	Sample 1	Sample 2
Participant Number	0.7%	0.0%
2031	0.70	0.0

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 at this time.

Table 64: Quantitative results for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

Event: RUR			
%w/w Fortification Level	0.0%	0.5%	
Participant Number	Result	Result	LOD
1782	0.00	0.40	0.3%

Table 65: 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 (%)
GA21	21	1.0	1.18	0.57	48.3	0.40 - 2.30
GA21	21	0.2	0.23	0.10	43.5	0.10 - 0.45
MON810	21	2.0	1.65	0.53	32.1	0..50 - 2.50
MON810	21	0.5	0.38	0.14	36.8	0.10 - 0.70
MON810	21	0.2	0.17	0.06	35.3	0.10 - 0.30
Herculex	17	1.0	0.45	0.2	42.2	0.10 - 0.82
MON863	16	1.0	1.06	0.30	28.3	0.22 - 1.47
HerculexRW	14	0.5	1.01	0.35	34.7	0.40 - 1.50
HerculexRW	14	0.2	0.46	0.24	52.2	0.27 - 1.22
MIR604	16	0.2	0.17	0.08	47.1	0.10 - 0.35
EV3272	12	0.5	0.62	0.20	32.3	0.21 - 0.78
EV3272	12	1.0	1.02	0.43	42.2	0.12 - 1.59
EV3272	12	0.2	0.26	0.10	38.5	0.10 - 0.40
MON88017	16	0.5	0.62	0.25	40.3	0.19 - 1.01
MON88017	16	0.2	0.23	0.12	52.2	0.10 - 0.55
MON89034	14	0.5	0.42	0.15	35.7	0.10 - 0.65
MON89034	14	1.0	0.86	0.30	34.9	0.36 - 1.40
MIR 162	14	0.2	0.43	0.15	34.9	0.20 - 0.70
MIR 162	14	1.0	1.90	0.68	35.8	0.50 - 2.76
MIR 162	14	0.8	1.45	0.60	41.4	0.45 - 2.55
RUR	33	0.5	0.47	0.19	40.4	0.20 - 1.00
LL	21	1.0	0.75	0.30	40.0	0.19 - 1.30
LL	21	0.5	0.36	0.15	41.7	0.10 - 0.58
RUR II	17	0.2	0.17	0.08	47.1	0.07 - 0.40
DP305424	17	0.5	0.45	0.21	46.7	0.14 - 0.96

Summary of Findings

It is recognized that some organizations participate in this program to retain their ISO accreditation. Participation also 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.

GIPSA does not dictate detection methods for biotechnology-derived traits. An individual laboratory may provide a Level of Detection (LOD) for its particular detection method. When the consensus mean in an event-fortified sample falls below the provided LOD, a negative result is considered a correct answer, and is assessed as a provided negative.

- **Qualitative Sample Analysis**

  DNA-based Testing. The typical method of DNA-based testing for 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 0.2% w/w; therefore, if the event was present it should be detectible by a laboratory that employs conventional PCR. As evidenced by the summary of performance scores (**Table 41** and **Figure 1**), all of the twenty transgenic events were correctly detected with greater than or equal to 90%, and nine (9) of the twenty (4/20) transgenic events were correctly detected with greater than or equal to 95% reliability, and two (2) of the twenty (2/20) transgenic events were correctly detected with 100% reliability.

  Eight participants reported using an End-point PCR test method. Six participants reported using Digital PCR. Two participants reported using DNA based Conventional PCR.

  Protein-based Testing. The methods of protein-based testing were lateral flow strip (LFS) and enzyme-linked immunosorbent assay (ELISA). The LFS test has a sensitivity ranging between 0.1- 2.0% w/w for corn events and 0.1- 0.50% w/w for soybean events according to some kit manufacturers. Generally, ELISA has a sensitivity of 0.1- 1.0% w/w for corn and soy events (Ahmed, 2004). The test results for MON863 and MON88017 are combined because both events express the *C3Bb1* protein, and protein-based testing cannot distinguish between the two events. Event Herculex® contain the *pat* (phosphinothricin N-transferase) gene, but combining the results is problematic.

- **Quantitative Sample Analysis**

  DNA-based Testing. The typical method of DNA-based testing for 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.

Five (5) participants submitted quantitative results for 35S event in corn and three (3) participants' submitted quantitative results for NOS in corn (**Table 64)**. The number of results for corn NOS is too small to hold statistical significance. The target %w/w levels for these traits should be additive for all events containing either 35S or NOS fortified into the sample. 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.

Four (4) laboratories submitted quantitative results for the 35S event in soybean, two (2) laboratories submitted quantitative results for the NOS event (**Tables 65**).

One laboratory submitted Quantitative results for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA) (**Table 66**)

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

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 66. 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., 0.2% w/w) and from tables with low numbers of results are not 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. Brian Beecher at US 816-891-0453, or by e-mail at Brian.S.Beecher@usda.gov or Dr. Ramaswamy Mani at US 816-891-0418, or by e-mail at Ramaswamy.Mani@usda.gov. For questions regarding this report, contact Dr. Ramaswamy Mani at US 816-891-0418, or by e-mail at Ramaswamy.Mani@usda.gov.

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