USDA/GIPSA Proficiency Program
Testing for the Presence of Biotechnology Events in Corn and Soybeans
April 2010 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 accuracy, capability and reliability.

Program Description
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 to 32 and Figure 1). 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. To assess accuracy of individual participant's submitted quantitative results for a specified transgenic event, z-scores (based on: reported value – fortification value / standard deviation) were computed for each reported quantification result (Tables 40 to 54). 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. Anything above a reported value of "0" for the 0.0% spike level would probably be 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 55) was prepared to show the accuracy and precision of the composite quantification results at each fortification level for the various transgenic events.

Sample Composition
The corn samples contained various combinations and concentrations of the following transgenic traits: T-25, CBH351, MON810, GA21, Bt-176, Bt-11, NK603, Herculex, MON863, Herculex RW, MIR 604 (Agrisure RW^{TM}), Event 3272; or, no events (i.e., negative corn sample). The various transgenic concentration levels were produced on a percentage weight-weight basis (%w/w). 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 were non-transgenic soybeans, or fortified soybean samples containing 0.1 to 1.5% of the transgenic glyphosate-tolerant soybeans (RoundUp Ready®) and/or the glufosinate ammonium tolerant soybeans (A2704-12). Each participant received six corn and four soybean samples. Each sample contained approximately 15 grams of ground material.

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, FAX, or regular mail. No analytical methodologies were specified, and organizations used both DNA- and protein-based testing technologies. Sixty-two organizations received samples in the April 2010 round of proficiency testing, and fifty-eight organizations submitted results.

- Twenty-three participants submitted **qualitative** results only, (2 participants included protein),
- Thirteen submitted **quantitative** results only (1 participant performed DNA and protein),
- Seventeen participants submitted a combination of **qualitative** and **quantitative** results (two participants performed DNA and protein based), and
- Five participants submitted **protein** based results, using Lateral Flow Strip (LFS) qualitative and 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; some 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:

<u>Qualitative Data Summaries</u>. This section summarizes qualitative sample analysis data:

- 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 T-25 for all participants (DNA-based assays).

2

- Table 36: Qualitative results for soybeans fortified with CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) Testing.

- Table 37: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) Testing.

- Table 38: Qualitative results for the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

- Table 39: Percentage of correct results in the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

- Table 40: Qualitative results for soybeans fortified with CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

- Table 41: Percentage of correct results in qualitative reports for CP4EPSPS for all participants 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 in Tables 40- 53 on non-fortified (0.0%) samples since a z-score assumes a normal distribution and the interpretation may be distorted).

- Table 42: Quantitative results and z-scores for corn fortified with T-25 for all participants (DNA-based assays).

- Table 43: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays).

- Table 44: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).

- Table 45: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).

- Table 46: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays).

- Table 47: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays).

- Table 48: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays).

- Table 49: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays).

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

35S Participant Number	Sample 1 P	Sample 2 N	Sample 3 P	Sample 4 P	Sample 5 P	Sample 6 P
1754	P	N	P	P	P	P
1761	P	N	P	P	P	P
1770	P	N	P	P	P	P
1774	P	N	P	P	P	P
1785	P	N	P	P	P	P
1844	P	N	P	P	P	P
1854	P	N	P	P	P	P
1858	P	N	P	P	P	P
1859	P	N	P	P	P	P
1862	P	N	P	P	P	P
1870	P	N	P	P	P	P
1892	P	N	P	P	P	P
2005	P	N	P	P	P	P
2032	P	N	P	P	P	P
2039	P	N	P	P	P	P
2054	P	N	P	P	P	P
2057	P	N	P	P	P	P
2076	P	N	P	P	P	P
2113	P	N	P	P	P	P
2131	P	N	P	P	P	P
2132	P	N	P	P	P	P
2560	P	N	P	P	P	P
2678	P	N	P	P	P	P
2691	P	N	P	P	P	P
2692	P	N	P	P	P	P
2708	P	N	P	P	P	P
2716	P	N	P	P	P	P
2720	P	N	P	P	P	P
2721	P	N	P	P	P	P
2724	P	N	P	P	P	P
2725	P	N	P	P	P	P
2727	P	N	P	P	P	P
2822	P	N	P	P	P	P
2815	P	N	P	P	P	P
2830	P	N	P	P	P	P
3922	P	N	P	P	P	P
3926	P	N	P	P	P	P
3928	P	N	P	P	P	P
3929	P	N	P	P	P	P
4827	P	N	P	P	P	P
4901	P	N	P	P	P	P
N, Results	41	41	41	41	41	41
# Negative	0	41	0	0	0	0
# Positive	41	0	41	41	41	41
% 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 2: Percentages of correct results, false negatives, and false positives in qualitative reports for 35S for all participants.

Total # Reported results	246
# Incorrect	0
% Correct	100.0%
# Provided Positives (P)	205
# False Negative	0
% False Negative	0.0%
# Provided Negatives (N)	41
# False Positive	0
% False Positive	0.0%

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

NOS	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	**P**	**N**	**P**	**P**	**P**	**P**
1754	P	N	P	P	P	P
1761	P	N	P	P	P	P
1770	P	N	P	P	P	P
1774	P	N	P	P	P	P
1785	P	N	P	P	P	P
1844	P	N	P	P	P	P
1854	P	N	P	P	P	P
1858	P	N	P	P	P	P
1859	P	N	P	P	P	P
1870	P	N	P	P	P	P
1892	P	N	P	P	P	P
2005	P	N	P	P	P	P
2032	P	N	P	P	P	P
2039	P	N	P	P	P	P
2057	P	N	P	P	P	P
2076	P	N	P	P	P	P
2113	P	N	P	P	P	P
2131	P	N	P	P	P	P
2132	P	N	P	P	P	P
2560	P	N	P	P	P	P
2678	P	N	P	P	P	P
2691	P	N	P	P	P	P
2692	P	N	P	P	P	P
2708	P	N	P	P	P	P
2716	P	N	P	P	P	P
2719	P	N	P	P	P	P
2721	P	N	P	P	P	P
2724	P	N	P	P	P	P
2727	P	N	P	P	P	P
2815	P	N	P	P	P	P
2822	P	N	P	P	P	P
2830	P	N	P	P	P	P
3922	P	N	P	P	P	P
3929	P	N	P	P	P	P
4827	P	N	P	P	P	P
4901	P	N	P	P	P	P
N, Results	36	36	36	36	36	36
# Negative	0	36	0	0	0	0
# Positive	36	0	36	36	36	36
% 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 4: Percentages of correct results, false negatives, and false positives in qualitative reports for NOS for all participants.

Total # Reported results	216
# Incorrect	0
% Correct	100.0%
# Provided Positives (P)	180
# False Negative	0
% False Negative	0.0%
# Provided Negatives (N)	36
# False Positive	0
% False Positive	0.0%

Table 5: Qualitative results for corn fortified with T-25 for all participants (DNA-based assays) (N = negative; P = positive).

T25	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.8%	0.0%	2.0%	0.5%	0.0%	1.0%
1774	P	N	P	P	N	P
1785	P	N	P	P	N	P
1788	P	N	P	P	N	P
1844	P	N	P	P	N	P
1854	P	N	P	P	N	P
1859	P	N	P	P	N	P
1862	P	N	P	P	N	P
1892	P	N	P	P	N	P
2032	P	N	P	P	N	P
2054	P	N	P	P	N	P
2057	P	N	P	P	N	P
2060	P	N	P	P	N	P
2089	P	N	P	P	N	P
2113	P	N	P	P	N	P
2131	P	N	P	P	N	P
2132	P	N	P	P	N	P
2692	P	N	P	P	N	P
2708	P	N	P	P	N	P
2822	P	N	P	P	N	P
2830	P	N	P	P	N	P
3922	P	N	P	P	N	P
3929	P	N	P	P	N	P
4901	P	N	P	P	N	P
N, Results	23	23	23	23	23	23
# Negative	0	23	0	0	23	0
# Positive	23	0	23	23	0	23
% 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 6: Percentages of correct results, false negatives, and false positives in qualitative reports for T-25 for all participants.

Total # Reported results	138
# Incorrect	0
% Correct	100.0%
# Provided Positives	92
# False Negative	0
% False Negative	0.0%
# Provided Negatives	46
# False Positive	0
% False Positive	0.0%

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%**	**0.1%**	**0.0%**	**0.0%**	**1.0%**
1770	N	N	P	N	N	P
1774	N	N	P	N	N	P
1785	**P**	N	P	N	N	P
1788	N	N	**N**	N	N	P
1844	N	N	**N**	N	N	P
1854	**P**	N	**N**	**P**	**P**	P
1859	N	N	P	N	N	P
1892	N	N	P	N	N	P
2005	N	N	P	N	N	P
2032	N	N	**N**	N	N	P
2057	N	N	P	N	N	P
2113	N	N	**N**	N	N	P
2131	N	N	P	N	N	P
2692	N	N	P	N	N	P
3922	**P**	N	P	N	N	P
4901	N	N	P	N	N	P
N, Results	16	16	16	16	16	16
# Negative	13	16	5	15	15	0
# Positive	3	0	11	1	1	16
% Correct	81.3%	100.0%	68.8%	93.8%	93.8%	100.0%
% Incorrect	18.8%	0.0%	31.3%	6.3%	6.3%	0.0%

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

Total # Reported results	96
# Incorrect	10
% Correct	89.6%
# Provided Positives	32
# False Negative	5
% False Negative	15.6%
# Provided Negatives	64
# False Positive	5
% False Positive	7.8%

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	0.1%	0.0%	2.0%	0.1%	0.5%	1.0%
1774	P	N	P	P	P	P
1785	P	N	P	P	P	P
1788	P	N	P	P	P	P
1844	P	N	P	P	P	P
1854	**N**	N	P	P	P	P
1858	P	N	P	P	P	P
1859	P	N	P	P	P	P
1862	P	N	P	P	P	P
1892	P	N	P	P	P	P
2032	P	N	P	P	P	P
2039	P	N	P	P	P	P
2054	P	N	P	P	P	P
2057	P	N	P	P	P	P
2060	P	N	P	P	P	P
2089	P	N	P	P	P	P
2113	P	N	P	P	P	P
2131	P	N	P	P	P	P
2132	**N**	N	P	**N**	P	P
2560	P	N	P	P	P	P
2569	P	N	P	P	P	P
2691	P	N	P	P	P	P
2692	P	N	P	P	P	P
2708	P	N	P	P	P	P
2721	P	N	P	P	P	P
2724	P	N	P	P	P	P
2822	**N**	N	P	**N**	P	P
2824	**N**	N	P	**N**	**N**	P
2830	P	N	P	P	P	P
3922	P	N	P	P	P	P
4901	P	N	P	P	P	P
4930	**N**	N	P	P	P	P

N, Results	31	31	31	31	31	31
# Negative	5	31	0	3	1	0
# Positive	26	0	31	28	30	31
% Correct	83.9%	100.0%	100.0%	90.3%	96.8%	100.0%
% Incorrect	16.1%	0.0%	0.0%	9.7%	3.2%	0.0%

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

Total # Reported results	186
# Incorrect	9
% Correct	95.2%
# Provided Positives	155
# False Negative	9
% False Negative	5.8%
# Provided Negatives	31
# 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 Participant Number	Sample 1 0.4%	Sample 2 0.0%	Sample 3 0.0%	Sample 4 1.0%	Sample 5 0.4%	Sample 6 0.1%
1774	P	N	N	P	P	P
1785	P	N	N	P	P	P
1788	P	N	N	P	P	**N**
1844	P	N	N	P	P	P
1854	P	N	N	P	P	P
1858	P	N	N	P	P	P
1859	P	N	N	P	P	P
1862	P	N	N	P	P	P
1892	P	N	N	P	P	P
2005	P	N	N	P	P	P
2032	P	N	N	P	P	P
2057	P	N	N	P	P	P
2060	P	N	N	P	P	P
2089	P	N	N	P	P	P
2113	P	N	N	P	P	**N**
2131	P	N	N	P	P	P
2560	P	N	N	P	P	P
2569	P	N	N	P	P	P
2691	P	N	N	P	P	P
2692	P	N	N	P	P	P
2708	P	N	N	P	P	P
2721	P	N	N	P	P	**N**
2822	P	N	N	P	P	P
2824	P	N	N	P	P	P
2830	P	N	N	P	P	P
3922	P	N	**P**	P	P	P
3929	P	N	N	P	P	P
4901	P	N	N	P	P	P
N, Results	28	28	28	28	28	28
# Negative	0	28	27	0	0	3
# Positive	28	0	1	28	28	25
% Correct	100.0%	100.0%	96.4%	100.0%	100.0%	89.3%
% Incorrect	0.0%	0.0%	3.6%	0.0%	0.0%	10.7%

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

Total # Reported results	168
# Incorrect	4
% Correct	97.6%
# Provided Positives	112
# False Negative	3
% False Negative	2.68%
# Provided Negatives	56
# False Positive	1
% False Positive	1.8%

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	0.1%	0.0%	1.5%	0.1%	0.5%	0.1%
1774	P	N	P	P	P	P
1785	P	N	P	P	P	P
1788	P	N	P	P	P	P
1844	P	N	P	P	P	P
1854	P	N	P	P	**N**	P
1858	P	N	P	P	P	P
1859	P	N	P	P	P	P
1862	P	N	P	P	P	P
1892	P	N	P	P	P	P
2032	P	N	P	P	P	P
2054	P	N	P	P	P	P
2057	P	N	P	P	P	P
2060	P	N	P	P	P	P
2113	**N**	N	P	P	P	P
2131	P	N	P	P	P	P
2132	P	N	P	P	P	P
2569	P	N	P	P	P	P
2691	P	N	P	P	P	P
2692	P	N	P	P	P	P
2708	P	N	P	P	P	P
2721	P	N	P	P	P	P
2724	P	N	P	P	P	P
2822	**N**	N	P	**N**	**N**	**N**
3922	P	N	P	P	P	P
3929	P	N	P	P	P	P
4901	P	N	P	P	P	P
4930	**N**	N	P	P	P	P
N, Results	27	27	27	27	27	27
# Negative	3	27	0	1	2	1
# Positive	24	0	27	26	25	26
% Correct	88.9%	100.0%	100.0%	96.3%	92.6%	96.3%
% Incorrect	11.1%	0.0%	0.0%	3.7%	7.4%	3.7%

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

Total # Reported results	162
# Incorrect	7
% Correct	95.7%
# Provided Positives	135
# False Negative	7
% False Negative	5.2%
# Provided Negatives	27
# 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%	0.0%	0.1%	2.0%	1.0%	0.0%
1774	N	N	P	P	P	N
1785	N	N	P	P	P	N
1788	N	N	P	P	P	N
1844	N	N	P	P	P	N
1854	**P**	N	P	**N**	P	N
1858	N	N	P	P	P	N
1859	N	N	P	P	P	N
1892	N	N	P	P	P	N
2032	N	N	P	P	P	N
2054	N	N	P	P	P	N
2057	N	N	P	P	P	N
2060	N	N	P	P	P	N
2089	N	N	**N**	P	P	N
2113	N	N	P	P	P	N
2131	N	N	P	P	P	N
2132	N	N	P	P	P	N
2560	N	N	P	P	P	N
2569	N	N	P	P	P	N
2692	N	N	P	P	P	N
2708	N	N	**N**	P	P	N
2721	**P**	N	P	P	P	**P**
2724	N	N	P	P	P	N
2822	N	N	P	P	P	N
2824	N	N	P	P	P	N
3922	N	N	P	P	P	N
3929	N	N	P	P	P	N
4901	N	N	P	P	P	N
N, Results	27	27	27	27	27	27
# Negative	25	27	2	1	0	26
# Positive	2	0	25	26	27	1
% Correct	92.6%	100.0%	92.6%	96.3%	100.0%	96.3%
% Incorrect	7.4%	0.0%	7.4%	3.7%	0.0%	3.7%

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

Total # Reported results	162
# Incorrect	6
% Correct	96.3%
# Provided Positives	81
# False Negative	3
% False Negative	3.7%
# Provided Negatives	81
# False Positive	3
% False Positive	3.7%

Table 17: Qualitative results for corn fortified with NK603 for all participants. (DNA-based assays) (N = negative; P = positive; NR = no result submitted; Incorrect results are shown in boldface).

NK603 Participant Number	Sample 1 0.0%	Sample 2 0.0%	Sample 3 1.0%	Sample 4 0.0%	Sample 5 0.0%	Sample 6 2.0%
1774	N	N	P	N	N	P
1785	N	N	P	N	N	P
1788	N	**P**	P	N	N	P
1844	N	N	P	N	N	P
1854	N	N	P	N	N	P
1858	N	N	P	N	N	P
1859	N	N	P	N	N	P
1862	N	N	P	N	N	P
2005	N	N	P	N	N	P
2032	N	N	P	N	N	P
2039	N	N	P	N	N	P
2057	N	N	P	N	N	P
2060	N	N	P	N	N	P
2089	N	N	P	N	N	P
2113	N	N	P	N	N	P
2131	N	N	P	N	N	P
2132	N	N	P	N	N	P
2560	N	N	P	N	N	P
2569	N	N	P	N	N	P
2691	N	N	P	N	N	P
2692	N	N	P	N	N	P
2708	N	N	NR	N	N	P
2721	N	N	P	N	N	P
2822	N	N	P	N	N	P
2824	N	N	P	N	N	P
3928	N	N	P	N	N	P
3922	N	N	P	N	N	P
3928	N	N	P	N	N	P
3929	N	N	P	N	N	P
4901	N	N	P	N	N	P
N, Results	30	30	29	30	30	30
# Negative	30	29	0	30	30	0
# Positive	0	1	29	0	0	30
% Correct	100.0%	96.7%	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	3.3%	0.0%	0.0%	0.0%	0.0%

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

Total # Reported results	179
# Incorrect	1
% Correct	99.4%
# Provided Positives	59
# False Negative	0
% False Negative	0.0%
# Provided Negatives	120
# False Positive	1
% False Positive	0.8%

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	0.8%	0.0%	0.0%	1.5%	0.0%	0.1%
1774	P	N	N	P	N	P
1785	P	N	N	P	N	P
1844	P	N	N	P	N	P
1854	P	N	N	P	N	P
1859	P	N	N	P	N	P
1862	P	N	N	P	N	P
2032	P	N	N	P	N	P
2057	P	N	N	P	N	P
2060	P	N	N	P	N	P
2089	P	N	N	P	N	P
2113	P	N	N	P	N	P
2131	P	N	N	P	N	P
2560	P	N	N	P	N	P
2569	P	N	N	P	N	P
2691	P	N	N	P	N	P
2692	P	N	N	P	N	P
2708	P	N	N	P	N	P
2721	P	N	N	P	N	P
2822	P	N	N	P	N	P
3922	P	N	N	P	N	**N**
3929	P	N	N	P	N	P
4901	P	N	N	P	N	P
N, Results	22	22	22	22	22	22
# Negative	0	22	22	0	22	1
# Positive	22	0	0	22	0	21
% Correct	100.0%	100.0%	100.0%	100.0%	100.0%	95.5%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	4.5%

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

Total # Reported results	132
# Incorrect	1
% Correct	99.2%
# Provided Positives	57
# False Negative	1
% False Negative	1.8%
# Provided Negatives	57
# 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	0.4%	0.0%	0.0%	0.8%	0.0%	0.0%
1774	P	N	N	P	N	N
1785	P	N	N	P	N	N
1788	P	N	**P**	P	N	N
1844	P	N	N	P	N	N
1854	P	N	N	P	**P**	**P**
1859	P	N	N	P	N	N
2032	P	N	N	P	N	N
2039	P	N	N	P	N	N
2057	P	N	N	P	N	N
2060	P	N	N	P	N	N
2089	P	N	N	P	N	N
2131	P	N	**P**	P	**P**	**P**
2560	P	N	N	P	N	N
2569	P	N	N	P	N	N
2691	P	N	N	P	N	N
2692	P	N	N	P	N	N
2708	P	N	N	P	N	N
2721	P	N	N	P	N	N
2822	P	N	N	P	N	N
2824	P	N	N	P	N	N
3922	P	N	N	P	N	N
3929	P	N	N	P	N	N
4901	P	N	N	P	N	N
N, Results	23	23	23	23	23	23
# Negative	0	23	21	0	21	21
# Positive	23	0	2	23	2	2
% Correct	100.0%	100.0%	91.3%	100.0%	91.3%	91.3%
% Incorrect	0.0%	0.0%	8.7%	0.0%	8.7%	8.7%

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

Total # Reported results	138
# Incorrect	6
% Correct	95.7%
# Provided Positives	46
# False Negative	0
% False Negative	0.0%
# Provided Negatives	92
# False Positive	6
% False Positive	6.5%

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	0.1%	0.0%	0.0%	0.1%	0.0%	2.0%
1774	P	N	N	P	N	P
1785	P	N	N	P	N	P
1844	P	N	N	P	N	P
1859	P	N	N	P	N	P
2032	P	N	N	P	N	P
2039	P	N	N	P	N	P
2057	P	N	N	P	N	P
2060	P	N	N	P	N	P
2089	P	N	N	P	N	P
2113	P	N	N	P	N	P
2131	P	N	N	P	N	P
2560	P	N	N	P	N	P
2569	P	N	N	P	N	P
2708	P	N	N	P	N	P
2721	P	N	N	P	N	P
2822	P	N	N	P	N	P
3922	P	N	N	P	N	P
3929	P	N	N	P	N	P
4901	P	N	N	P	N	P
N, Results	19	19	19	19	19	19
# Negative	0	19	19	0	19	0
# Positive	19	0	0	19	0	19
% 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 24: Percentages of correct results, false negatives, and false positives in qualitative reports for Herculex RW for all participants.

Total # Reported results	114
# Incorrect	0
% Correct	100.0%
# Provided Positives	57
# False Negative	0
% False Negative	0.0%
# Provided Negatives	57
# False Positive	0
% False Positive	0.0%

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	1.5%	0.0%	0.0%	0.0%	0.8%	0.5%
1774	P	N	N	N	P	P
1785	P	N	N	N	P	P
1844	P	N	N	N	P	P
1859	P	N	N	N	P	P
2032	P	N	N	N	P	P
2039	P	N	N	N	P	P
2057	P	N	N	N	P	P
2060	P	N	N	N	P	P
2089	P	N	N	N	P	P
2113	P	N	N	N	P	P
2131	P	N	**P**	N	P	P
2560	P	N	N	N	P	P
2708	P	N	N	N	P	P
2721	P	N	N	N	P	P
2822	P	N	N	N	P	P
2824	P	N	N	N	P	P
3922	P	N	N	N	P	**N**
3929	P	N	N	N	P	P
4901	P	N	N	N	P	P
N, Results	19	19	19	19	19	19
# Negative	0	19	18	19	0	1
# Positive	19	0	1	0	19	18
% Correct	100.0%	100.0%	94.7%	100.0%	100.0%	94.7%
% Incorrect	0.0%	0.0%	5.3%	0.0%	0.0%	5.3%

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

# Reported results	114
# Incorrect	2
% Correct	98.2%
# Provided Positives	57
# False Negative	1
% False Negative	1.8%
# Provided Negatives	57
# False Positive	1
% False Positive	1.8%

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%**	**0.0%**	**0.5%**	**1.0%**	**0.2%**	**0.1%**
1774	N	N	P	P	P	P
1785	N	N	P	P	P	P
1844	N	N	P	P	P	P
1859	N	N	P	P	P	P
2032	N	N	P	P	P	P
2057	N	N	P	P	P	P
2062	N	N	P	P	P	P
2113	N	N	P	P	P	P
2131	N	N	P	P	P	P
2708	N	N	P	P	**N**	P
2721	N	N	P	P	P	P
2723	N	N	P	P	P	P
2822	N	N	P	P	P	P
3922	N	N	P	P	P	**N**
4901	N	N	P	P	P	P
N, Results	15	15	15	15	15	15
# Negative	15	15	0	0	1	1
# Positive	0	0	15	15	14	14
% Correct	100.0%	100.0%	100.0%	100.0%	93.3%	93.3%
% Incorrect	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%

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

# Reported results	90
# Incorrect	2
% Correct	97.8%
# Provided Positives	60
# False Negative	2
% False Negative	3.3%
# Provided Negatives	30
# False Positive	0
% False Positive	0.0%

Table 29: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays) (N = negative; P = positive; NR = no result submitted; Incorrect results are shown in boldface).

CP4 EPSPS	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	**0.0%**	**0.2%**	**1.5%**	**0.0%**
1774	N	P	P	N
1788	N	P	P	N
1844	N	P	P	N
1854	N	P	P	N
1859	N	NR	P	N
1892	N	P	P	N
2039	N	P	P	**P**
2054	N	P	P	N
2057	N	P	P	N
2076	N	P	P	N
2131	N	P	P	N
2132	N	P	P	N
2560	N	P	P	N
2692	N	P	P	N
2721	N	P	P	N
2724	N	P	P	N
2815	N	P	P	N
2822	N	P	P	N
2830	N	P	P	N
3922	N	P	P	N
3928	N	P	P	N
4827	N	P	P	N
4930	N	**N**	**N**	N
N, Results	23	22	23	23
# Negative	23	1	1	22
# Positive	0	21	22	1
% Correct	100%	95.4%	95.6%	95.6%
% Incorrect	0.0%	4.6%	4.4%	4.4%

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

Total # Reported results	91
# Incorrect	3
% Correct	96.7%
# Provided Positives	45
# False Negative	2
% False Negative	4.4%
# Provided Negatives	46
# False Positive	1
% False Positive	2.2%

Table 31: Qualitative results for soybeans fortified with A2704-12 (Liberty Link Soy) for all participants (DNA-based assays) (N = negative; P = positive; NR = no result submitted; Incorrect results are shown in boldface).

A2704-12	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.1%	0.2%	0.0%	0.0%
1774	P	P	N	N
1785	P	P	N	N
1844	P	P	N	N
1859	P	NR	N	N
2005	P	P	N	N
2032	P	P	N	N
2057	P	P	N	N
2060	P	P	N	N
2062	P	P	N	N
2131	P	P	N	N
2132	P	P	N	N
2560	P	P	N	N
2716	P	P	N	N
2721	P	P	N	N
2815	P	**N**	N	**P**
3922	P	P	N	**P**
4827	P	**N**	N	**P**
4901	P	P	N	N
N, Results	18	17	18	18
# Negative	0	2	18	15
# Positive	18	15	0	3
% Correct	100.0%	88.2%	100.0%	83.3%
% Incorrect	0.0%	11.8%	0.0%	16.7%

Table 32: Percentages of correct results, false negatives, and false positives in qualitative reports for A2704-12 (Liberty Link Soy) for all participants.

Total # Reported results	71
# Incorrect	5
% Correct	93.0%
# Provided Positives	35
# False Negative	2
% False Negative	5.7%
# Provided Negatives	36
# False Positive	3
% False Positive	8.3%

Table 33: 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	Bt11
N, Results	246	216	138	96	186	168	162	162
Reported Incorrect	0	0	0	10	9	4	7	6
% Correct	100.0%	100.0%	100.0%	89.6%	95.2%	97.6%	95.7%	96.3%
N, Provided Positives	205	180	92	32	155	112	135	81
N, False Negatives	0	0	0	5	9	3	7	3
% False Negative	0.0%	0.0%	0.0%	15.6%	5.8%	2.7%	5.2%	3.7%
N, Provided Negatives	41	36	46	64	31	56	27	81
N, False Positives	0	0	0	5	0	1	0	3
% False Positives	0.0%	0.0%	0.0%	7.8%	0.0%	1.8%	0.0%	3.7%

Event	NK603	Herculex	MON863	HerculexRW	MIR604	EV3272	RUR	A2704-12
N, Results	179	132	138	114	114	90	91	71
Reported Incorrect	1	1	6	0	2	2	3	5
% Correct	99.4%	99.2%	95.7%	100.0%	98.2%	97.8%	96.7%	93.0%
N, Provided Positives	59	57	46	57	57	60	45	35
N, False Negatives	0	1	0	0	1	2	2	2
% False Negative	0.0%	1.8%	0.0%	0.0%	1.8%	3.3%	4.4%	5.7%
N, Provided Negatives	120	57	92	57	57	30	46	36
N, False Positives	1	0	6	0	1	0	2	3
% False Positives	0.8%	0.0%	6.5%	0.0%	1.8%	0.0%	4.3%	8.3%

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 33.
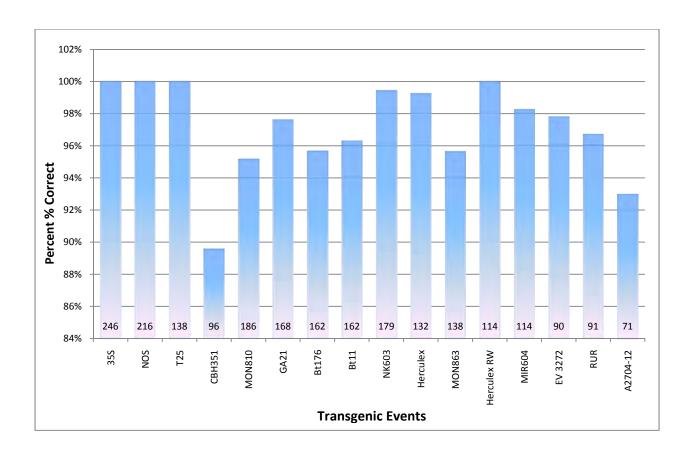
Table 34: Qualitative results for the detection of transgenic events in corn using Lateral Flow Strip (LFS) Testing (Protein-based testing) (N = negative; P = positive; NR = no result submitted; Incorrect results are shown in boldface).

Participant	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	LOD
T-25	0.8%	0.0%	2.0%	0.5%	0.0%	1.0%	
2815	≥ 1.0%	< 1.0%	≥ 1.0%	≥ 1.0%	< 1.0%	≥ 1.0%	1.0%
NK603	0.0%	0.0%	1.0%	0.0%	0.0%	2.0%	
1843	< 0.5%	< 0.5%	≥ 0.5%	< 0.5%	< 0.5%	≥ 0.5%	0.5%
2815	< 0.5%	< 0.5%	**< 0.5%**	≥ 0.5%	< 0.5%	≥ 0.5%	0.5%
3931	N	N	P	N	N	P	Not Provided
2824	N	N	P	N	N	P	Not Provided
Cry 1Ab	0.1%	0.0%	2.1%	2.1%	1.5%	1.0%	
1843	< 2.0%	< 2.0%	**< 2.0%**	≥ 2.0%	< 2.0%	< 2.0%	2.0%
2815	< 1.0%	< 1.0%	≥ 1.0%	≥ 1.0%	≥ 1.0%	≥ 1.0%	1.0%
3931	N	N	P	P	P	P	Not Provided
3926	NR	N	NR	P	NR	P	Not Provided
Herculex	0.4%	0.0%	0.0%	0.75%	0.0%	0.1%	
1843	≥ 0.5%	< 0.5%	< 0.5%	≥ 0.5%	< 0.5%	< 0.5%	0.5%
2815	≥ 0.5%	< 0.5%	**≥ 0.5%**	**< 0.5%**	< 0.5%	< 0.5%	0.5%
3931	P	N	N	P	N	P	Not Provided
MON863	0.4%	0.0%	0.0%	0.8%	0.0%	0.0%	
1843	≥ 0.5%	< 0.5%	< 0.5%	≥ 0.5%	< 0.5%	< 0.5%	0.5%
2815	≥ 0.5%	< 0.5%	**≥ 0.5%**	**< 0.5%**	< 0.5%	< 0.5%	0.5%

*Note: Only samples fortified **at or above** the participants LOD are considered in this table as provided positives. In some instances, the actual fortified amount is below the participants reported LOD (i.e. T-25, Cry 1Ab, Herculex, Mon863). If the participant correctly identified the presence of the trait, even though the sample was fortified below their reported LOD, it was assessed as a correct result. Only samples fortified **below** the participants LOD where a negative result was reported are considered in this table as provided negatives.

Table 35: Percentage of correct results, false negatives, and false positives in qualitative reports for transgenic events in corn using Lateral Flow Strip (LFS) Testing.

Event	T-25	NK 603	Cry 1Ab	Herculex	Mon863
Total # Reported Results	6	24	21	18	12
# Incorrect	0	1	1	2	2
% Correct	100%	95.8%	95.2%	88.9%	83.3%
# Provided Positives	4	8	14	9	4
# False Negatives	0	1	1	1	1
% False Negatives	0.0%	12.5%	7.1%	11.1%	25.0%
# Provided Negatives	2	16	7	9	8
# False Positives	0	0	0	1	1
% False Positive	0.0%	0.0%	0.0%	11.1%	12.5%

Table 36: Qualitative 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).

Participant	Sample 1	Sample 2	Sample 3	Sample 4	
CP4 EPSPS (RUR)	0.0%	0.2%	1.5%	0.0%	LOD
1843	< 0.5%	≥ 0.5%	≥ 0.5%	**≥ 0.5%**	0.5%
2815	< 0.1%	≥ 0.1%	≥ 0.1%	**≥ 0.1%**	0.1%
3926	N	P	P	N	Not Provided
3931	N	P	P	**P**	Not Provided
4902	N	P	P	N	Not Provided
N, Results	5	5	5	5	
# Negative	5	0	0	2	
# Positive	0	5	5	3	
% Correct	100%	100%	100%	40.0%	
% Incorrect	0.0%	0.0%	0.0%	60.0%	
A2704-12 (Liberty Link)	0.1%	0.2%	0.0%	0.0%	LOD
1843	< 0.5%	< 0.5%	< 0.5%	< 0.5%	0.5%

*Note: Sample 2 contained RUR trait that was fortified at a level below the LOD for LFS testing used by participant 1843 (0.5%). The participant detected the presence of RUR even though the fortification was below the reported LOD and thus assessed as a correct result.

Table 37: 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	20	4
# Incorrect	3	0
% Correct	85.0%	100%
# Provided Positives	10	2
# False Negative	0	0
% False Negative	0.0%	0.0%
# Provided Negatives	10	2
# False Positive	3	0
% False Positive	30.0%	0.0%

Table 38: Qualitative results for the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

Participant	1	2	3	4	5	6	LOD
T-25	**0.8%**	**0.0%**	**2.0%**	**0.5%**	**0.0%**	**1.0 %**	
1843	≥ 0.5 %	< 0.5 %	≥ 0.5 %	≥ 0.5 %	< 0.5 %	≥ 0.5 %	0.50%
Herculex RW	**0.1%**	**0.0%**	**0.0%**	**0.1%**	**0.0%**	**2.0%**	
1843	≥ 0.5%	< 0.5%	< 0.5%	< 0.5%	< 0.5%	**< 0.5%**	0.50%
2815	≥ 0.5%	< 05%	< 0.5%	< 0.5%	< 0.5%	≥ 0.5%	0.50%
MIR 604	**1.5%**	**0.0%**	**0.0%**	**0.0%**	**0.8%**	**0.5%**	
1843	≥ 0.13%	< 0.13%	< 0.13 %	**≥ 0.13%**	**< 0.13 %**	≥ 0.13%	0.13%
2815	≥ 1.0 %	< 1.0%	< 1.0 %	< 1.0%	≥ 1.0 %	≥ 1.0 %	1.00%
NK 603	**0.0%**	**0.0%**	**0.65%**	**0.0%**	**0.0%**	**1.3%**	
3931	**P**	N	P	N	**P**	P	Not Provided
Cry1 Ab	**0.1%**	**0.0%**	**2.1%**	**2.1%**	**1.5%**	**1.0%**	
3931	P	**P**	P	P	P	P	Not Provided
Herculex	**0.4%**	**0.0%**	**0.0%**	**0.75%**	**0.0%**	**0.1%**	
3931	P	**P**	**P**	P	**P**	P	Not Provided

Table 39: Percentage of correct results in the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

Event	T-25	Herculex RW	MIR 604	NK 603	Cry1 Ab	Herculex
Total # Reported results	6	12	12	6	6	6
# Incorrect	0	2	2	2	1	3
% Correct	100.0%	83.3%	83.3%	66.7%	83.3%	50.0%
# Provided Positives	4	6	6	2	5	3
# False Negative	0	2	1	0	0	0
% False Negative	0.0%	33.3%	16.7%	0.0%	0.0%	0.0%
# Provided Negatives	2	6	6	4	1	3
# False Positive	0	0	1	2	1	3
% False Positive	0.0%	0.0%	16.7%	50.0%	100%	100%

Table 40: Qualitative results for soybeans fortified with CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

CP4 EPSPS (RUR)	Sample 1	Sample 2	Sample 3	Sample 4	
Participant Number	0.0%	0.20%	1.50%	0.0%	LOD
2113	< 0.1%	≥ 0.1%	≥ 0.1%	< 0.1%	0.10%
2817	N	P	**N**	N	Not Provided

Table 41: Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

Total # Reported results	8
# Incorrect	1
% Correct	87.5%
# Provided Positives	4
# False Negative	1
% False Negative	25.0%
# Provided Negatives	4
# False Positive	0
% False Positive	0.0%

Table 42: Quantitative results and z-scores for corn fortified with T-25 for all participants (DNA-based assays). Values highlighted in <mark>yellow</mark> indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: T-25											
%w/w Fortification Level	0.8%		0.0%		2.0%		0.5%		0.0%		1.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.90	0.42	0.00		1.60	-1.16	0.30	-0.83	0.00		0.70	-0.50
1761	0.70	-0.42	0.00		1.95	-0.15	0.83	1.37	0.00		2.21	2.03
1770	0.90	0.42	0.00		2.00	0.00	0.50	0.00	0.00		0.90	-0.17
1780	0.83	0.13	0.00		1.57	-1.25	0.25	-1.03	0.00		0.88	-0.20
1870	0.64	-0.67	0.00		1.70	-0.87	0.40	-0.41	0.00		1.00	0.00
2716	0.72	-0.34	0.00		2.36	1.05	0.43	-0.29	0.00		1.41	0.69
2723	0.21	-2.47	0.00		1.32	-1.98	0.05	-1.86	0.00		0.35	-1.09

Table 43: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays). Values highlighted in <mark>yellow</mark> indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: CBH351											
%w/w Fortification Level	0.0%		0.0%		0.1%		0.0%		0.0%		1.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		0.20	2.29	0.00		0.00		1.00	0
1870	0.00		0.00		0.12	0.46	0.00		0.00		1.00	0
2723	0.00		0.00		0.13	0.69	0.00		0.00		1.81	0.64

Table 44: Quantitative results and z-scores for corn fortified with MON810 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 a negative value for a fortified sample (i.e. a false negative result).

Event: MON810												
%w/w Fortification Level	0.1%		0.0%		2.0%		0.1%		0.5%		1.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.10	0.00	0.00		1.30	-1.17	0.10	0.00	0.40	-0.62	0.70	-0.93
1761	0.15	1.16	0.00		2.70	1.17	0.07	-0.98	0.45	-0.31	1.40	1.24
1770	0.10	0.00	0.00		1.50	-0.84	0.10	0.00	0.40	-0.62	0.80	-0.62
1780	0.15	1.16	0.00		2.19	0.32	0.07	-0.98	0.42	-0.49	1.11	0.34
1788	0.10	0.00	0.00		0.81	-1.99	0.10	0.00	0.10	-2.47	0.27	-2.26
1870	0.13	0.70	0.00		2.20	0.33	0.09	-0.33	0.39	-0.68	1.00	0.00
1892	0.10	0.00	0.00		1.40	-1.00	0.10	0.00	0.30	-1.24	0.50	-1.55
2062	0.04	-1.32	0.00		0.87	-1.89	0.03	-2.16	0.20	-1.85	0.46	-1.67
2692	0.10	0.00	0.00		0.60	-2.34	0.10	0.00	0.19	-1.91	0.40	-1.86
2716	0.00	-2.32	0.00		1.42	-0.97	0.10	0.00	0.55	0.31	1.03	0.09
2719	0.10	0.00	0.00		0.77	-2.06	0.10	0.00	0.16	-2.10	0.40	-1.86
2723	0.00	-2.32	0.00		0.53	-2.46	0.00	-3.27	0.06	-2.72	0.22	-2.42
2727	0.22	2.78	0.00		0.84	-1.94	0.10	0.00	0.60	0.62	0.60	-1.24
2822	0.00	-2.32	0.00		1.20	-1.34	0.00	-3.27	0.20	-1.85	0.50	-1.55
3926	0.00	-2.32	0.00		1.27	-1.22	0.09	-0.33	0.45	-0.31	0.85	-0.47
3927	0.00	-2.32	0.00		1.04	-1.61	0.00	-3.27	0.12	-2.35	0.49	-1.58
3929	0.10	0.00	0.00		1.36	-1.07	0.10	0.00	0.30	-1.24	0.64	-1.12

Table 45: Quantitative results and z-scores for corn fortified with GA21 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 outliers by the "Grubb's Test for Outliers".

Event: GA21												
%w/w Fortification Level	0.4%		0.0%		0.0%		0.6%		0.2%		0.1%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.20	-2.13	0.00		0.00		0.30	-1.93	0.10	-1.88	0.10	0.00
1761	0.06	-3.61	0.00		0.00		0.06	-3.48	0.04	-3.01	0.04	-0.85
1770	0.30	-1.06	0.00		0.00		0.40	-1.29	0.10	-1.88	0.20	1.42
1780	0.36	-0.43	0.00		0.00		0.55	-0.32	0.20	0.00	0.21	1.56
1870	0.29	-1.17	0.00		0.00		0.56	-0.26	0.16	-0.75	0.16	0.85
2062	0.16	-2.55	0.00		0.00		0.34	-1.68	0.06	-2.69	0.08	-0.23
2692	0.25	-1.59	0.00		0.00		0.35	-1.61	0.11	-1.69	0.16	0.85
2719	1.93	16.26	0.00		0.00		0.46	-0.90	0.99	14.86	0.40	4.26
2720	0.20	-2.13	0.00		0.00		0.12	-3.09	0.14	-1.13	0.10	0.00
2723	0.12	-2.98	0.00		0.00		0.33	-1.74	0.17	-0.56	0.20	1.42
2727	0.31	-0.96	0.00		0.00		0.45	-0.97	0.60	7.52	0.62	7.39
3927	0.44	0.43	0.00		0.00		0.49	-0.71	0.18	-0.38	0.27	2.41

Table 46: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays). Values highlighted in <mark>yellow</mark> indicate z-scores outside of the expected range, i.e., z > +2 or z < -2. Quantifications marked in <mark>red</mark> indicate values determined to be either: (1) outliers 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	0.1%		0.0%		1.5%		0.1%		0.5%		0.1%	
Participant Number	Result	Z-score	Result	Z-score	Result	Z-score	Result	Z-score	Result	Z-score	Result	Z-score
1754	0.10	0.00	0.00		1.00	-0.68	0.10	0.00	0.30	-0.44	0.10	0.00
1761	0.10	0.00	0.00		1.50	0.00	0.07	-0.58	0.39	-0.24	0.10	0.00
1770	0.10	0.00	0.00		1.40	-0.14	0.10	0.00	0.40	-0.22	0.10	0.00
1780	0.11	0.53	0.00		1.59	0.12	0.08	-0.38	0.41	-0.20	0.11	0.67
1788	0.10	0.00	0.00		1.02	-0.65	0.10	0.00	0.28	-0.48	0.10	0.00
1870	0.07	-1.60	0.00		0.92	-0.78	0.06	-0.77	0.23	-0.59	<mark>0.07</mark>	<mark>-2.01</mark>
2005	0.10	0.00	0.00		0.48	-1.38	<mark>0.00</mark>	<mark>-1.92</mark>	0.41	-0.20	0.10	0.00
2062	<mark>0.05</mark>	<mark>-2.77</mark>	0.00		1.03	-0.64	0.04	-1.25	0.14	-0.79	<mark>0.06</mark>	<mark>-2.48</mark>
2692	0.10	0.00	0.00		1.32	-0.24	0.10	0.00	0.49	-0.02	0.10	0.00
2716	0.10	0.00	0.00		2.45	1.28	0.10	0.00	0.79	0.64	0.11	0.67
2719	0.10	0.00	0.00		1.48	-0.03	<mark>0.24</mark>	<mark>2.69</mark>	<mark>1.80</mark>	<mark>2.85</mark>	0.10	0.00
2723	0.12	1.07	0.00		1.30	-0.27	0.08	-0.38	0.64	0.31	0.11	0.67
2727	<mark>0.85</mark>	<mark>39.94</mark>	0.00		<mark>3.50</mark>	<mark>2.70</mark>	<mark>0.60</mark>	<mark>9.62</mark>	1.30	1.75	<mark>0.96</mark>	<mark>57.57</mark>
3927	<mark>0.45</mark>	<mark>18.64</mark>	0.00		1.19	-0.42	<mark>0.00</mark>	<mark>-1.92</mark>	0.39	-0.24	<mark>0.30</mark>	<mark>13.39</mark>

Table 47: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays). Values highlighted in <mark>yellow</mark> indicate z-scores outside of the expected range, i.e., z > 2. Quantifications marked in <mark>red</mark> indicate values determined to be either: (1) outliers by the "Grubb's Test for Outliers"; (2) a quantitative value for a non-fortified sample (i.e. a false positive result); or (3) a negative value for a fortified sample (i.e. a false negative result).

Event: Bt11												
%w/w Fortification Level	0.0%		0.0%		0.1%		1.5%		0.75%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		0.10	0.00	1.40	-0.23	0.70	-0.14	0.00	
1770	0.00		0.00		0.10	0.00	1.60	0.23	1.10	0.99	0.00	
1780	0.00		0.00		0.14	1.59	1.36	-0.32	1.17	1.19	0.00	
1788	0.00		0.00		0.10	0.00	0.73	-1.78	0.82	0.20	0.00	
1870	0.00		0.00		0.06	-1.59	1.80	0.69	0.70	-0.14	0.00	
2005	0.00		0.00		0.10	0.00	<mark>0.00</mark>	<mark>-3.47</mark>	0.57	-0.51	<mark>1.00</mark>	
2062	0.00		0.00		0.08	-0.99	1.50	0.00	0.90	0.43	0.00	
2691	0.00		0.00		0.11	0.40	1.66	0.37	0.91	0.45	0.00	
2692	0.00		0.00		0.15	1.99	<mark>2.26</mark>	<mark>3.75</mark>	<mark>1.60</mark>	<mark>2.41</mark>	0.00	
2716	0.00		0.00		0.10	0.00	1.89	0.90	<mark>1.45</mark>	<mark>1.99</mark>	0.00	
2723	0.00		0.00		0.10	0.00	1.92	0.97	0.95	0.57	0.00	
2727	0.00		0.00		<mark>0.00</mark>	<mark>-3.98</mark>	1.30	-0.46	<mark>1.60</mark>	<mark>2.41</mark>	0.00	
2822	0.00		0.00		<mark>0.50</mark>	<mark>15.92</mark>	2.20	1.62	1.30	1.56	0.00	
3927	0.00		0.00		<mark>0.24</mark>	<mark>5.57</mark>	2.18	1.57	<mark>1.51</mark>	<mark>2.16</mark>	0.00	

Table 48: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays). The **v**alues highlighted in <mark>yellow</mark> indicates a z-score outside of the expected range, i.e., z > +2. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

	Event: NK603											
%w/w Fortification Level	0.0%		0.0%		0.65%		0.0%		0.0%		1.3%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		1.20	1.05	0.00		0.00		2.10	1.07
1761	0.00		0.00		0.10	-1.05	0.00		0.00		0.17	-1.50
1770	0.00		0.00		0.40	-0.48	0.00		0.00		0.70	-0.80
1780	0.00		0.00		0.85	0.38	0.00		0.00		1.92	0.83
1870	0.00		0.00		0.58	-0.13	0.00		0.00		1.20	-0.13
2062	0.00		0.00		0.16	-0.94	0.00		0.00		0.46	-1.12
2692	0.00		0.00		0.40	-0.48	0.00		0.00		0.82	-0.64
2716	0.00		0.00		0.80	0.29	0.00		0.00		1.49	0.25
2723	0.00		0.00		0.29	-0.69	0.00		0.00		0.49	-1.08
2727	0.00		0.00		<mark>2.00</mark>	<mark>2.58</mark>	0.00		0.00		2.70	1.86
2822	0.00		0.00		0.70	0.10	0.00		0.00		1.40	0.13
3927	0.00		0.00		0.54	-0.21	0.00		0.00		1.23	-0.09

Table 49: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays). Values highlighted in <mark>yellow</mark> indicate z-scores outside of the expected range, i.e., z > +2 or z < -2. Quantifications marked in <mark style="background:red">red</mark> indicate values determined to be either: (1) outliers 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	0.4%		0.0%		0.0%		0.75%		0.0%		0.1%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.70	1.24	0.00		0.00		0.90	0.45	0.00		0.10	0.00
1761	0.42	0.08	0.00		0.00		0.40	-1.06	0.00		0.07	-0.92
1770	0.40	0.00	0.00		0.00		0.50	-0.76	0.00		0.10	0.00
1780	0.78	1.57	0.00		0.00		0.74	-0.03	0.00		0.09	-0.31
1870	0.50	0.41	0.00		0.00		0.65	-0.30	0.00		0.08	-0.62
2062	0.38	-0.08	0.00		0.00		0.51	-0.73	0.00		<mark>0.03</mark>	<mark>-2.28</mark>
2692	0.49	0.37	0.00		0.00		0.66	-0.27	0.00		0.10	0.00
2716	<mark>1.00</mark>	<mark>2.48</mark>	0.00		0.00		1.42	2.03	0.00		<mark style="background:red">0.44</mark>	<mark style="background:red">10.48</mark>
2723	0.14	-1.08	0.00		0.00		0.14	-1.85	0.00		<mark style="background:red">0.00</mark>	<mark style="background:red">-3.08</mark>
2727	0.35	-0.21	0.00		0.00		0.91	0.48	0.00		0.14	1.23
3927	0.32	-0.33	0.00		0.00		0.59	-0.48	0.00		<mark style="background:red">0.00</mark>	<mark style="background:red">-3.08</mark>

Table 50: Quantitative results and z-scores for corn fortified with MON863 for all participants (DNA-based assays). Values highlighted in <mark>yellow</mark> indicate z-scores outside of the expected range, i.e., z > +2 or z < -2. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

	Event: MON863											
%w/w Fortification Level	0.4%		0.0%		0.0%		0.8%		0.0%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.40	0.00	0.00		0.00		0.50	-1.56	0.00		0.00	
1761	0.70	1.71	0.00		0.00		0.60	-1.04	0.00		0.00	
1770	0.60	1.14	0.00		0.00		0.60	-1.04	0.00		0.00	
1780	0.57	0.97	0.00		0.00		0.54	-1.35	0.00		0.00	
1870	0.30	-0.57	0.00		0.00		0.68	-0.62	0.00		0.00	
2062	0.48	0.46	0.00		0.00		0.66	-0.73	0.00		0.00	
2692	0.23	-0.97	0.00		0.00		<mark>0.30</mark>	<mark>-2.60</mark>	0.00		0.00	
2716	0.41	0.06	0.00		0.00		0.55	-1.30	0.00		0.00	
2719	0.39	-0.06	0.00		0.00		<mark>0.10</mark>	<mark>-3.64</mark>	0.00		0.00	
2723	<mark>0.81</mark>	<mark>2.34</mark>	0.00		0.00		0.83	0.16	0.00		0.00	
2727	0.45	0.29	0.00		0.00		0.48	-1.66	0.00		0.00	
2822	0.70	1.71	0.00		0.00		0.70	-0.52	0.00		0.00	

Table 51: Quantitative results and z-scores for corn fortified with Herculex RW for all participants (DNA-based assays). Values highlighted in <mark>yellow</mark> indicate z-scores outside of the expected range, i.e., z > +2 or z < -2. The quantification marked in <mark style="background:red">red</mark> indicates a value determined an outlier by the "Grubb's Test for Outliers".

%w/w Fortification Level	0.1%		0.0%		0.0%		0.1%		0.0%		2.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.20	0.94	0.00		0.00		0.20	1.94	0.00		1.90	-0.33
1761	0.13	0.28	0.00		0.00		0.06	-0.78	0.00		1.80	-0.65
1780	0.13	0.28	0.00		0.00		0.11	0.19	0.00		2.16	0.52
1870	0.35	2.36	0.00		0.00		0.17	1.36	0.00		4.00	6.55
2062	0.24	1.32	0.00		0.00		0.14	0.78	0.00		2.10	0.33
2716	0.10	0.00	0.00		0.00		0.10	0.00	0.00		1.43	-1.87
2723	0.03	-0.66	0.00		0.00		0.05	-0.97	0.00		1.40	-1.96
2727	0.29	1.79	0.00		0.00		0.10	0.00	0.00		1.60	-1.31

Table 52: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays). Values in <mark>yellow</mark> indicate z-scores outside of expected range i.e., z > +2 or z < -2. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

%w/w Fortification Level	1.5%		0.0%		0.0%		0.0%		0.8%		0.5%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	1.10	-0.96	0.00		0.00		0.00		0.60	-0.86	0.50	0.00
1761	0.72	-1.86	0.00		0.00		0.00		0.20	-2.58	0.21	-1.22
1780	1.70	0.48	0.00		0.00		0.00		0.73	-0.30	0.47	-0.18
1870	1.00	-1.19	0.00		0.00		0.00		0.50	-1.29	0.25	3.04
2062	0.49	-2.41	0.00		0.00		0.00		0.19	-2.62	0.16	-2.07
2716	1.42	-0.19	0.00		0.00		0.00		0.77	-0.13	0.50	0.00
2723	0.79	-1.70	0.00		0.00		0.00		0.44	-1.55	0.14	-2.19

Table 53: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays). Values in <mark>yellow</mark> indicate z-scores outside of expected range i.e., z > +2 or z < -2. The quantification marked in <mark style="background:red">red</mark> indicates a negative value for a fortified sample (i.e. a false negative result).

%w/w Fortification Level	0.0%		0.0%		0.5%		1.0%		0.2%		0.1%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		0.50	0.00	0.90	-0.94	0.20	0.00	0.20	
1780	0.00		0.00		0.46	-0.15	0.77	-2.17	0.07	-1.95	0.00	
1870	0.00		0.00		0.95	1.65	0.98	-0.19	0.16	-0.60	0.20	

Table 54: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS (RUR) for all participants (DNA-based assays). Values highlighted in <mark>yellow</mark> indicate z-scores outside of expected range, i.e., z > +2 or z < -2. Quantifications marked in <mark>red</mark> indicate values determined to be either: (1) outliers by the "Grubb's Test for Outliers"; (2) a quantitative value for a non-fortified sample (i.e. a false positive result); or (3) a negative value for a fortified sample (i.e. a false negative result).

Event: RUR								
%w/w Fortification Level	0.0%		0.2%		1.5%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.10		0.20	0.00	1.30	-0.38	0.10	
1761	0.00		0.90	7.66	1.70	0.38	0.00	
1770	0.00		0.20	0.00	0.90	-1.14	0.10	
1780	0.00		0.23	0.33	1.24	-0.50	0.00	
1783	0.00		0.17	-0.33	1.33	-0.32	0.00	
1785	0.00		0.11	-0.98	0.78	-1.37	0.00	
1788	0.00		0.10	-1.09	1.17	-0.63	0.10	
1858	0.00		0.10	-1.09	0.10	-2.67	0.00	
1868	0.00		0.40	2.19	2.30	1.52	0.00	
1870	0.00		0.20	0.00	0.94	-1.07	0.00	
1892	0.00		0.20	0.00	0.50	-1.91	0.00	
2005	0.00		0.19	-0.11	1.23	-0.51	0.00	
2032	0.00		0.10	-1.09	0.80	-1.33	0.00	
2054	0.00		0.10	-1.09	1.20	-0.57	0.00	
2060	0.00		0.16	-0.44	1.29	-0.40	0.00	
2062	0.00		0.13	-0.77	1.00	-0.95	0.00	
2075	0.12		0.39	2.08	1.48	-0.04	0.00	
2691	0.00		0.30	1.09	1.40	-0.19	0.00	
2692	0.00		0.17	-0.33	1.62	0.23	0.00	
2716	0.00		0.15	-0.55	1.66	0.30	0.00	
2719	0.00		0.20	0.00	0.80	-1.33	0.00	
2720	0.41		1.20	10.94	1.72	0.42	0.00	
2723	0.00		0.17	-0.33	1.09	-0.78	0.00	
2725	0.00		0.01	-2.08	0.07	-2.72	0.00	
2727	0.00		0.41	2.30	2.20	1.33	0.00	
2822	0.00		0.10	-1.09	0.60	-1.72	0.00	
3926	0.00		0.25	0.55	1.60	0.19	0.00	
3927	0.00		0.13	-0.77	0.69	-1.54	0.00	
4901	0.00		0.16	-0.44	1.20	-0.57	0.00	

Table 55: Quantitative results and z-scores for soybeans fortified with A2704-12 (Liberty Link) for all participants (DNA-based assays). The quantification marked in <mark>red</mark> indicates a negative value for a fortified sample (i.e. a false negative result).

Event: A2704-12								
%w/w Fortification Level	0.1%		0.2%		0.0%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.10	0.00	0.10	-0.30	0.00		0.00	
1761	1.00	2.52	0.90	2.09	0.00		0.00	
1780	0.12	0.06	0.22	0.06	0.00		0.00	
1868	0.10	0.00	0.14	-0.18	0.00		0.00	
1870	0.43	0.92	0.82	1.85	0.00		0.00	
2719	0.00	-0.28	0.30	0.30	0.00		0.00	
2723	0.16	0.17	0.17	-0.09	0.00		0.00	

Table 56: Quantitative results for 35S in soybeans (DNA based assay) for Participant 1862

Event: 35S Soy								
%w/w Fortification Level	0.1%		0.4%		1.5%		0.0%	
Participant Number	Result	Absolute Difference	Result	Absolute Difference	Result	Absolute Difference	Result	Absolute Difference
1862	0.16	0.06	0.38	0.02	0.65	0.85	0.00	0.00

*Note: As 35S accompanies both RUR and LL genetic modification events, its presence is equivalent to the sum of these events in the sample

Table 57: 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]; % Relative error = [reported value – fortified value/fortified value x 100]. Outliers were determined by the Grubb's Test for Outliers and **excluded** from calculations involving reported mean, standard deviation, % relative deviation, and % relative error but were **included** in the range of results.

Transgenic Event	Reported Results (N)	Fortification (%w/w)	Reported Mean	Standard Deviation	% Relative Standard Deviation	% Relative Error	Range of Results (%)
T25	7	0.5	0.39	0.24	61.3	-21.1	0.05- 0.83
T25	7	0.8	0.70	0.24	34.1	-12.5	0.21- 0.90
T25	7	1.0	1.06	0.60	56.1	+6.4	0.35- 2.21
T25	7	2.0	1.79	0.34	19.2	-10.7	1.32- 2.36
CBH351	3	0.1	0.15	0.04	29.1	+50.0	0.12- 0.20
CBH351	3	1.0	1.27	0.47	36.8	+27.0	1.00- 1.81
MON810	17	0.10	0.11	0.04	37.7	+14.3	0.0- 0.22
MON810	17	0.10	0.08	0.03	36.1	-15.4	0.0- 0.10
MON810	17	0.5	0.31	0.16	52.0	-37.8	0.06- 0.60
MON810	17	1.0	0.67	0.32	48.2	-33.1	0.22- 1.40
MON810	17	2.0	1.29	0.60	46.2	-35.3	0.53- 2.70
GA21	12	0.1	0.15	0.07	46.2	+52.4	0.04- 0.62
GA21	12	0.2	0.13	0.05	42.3	-37.2	0.04- 0.99
GA21	12	0.4	0.23	0.09	41.8	-43.8	0.06- 1.93
GA21	12	0.6	0.37	0.16	42.2	-38.8	0.06- 0.56
Bt176	14	0.1	0.10	0.02	19.6	-4.3	0.05- 0.85
Bt176	14	0.1	0.10	0.05	53.7	-3.2	0.0- 0.60
Bt176	14	0.1	0.10	0.01	15.4	-3.1	0.06- 0.96
Bt176	14	0.5	0.57	0.46	80.2	+13.9	0.14- 1.80
Bt176	14	1.5	1.44	0.74	51.3	-3.9	0.48- 3.50

Table 57:
(continued)

Transgenic Event	Reported Results (N)	Fortification (%w/w)	Reported Mean	Standard Deviation	% Relative Standard Deviation	% Relative Error	Range of Results (%)
Bt11	14	0.1	0.10	0.03	24.4	0.0	0.0- 0.50
Bt11	14	0.75	1.09	0.35	32.3	+45.5	0.57- 1.60
Bt11	14	1.5	1.68	0.43	25.8	+11.8	0.0- 2.26
NK603	12	0.65	0.67	0.52	78.1	+2.8	0.10- 2.00
NK603	12	1.3	1.22	0.75	61.4	-5.9	0.10- 2.70
Herculex	11	0.05	0.09	0.03	36.8	+76.5	0.0- 0.44
Herculex	11	0.40	0.50	0.24	48.5	+24.5	0.14- 1.00
Herculex	11	0.75	0.67	0.33	49.0	-10.1	0.14- 1.42
MON863	12	0.4	0.51	0.19	36.6	+27.5	0.23- 0.81
MON863	12	0.8	0.56	0.21	36.6	-30.0	0.10- 0.83
HerculexRW	8	0.1	0.18	0.11	60.4	+80.0	0.03- 0.35
HerculexRW	8	0.1	0.12	0.05	38.8	+20.0	0.05- 2.00
HerculexRW	8	2.0	1.73	0.32	18.6	-13.5	1.40- 4.00
MIR604	7	0.5	0.30	0.18	59.8	-40.0	0.10- 0.50
MIR604	7	0.8	0.48	0.26	53.7	-40.0	0.10- 0.77
MIR604	7	1.5	0.99	0.47	47.9	-34.0	0.40- 1.70
EV3272	3	0.1	0.13	0.12	86.6	+30.0	0.0- 0.20
EV3272	3	0.2	0.14	0.07	46.5	-30.0	0.07- 0.20
EV3272	3	0.5	0.64	0.27	42.7	+28.0	0.46- 0.95
EV3272	3	1.0	0.88	0.11	12.0	-12.0	0.77- 0.98
RUR	29	0.2	0.19	0.09	47.3	-3.5	0.01- 1.20
RUR	29	1.5	1.17	0.52	44.9	-22.0	0.07- 2.30
A2704-12	7	0.1	0.32	0.36	112.1	+220.0	0.0- 1.00
A2704-12	7	0.2	0.38	0.34	88.7	+90.0	0.10- 0.90

Table 58: Quantitative results for corn fortified with CBH 531 using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing) for Participant # 1754 (only this participant submitted results).

Event: CBH351												
%w/w Fortification Level	0.0%		0.0%		0.1%		0.0%		0.0%		1.0%	
Participant Number	Result	Absolute Difference	Result	Absolute Difference	Result	Absolute Difference	Result	Absolute Difference	Result	Absolute Difference	Result	Absolute Difference
1754	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	1.3	0.3

Table 59: Quantitative results for soybeans fortified with CP4EPSPS (RUR) using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing) for Participant # 1754 (only this participant submitted results). ND = None Detected

Event: RUR								
%w/w Fortification Level	**0.0%**		**0.2%**		**1.5%**		**0.0%**	
Participant Number	**Result**	**Absolute Difference**	**Result**	**Absolute Difference**	**Result**	**Absolute Difference**	**Result**	**Absolute Difference**
1754	ND	0.0	0.10	0.10	0.80	0.70	ND	0.0

Summary of Findings

- **Qualitative Sample Analysis**

  DNA-based Testing. The method of DNA-based testing for the qualitative determination of events was by a conventional polymerase chain reaction assay (PCR) which generally has a sensitivity of 0.01% w/w transgenic event. The lowest fortification level in this round of proficiency testing was 0.1% w/w; therefore, if the event was present it should be detectible by a given laboratory that employs conventional PCR. As evidenced by the summary of performance scores (**Table 33** and **Figure 1**), all of the sixteen transgenic events were correctly detected with greater than or equal to 90% reliability, and fourteen of the sixteen transgenic events were correctly detected with greater than or equal to 95% reliability. This was a slight increase over the performance in the November 2009 round wherein twelve of the sixteen transgenic events were correctly detected with greater than or equal to 95% reliability. Events that tested with less than 95% reliability were CBH 351 and A2704-12 (90.0 and 92.5% respectively). Four events, namely 35S, NOS, T-25, and Herculex RW, showed 100% correctly detection.

  When laboratories used qualitative methods to detect RUR soy, only one of forty-six (2.2%) test results generated a false positive result; whereas, six of fifty-eight test results (10.3%) generated false positives using quantitative detection methods on the RUR trait. The possibility of low level contamination of RUR in the event-free samples, below 0.01%, should be considered as plausible and that quantitative methods have higher sensitivity.

  Both events Bt-11and MIR604 showed an equal percentage of false positives and false negative results i.e. 3.85% and 1.8% respectively. For the other events, the percentage of false negatives was greater than that of false positives (see summary Table 33). Collectively, for all qualitative testing submissions, twenty-four out of thirty-two (24/32) false negative results (75%) were reported on samples fortified at the 0.1% level. These data are consistent with what has been reported by Lipp et.al and represents the lowest concentration of GM that can be reliably detected by qualitative PCR.

Protein-based Testing. The principle methods of protein-based testing were lateral flow strips (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 Strategic Diagnostics Inc. (2001 & 2003). 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 34 through 41**). When using LFS to detect GM traits, all methods provided between 83.3 – 100% correct responses. The LFS's generated a higher than expected percentage of false positive results (30%) for the RUR trait. However, because of the small sample set (n=5), it is difficult to draw any conclusions from these data (see **Tables 36 and 37**). ELISA detection methods provided the greatest range of variability for correct responses (50 – 100%) by participants when used qualitatively, but were generally lower than LFS or PCR detection methods (see **Tables 38 – 41**). Again, because of the small sample set for detection of GM traits, no real conclusions can be drawn from these data sets.

- **Quantitative Sample Analysis**

  DNA-based Testing. The method of DNA-based testing for the quantitative determination of transgenic event was by real-time quantitative PCR. 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 57**). Because test samples were fortified ranging from 0.1 – 2.0% w/w of a particular event, it was expected that quantitative PCR (qPCR) technologies would detect the traits in all of the fortified samples but not in non-fortified samples. Remarkably, only one false positive result was reported (Event Bt-11, Table 47) when using qPCR to detect the presence of GM traits in these proficiency samples, with the exception of CP4EPSPS Soy. CP4EPSPS soy samples contained six false positive results in two non-fortified challenge samples examined by twenty-eight participants. Compared with qualitative PCR results (only one false positive in two non-fortified challenge samples), this data suggests the possibility that low levels of CP4EPSPS contamination exists in "event-free" RUR samples and that qPCR is more sensitive compared with qualitative methods of detection for this trait. Collectively, sixteen out of seventeen (16/17) or 94.1% false negative results were observed for samples fortified at the 0.1% level for all of the events combined. This suggests lesser confidence in analytical measurements at a 0.1% fortification level when using qPCR. One laboratory submitted quantitative results using qPCR (DNA-based testing) for the 35S genome in Soy. As 35S accompanies both RUR and LL genetic modification events, its presence is equivalent to the sum of these events in the sample. That participant showed good agreement at the 0.1% and 0.4% fortification level.

  Historical results show lower reported concentrations compared with gravimetric fortification of prepared proficiency samples. The trend of generating lower than expected reported values is possibly due to zygosity in the corn and soy samples. GIPSA in-house validated methods reflect similar observations compared with historical results of participants.

The expected observation from data generated in this report was that inter-laboratory variation observed in reported quantifications, as measured by the % Relative Standard Deviation, should be higher in samples fortified at lower amounts (e.g. 0.1% w/w) as compared to the variation observed in samples fortified at higher amounts (e.g. 2.0% w/w). This inverse relationship between variability (%RSD$_R$) in reported quantifications and fortification level, the trend generally held true for T-25, CBH351, NK603, Herculex RW, and Event 3272, RUR, and A2701-12 (see **Table 57**). This inverse relationship has been observed in the quantitative data from previous rounds of USDA/GIPSA proficiency sample distributions. Though similar trends in these characteristics of inter-laboratory variation were observed, the amount of this variation was for the most part greater than the acceptance criteria of ≤ 35% as established by the Joint Research Council/ENGL (http://gmo-crl.jrc.ec.europa.eu). The Joint Research Council/ENGL criterion for acceptable "trueness" is that percentage relative error in the result should be ≤ 25% in comparison to an accepted reference value—in this case the reference value was the %w/w fortification of the samples. In this round of proficiency testing, there were forty-four trials of inter-laboratory quantifications (i.e., total number of events at the total number of fortification levels) and in twenty-one of those trials the **inter-laboratory relative error** was observed to be ≤ 25% (**Table 57**). This is similar to what was observed in the November 2009 distribution whereby twenty of forty-five trials was observed to be ≤ 25%. Thus, these results were approximately 45% concordant with the acceptance criteria for trueness as established by the Joint Research Council/ENGL. Furthermore, reported quantifications were under-estimated (low bias) in approximately 54% of the trials (**Table 57**). This trend of low bias in the quantifications in comparison to accepted values is an improvement over previous reports (compare to 67% in November 2009 report). Quantitative data from previous rounds of our proficiency sample distributions can be found at:

http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=iws-prof-rep.

Individual Performance Assessment. The performance of each participating laboratory for quantifying transgenic events in the proficiency samples can be observed by inspecting Tables 42 through 56. 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 expected 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.

In this round of inter-laboratory proficiency testing, the %RSD$_R$ for several of the transgenic events was greater than 35% for samples that were fortified above 0.1% (**Table 57**). This observation could be due to numerous confounders including: zygosity, lack of standardization, the presence of inhibitors in the reaction mix, etc. 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.

Protein-based Testing. Only two laboratories submitted quantitative results using a protein-based method (i.e. ELISA). The traits CBH351 and CP4EPSPS were quantified and values

similar to what was observed with DNA based methods were reported (**see Tables 58 and 59**). A greater number of reported results are needed before any conclusions can be drawn from these observations and further studies should be considered. Absolute difference values are shown in the tables since z-scores could not be calculated from these results.

References

Ahmed, F.E. (editor.). 2004. Testing of genetically modified organisms in foods. The Haworth Press, Inc., Binghampton, 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 Bt1 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.

*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 816-891-0452, or by e-mail at Tandace.A.Scholdberg@usda.gov.

Appendix I: List of organizations who wished to be identified as a participant in the GIPSA April 2010 Proficiency Program. Participant identification numbers are listed below with permission from the organization.

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