USDA/GIPSA Proficiency Program
Testing for the Presence of Biotechnology Events in Corn and Soybeans
November 2009 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 53). Tests for outliers and z-scores assume a normal distribution. At the 0% or 0.1% fortification levels, the distributions are not likely normal and are probably skewed. Anything above 0 for the 0.0% spike level would probably be considered an outlier. At the 0.1% 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 54) 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: T25, CBH351, MON810, GA21, Bt-176, Bt-11, NK603, Herculex, MON863, Herculex RW, MIR 604, 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 2% 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. Fifty-one organizations received samples in the November 2009 round of proficiency testing, and forty-two organizations submitted results.

- Sixteen participants submitted **qualitative** results only (14 DNA- and 2 protein-based),
- Nine submitted **quantitative** results only (1 participant performed DNA and protein), and
- Seventeen participants submitted a combination of **qualitative** and **quantitative** results (one participant performed DNA and protein based).

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 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 for corn fortified with 35S for all participants (DNA-based assays).
- Table 2: Percentages of correct results, false negatives, and false positives in qualitative reports for 35S for all participants.
- Table 3: Qualitative results for corn fortified with NOS for all participants (DNA-based assays).
- Table 4: Percentages of correct results, false negatives, and false positives in qualitative reports for NOS for all participants.
- Table 5: Qualitative results for corn fortified with T25 for all participants (DNA-based assays).
- Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports for T25 for all participants.
- Table 7: Qualitative results for corn fortified CBH351 with for all participants (DNA-based assays).

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

- Table 9: Qualitative results for corn fortified with MON810 for all participants (DNA-based assays).

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

- Table 11: Qualitative results for corn fortified with GA21 for all participants (DNA-based assays).

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

- Table 13: Qualitative results for corn fortified with Bt176 for all participants (DNA-based assays).

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

- Table 15: Qualitative results for corn fortified with Bt-11 for all participants (DNA-based assays).

- Table 16: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt-11 for all participants.

- Table 17: Qualitative results for corn fortified with NK603 for all participants. (DNA-based assays).

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

- Table 19: Qualitative results for corn fortified with Herculex for all participants (DNA-based assays).

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

- Table 21: Qualitative results for corn fortified with MON863 for all participants (DNA-based assays).

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

- Table 23: Qualitative results for corn fortified with Herculex RW for all participants (DNA-based assays).

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

- Table 25: Qualitative results for corn fortified with MIR604 for all participants (DNA-based assays).

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

- Table 27: Qualitative results for corn fortified with Event 3272 for all participants (DNA-based assays).

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

- Table 29: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays).

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

- Table 31: Qualitative results for soybeans fortified with A2704-12 (Liberty Link) for all participants (DNA-based assays).

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

- 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).

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

- Table 34: Qualitative results for the detection of transgenic events in corn using Lateral Flow Strip (LFS) Testing (Protein-based testing) for Participants #2823 and #3926.

- Table 35: Qualitative results for soybeans fortified with CP4EPSPS (RUR) for all participants using Lateral Flow Strip (LFS) Testing.

- Table 36: Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Lateral Flow Strip (LFS) Testing.

- Table 37: Qualitative results for the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing) for Participants #2823.

- Table 38: Qualitative results for soybeans fortified with CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

- Table 39: 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 40: Quantitative results and z-scores for corn fortified with T25 for all participants (DNA-based assays).

- Table 41: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays).

- Table 42: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).

- Table 43: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).

- Table 44: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays).

- Table 45: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays).

- Table 46: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays).

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

- Table 48: Quantitative results and z-scores for corn fortified with MON863 for all participants (DNA-based assays).

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

- Table 50: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays).

- Table 51: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays).

- Table 52: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS for all participants (DNA-based assays).

- Table 53: Quantitative results and z-scores for soybeans fortified with A2704-12 for all participants (DNA-based assays).

- Table 54: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays.

- Table 55: Quantitative results for corn fortified with CBH 351 using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing) for Participant # 1754 (only this participant submitted results).

- Table 56: 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).

- Appendix I: List of organizations who wished to be identified as a participant in the GIPSA May 2009 Proficiency Program.

Table 1: Qualitative results for corn fortified with 35S for all participants (DNA-based assays) (N = negative; P = positive; NR = (1) no result submitted or (2) duplicate sample sent; Incorrect results are shown in boldface).

35S	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	**N**	**P**	**P**	**P**	**P**	**P**
1752	N	P	P	P	P	P
1754	N	P	P	P	P	P
1761	N	P	P	P	P	P
1769	N	P	P	P	P	P

1774	N	P	P	P	P	P
1781	N	P	P	P	P	P
1785	N	P	P	P	P	P
1854	N	P	P	P	P	P
1859	N	P	P	P	P	P
1862	N	P	P	P	P	P
1870	N	P	P	P	P	P
1875	N	P	P	P	P	P
1892	N	P	P	P	P	P
2034	N	P	P	P	P	P
2057	N	P	P	P	P	P
2095	NR	P	P	P	P	P
2100	N	P	P	P	P	P
2112	N	P	P	P	P	P
2126	N	P	P	P	P	P
2132	N	P	P	P	P	P
2692	N	P	P	P	P	P
2694	N	P	P	P	P	P
2707	N	P	P	P	P	P
2720	N	P	P	P	P	P
2724	N	P	P	P	P	P
2727	N	P	P	P	P	P
2732	N	P	P	P	P	P
2808	**P**	P	P	P	P	P
2822	N	P	P	P	P	P
2827	N	P	P	P	P	P
2830	N	P	P	P	P	P
3922	N	P	P	P	P	P
3926	N	P	P	P	P	P
3927	N	P	P	P	P	P
3929	N	P	P	P	P	P
N, Results	34	35	35	35	35	35
# Negative	33	0	0	0	0	0
# Positive	1	35	35	35	35	35
% Correct	97.1%	100.0%	100.0%	100.0%	100.0%	100.0%
% Incorrect	2.9%	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	209
# Incorrect	1
% Correct	99.5%
# Provided Positives (P)	175
# False Negative	0
% False Negative	0.0%
# Provided Negatives (N)	34
# False Positive	1
% False Positive	2.9%

Table 3: Qualitative results for corn fortified with NOS for all participants (DNA-based assays) (N = negative; P = positive; NR = (1) no result submitted or (2) duplicate sample sent; Incorrect results are shown in boldface).

NOS	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Sample 6**
Participant Number	**N**	**P**	**P**	**P**	**P**	**P**
1752	N	P	P	P	P	P
1754	N	P	P	P	P	P
1761	N	P	P	P	P	P
1774	N	P	P	P	P	P
1781	N	P	P	P	P	P
1785	N	P	P	P	P	P
1854	N	P	P	P	P	P
1859	N	P	P	P	P	P

1870	N	P	P	P	P	P
1875	N	P	P	P	P	P
1892	N	P	P	P	P	P
2034	N	P	P	P	P	P
2057	N	P	P	P	P	P
2095	NR	P	P	P	P	P
2112	N	P	P	P	P	P
2126	N	P	P	P	P	P
2132	N	P	P	P	P	P
2692	N	P	P	P	P	P
2694	N	P	P	P	P	P
2707	N	P	P	P	P	P
2720	N	**N**	**N**	P	P	**N**
2724	N	P	P	P	P	P
2727	N	P	P	P	P	P
2732	N	P	P	P	P	P
2808	**P**	P	P	P	P	P
2822	N	P	P	P	P	P
2827	N	P	P	P	P	P
2830	N	P	P	P	P	P
3922	N	P	P	P	P	P
3929	N	P	P	P	P	P
N, Results	29	30	30	30	30	30
# Negative	28	1	1	0	0	1
# Positive	1	29	29	30	30	29
% Correct	96.6%	96.7%	96.7%	100.0%	100.0%	96.7%
% Incorrect	3.4%	3.3%	3.3%	0.0%	0.0%	3.3%

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

Total # Reported results	179
# Incorrect	4
% Correct	97.8%
# Provided Positives (P)	150
# False Negative	3
% False Negative	2.0%
# Provided Negatives (N)	29
# False Positive	1
% False Positive	3.4%

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

T25	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	**0.0%**	**2.0%**	**1.0%**	**0.5%**	**0.0%**	**0.1%**
1752	N	P	P	P	N	P
1761	N	P	P	P	N	P
1774	N	P	P	P	N	P
1781	N	P	P	P	N	P
1785	N	P	P	P	N	P
1788	N	P	P	P	N	P
1854	N	P	P	P	N	P
1859	N	P	P	P	N	P
1862	N	P	P	P	N	P
1892	N	P	P	P	N	P
2034	N	P	P	P	N	P
2057	N	P	P	P	N	P

2089	N	P	P	P	N	**N**
2126	N	P	P	P	N	P
2132	N	P	P	P	N	P
2692	N	P	P	P	N	P
2694	N	P	P	P	N	P
2707	N	P	P	P	N	P
2732	N	P	P	P	N	P
2822	N	P	P	P	N	P
3929	N	P	P	P	N	P
N, Results	21	21	21	21	21	21
# Negative	21	0	0	0	21	1
# Positive	0	21	21	21	0	20
% Correct	100.0%	100.0%	100.0%	100.0%	100.0%	95.2%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	4.8%

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

Total # Reported results	126
# Incorrect	1
% Correct	99.2%
# Provided Positives (P)	84
# False Negative	1
% False Negative	1.2%
# Provided Negatives (N)	42
# 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; NR = (1) no result submitted or (2) duplicate sample sent; Incorrect results are shown in boldface).

CBH351	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Sample 6**
Participant Number	**0.0%**	**0.1%**	**1.0%**	**0.0%**	**0.0%**	**0.0%**

1752	N	P	P	N	N	N
1774	N	P	P	N	N	N
1781	N	P	P	N	N	N
1785	N	P	P	N	N	N
1788	N	**N**	P	N	N	N
1854	N	**N**	P	N	**P**	N
1859	N	P	P	N	N	N
1892	N	P	P	N	N	N
2034	N	**N**	P	N	N	N
2057	N	P	P	N	N	N
2095	NR	P	P	N	N	N
2692	N	P	P	N	N	N
2694	N	P	P	N	N	N
2707	N	P	P	N	N	N
2732	N	P	P	N	N	N
N, Results	14	15	15	15	15	15
# Negative	14	3	0	15	14	15
# Positive	0	12	15	0	1	0
% Correct	100.0%	80.0%	100.0%	100.0%	93.3%	100.0%
% Incorrect	0.0%	20.0%	0.0%	0.0%	6.7%	0.0%

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

Total # Reported results	89
# Incorrect	4
% Correct	95.5%
# Provided Positives (P)	30
# False Negative	3
% False Negative	10.0%
# Provided Negatives (N)	59
# False Positive	1
% False Positive	1.7%

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

MON810	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Sample 6**
Participant Number	**0.0%**	**2.0%**	**1.0%**	**0.1%**	**0.5%**	**0.8%**
1752	N	P	P	P	P	P
1774	N	P	P	P	P	P
1785	N	P	P	P	P	P

1788	N	P	P	P	P	P
1854	N	P	P	**N**	**N**	**N**
1859	N	P	P	P	P	P
1862	N	P	P	P	P	P
1892	N	P	P	P	P	P
2034	N	P	P	**N**	P	P
2057	N	P	P	P	P	P
2089	N	P	P	P	P	P
2126	N	P	P	P	P	P
2132	N	P	P	P	P	P
2692	N	P	P	P	P	P
2724	N	P	P	P	P	P
2808	N	**N**	P	P	**N**	P
2822	N	P	P	**N**	P	P
N, Results	17	17	17	17	17	17
# Negative	17	1	0	3	2	1
# Positive	0	16	17	14	15	16
% Correct	100.0%	94.1%	100.0%	82.4%	88.2%	94.1%
% Incorrect	0.0%	5.9%	0.0%	17.6%	11.8%	5.9%

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

Total # Reported results	102
# Incorrect	7
% Correct	93.1%
# Provided Positives (P)	85
# False Negative	7
% False Negative	8.2%
# Provided Negatives (N)	17
# 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; NR = no conclusive result could be acquired, and thus was not included in the results.

GA21	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	**0.0%**	**0.0%**	**0.1%**	**1.0%**	**0.4%**	**0.4%**
1752	N	N	P	P	P	P
1774	N	N	P	P	P	P
1785	N	N	P	P	P	P
1788	N	N	P	P	P	P
1854	N	N	P	P	P	P
1859	N	N	P	P	P	P
1862	N	N	P	P	P	P
1892	N	N	P	P	P	P
2034	N	N	P	P	P	P
2057	N	N	P	P	P	P
2089	N	N	P	P	P	P
2095	NR	N	P	P	P	P
2112	N	N	P	P	P	P
2126	N	N	P	P	P	P
2692	N	N	P	P	P	P
2707	N	N	P	P	P	P
2727	N	N	P	P	P	P
2822	N	N	P	P	P	P
3929	N	N	P	P	P	P

N, Results	18	19	19	19	19	19
# Negative	18	19	0	0	0	0
# Positive	0	0	19	19	19	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 12: Percentages of correct results, false negatives, and false positives in qualitative reports for GA21 for all participants.

Total # Reported results	113
# Incorrect	0
% Correct	100.0%
# Provided Positives (P)	76
# False Negative	0
% False Negative	0.0%
# Provided Negatives (N)	37
# False Positive	0
% False Positive	0.0%

Table 13: Qualitative results for corn fortified with Bt176 for all participants (DNA-based assays) (N = negative; P = positive; NR = no conclusive result could be acquired, and thus was not included in the results.

Bt176	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	**0.0%**	**1.5%**	**0.1%**	**0.1%**	**0.5%**	**0.0%**
1752	N	P	P	P	P	N
1774	N	P	P	P	P	N
1781	N	P	P	P	P	N
1785	N	P	P	P	P	N
1788	N	P	P	P	P	N
1854	N	P	P	P	P	N
1859	N	P	P	P	P	N
1862	N	P	P	P	P	N
1892	N	P	P	P	P	N
2034	N	P	**N**	**N**	P	N
2057	N	P	P	P	P	N
2095	NR	P	P	P	P	**P**
2126	N	P	P	P	P	N
2132	N	P	P	P	P	N
2692	N	P	P	P	P	N
2707	N	P	P	P	P	N
2724	N	P	P	P	P	N
2808	**P**	P	P	P	P	N
2822	N	P	**N**	**N**	**N**	N
3929	N	P	P	P	P	N
N, Results	19	20	20	20	20	20
# Negative	18	0	2	2	1	19
# Positive	1	20	18	18	19	1
% Correct	94.7%	100.0%	90.0%	90.0%	95.0%	95.0%

% Incorrect	5.3%	0.0%	10.0%	10.0%	5.0%	5.0%

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

Total # Reported results	119
# Incorrect	7
% Correct	94.1%
# Provided Positives (P)	80
# False Negative	5
% False Negative	6.2%
# Provided Negatives (N)	39
# False Positive	2
% False Positive	5.1%

Table 15: Qualitative results for corn fortified with Bt11 for all participants (DNA-based assays) (N = negative; P = positive; NR = no conclusive result could be acquired, and thus was not included in the results.

Bt11	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	**0.0%**	**0.1%**	**0.0%**	**2.0%**	**1.0%**	**0.5%**
1752	N	P	N	P	P	P
1774	N	P	N	P	P	P
1781	N	P	N	P	P	P
1785	N	P	N	P	P	P
1788	N	P	N	P	P	P
1854	N	P	N	P	**N**	P
1859	N	P	N	P	P	P
1862	N	P	N	P	P	P
1892	N	P	N	P	P	P
2034	N	P	N	P	P	P
2057	N	P	N	P	P	P
2089	N	P	N	P	P	P
2095	NR	P	N	P	P	P
2126	N	P	N	P	P	P
2132	N	**N**	N	P	P	P
2692	N	P	N	P	P	P
2707	N	P	N	P	P	P
2724	N	P	N	P	P	P
2822	N	P	N	P	P	P
3929	N	P	N	P	P	P
N, Results	19	20	20	20	20	20
# Negative	19	1	20	0	1	0
# Positive	0	19	0	20	19	20
% Correct	100.0%	95.0%	100.0%	100.0%	95.0%	100.0%
% Incorrect	0.0%	5.0%	0.0%	0.0%	5.0%	0.0%

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

Total # Reported results	119
# Incorrect	2
% Correct	98.3%
# Provided Positives (P)	80
# False Negative	2
% False Negative	2.5%
# Provided Negatives (N)	39
# False Positive	0
% False Positive	0.0%

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

NK603	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Sample 6**
Participant Number	**0.0%**	**1.0%**	**2.0%**	**0.0%**	**0.0%**	**0.1%**
1752	N	P	P	N	N	P
1774	N	P	P	N	N	P
1785	N	P	P	N	N	P
1788	N	P	P	N	N	P
1854	N	P	**N**	N	N	P
1859	N	P	P	N	N	P
1862	N	P	P	N	N	P
2034	N	P	P	N	N	P
2057	N	P	P	N	N	P
2089	N	P	P	N	N	P
2126	N	P	P	N	N	P
2692	N	P	P	N	N	P
2707	N	P	P	N	N	P
2808	**P**	**N**	P	**P**	**P**	**N**
2822	N	P	P	N	N	P
3929	N	P	P	N	N	P
N, Results	16	16	16	16	16	16
# Negative	15	1	1	15	15	1
# Positive	1	15	15	1	1	15

% Correct	93.8%	93.8%	93.8%	93.8%	93.8%	93.8%
% Incorrect	6.2%	6.2%	6.2%	6.2%	6.2%	6.2%

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

Total # Reported results	96
# Incorrect	6
% Correct	93.8%
# Provided Positives (P)	48
# False Negative	3
% False Negative	6.2%
# Provided Negatives (N)	48
# False Positive	3
% False Positive	6.3%

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

Herculex	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Sample 6**
Participant Number	**0.0%**	**0.0%**	**0.1%**	**1.5%**	**0.0%**	**0.5%**
1752	N	N	P	P	N	P
1774	N	N	P	P	N	P
1785	N	N	P	P	N	P
1854	N	**P**	**N**	P	**P**	P
1859	N	N	P	P	N	P
1862	N	N	P	P	N	P
2034	N	N	P	P	N	P
2057	N	N	P	P	N	P
2089	N	N	P	P	N	P
2126	N	N	P	P	N	P
2692	N	N	P	P	N	P
2707	N	N	P	P	N	P
2822	N	N	P	P	N	P
3929	N	N	P	P	N	P
N, Results	14	14	14	14	14	14
# Negative	14	13	1	0	13	0
# Positive	0	1	13	14	1	14
% Correct	100.0%	92.9%	92.9%	100.0%	92.9%	100.0%

% Incorrect	0.0%	7.1%	7.1%	0.0%	7.1%	0.0%

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

Total # Reported results	84
# Incorrect	3
% Correct	96.4%
# Provided Positives (P)	42
# False Negative	1
% False Negative	2.4%
# Provided Negatives (N)	42
# False Positive	2
% False Positive	4.8%

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

MON863	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.0%	0.8%	0.0%	0.5%
1752	N	N	N	P	N	P
1761	N	N	N	P	N	P
1774	N	N	N	P	N	P
1785	N	N	N	P	N	P
1788	N	N	N	P	N	P
1854	N	**P**	**P**	P	**P**	P
1859	N	N	N	P	N	P
2034	N	N	N	P	N	P
2057	N	N	N	P	N	P
2089	N	N	N	P	N	P
2126	N	N	N	P	N	P
2692	N	N	N	P	N	P
2707	N	N	N	P	N	P
2727	N	N	N	P	N	P
2822	N	N	N	P	N	P
3929	N	N	N	P	N	P
N, Results	16	16	16	16	16	16
# Negative	16	15	15	0	15	0
# Positive	0	1	1	16	1	16
% Correct	100.0%	93.8%	93.8%	100.0%	93.8%	100.0%
% Incorrect	0.0%	6.2%	6.2%	0.0%	6.2%	0.0%

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

Total # Reported results	96
# Incorrect	3
% Correct	96.9%
# Provided Positives (P)	32
# False Negative	0
% False Negative	0.0%
# Provided Negatives (N)	64
# False Positive	3
% False Positive	4.7%

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

Herculex RW	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	**0.0%**	**0.0%**	**2.0%**	**0.1%**	**0.0%**	**0.5%**
1752	N	N	P	P	N	P
1774	N	N	P	P	N	P
1785	N	N	P	P	N	P
1859	N	N	P	P	N	P
2034	N	N	P	P	N	P
2057	N	N	P	P	N	P
2089	N	N	P	P	N	P
2707	N	N	P	P	N	P
2822	N	N	P	P	N	P
3929	N	N	P	P	N	P
N, Results	10	10	10	10	10	10
# Negative	10	10	0	0	10	0
# Positive	0	0	10	10	0	10
% 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	60
# Incorrect	0
% Correct	100.0%
# Provided Positives (P)	30
# False Negative	0
% False Negative	0.0%
# Provided Negatives (N)	30
# False Positive	0
% False Positive	0.0%

Table 25: Qualitative results for corn fortified with MIR604 for all participants (DNA-based assays).

MIR604	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	**0.0%**	**0.0%**	**0.5%**	**0.0%**	**0.8%**	**0.1%**

1752	N	N	P	N	P	P
1774	N	N	P	N	P	P
1781	N	N	P	N	P	P
1785	N	N	P	N	P	P
1859	N	N	P	N	P	P
2034	N	N	P	N	P	P
2057	N	N	P	N	P	P
2089	N	N	P	N	P	P
2126	N	N	P	N	P	P
2707	N	N	P	N	P	P
2822	N	N	P	N	P	P
3929	N	N	P	N	P	P
N, Results	12	12	12	12	12	12
# Negative	12	12	0	12	0	0
# Positive	0	0	12	0	12	12
% 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 26: Percentages of correct results, false negatives, and false positives in qualitative reports for MIR604 for all participants.

# Reported results	72
# Incorrect	0
% Correct	100.0%
# Provided Positives (P)	36
# False Negative	0
% False Negative	0.0%
# Provided Negatives (N)	36
# False Positive	0
% False Positive	0.0%

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**	**Sample**	**Sample**	**Sample**	**Sample**	**Sample**

	1	2	3	4	5	6
Participant Number	**0.0%**	**0.5%**	**0.1%**	**1.0%**	**0.2%**	**0.0%**
1774	N	P	P	P	P	N
1781	N	P	P	P	P	N
1785	N	P	P	P	P	N
1859	N	P	P	P	P	N
2822	N	P	P	P	P	N
N, Results	5	5	5	5	5	5
# Negative	5	0	0	0	0	5
# Positive	0	5	5	5	5	0
% Correct	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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

# Reported results	30
# Incorrect	0
% Correct	100.0%
# Provided Positives (P)	20
# False Negative	0
% False Negative	0.0%
# Provided Negatives (N)	10
# 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 = (1) no result submitted or (2) duplicate sample sent; Incorrect results are shown in boldface).

CP4 EPSPS	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	1.5%	0.0%	0.0%	0.2%
1752	P	N	N	P
1774	P	**P**	N	P
1788	P	N	N	P
1854	P	N	N	P
1859	P	N	N	P
1892	P	N	N	P
2034	P	N	**P**	P
2095	P	N	N	P
2100	P	N	N	P
2112	P	N	N	P
2692	P	N	N	P
2707	P	N/R	N	P
2724	P	N	**P**	P
2822	P	N	N	P
2830	P	N	N	P
N, Results	15	14	15	15
# Negative	0	13	13	0
# Positive	14	1	2	14
% Correct	100.00%	92.86%	86.67%	100.00%
% Incorrect	0.00%	7.14%	13.33%	0.00%

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	59
# Incorrect	3
% Correct	94.92%
# Provided Positives	30
# False Negative	0
% False Negative	0.0%
# Provided Negatives	29
# False Positive	3
% False Positive	10.34%

Table 31: Qualitative results for soybeans fortified with A2704-12 (Liberty Link Soy) for all participants (DNA-based assays) (N = negative; P = positive; NR = (1) no result submitted or (2) duplicate sample sent; Incorrect results are shown in boldface).

A2704-12	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	**0.0%**	**0.0%**	**0.1%**	**0.2%**
1781	N	N	P	P
1785	N	N	P	P
1859	N	N	P	P
2034	N	N	P	P
2095	N	N	P	P
2112	N	N	P	P
2132	N	N	P	P
2707	N	NR	P	P
N, Results	8	7	8	8
# Negative	8	7	0	0
# Positive	0	0	8	8
% Correct	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%

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	31
# Incorrect	0
% Correct	100.0%
# Provided Positives	16
# False Negative	0
% False Negative	0.0%
# Provided Negatives	15
# False Positive	0
% False Positive	0.0%

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	209	179	126	89	102	113	119	119
Reported Incorrect	1	4	1	4	7	0	7	2
% Correct	99.52%	97.77%	99.21%	95.51%	93.14%	100.00%	94.12%	98.32%
N, Provided Positives	175	150	84	30	85	76	80	80
N, False Negatives	0	3	1	3	7	0	5	2
% False Negative	0.00%	2.00%	1.19%	10.00%	8.24%	0.00%	6.25%	2.50%
N, Provided Negatives	34	29	42	59	17	37	39	39
N, False Positives	1	1	0	1	0	0	2	0
% False Positives	2.94%	3.45%	0.00%	1.69%	0.00%	0.00%	5.13%	0.00%

Event	NK603	Herculex	MON863	HerculexRW	MIR604	EV3272	RUR	A2704-12
N, Results	96	84	96	60	72	30	59	31
Reported Incorrect	6	3	3	0	0	0	3	0
% Correct	93.75%	96.43%	96.86%	100.0%	100.0%	100.0%	94.92%	100.0%
N, Provided Positives	48	42	32	30	36	20	30	16
N, False Negatives	3	1	0	0	0	0	0	0
% False Negative	6.25%	2.38%	0.00%	0.0%	0.0%	0.0%	0.0%	0.0%
N, Provided Negatives	48	42	64	30	36	10	29	15
N, False Positives	3	2	3	0	0	0	3	0
% False Positives	6.3%	4.76%	4.69%	0.0%	0.0%	0.0%	10.34%	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 33.

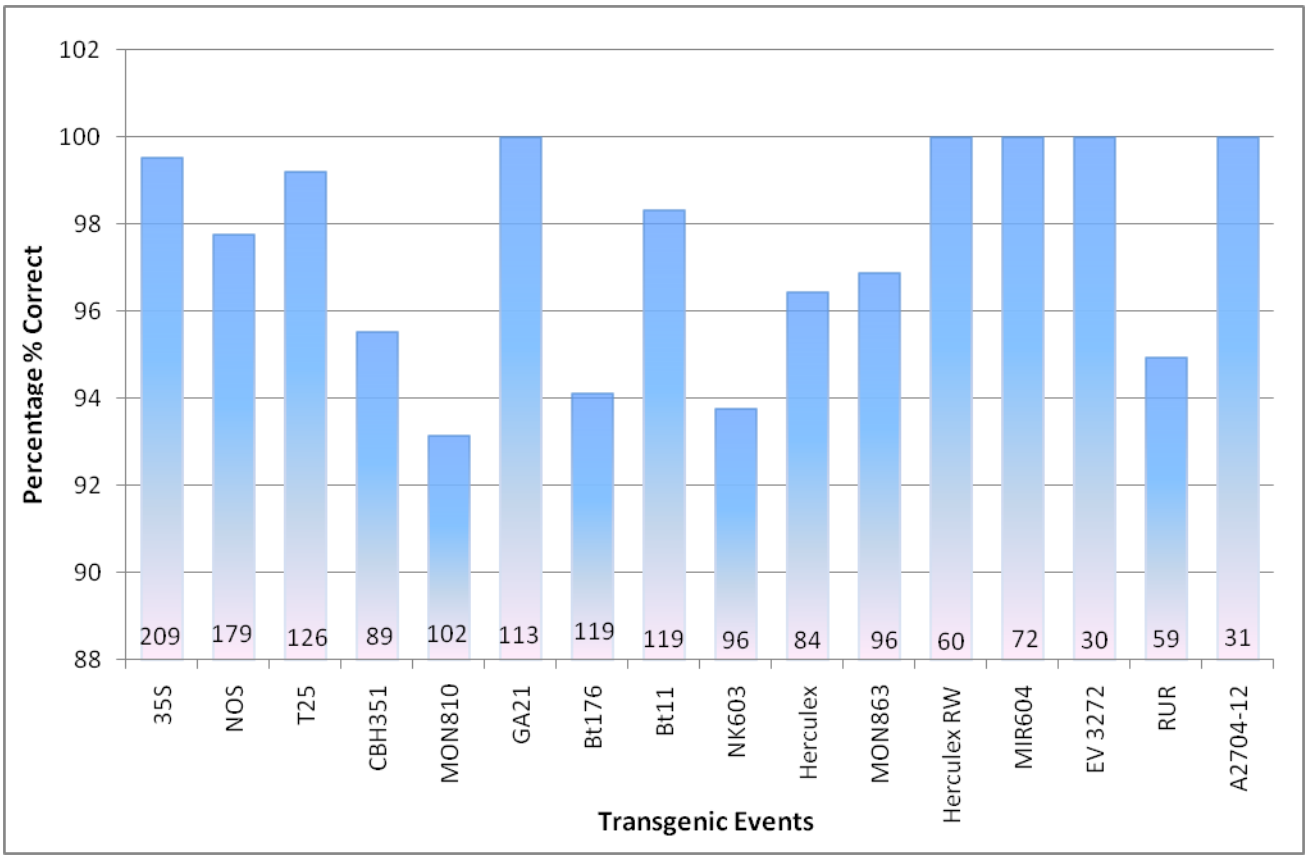

Table 34: Qualitative results for the detection of transgenic events in corn using Lateral Flow Strip (LFS) Testing (Protein-based testing) for Participants #2823 and #3926.

Participant Number 2823	Transgenic Event	
Sample Number	**NK603**	**Cry 1Ab**
1	<5.0%	<5.0%
2	<5.0%	<5.0%

Participant Number 3926	Transgenic Event
Sample Number	**Cry 1Ab**
1	N
2	P

3	<5.0%	<5.0%
4	<5.0%	<5.0%
5	<5.0%	<5.0%
6	<5.0%	<5.0%
Total # Reported Results	6	6
# Incorrect	0	0
% Correct	100.0%	100.0%
# Provided Positives	0	0
# False Negatives	0	0
% False Negatives	0.0%	0.0%
# Provided Negatives	6	6
# False Positives	0	0
% False Positive	0.0%	0.0%
LODs	**5.0%**	**5.0%**

3	P
4	P
5	P
6	P
Total # Reported Results	6
# Incorrect	0
% Correct	100.0%
# Provided Positives	5
# False Negatives	0
% False Negatives	0.0%
# Provided Negatives	1
# False Positives	0
% False Positives	0.0%
LODs	**Not Provided**

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. NK603 and Cry 1Ab).

Only samples fortified **below** the participants LOD where a negative result was reported, are considered in this table as provided negatives.

Participant 3926

Participant did not provide a LOD. Therefore, all samples fortified with Cry 1Ab protein at all levels were included in the report.

Table 35: Qualitative results for soybeans fortified with CP4EPSPS (RUR) for all participants using Lateral Flow Strip (LFS) Testing (N = negative; P = positive; NR = (1) no result submitted or (2) duplicate sample sent).

CP4 EPSPS (RUR)	Sample 1	Sample 2	Sample 3	Sample 4	
Participant Number	1.5%	0.0%	0.0%	0.2%	LOD
2823	≥1%	NR	<1%	≥1%*	1.00%
3926	P	N	N	P	N/A
3927	>0.14%	<0.14%	<0.14%	>0.14%	0.14%

N, Results	3	2	3	3
# Negative	0	2	3	0
# Positive	3	0	0	3
% Correct	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%

*Note: Sample 4 was fortified below the LOD provided but participant 2823 reported a positive result and was scored as correct.

Participant 3926

Participant did not provide a LOD. Therefore, all samples fortified with CP4EPSPS protein at all levels were included in the report

Table 36: Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Lateral Flow Strip (LFS) Testing.

Total # Reported results	11
# Incorrect	0
% Correct	100.0%
# Provided Positives	6
# False Negative	0
% False Negative	0.0%
# Provided Negatives	5
# False Positive	0
% False Positive	0.0%

Table 37: Qualitative results for the detection of transgenic events in corn for Participant 2823 using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

Participant Number 2823	**Transgenic Event**	
Sample Number	**NK603**	**Cry 1 Ab**
1	<1.0%	<1.0%
2	**<1.0%**	**<1.0%**
3	≥1.0%	<1.0%
4	<1.0%	**<1.0%**
5	<1.0%	**<1.0%**

6	<1.0%	<1.0%
Total # Reported results	6	6
# Incorrect	1	3
% Correct	83.3%	50.0%
# Provided Positives	2	3
# False Negative	1	3
% False Negative	50.0%	100.0%
# Provided Negatives	4	3
# False Positive	0	0
% False Positive	0.0%	0.0%
LODs	1.0%	1.0%

Table 38: 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	1.5%	0.0%	0.0%	0.2%	LOD
2817	P	N	N	**N**	N/A
2823	≥1%	NR	<1%	≥1%*	1%

*Note: Sample 4 was fortified below the LOD provided but participant 2823 reported a positive result and was scored as correct.

Participant 2817
Participant did not provide a LOD. Therefore, all samples fortified with CP4EPSPS protein at all levels were included in the report.

Table 39: Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

Total # Reported results	7
# Incorrect	1
% Correct	85.7%
# Provided Positives	4
# False Negative	1
% False Negative	25.0%
# Provided Negatives	3
# False Positive	0
% False Positive	0.0%

Table 40: Quantitative results and z-scores for corn fortified with T25 for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., z > +2 or z < -2. Quantifications marked in red indicate values determined to be either: (1) 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: T25												
%w/w Fortification Level	0.0%		2.0%		1.0%		0.5%		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	0.00		0.60	-3.17	0.50	-1.26	0.10	-3.00	0.00		0.00	-0.98
1769	0.00		0.86	-2.58	0.44	-1.42	0.16	-2.55	0.00		0.03	-0.69
1780	0.00		1.54	-1.04	0.83	-0.43	0.00	-3.75	0.00		0.09	-0.10
1870	0.00		1.60	-0.91	0.90	-0.25	0.40	-0.75	0.00		0.15	0.49
1871	0.00		0.90	-2.49	0.40	-1.52	0.20	-2.25	0.00		0.04	-0.59
1875	0.00		0.63	-3.10	0.48	-1.31	0.21	-2.18	0.00		0.06	-0.39
3922	0.00		*5.00	6.79	1.50	1.26	*1.4	6.75	0.00		0.30	1.96

Table 41: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays). Z-scores outside of the expected range of z > 2 were not observed in this data set except that one result was submitted as a qualitative result and was reported as "P".

Event: CBH351												
%w/w Fortification Level	0.0%		0.1%		1.0%		0.0%		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	0.00		0.10	0.00	0.80	-0.57	0.00		0.00		0.00	
1781	0.00		0.10	0.00	P		0.00		0.00		0.00	
1870	0.00		0.20	2.00	1.10	0.28	0.00		0.00		0.00	
3922	0.00		0.10	0.00	1.50	1.42	0.00		0.00		0.00	

Table 42: 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 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: MON810												
%w/w Fortification Level	0.0%		2.0%		1.0%		0.1%		0.5%		0.8%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.80	-2.60	0.20	-2.82	0.10	0.00	0.10	-3.31	0.40	-1.90
1761	0.00		1.90	-0.22	1.00	0.00	0.10	0.00	0.40	-0.83	0.80	0.00
1769	0.00		1.02	-2.12	0.47	-1.87	0.02	-1.90	0.19	-2.57	0.37	-2.04
1780	0.00		1.28	-1.56	0.81	-0.67	0.06	-0.95	0.32	-1.49	0.66	-0.67
1781	0.00		1.58	-0.91	0.43	-2.01	0.10	0.00	0.25	-2.07	0.69	-0.52
1788	0.00		0.87	-2.45	0.44	-1.98	0.10	0.00	0.17	-2.73	0.29	-2.43
1870	0.00		0.90	-2.38	0.50	-1.76	0.04	-1.43	0.20	-2.48	0.30	-2.38
1875	0.00		0.70	-2.82	0.40	-2.12	0.02	-1.90	0.18	-2.65	0.34	-2.19
2095	N/R		2.00	0.00	0.80	-0.71	0.10	0.00	0.50	0.00	0.70	-0.48
2112	0.00		1.86	-0.30	1.08	0.28	0.11	0.24	0.52	0.17	0.97	0.81
2692	0.00		0.75	-2.71	0.40	-2.12	0.10	0.00	0.31	-1.57	0.38	-2.00
2694	0.00		0.89	-2.41	0.48	-1.83	0.03	-1.66	0.17	-2.73	0.39	-1.95
2707	0.00		1.12	-1.91	0.62	-1.34	0.03	-1.66	0.25	-2.07	0.44	-1.71
2727	0.00		0.90	-2.38	0.27	-2.58	0.00	-2.38	0.21	-2.40	0.49	-1.47
2822	0.00		1.40	-1.30	1.00	0.00	0.00	-2.38	0.30	-1.66	0.40	-1.90
3922	0.00		2.00	0.00	0.80	-0.71	0.10	0.00	0.40	-0.83	0.80	0.00
3926	0.00		1.65	-0.76	1.10	0.35	0.11	0.24	0.37	-1.08	0.77	-0.14
3929	0.00		1.55	-0.98	0.50	-1.76	0.11	0.24	0.41	-0.75	0.37	-2.04

Table 43: 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 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: GA21												
%w/w Fortification Level	0.0%		0.0%		0.1%		1.0%		0.4%		0.4%	
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	0.30	-3.63	0.10	-4.38	0.10	-2.53
1761	0.00		0.00		0.20	1.22	0.45	-2.85	0.16	-3.51	0.25	-1.27
1769	0.00		P		0.18	0.98	0.47	-2.75	0.17	-3.36	0.27	-1.10
1780	0.00		0.00		0.29	2.32	0.82	-0.93	0.29	-1.61	0.47	0.59
1781	0.00		0.10		0.21	1.35	0.54	-2.39	0.15	-3.65	0.31	-0.76
1870	0.00		0.00		0.20	1.22	0.60	-2.08	0.20	-2.92	0.40	0.00
1871	0.00		0.00		0.14	0.49	0.40	-3.11	0.06	-4.97	0.30	-0.84
1875	0.00		0.00		0.15	0.61	0.32	-3.53	0.09	-4.53	0.24	-1.35
2692	0.00		0.00		0.13	0.37	0.33	-3.48	0.11	-4.24	0.23	-1.43
2694	0.00		0.00		0.22	1.47	0.46	-2.80	0.18	-3.22	0.35	-0.42
2720	0.00		0.00		0.00	-1.22	0.10	-4.67	0.10	-4.38	0.10	-2.53
3922	0.00		0.00		0.30	2.45	0.70	-1.56	0.25	-2.19	0.45	0.42

Table 44: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., z > +2 or z < -2. Quantifications marked in red indicate values determined to be either: (1) 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: Bt176												
%w/w Fortification Level	0.0%		1.5%		0.1%		0.1%		0.5%		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		1.70	0.40	0.10	0.00	0.10	0.00	0.20	-2.35	0.00	
1761	0.00		0.10	-2.80	0.10	0.00	0.00	-2.35	0.18	-2.51	0.00	
1769	0.00		1.14	-0.72	0.08	-0.50	0.08	-0.47	0.33	-1.33	0.00	
1780	0.00		1.49	-0.02	0.08	-0.50	0.09	-0.24	0.39	-0.86	0.00	
1788	0.00		0.89	-1.22	0.10	0.00	0.10	0.00	0.28	-1.72	0.00	
1870	0.00		1.60	0.20	0.13	0.75	0.07	-0.71	0.35	-1.17	0.00	
1875	0.00		0.91	-1.18	0.07	-0.75	0.03	-1.65	0.29	-1.64	0.00	
2692	0.00		1.86	0.72	0.10	0.00	0.10	0.00	0.46	-0.31	0.00	
2694	0.00		1.47	-0.06	0.07	-0.75	0.04	-1.41	0.34	-1.25	0.00	
2727	0.00		*4.1	5.19	0.00	-2.51	0.00	-2.35	*1.3	6.27	0.00	
2822	0.00		1.00	-1.00	0.00	-2.51	0.00	-2.35	0.00	-3.92	0.00	
3922	0.00		1.50	0.00	0.10	0.00	0.10	0.00	0.40	-0.78	0.00	

Table 45: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., z > 2. Quantifications marked in red 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%		0.1%		0.0%		2.0%		1.0%		0.5%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.10	0.00	0.00		1.00	-2.03	0.50	-2.19	0.30	-1.31
1761	0.00		0.10	0.00	0.00		1.50	-1.01	1.00	0.00	0.51	0.07
1769	0.00		0.06	-1.24	0.00		1.04	-1.95	0.60	-1.75	0.33	-1.11
1780	0.00		0.08	-0.62	0.00		1.28	-1.46	0.79	-0.92	0.48	-0.13
1788	0.00		0.15	1.55	0.00		1.20	-1.62	0.62	-1.67	0.46	-0.26
1870	0.00		0.10	0.00	0.00		1.50	-1.01	0.90	-0.44	0.50	0.00
1871	0.00		0.07	-0.93	0.00		1.30	-1.42	0.90	-0.44	0.40	-0.65
1875	0.00		0.14	1.24	0.00		0.93	-2.17	0.60	-1.75	0.44	-0.39
2692	0.00		*0.4	9.32	0.00		*3.12	2.27	1.36	1.58	*0.91	2.68
2694	0.00		0.07	-0.93	0.00		1.73	-0.55	0.76	-1.05	0.39	-0.72
2727	0.00		*0.46	11.18	0.00		0.00	-4.05	0.93	-0.31	0.00	-3.27
2822	0.00		0.10	0.00	0.00		1.60	-0.81	0.80	-0.88	0.50	0.00
3922	0.00		0.15	1.55	0.00		1.90	-0.20	1.00	0.00	0.60	0.65

Table 46: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., z > +2 or z < -2 . Quantifications marked in red indicate values determined to be either: (1) 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: NK603												
%w/w Fortification Level	0.0%		1.0%		2.0%		0.0%		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	0.00		0.80	-1.09	1.70	-0.77	0.00		0.00		0.10	0.00
1761	0.00		0.40	-3.27	0.50	-3.86	0.00		0.00		*0.3	13.28
1769	0.00		0.45	-3.00	0.88	-2.89	0.00		0.00		0.06	-2.66
1780	0.00		0.60	-2.18	1.22	-2.01	0.00		0.00		0.12	1.33
1781	0.00		0.62	-2.07	1.57	-1.11	0.00		0.00		0.10	0.00
1870	0.00		0.80	-1.09	1.90	-0.26	0.00		0.00		0.10	0.00
1871	0.00		0.70	-1.64	1.50	-1.29	0.00		0.00		0.08	-1.33
1875	0.00		0.53	-2.56	1.15	-2.19	0.00		0.00		0.08	-1.33
2095	NR		0.20	-4.36	1.00	-2.58	0.00		0.00		0.10	0.00
2692	0.00		0.67	-1.80	1.11	-2.29	0.00		0.00		0.10	0.00
2694	0.00		0.53	-2.56	1.02	-2.53	0.00		0.00		0.09	-0.66
2727	0.00		0.28	-3.93	1.00	-2.58	0.00		0.00		0.11	0.66
2822	0.00		0.70	-1.64	1.50	-1.29	0.00		0.00		0.10	0.00
3922	0.00		0.70	-1.64	1.70	-0.77	0.00		0.00		0.10	0.00

Table 47: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., z > +2 or z < -2 . Quantifications marked in red 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: Herculex												
%w/w Fortification Level	0.0%		0.0%		0.1%		1.5%		0.0%		0.5%	
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	0.30	-5.35	0.00		0.10	-2.55
1761	0.00		0.00		0.10	0.00	0.80	-3.12	0.00		0.50	0.00
1769	0.00		0.00		0.02	-2.11	0.51	-4.41	0.00		0.16	-2.17
1780	0.00		0.00		0.07	-0.79	0.64	-3.83	0.00		0.35	-0.96
1781	0.00		0.00		0.10	0.00	0.33	-5.22	0.00		0.29	-1.34
1870	0.00		0.00		0.06	-1.05	0.50	-4.46	0.00		0.30	-1.28
1875	0.00		0.00		0.03	-1.84	0.41	-4.86	0.00		0.23	-1.72
2692	0.00		0.00		0.10	0.00	0.53	-4.32	0.00		0.17	-2.11
2694	0.00		0.00		0.04	-1.58	0.42	-4.81	0.00		0.23	-1.72
2727	0.00		0.00		0.00	-2.64	0.25	-5.57	0.00		0.12	-2.42
3922	0.00		0.00		*1.3	31.62	1.00	-2.23	0.00		0.60	0.64

Table 48: 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. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: MON863												
%w/w Fortification Level	0.0%		0.0%		0.0%		0.8%		0.0%		0.5%	
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		0.00		0.50	-1.79	0.00		0.50	0.00
1769	0.00		0.00		0.00		0.67	-0.78	0.00		0.49	-0.06
1780	0.00		0.00		0.00		0.55	-1.49	0.00		0.69	1.15
1781	0.00		0.00		0.00		0.45	-2.09	0.00		0.65	0.90
1870	0.00		0.00		0.00		0.60	-1.19	0.00		0.60	0.60
1875	0.00		0.00		0.00		0.45	-2.09	0.00		0.45	-0.30
2692	0.00		0.00		0.00		0.92	0.72	0.00		1.02	3.14
2694	0.00		0.00		0.00		0.81	0.06	0.00		0.61	0.66
2822	0.00		0.00		0.00		0.80	0.00	0.00		0.70	1.21
3922	0.00		0.00		0.00		0.50	-1.79	0.00		0.50	0.00

Table 49: Quantitative results and z-scores for corn fortified with Herculex RW for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., z > +2 or z < -2. Quantifications marked in red indicate 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: Herculex RW												
%w/w Fortification Level	0.0%		0.0%		2.0%		0.1%		0.0%		0.5%	
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		3.40	1.38	0.10	0.00	0.00		1.10	2.37
1761	0.00		0.00		2.30	0.30	0.10	0.00	0.00		0.80	1.19
1780	0.00		0.00		1.84	-0.16	0.08	-0.51	0.00		0.46	-0.16
1781	0.00		0.00		2.93	0.92	0.14	1.01	0.00		1.14	2.53
1870	0.00		0.00		3.50	1.48	0.20	2.54	0.00		1.00	1.98
1875	0.00		0.00		3.10	1.08	0.15	1.27	0.00		0.74	0.95
2694	0.00		0.00		3.65	1.62	0.10	0.00	0.00		1.19	2.73
2727	0.00		0.00		0.52	-1.46	*0.47	9.38	0.00		0.94	1.74
3922	0.00		0.00		2.00	0.00	0.10	0.00	0.00		0.60	0.40

Table 50: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays). Values in yellow indicate z-scores outside of expected range i.e., z > +2 or z < -2. Quantifications marked in red 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: MIR604												
%w/w Fortification Level	0.0%		0.0%		0.5%		0.0%		0.8%		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	0.00		0.70	-0.66	0.10	0.00
1761	0.00		0.00		0.20	-2.75	0.00		0.20	-3.97	*0.30	13.44
1769	0.00		0.00		0.37	-1.19	0.00		0.60	-1.32	0.07	-2.02
1780	0.00		0.00		0.49	-0.09	0.00		0.58	-1.46	0.10	0.00
1870	0.00		0.00		0.40	-0.92	0.00		0.50	-1.99	0.10	0.00
1871	0.00		0.00		0.30	-1.84	0.00		0.50	-1.99	0.09	-0.67
1875	0.00		0.00		0.30	-1.84	0.00		0.31	-3.24	0.07	-2.02
2694	0.00		0.00		0.48	-0.18	0.00		0.53	-1.79	0.07	-2.02
3922	0.00		0.00		0.50	0.00	0.00		0.50	-1.99	0.10	0.00

Table 51: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays). Values in yellow indicate z-scores outside of expected range i.e., z > +2 or z < -2. Quantifications marked in red 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: Event 3272												
%w/w Fortification Level	0.0%		0.5%		0.1%		1.0%		0.2%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1769	0.00		0.49	-0.03	0.09	-0.12	0.67	-0.68	0.12	-0.36	0.00	
1780	0.00		0.45	-0.15	0.00	-1.22	0.72	-0.57	0.00	-0.90	0.00	
1870	0.00		0.60	0.30	0.10	0.00	0.90	-0.21	0.10	-0.45	0.00	
2057	0.00		1.20	2.10	0.20	1.22	1.80	1.64	0.50	1.35	0.00	
3922	0.00		0.60	0.30	0.10	0.00	0.90	-0.21	0.10	-0.45	0.00	

Table 52: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS (RUR) for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of expected range, i.e., z > +2 or z < -2. Quantifications marked in red 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	1.5%		0.0%		0.0%		0.2%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	1.10	-0.74	0.00		0.00		0.20	0.00
1761	1.10	-0.74	0.20		0.00		0.30	1.17
1769	1.30	-0.37	0.00		P		0.17	-0.35
1780	1.63	0.24	0.00		0.00		0.30	1.17
1781	1.23	-0.50	0.00		0.00		0.31	1.28
1785	0.82	-1.26	0.00		0.00		0.20	0.00
1788	0.84	-1.23	0.00		0.00		0.16	-0.47
1870	1.20	-0.56	0.00		0.00		0.10	-1.17
1871	0.90	-1.11	0.00		0.00		0.30	1.17
1875	1.79	0.54	0.00		0.00		0.24	0.47
2057	2.20	1.30	0.00		0.00		0.20	0.00
2075	1.31	-0.35	0.00		0.26		*1.05	9.92
2095	0.70	-1.49	0.00		0.00		0.20	0.00
2112	1.80	0.56	0.00		0.00		P	
2132	2.66	2.16	0.00		0.00		0.32	1.40
2692	2.07	1.06	0.00		0.00		0.34	1.63
2694	1.62	0.22	0.00		0.00		0.21	0.12
2720	0.80	-1.30	0.00		0.00		0.40	2.33
2727	1.30	-0.37	0.00		0.00		0.13	-0.82
2808	0.52	-1.82	0.00		0.00		0.19	-0.12
3922	0.60	-1.67	0.00		0.00		0.10	-1.17
3926	1.24	-0.48	0.00		0.00		0.23	0.35
3927	1.40	-0.19	0.00		0.00		0.37	1.98

Table 53: Quantitative results and z-scores for soybeans fortified with A2704-12 (Liberty Link) for all participants (DNA-based assays). Values highlighted in yellow 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.

Event: A2704-12								
%w/w Fortification Level	0.0%		0.0%		0.1%		0.2%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		0.10	0.00	0.20	0.00
1780	0.00		0.00		0.12	1.37	0.24	0.76
1870	0.00		0.00		0.10	0.00	0.10	-1.91
1871	0.00		0.00		0.07	-2.05	0.11	-1.72
1875	0.00		0.00		0.10	0.00	0.20	0.00
2057	0.00		0.00		0.10	0.00	0.20	0.00
3922	0.00		0.00		0.10	0.00	0.20	0.00

Table 54: 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	0.1	0.10	0.1	100.0%	0.0%	0.00-0.30
T25	7	0.5	0.18	0.13	72.2%	-80.0%	0.00-1.40
T25	7	1.0	0.72	0.39	54.2%	-28.0%	0.40-1.50
T25	7	2.0	1.02	0.44	43.1%	-49.0%	0.60-5.00
CBH351	4	0.1	0.13	0.05	38.5%	30.0%	0.10-0.20
CBH351	4	1.0	1.13	0.35	31.0%	13.0%	0.80-1.50
MON810	18	0.1	0.07	0.04	57.1%	-30.0%	0.0-0.11
MON810	18	0.5	0.29	0.12	41.4%	-42.0%	0.100.52
MON810	18	0.8	0.53	0.21	39.6%	-33.8%	0.29-0.97
MON810	18	1.0	0.63	0.28	44.4%	-37.0%	0.20-1.10
MON810	18	2.0	1.29	0.46	35.7%	-35.5%	0.70-2.00
GA21	12	0.1	0.18	0.08	44.4%	80.0%	0.0-0.30
GA21	12	0.4	0.16	0.07	43.8%	-60.0%	0.06-0.29
GA21	12	0.4	0.29	0.12	41.4%	-27.5%	0.10-0.47
GA21	12	1.0	0.46	0.19	41.3%	-54.0%	0.10-0.82
Bt176	12	0.1	0.08	0.04	50.0%	-20.0%	0.0-0.13
Bt176	12	0.1	0.06	0.04	66.7%	-40.0%	0.0-0.10
Bt176	12	0.5	0.29	0.13	44.8%	-42.0%	0.0-1.30
Bt176	12	1.5	1.24	0.5	40.3%	-17.3%	0.10-4.10
Bt11	13	0.1	0.10	0.03	30.0%	0.0%	0.06-0.46
Bt11	13	0.5	0.41	0.15	36.6%	-18.0%	0.0-0.91
Bt11	13	1.0	0.83	0.23	27.7%	-17.0%	0.50-1.36
Bt11	13	2.0	1.25	0.49	39.2%	-37.5%	0.0-3.12
NK603	14	0.1	0.10	0.02	20.0%	0.0%	0.06-0.30
NK603	14	1.0	0.57	0.18	31.6%	-43.0%	0.20-0.80
NK603	14	2.0	1.27	0.39	30.7%	-36.5%	0.50-1.90
Herculex	11	0.1	0.06	0.04	66.7%	-40.0%	0.0-1.30
Herculex	11	0.5	0.28	0.16	57.1%	-44.0%	0.10-0.60
Herculex	11	1.5	0.52	0.22	42.3%	-65.3%	0.25-1.00
MON863	10	0.5	0.62	0.17	27.4%	24.0%	0.45-1.02
MON863	10	0.8	0.63	0.17	27.0%	-21.3%	0.45-0.92
HerculexRW	9	0.1	0.12	0.04	33.3%	20.0%	0.08-0.47
HerculexRW	9	0.5	0.89	0.25	28.1%	78.0%	0.46-1.19
HerculexRW	9	2.0	2.58	1.02	39.5%	29.0%	0.52-3.65
MIR604	9	0.1	0.09	0.01	11.1%	-10.0%	0.07-0.30
MIR604	9	0.5	0.39	0.11	28.2%	-22.0%	0.20-0.50
MIR604	9	0.8	0.44	0.15	34.1%	-45.0%	0.0-0.70
EV3272	5	0.1	0.10	0.08	80.0%	0.0%	0.0-0.20
EV3272	5	0.2	0.18	0.33	122.2%	-10.0%	0.0-0.50
EV3272	5	0.5	0.71	0.49	46.5%	42.0%	0.45-1.20
EV3272	5	1.0	1.08	0.22	45.4%	8.0%	0.72-1.80
RUR	23	0.2	0.24	0.09	37.5%	20.0%	0.10-1.05
RUR	23	1.5	1.31	0.54	41.2%	-12.7%	0.52-2.66
A2704-12	7	0.1	0.10	0.01	10.0%	0.0%	0.07-0.12
A2704-12	7	0.2	0.18	0.05	27.8%	-10.0%	0.10-0.24

Table 55: 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%		0.10%		1.0%		0.0%		0.0%	
Participant Number	Result	Absolute difference	Result	Absolute difference	Result	Absolute difference	Result	Absolute difference	Result	Absolute difference
1754	0.0	0.0	0.10	0.0	0.70	0.30	0.0	0.0	0.0	0.0

Table 56: 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).

Event: RUR Soybean								
%w/w Fortification Level	1.5%		0.0%		0.0%		0.20%	
Participant Number	Result	Absolute difference	Result	Absolute difference	Result	Absolute difference	Result	Absolute difference
1754	0.8	0.7	0.0	0.0	0.0	0.0	0.1	0.1

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**), twelve 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 April 2009 round wherein eleven of the fifteen transgenic events were correctly detected with greater than or equal to 95% reliability. The only events that tested with less than 95% reliability included: Bt 176 (94.1%), Mon810 (93.1%), NK 603 (93.8%), and Roundup Ready Soy (94.9%). The failure of Roundup Ready soy to test with greater than 95% reliability was due to a higher incidence of false positives (RUR Soy = 10.34%) and not false negatives. Thus, the possibility of low level contamination of RUR in the event-free samples, below 0.01%, should be considered as plausible. Events Bt 176 and NK 603 were relatively equal in the percentage of false positives (5.13% and 6.30%, respectively) and false negatives (6.25% and 6.25%, respectively) reported. The low testing reliability of MON 810 is attributed to a higher incidence of false negatives (MON 810= 8.2%) and not false positives.

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). Curiously, some laboratories reported LOD's as high as 5% for detection of some traits (i.e.NK603). ELISA has a sensitivity of 0.5 - 1% w/w for corn and soy events (Ahmed, 2004). Generally, 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 (see **Tables 34, 35, 36, 38, 39**). One exception to this general trend was noted (**see Table 37**). This particular participant reported 3 of 3 false negative results when testing for the presence of Cry 1Ab, even though samples were fortified above their reported LOD.

Laboratories demonstrated good proficiency, with 0 of 8 false positive and only 1of 10 false negative results, when using protein-based methods to detect the presence of the CP4EPSPS protein in samples fortified with the RoundUp Ready trait (**Tables 35, 36, 38, 39**).

- **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 54**). 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. With regard to the detection specificity and qPCR, a scattered number of detects in non-fortified samples were observed (i.e. false positive results, see **Tables 43 and 52**). A greater number of false negative results were observed for the different traits, (i.e. see **Tables 40, 42, 43, 44, 45, 47, 50,** and **51**). Another expectation was that the 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). With regard to this inverse relationship between variability ($\%RSD_R$) in reported quantifications and fortification level, the trend generally held true for T25, CBH351, MON 810, GA21, Bt-176, Herculex, and Event 3272 (**Table 54**). 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). As established by the Joint Research Council/ENGL, the acceptance criterion for trueness is that the 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-five trials of inter-laboratory quantifications (i.e., total number of events at the total number of fortification levels) and in twenty of those trials the **inter-laboratory relative error** was observed to be ≤ 25% (**Table 54**). This is similar to what was observed in the May 2009 distribution whereby twenty-three of forty-three trials was observed to be ≤ 25%. Thus, these results were approximately 44% concordant with the acceptance criteria for trueness as established by the Joint Research Council/ENGL. Furthermore, there was a tendency for the reported quantifications to be moderately under-estimated (low bias) as evidenced by the observation that approximately 67% of the quantification trials had percentage relative error values that were negative (**Table 54**). This same trend of a low bias in the quantifications in comparison to accepted values was observed in the quantitative data from previous rounds of our proficiency sample distributions, which 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 40 through 53. 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) 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 54**). 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 one laboratory submitted quantitative results using a protein-based method (i.e. ELISA). The trait CBH351 and CP4EPSPS were quantified and values similar to what was observed with DNA based methods were reported (**see Table 55 and 56**). 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.

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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 Novenber 2009 Proficiency Program. Participant identification numbers are listed below with permission from the organization.

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