USDA/GIPSA Proficiency Program
Testing for the Presence of Biotechnology Events in Corn and Soybeans
April 2007 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 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 results was done by computing the "percentage of correctly reported transgenic traits" in the samples.

Sample Composition

The corn samples contained various combinations and concentrations of the following transgenic traits: T25, CBH351, MON810, GA21, E176, Bt11, NK603, Herculex, and MON863; 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 mixed with a calculated amount of non-transgenic corn to produce concentrations from 0.1% to 5.0% of the event. The soybean samples were either non-transgenic soybeans, or fortified soybean samples containing 1.5%, or 2.5% of the transgenic glyphosate-tolerant soybeans (RoundUp Ready®). Each participant received six corn and three soybean samples. Each sample contained approximately 20 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-two organizations participated in the April 2007 round of proficiency testing.

- Eightteen participants submitted **qualitative** results only,
- Six participants submitted **quantitative** results only, and
- Twenty-eight participants submitted a combination of **qualitative** and **quantitative** results.

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.

Data Summary Results

Data submitted by the participants are 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: Percentage of correct results 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: Percentage of correct results 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: Percentage of correct results in qualitative reports for T25 for all participants.
- Table 7: Qualitative results for corn fortified GA21with for all participants (DNA-based assays).
- Table 8: Percentage of correct results in qualitative reports for GA21 for all participants.
- Table 9: Qualitative results for corn fortified with CBH351 for all participants (DNA-based assays).
- Table 10: Percentage of correct results in qualitative reports for CBH351 for all participants.
- Table 11: Qualitative results for corn fortified with MON810 for all participants (DNA-based assays).
- Table 12: Percentage of correct results in qualitative reports for MON810 for all participants.
- Table 13: Qualitative results for corn fortified with E176 for all participants (DNA-based assays).
- Table 14: Percentage of correct results in qualitative reports for E176 for all participants.
- Table 15: Qualitative results for corn fortified with Bt11 for all participants (DNA-based assays).
- Table 16: Percentage of correct results in qualitative reports for Bt11 for all participants.
- Table 17: Qualitative results for corn fortified with NK603 for all participants. (DNA-based assays).
- Table 18: Percentage of correct results 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: Percentage of correct results 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: Percentage of correct results in qualitative reports for MON863 for all participants.

- Table 23: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays).

- Table 24: Percentage of correct results in qualitative reports for CP4 EPSPS for all participants.

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- Table 26: Qualitative results for corn fortified with T25 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

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- Table 28: Qualitative results for corn fortified with CBH351 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 29: Percentage of correct results in qualitative reports for CBH351 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 30: Qualitative results for corn fortified with NK603 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 31: Percentage of correct results in qualitative reports for NK603 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 32: Qualitative results for corn fortified with Herculex for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 33: Percentage of correct results in qualitative reports for Herculex for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 34: Qualitative results for corn fortified with MON863 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 35: Percentage of correct results in qualitative reports for MON863 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 36: Qualitative results for corn fortified with Cry1Ab for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 37: Qualitative results for soybeans fortified with CP4EPSPS for all participants using Lateral Flow Strip (LFS) Testing and Enzyme-Linked Immunosorbent Assay (ELISA) Testing (Protein-based testing).

- Table 38: Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Lateral Flow Strip (LFS) Testing and Enzyme-Linked Immunosorbent Assay (ELISA) Testing (Protein-based testing).

Quantitative Data Summaries. This section summarizes quantitative sample analysis data:

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

- Table 40: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).

- Table 41: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).

- Table 42: Quantitative results and z-scores for corn fortified with E176 for all participants (DNA-based assays).

- Table 43: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays).

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

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- Table 47: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays).

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

- Table 49: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS for all participants (DNA-based assays).

- Table 50: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays.

- Appendix I: List of organizations who wished to be identified as a participant in the GIPSA April 2007 Proficiency Program.

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

35S	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	P	P	P	P	P	N
1752	P	P	P	P	P	N
1754	P	P	P	P	P	N
1755	P	P	P	P	P	N
1761	P	P	P	P	P	N
1763	P	P	P	P	P	N
1764	P	P	P	P	P	N
1770	P	P	P	P	P	N
1773	P	P	P	P	P	N
1774	P	P	P	P	P	N
1785	P	P	P	P	P	N
1786	P	P	P	P	P	N
1854	P	P	P	P	P	N
1859	P	P	P	P	P	N
1870	P	P	P	P	P	N
1891	P	P	P	P	P	N
1892	P	P	P	P	P	N
2031	P	P	P	P	P	N
2032	P	P	P	P	P	N
2034	P	P	P	P	P	N
2039	P	P	P	P	P	N
2044	P	P	P	P	P	N
2045	P	P	P	P	P	N
2050	P	P	P	P	P	N
2057	P	P	P	P	P	N
2075	P	P	P	P	P	N
2076	P	P	P	P	P	N
2095	P	P	P	P	P	N
2098	P	P	P	P	P	N
2100	P	P	P	P	P	P
2108	P	P	P	P	P	N
2112	P	P	P	P	P	N
2113	P	P	P	P	P	N
2129	P	P	P	P	P	N
2132	P	P	P	P	P	N
2691	P	P	P	P	P	N
2692	P	P	P	P	P	N
2693	P	P	P	P	P	N
2717	P	P	P	P	P	P
2721	N	N	P	N	P	N
2724	P	P	P	P	P	N
2727	P	P	P	P	P	N

Number of Results	41	41	41	41	41	41
# Negative	1	1	0	1	0	39
# Positive	40	40	41	40	41	2
% Correct	97.6%	97.6%	100.0%	97.6%	100.0%	95.1%
% Incorrect	2.4%	2.4%	0.0%	2.4%	0.0%	4.9%

Table 2: Percentage of correct results in qualitative reports for 35S for all participants.
Table 2 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	246
# Reported Incorrect	5
% Correct	98.0%
# of Provided Positives (P)	204
# of False Negatives	3
%False Negative	1.4%
# of Provided Negatives (N)	42
# of False Positives	2
%False Positive	4.5%

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 #	P	P	P	P	P	N
Participant #	P	P	P	P	P	N
1752	P	P	P	P	P	N
1754	P	P	P	P	P	N
1755	P	P	P	P	P	N
1761	P	P	P	P	P	N
1763	P	P	P	P	P	N
1764	P	P	P	P	P	N
1770	P	P	P	P	P	N
1773	P	P	P	P	P	N
1774	P	P	P	P	P	N
1785	P	P	P	P	P	N
1786	P	P	P	P	P	N
1854	P	P	P	P	P	N
1859	P	P	P	P	P	N
1870	P	P	P	P	P	N
1891	P	P	P	P	P	N
1892	P	P	P	P	P	N
2031	P	P	P	P	P	N
2032	P	P	P	P	P	N
2034	P	P	P	P	P	N
2039	P	P	P	P	P	N
2044	P	P	P	P	P	N
2050	P	P	P	P	P	N
2057	P	P	P	P	P	N
2095	P	P	P	P	P	N
2098	P	P	P	P	P	N
2108	P	P	P	P	P	N
2112	P	P	P	P	P	N
2113	P	P	P	P	P	N
2129	P	P	P	P	P	N
2132	P	P	P	P	P	N
2691	P	P	P	P	P	N
2692	P	P	P	P	P	N
2693	P	P	P	P	P	N
2717	P	P	P	P	P	P
2721	N	N	P	P	P	N
2724	N	P	P	N	P	N

Number of Results	36	36	36	36	36	36
# Negative	2	1	0	1	0	35
# Positive	34	35	36	35	36	1
% Correct	94.4%	97.2%	100.0%	97.2%	100.0%	97.2%
% Incorrect	5.6%	2.8%	0.0%	2.8%	0.0%	2.8%

Table 4: Percentage of correct results in qualitative reports for NOS for all participants.
Table 4 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	216
# Reported Incorrect	5
% Correct	97.7%
# of Provided Positives (P)	177
# of False Negatives	4
%False Negative	2.2%
# of Provided Negatives (N)	39
# of False Positives	1
%False Positive	2.5%

Table 5: Qualitative results for corn fortified with T25 for all participants (DNA-based assays). (N=negative, P=positive)

T25	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.1%	1.5%	5.0%	0.1%	0.1%	0.0%
1752	P	P	P	P	P	N
1773	P	P	P	P	P	N
1774	P	P	P	P	P	N
1785	P	P	P	P	P	N
1786	P	P	P	P	P	N
1788	N/A	P	P	P	P	N
1854	N	P	P	P	P	N
1859	P	P	P	P	P	N
1892	P	P	P	P	P	N
2032	P	P	P	P	P	N
2034	N/A	P	P	P	P	N
2039	N/A	P	P	P	P	N
2051	P	P	P			N
2060	P	P	P	P	P	N
2075	N	P	P	P	P	N
2095	P	P	N	N	P	N
2112	P	P	P	P	P	N
2113	N	P	P	N	N	N
2132	P	P	P	P	P	N
2692	P	P	P	P	P	N
2693	N	N	N	N	N	N
2705	P	P	P	P	P	N

Number of Results	18	22	22	21	21	22
# Negative	4	1	2	3	2	22
# Positive	14	21	20	18	19	0
% Correct	77.8%	95.5%	90.9%	85.7%	90.5%	100.0%
% Incorrect	22.2%	4.5%	9.1%	14.3%	9.5%	0.0%

Table 6: Percentage of correct results in qualitative reports for T25 for all participants.
Table 6 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	126
# Reported Incorrect	12
% Correct	90.5%
# of Provided Positives (P)	92
# of False Negatives	12
%False Negative	11.5%
# of Provided Negatives (N)	34
# of False Positives	0
%False Positive	0.0%

Table 7: Qualitative results for corn fortified with GA21 for all participants (DNA-based assays). (N=negative, P=positive)

GA21	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	1.5%	0.0%	0.1%	0.1%	0.4%	0.0%
1752	P	N	P	P	P	N
1773	P	N	P	P	P	N
1774	P	N	P	P	P	N
1785	P	N	P	P	P	N
1786	P	N	P	P	P	N
1788	P	N	P	P	P	N
1854	P	N	P	P	P	N
1859	P	N	P	P	P	N
1892	P	N	P	P	P	N
2032	P	P	P	P	P	N
2034	P	N	P	P	P	N
2039	P	N	P	P	P	N
2060	P	N	P	P	P	N
2075	P	N	P	P	P	N
2095	P	N	P	P	P	N
2112	P	P	P	P	P	N
2113	P	N	P	N	P	N
2692	P	N	P	P	P	N
2693	P	N	N	N	P	N
2705	P	N	P	P	P	N

Number of Results	20	20	20	20	20	20
# Negative	0	18	1	2	0	20
# Positive	20	2	19	18	20	0
% Correct	100.0%	90.0%	95.0%	90.0%	100.0%	100.0%
% Incorrect	0.0%	10.0%	5.0%	10.0%	0.0%	0.0%

Table 8: Percentage of correct results in qualitative reports for GA21 for all participants.
Table 12 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	120
# Reported Incorrect	5
% Correct	95.8%
# of Provided Positives (P)	79
# of False Negatives	3
%False Negative	3.7%
# of Provided Negatives (N)	41
# of False Positives	2
%False Positive	4.7%

Table 9: Qualitative results for corn fortified with CBH351 for all participants (DNA-based assays). (N=negative, P=positive)

CBH351	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.0%	0.5%	1.5%	0.1%	0.0%	0.0%
1752	N	P	P	P	N	N
1761	N	P	P	P	N	N
1770	N	P	P	P	N	N
1773	N	P	P	P	N	N
1774	N	P	P	P	N	N
1785	N	P	P	P	N	N
1788	N	P	P	N/A	N	N
1854	N	P	P	N/A	P	N
1859	N	P	P	P	N	N
1891	N	P	P	P	N	N
1892	N	P	P	P	N	N
2032	N	P	P	P	N	N
2034	N	P	P	P	N	N
2039	N	P	P	P	N	N
2098	N	P	P	P	N	N
2113	N	P	P	P	P	N
2692	N	P	P	P	N	N

Number of Results	17	17	17	15	17	17
# Negative	17	0	0	0	15	17
# Positive	0	17	17	15	2	0
% Correct	100.0%	100.0%	100.0%	100.0%	88.2%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%	11.8%	0.0%

Table 10: Percentage of correct results in qualitative reports for CBH351 for all participants. Table 8 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	100
# Reported Incorrect	2
% Correct	98.0%
# of Provided Positives (P)	51
# of False Negatives	0
%False Negative	0.0%
# of Provided Negatives (N)	49
# of False Positives	2
%False Positive	3.9%

Table 11: Qualitative results for corn fortified with MON810 for all participants (DNA-based assays). (N=negative, P=positive)

MON810	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	3.0%	0.1%	0.5%	0.0%	0.8%	0.0%
1752	P	P	P	N	P	N
1773	P	P	P	N	P	N
1774	P	P	P	N	P	N
1785	P	P	P	N	P	N
1786	P	P	P	N	P	N
1788	P	P	P	N	P	N
1854	P	P	P	P	P	N
1859	P	P	P	N	P	N
1892	P	P	P	N	P	N
2032	P	P	P	N	P	N
2034	P	N/A	P	N	P	N
2039	P	P	P	N	P	N
2060	P	P	P	P	P	N
2075	P	P	P	P	P	N
2095	P	P	P	N	P	N
2112	P	P	P	N	P	N
2113	P	P	P	N	P	N
2132	P	P	P	N	P	N
2692	P	P	P	N	P	N
2693	P	N/A	P	N	P	N
2705	P	N	P	N	P	N
2724	P	N	N	N	N	N
2727	P	N/A	P	N	P	N

Number of Results	23	20	23	23	23	23
# Negative	0	2	1	20	1	23
# Positive	23	18	22	3	22	0
% Correct	100.0%	90.0%	95.7%	87.0%	95.7%	100.0%
% Incorrect	0.0%	10.0%	4.3%	13.0%	4.3%	0.0%

Table 12: Percentage of correct results in qualitative reports for MON810 for all participants. Table 10 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	135
# Reported Incorrect	7
% Correct	94.8%
# of Provided Positives (P)	88
# of False Negatives	4
%False Negative	4.3%
# of Provided Negatives (N)	47
# of False Positives	3
%False Positive	6.0%

Table 13: Qualitative results for corn fortified with E176 for all participants (DNA-based assays). (N=negative, P=positive)

E176	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.5%	3.0%	0.0%	0.0%	0.1%	0.0%
1752	P	P	N	N	P	N
1773	P	P	N	N	P	N
1774	P	P	N	N	P	N
1785	P	P	N	N	P	N
1786	P	P	N	N	P	N
1788	P	P	N	N	P	N
1854	P	P	N	N	P	N
1859	P	P	N	N	P	N
1892	P	P	N	N	P	N
2032	P	N	N	N	P	N
2034	P	P	N	N	N/A	N
2039	P	P	N	N	P	N
2075	P	P	N	N	P	N
2095	P	P	N	N	P	N
2112	P	P	N	P	P	N
2113	P	P	N	N	P	N
2132	N	N	N	N	N	N
2692	P	P	N	N	P	N
2693	P	P	N	N	P	N
2705	P	P	N	P	P	N
2724	N	N	N	N	N	N
2727	P	P	N	N	N/A	N

Number of Results	22	22	22	22	20	22
# Negative	2	3	22	20	2	22
# Positive	20	19	0	2	18	0
% Correct	90.9%	86.4%	100.0%	90.9%	90.0%	100.0%
% Incorrect	9.1%	13.6%	0.0%	9.1%	10.0%	0.0%

Table 14: Percentage of correct results in qualitative reports for E176 for all participants.
Table 14 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	130
# Reported Incorrect	9
% Correct	93.1%
# of Provided Positives (P)	59
# of False Negatives	7
%False Negative	10.6%
# of Provided Negatives (N)	71
# of False Positives	2
%False Positive	2.7%

Table 15: Qualitative results for corn fortified with Bt11 for all participants (DNA-based assays). (N=negative, P=positive)

Bt11	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.5%	1.5%	0.0%	0.1%	0.4%	0.0%
1752	P	P	N	P	P	N
1773	P	P	N	P	P	N
1774	P	P	N	P	P	N
1785	P	P	N	P	P	N
1786	P	P	N	P	P	N
1788	P	P	N	P	P	N
1854	N/A	P	P	P	P	N
1859	P	P	N	P	P	N
1892	P	P	N	P	P	N
2032	P	N	N	P	P	N
2034	P	P	N	P	P	N
2039	P	P	N	P	P	N
2060	P	P	N	P	P	N
2075	P	P	N	N	P	N
2095	P	P	N	P	P	N
2112	P	P	N	P	P	N
2113	P	P	N	P	N	N
2132	P	P	N		P	N
2692	P	P	N	P	P	N
2693	P	P	N	P	P	N
2705	P	P	N	P	P	N
2724	N	N	N	N	N	N
2727	P	P	N	N/A	N/A	N

Number of Results	22	23	23	21	22	23
# Negative	1	2	22	2	2	23
# Positive	21	21	1	19	20	0
% Correct	95.5%	91.3%	95.7%	90.5%	90.9%	100.0%
% Incorrect	4.5%	8.7%	4.3%	9.5%	9.1%	0.0%

Table 16: Percentage of correct results in qualitative reports for Bt11 for all participants.
Table 16 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	134
# Reported Incorrect	8
% Correct	94.0%
# of Provided Positives (P)	82
# of False Negatives	7
%False Negative	7.9%
# of Provided Negatives (N)	52
# of False Positives	1
%False Positive	1.9%

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

NK603	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.1%	0.5%	5.0%	0.4%	0.8%	0.0%
1752	P	P	P	P	P	N
1761	N	P	P	P	P	N
1773	P	P	P	P	P	N
1774	P	P	P	P	P	N
1785	P	P	P	P	P	N
1788	P	P	P	P	P	N
1854	P	P	P	P	P	N
1859	P	P	P	P	P	N
2032	P	P	P	P	P	N
2034	N/A	P	P	P	P	N
2039	P	P	P	P	P	N
2060	P	P	P	P	P	N
2075	N	P	P	P	P	N
2112	P	P	P	P	P	N
2113	N	P	P	N	P	N
2692	P	P	P	N	P	N
2693	P	P	P	P	P	N

Number of Results	16	17	17	17	17	17
# Negative	3	0	0	2	0	17
# Positive	13	17	17	15	17	0
% Correct	81.3%	100.0%	100.0%	88.2%	100.0%	100.0%
% Incorrect	18.8%	0.0%	0.0%	11.8%	0.0%	0.0%

Table 18: Percentage of correct results in qualitative reports for NK603 for all participants. Table 18 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	101
# Reported Incorrect	5
% Correct	95.0%
# of Provided Positives (P)	79
# of False Negatives	5
%False Negative	6.0%
# of Provided Negatives (N)	22
# of False Positives	0
%False Positive	0.0%

Table 19: Qualitative results for corn fortified with Herculex for all participants (DNA-based assays). (N=negative, P=positive)

Herculex	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.0%	0.0%	0.0%	0.4%	0.8%	0.0%
1752	N	N	N	P	P	N
1763	N	N	N	P	P	N
1773	N	N	N	P	P	N
1774	N	N	N	P	P	N
1785	N	N	N	P	P	N
1786	N	N	N	N	N	N
1859	N	N	N	P	P	N
2032	N	N	N	P	P	N
2034	N	N	N	P	P	N
2039	N	N	N	P	P	N
2060	N	N	N	P	P	N
2112	N	N	N	P	P	N
2113	N	P	N	N	P	N
2692	N	N	N	P	P	N

N	14	14	14	14	14	14
# Neg	14	13	14	2	1	14
# Pos	0	1	0	12	13	0
% Correct	100.0%	92.9%	100.0%	85.7%	92.9%	100.0%
% Incorrect	0.0%	7.1%	0.0%	14.3%	7.1%	0.0%

Table 20: Percentage of correct results in qualitative reports for Herculex for all participants. Table 20 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	84
Reported Incorrect	4
% Correct	95.2%
# of Provided Positives (P)	26
# of False Negatives	3
%False Negative	10.3%
# of Provided Negatives (N)	58
# of False Positives	1
%False Positive	1.7%

Table 21: Qualitative results for corn fortified with MON863 for all participants (DNA-based assays). (N=negative, P=positive)

MON863	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.0%	0.0%	0.0%	0.4%	0.0%	0.0%
1752	N	N	N	P	N	N
1773	N	N	N	P	N	N
1774	N	N	N	P	N	N
1785	N	N	N	P	N	N
1788	N	N	N	P	N	N
1854	N	P	N	P	N	N
1859	N	N	N	P	N	N
2032	N	N	N	P	N	N
2034	N	N	N	P	N	N
2039	N	N	N	P	N	N
2060	N	N	N	P	N	N
2075	P	P	P	P	P	N
2113	N	N	N	P	N	N
2692	N	N	N	P	N	N
2693	N	N	N	P	N	N
2705	P	P	N	P	P	N

N	16	16	16	16	16	16
# Neg	14	13	15	0	14	16
# Pos	2	3	1	16	2	0
% Correct	87.5%	81.3%	93.8%	100.0%	87.5%	100.0%
% Incorrect	12.5%	18.8%	6.3%	0.0%	12.5%	0.0%

Table 22: Percentage of correct results in qualitative reports for MON863 for all participants. Table 22 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	96
# Reported Incorrect	8
% Correct	91.7%
# of Provided Positives (P)	24
# of False Negatives	0
%False Negative	0.0%
# of Provided Negatives (N)	72
# of False Positives	8
%False Positive	10.0%

Table 23: Qualitative results for soybeans fortified with CP4 EPSPS for all participants (DNA-based assays). (N=negative, P=positive)

CP4 EPSPS	Sample 1	Sample 2	Sample 3
Participant #	1.50	2.50	0.00
1752	P	P	N
1773	P	P	N
1774	P	P	N
1785	P	P	N
1786	P	P	N
1788	P	P	N
1854	P	P	N
1859	P	P	N
2031	P	P	N
2076	P	P	N
2095	P	P	N
2100	P	P	N
2108	P	P	N
2113	P	P	N
2691	P	P	N
2693	P	P	N
2705	P	P	N
2717	N	P	N
2724	P	P	N
2727	P	P	N

Number of Results	20	20	20
# Negative	1	0	20
# Positive	19	20	0
% Correct	95.0%	100.0%	100.0%
% Incorrect	5.0%	0.0%	0.0%

Table 24: Percentage of correct results in qualitative reports for CP4 EPSPS for all participants. Table 24 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	60
# Reported Incorrect	1
% Correct	98.3%
# of Provided Positives (P)	39
# of False Negatives	1
%False Negative	2.5%
# of Provided Negatives (N)	21
# of False Positives	0
%False Positive	0.0%

Table 25: Percentage of correct results in Qualitative reports for each transgenic event for all participants. N = number of results submitted. Table 2 includes information for the provided positive (+) and negative (-) results and the corresponding % false positive and % false negative results for each event. [(incorrectly reported result /Number (+) or (-)) x 100]

Event	35S	NOS	T25	CBH351	MON810	GA21	E176	Bt11	NK603	Herculex	MON863	RUR
N	246	216	126	100	135	120	130	134	101	84	96	60
Reported Incorrect	5	5	12	2	7	5	9	8	5	4	8	1
% Correct	98.0%	97.7%	90.5%	98.0%	94.8%	95.8%	93.1%	94.0%	95.0%	95.2%	91.7%	98.3%
Provided (+)	204	177	92	51	88	79	59	82	79	26	24	39
False Negatives	3	4	12	0	4	3	7	7	5	3	0	1
%False Negative	1.4%	2.2%	11.5%	0.0%	4.3%	3.7%	10.6%	7.9%	6.0%	10.3%	0.0%	2.5%
Provided (-)	42	39	34	49	47	41	71	52	22	58	72	21
False Positives	2	1	0	2	3	2	2	1	0	1	8	0
%False Positive	4.5%	2.5%	0.0%	3.9%	6.0%	4.7%	2.7%	1.9%	0.0%	1.7%	10.0%	0.0%

Figure 1. Group average of percentage correct for Qualitative reports on each event combined with the total number of results reported using DNA-based testing. Events labeled as 35S through MON863 were assayed in corn samples. The soybean samples contained the glyphosate tolerant event (RoundUp Ready/RUR) producing the CP4 EPSPS protein. Numbers embedded in the histogram represent the total number of reported results for that event. Data are shown on a composite basis (i.e., all participants results combined)

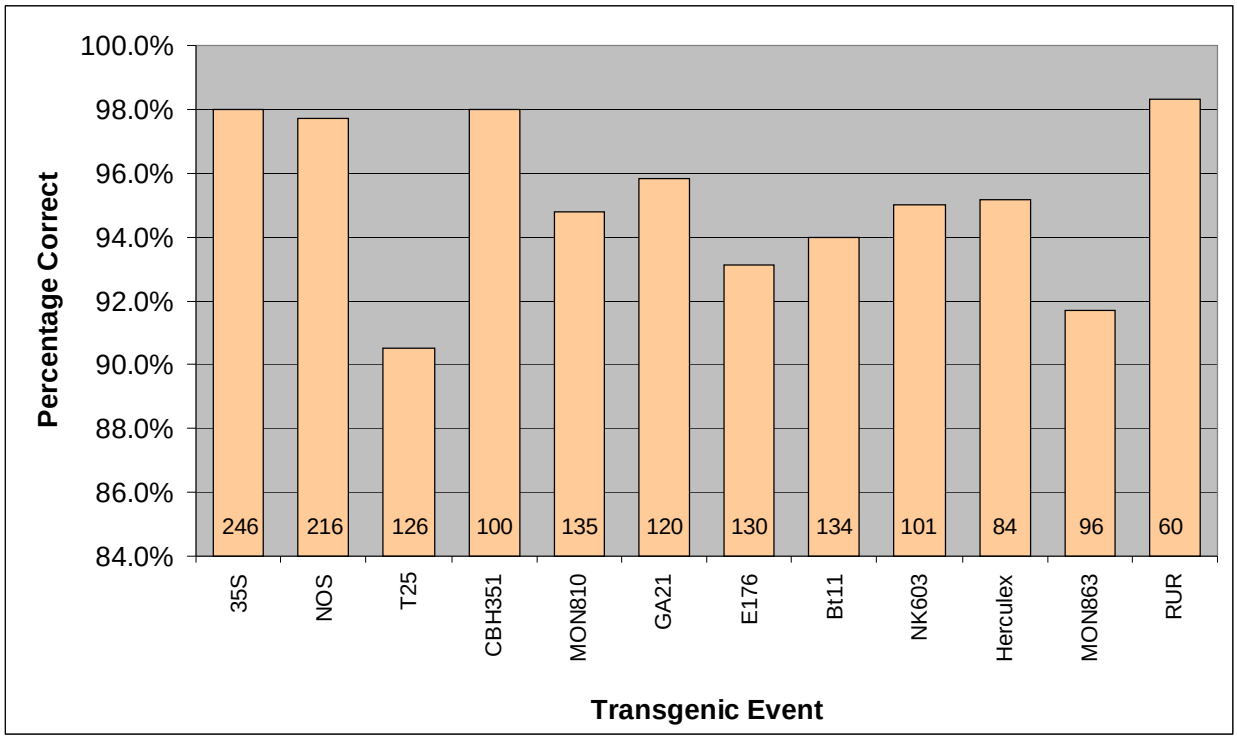

Table 28: Qualitative results for corn fortified with CBH351 - (Lateral Flow Strip) (Protein-based assays). (N=negative, P=positive)

CBH351	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.0	0.5	1.5	0.1	0.0	0.0
1764 LFS	N	P	P	N	N	N

Number of Results	1	1	1	1	1	1
# Negative	1	0	0	1	1	1
# Positive	0	1	1	0	0	0
% Correct	100.0%	100.0%	100.0%	0.0%	100.0%	100.0%

Table 29: Percentage of correct results in qualitative reports for CBH351 for all participants.

Total # of Reported Results	6
Reported Incorrect	1
% Correct	83.3%
# of Provided Positives (P)	2
# of False Negatives	1
% False Negative	33.3%
# of Provided Negatives (N)	4
# of False Positives	0
% False Positive	0.0%

Table 30: Qualitative results for corn fortified with NK603 - Enzyme-Linked Immunosorbent Assay (ELISA). (N=negative, P=positive)

NK603	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.1	0.5	5.0	0.4	0.8	0.0
2133 PLATE	N	P	P	N	P	N

Number of Results	1	1	1	1	1	1
# Negative	1	0	0	1	0	1
# Positive	0	1	1	0	1	0
% Correct	0.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Table 31: Percentage of correct results in qualitative reports for NK603 for all participants. Table 31 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	6
Reported Incorrect	1
% Correct	83.3%
# of Provided Positives (P)	3
# of False Negatives	1
% False Negative	25.0%
# of Provided Negatives (N)	3
# of False Positives	0
% False Positive	0.0%

Table 32: Qualitative results for soybeans fortified with CP4 EPSPS for all participants (Lateral Flow Strip) (Protein-based assays). (N=negative, P=positive)

CP4 EPSPS	Sample 1	Sample 2	Sample 3
	1.50	2.50	0.00
1764 LFS	P	P	N
2133 LFS	P	P	N

Number of Results	2	2	2
# Negative	0	0	2
# Positive	2	2	0
% Correct	100.0%	100.0%	100.0%

Table 33: Percentage of correct results in qualitative reports for CP4 EPSPS for all participants.

Total # of Reported Results	6
# Reported Incorrect	0
% Correct	100.0%
# of Provided Positives (P)	4
# of False Negatives	0
%False Negative	0.0%
# of Provided Negatives (N)	2
# of False Positives	0
%False Positive	0.0%

Table 34: Quantitative Results and z-Scores for Corn Fortified with T25 using DNA-based Assays

Event: T25										
Fortification Level (w/w%)	Fortified @ 0.1 (w/w%)		Fortified @ 1.5 (w/w%)		Fortified @ 5.0 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 0.1 (w/w%)	
Participant Number	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score
1754	0.1	0.0	1.5	0.0	8.5	**2.2**	0.1	0.0	0.1	0.0
1755	0.1	0.0	0.7	-1.8	4.4	-0.4	0.7	1.7	0.9	1.6
1761	0.10	0.0	1.30	-0.4	5.20	0.1	0.70	1.7	1.40	**2.6**
1764	0.0	-1.5	1.6	0.2	5.1	0.1	0.4	0.9	0.7	1.2
1770	0.1	0.0	1.5	0.0	4.8	-0.1	0.9	**2.3**	1.2	**2.2**
1780	0.10	0.0	1.60	0.2	4.99	0.0	0.12	0.1	0.12	0.0
1870	*0.2	1.5	1.8	0.7	4.8	-0.1	0.2	0.3	0.2	0.2
1891	<0.2		0.7	-1.8	2.4	-1.6	0.1	0.0	<0.2	
2044	0.1	0.0	0.9	-1.3	1.5	**-2.2**	0.1	0.0	0.1	0.0
2050	0.10	0.0	1.50	0.0	5.00	0.0	1.20	**3.1**	1.20	**2.2**
2057	0.1	0.0	0.95	-1.2	3.3	-1.1	0.2	0.3	0.1	0.0
2098	0.11	0.2	1.04	-1.0	4.05	-0.6	0.25	0.4	0.39	0.6
2129	0.10	0.0	1.98	1.1	5.00	0.0	0.10	0.0	0.00	-0.2
2675	*0.29	**2.9**	2.09	1.3	4.61	-0.2	0.31	0.6	0.39	0.6

Table 35: Quantitative Results and z-Scores for Corn Fortified with MON810 using DNA-based Assays

Event: MON810								
Fortification Level (w/w%)	Fortified @ 3.0 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 0.5 (w/w%)		Fortified @ 0.8 (w/w%)	
Participant Number	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score
1754	1.7	**-2.1**	0.1	0.0	0.3	-0.2	0.4	-1.1
1755	1.6	**-2.3**	0.2	0.8	1.3	0.7	0.8	0.0
1761	2.50	-0.8	0.10	0.0	0.20	-0.3	1.00	0.6
1763	1.04	**-3.2**	0.03	-0.6	0.12	-0.4	0.47	-0.9
1764	2.5	-0.8	0.0	-0.8	0.6	0.1	0.4	-1.1
1770	2.4	-1.0	0.1	0.0	0.5	0.0	1.0	0.6
1780	2.25	-1.2	0.10	0.0	0.45	0.0	1.01	0.6
1788	1.30	**-2.8**	<0.1		0.17	-0.3	0.81	0.0
1847	2.85	-0.2	0.08	-0.2	0.436	-0.1	1.34	1.5
1870	1.3	**-2.8**	0.04	-0.5	0.3	-0.2	0.5	-0.8
1891	1.5	**-2.4**	<0.1		0.3	-0.2	0.6	-0.6
1892	1.8	-1.9	0.1	0.0	0.3	-0.2	0.7	-0.3
2044	0.5	**-4.1**	0.1	0.0	0.1	-0.4	0.1	-2.0
2050	2.50	-0.8	0.10	0.0	0.50	0.0	1.30	1.4
2051	1.16	**-3.0**	0.06	-0.3	0.27	-0.2	0.46	-1.0
2057	1.0	**-3.2**	0.3	1.6	2.3	1.7	0.8	0.0
2095	0.95	**-3.3**	0.1	0.0	0.2	-0.3	0.6	-0.6
2098	1.64	**-2.2**	*0.5	**3.2**	*3.9	**3.2**	1.06	0.7
2129	2.01	-1.6	0.10	0.0	0.31	-0.2	0.33	-1.3
2675	1.87	-1.8	*0.4	**2.4**	*3.53	**2.8**	1.40	1.7
2691	1.90	-1.8	0.11	0.1	0.35	-0.1	0.75	-0.1
2719	1.3	**-2.8**	0.1	0.0	0.3	-0.2	1.2	1.1

(Note: z-scores outside the satisfactory range, i.e. z > 2, are shown in **bold.)**

* This result was determined to be an outlier and will not be included in the statistical analysis of

the data.

Table 36: Quantitative Results and z-Scores for Corn Fortified with GA21 using DNA-based Assays

Event: GA21								
Fortification Level (w/w%)	**Fortified @ 1.5 (w/w%)**		**Fortified @ 0.1 (w/w%)**		**Fortified @ 0.1 (w/w%)**		**Fortified @ 0.4 (w/w%)**	
Participant Number	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**
1754	1.4	-0.3	0.1	0.0	0.2	**2.1**	0.5	0.6
1755	0.9	-1.6	0.1	0.0	0.1	0.0	0.3	-0.6
1761	0.80	-1.9	0.10	0.0	0.10	0.10	0.40	0.0
1763	1.02	-1.3	0.07	-1.4	0.09	-0.2	0.39	-0.1
1764	1.2	-0.8	0.1	0.0	0.1	0.0	0.4	0.0
1770	2.1	1.6	0.1	0.0	0.2	**2.1**	0.8	**2.3**
1780	1.05	-1.2	0.09	-0.5	0.10	0.0	0.41	0.1
1870	1.2	-0.8	0.05	**-2.3**	0.1	0.0	0.2	-1.2
1891	1.1	-1.1	<0.1		<0.1		0.4	0.0
2044	0.4	**-3.0**	0.1	0.0	0.1	0.0	0.1	-1.8
2050	1.00	-1.3	0.10	0.0	0.10	0.0	0.40	0.0
2051	1.13	-1.0	0.06	-1.8	0.05	-1.1	0.35	-0.3
2057	1.1	-1.1	0.12	0.9	0.2	**2.1**	0.3	-0.6
2098	0.77	-2.0	<0.1		<0.1		0.08	-1.9
2129	0.99	-1.4	0.10	0.0	0.10	0.0	0.24	-0.9
2675	1.56	0.2	0.05	**-2.3**	0.13	0.6	0.50	0.6

Table 37: Quantitative Results and z-Scores for Corn Fortified with E176 using DNA-based Assays

Event: E176						
Fortification Level (w/w%)	**Fortified @ 0.5 (w/w%)**		**Fortified @ 3.0 (w/w%)**		**Fortified @ 0.1 (w/w%)**	
Participant Number	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**
1754	0.2	-1.8	0.9	**-2.8**	0.1	0.0
1755	0.2	-1.8	1.8	-1.6	0.1	0.0
1761	0.20	-1.8	1.70	-1.7	0.10	0.0
1764	0.4	-0.6	1.4	**-2.1**	0.1	0.0
1770	0.3	-1.2	2.1	-1.2	0.1	0.0
1780	0.26	-1.4	2.03	-1.3	0.11	0.2
1788	0.26	-1.4	2.30	-0.9	0.11	0.2
1870	0.4	-0.6	2.8	-0.3	0.1	0.0
1891	0.5	0.0	2.8	-0.3	0.1	0.0
1892	0.1	**-2.4**	1.8	-1.6	0.2	**2.5**
2044	0.4	-0.6	3.0	0.0	0.0	**-2.5**
2050	0.40	-0.6	2.00	-1.3	0.10	0.0
2051	0.39	-0.7	2.83	-0.2	0.11	0.2
2057	0.6	0.6	3.7	0.9	0.2	**2.5**
2060	0.30	-1.2	2.34	-0.9	0.11	0.2
2098	0.34	-1.0	2.48	-0.7	0.09	-0.2
2129	0.17	-2.0	0.97	**-2.7**	0.10	0.0
2675	0.56	0.4	2.85	-0.2	0.15	1.2
2691	0.45	-0.3	2.80	-0.3	0.11	0.2
2719	0.8	1.8	1.0	**-2.7**	0.1	0.0

(Note: z-scores outside the satisfactory range, i.e. z > 2, are shown in **bold.)**

Table 38: Quantitative Results and z-Scores for Corn Fortified with Bt11 using DNA-based Assays

Event: Bt11								
Fortification Level (w/w%)	**Fortified @ 0.5 (w/w%)**		**Fortified @ 1.5 (w/w%)**		**Fortified @ 0.1 (w/w%)**		**Fortified @ 0.4 (w/w%)**	
Participant Number	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**
1754	0.3	-1.2	1.1	-0.6	0.1	0.0	0.4	0.0
1755	0.4	-0.6	1.3	-0.3	0.1	0.0	0.5	0.5
1761	0.40	-0.6	0.10	**-2.3**	*3.6	**4.0**	0.60	1.0
1764	0.8	1.8	1.4	-0.2	0.1	0.0	0.5	0.5
1770	0.5	0.0	1.4	-0.2	0.2	0.1	0.6	1.0
1780	0.42	-0.5	1.13	-0.6	0.14	0.0	0.52	0.6
1788	0.24	-1.6	0.82	-1.1	<0.1		0.21	-0.9
1870	0.5	0.0	1.1	-0.6	0.1	0.0	0.4	0.0
1891	0.5	0.0	0.9	-1.0	<0.1		0.4	0.0
2044	0.5	0.0	3.0	**2.4**	0.3	0.2	1.0	**2.9**
2050	0.50	0.0	1.20	-0.5	0.40	0.3	0.80	1.9
2051	0.27	-1.4	1.16	-0.5	0.05	-0.1	0.46	0.3
2057	0.2	-1.8	0.8	-1.1	0.1	0.0	0.3	-0.5
2098	0.28	-1.3	1.50	0.0	0.10	0.0	0.31	-0.4
2129	0.18	-1.9	0.19	**-2.1**	0.10	0.0	0.15	-1.2
2675	0.63	0.8	1.68	0.3	0.16	0.1	0.54	0.7
2691	0.55	0.3	1.04	-0.7	0.12	0.0	0.52	0.6
2719	0.6	0.6	1.7	0.3	0.3	0.2	0.7	1.5

Table 39: Quantitative Results and z-Scores for Corn Fortified with Herculex using DNA-based Assays

Event: Herculex				
Fortification Level (w/w%)	**Fortified @ 041 (w/w%)**		**Fortified @ 0.8 (w/w%)**	
Participant Number	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**
1754	0.2	-0.8	0.4	-0.7
1755	0.3	-0.4	0.7	-0.2
1770	0.4	0.0	0.6	-0.4
1780	0.51	0.5	1.14	0.6
1847	0.48	0.3	1.98	**2.1**
1870	0.2	-0.8	0.6	-0.4
1891	0.2	-0.8	0.5	-0.5
2044	0.1	-1.3	0.1	-1.3
2050	*1	**2.5**	1.50	1.3
2051	0.19	-0.9	0.50	-0.5
2057	0.5	0.4	1.5	1.3
2098	0.14	-1.1	0.38	-0.8
2129	0.11	-1.2	0.22	-1.0
2675	0.33	-0.3	0.53	-0.5

(Note: z-scores outside the satisfactory range, i.e. z > 2, are shown in **bold.)**
* This result was determined to be an outlier and will not be included in the statistical analysis of the data.

Table 40: Quantitative Results and z-Scores for Corn Fortified with CBH351 using DNA-based Assays

Event: CBH351						
Fortification Level (w/w%)	Fortified @ 0.5 (w/w%)		Fortified @ 1.5 (w/w%)		Fortified @ 0.1 (w/w%)	
Participant Number	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score
1754	0.3	-0.5	0.9	-0.7	0.1	0.0
1755	0.2	-0.8	0.6	-1.1	0.1	0.0
1870	0.4	-0.3	1.1	-0.5	0.1	0.0
2044	1.0	1.4	3.0	1.9	0.2	1.7
2050	0.50	0.0	1.50	0.0	0.10	0.0
2051	0.50	0.0	1.35	-0.2	0.12	0.3
2057	1.1	1.6	1.4	-0.1	0.2	1.7
2129	0.11	-1.1	0.41	-1.4	0.10	0.0
2675	0.07	-1.2	0.38	-1.4	0.01	-1.6

Table 41: Quantitative Results and z-Scores for Corn Fortified with NK603 using DNA-based Assays

Event: NK603										
Fortification Level (w/w%)	Fortified @ 0.1 (w/w%)		Fortified @ 0.5 (w/w%)		Fortified @ 5.0 (w/w%)		Fortified @ 0.4 (w/w%)		Fortified @ 0.8 (w/w%)	
Participant Number	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score
1754	0.1	0.0	0.2	-0.8	2.9	-1.1	0.2	-0.6	0.4	-0.5
1755	0.1	0.0	0.3	-0.5	4.2	-0.4	0.7	0.9	0.9	0.1
1764	0.0	**-2.9**	0.2	-0.8	5.0	0.0	0.1	-0.9	1.0	0.2
1770	0.1	0.0	0.4	-0.3	4.1	-0.5	0.4	0.0	0.8	0.0
1780	0.07	-0.9	0.48	-0.1	5.11	0.1	0.54	0.4	1.13	0.4
1847	0.08	-0.6	0.69	0.5	*10.61	**2.9**	1.25	**2.7**	*2.79	**2.3**
1870	0.06	-1.1	0.3	-0.5	4.7	-0.2	0.3	-0.3	0.7	-0.1
1891	0.15	1.4	0.5	0.0	4.1	-0.5	0.4	0.0	1.0	0.2
2044	0.1	0.0	0.3	-0.5	3.0	-1.0	0.3	-0.3	0.5	-0.3
2050	0.10	0.0	0.40	-0.3	5.00	0.0	0.50	0.3	0.80	0.0
2051	0.06	-1.1	0.34	-0.4	4.09	-0.5	0.29	-0.3	0.79	0.0
2057	0.12	0.6	*1.8	**3.4**	5.0	0.0	1.0	1.9	*3.4	**3.0**
2098	0.04	-1.7	0.43	-0.2	3.09	-1.0	0.31	-0.3	0.55	-0.3
2129	0.10	0.0	0.24	-0.7	2.08	-1.5	0.12	-0.9	0.30	-0.6
2675	0.11	0.3	0.47	-0.1	4.40	-0.3	0.64	0.7	0.95	0.2
2719	0.1	0.0	0.3	-0.5	6.8	0.9	0.8	1.2	2.2	1.6

Table 42: Quantitative Results and z-Scores for Corn Fortified with MON 863 using DNA-based Assays

Event: MON863		
Fortification Level (w/w%)	Fortified @ 0.4 (w/w%)	
1754	0.3	-0.5
1755	0.6	1.0
1764	0.3	-0.5
1770	0.7	1.5
1780	0.57	0.9
1870	0.3	-0.5
1891	0.4	0.0
2050	0.50	0.5
2051	0.35	-0.3
2057	0.3	-0.5
2098	0.80	2.0
2129	0.20	-1.0
2675	0.72	1.6

(Note: z-scores outside the satisfactory range, i.e. z > 2, are shown in **bold.)**

* This result was determined to be an outlier and will not be included in the statistical analysis of the data.

Table 43: Quantitative results for soybeans fortified with CP4 EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based assays).

Event: RUR		
Fortification Level (w/w%)	**Fortified @ 1.5 (w/w%)**	**Fortified @ 0.5 (w/w%)**
Participant Number	**Reported Result (w/w%)**	**Reported Result (w/w%)**
1754	1.1	1.5

Table 44: Quantitative Results and z-Scores for Soybeans Fortified with RUR using DNA-based Assays

Event: RUR				
Fortification Level (w/w%)	**Fortified @ 1.5 (w/w%)**		**Fortified @ 2.5 (w/w%)**	
Participant Number	**Reported Result (w/w%)**	**z-Score**	**Reported Result (w/w%)**	**z-Score**
1754	0.90	-1.4	1.20	-1.7
1755	1.7	0.5	3.2	0.9
1763	1.63	0.3	2.37	-0.2
1764	1.4	-0.2	2.4	-0.1
1770	1.8	0.7	2.9	0.5
1780	1.03	-1.1	1.93	-0.8
1788	1.40	-0.2	1.90	-0.8
1847	0.593	**-2.1**	0.916	-2.1
1870	1.3	-0.5	2.2	-0.4
1891	1.6	0.2	2.1	-0.5
1892	2.1	1.4	3.2	0.9
2032	1.40	-0.2	1.80	-0.9
2034	0.54	**-2.3**	3.15	0.9
2039	1.50	0.0	2.50	0.0
2044	0.4	**-2.6**	1.0	-2.0
2050	1.00	-1.2	3.00	0.7
2051	1.26	-0.6	2.26	-0.3
2057	1.7	0.5	*5	3.3
2060	1.90	0.9	2.49	0.0
2075	1.26	-0.6	2.08	-0.6
2095	1.5	0.0	2.9	0.5
2098	1.62	0.3	1.70	-1.1
2112	1.19	-0.7	2.14	-0.5
2129	1.73	0.5	2.42	-0.1
2132	0.65	-2.0	2.40	-0.1
2675	0.72	-1.8	1.70	-1.1
2691	1.14	-0.8	1.82	-0.9
2692	1.57	0.2	2.13	-0.5
2693	1.5	0.0	2.5	0.0
2705	1.1	-0.9	2.0	-0.7
2719	1.5	0.0	2.4	-0.1
2720	1.37	-0.3	2.15	-0.5
2725	1.98	1.1	2.88	0.5

(Note: z-scores outside the satisfactory range, i.e. z > 2, are shown in **bold.)**
* This result was determined to be an outlier and will not be included in the statistical analysis of the data.

Table 45: Descriptive statistics for participant's reported quantifications relative to GIPSA fortification levels using DNA-based assays. N = total number of quantitative results reported; Reported Mean = average of all reported quantitations; Standard Deviation of all reported quantitations; %Relative Standard Deviation = [standard deviation/mean value x 100%] for the reported means; %R.E. = percentage relative error between the fortified and reported levels [reported value – fortification value / fortification value x 100]. Outliers were determined and eliminated from final results.

Event	N - Results	Fortification (%w/w)	Reported Mean (%w/w)	Standard Deviation	% Relative Standard Deviation	% Relative Error	Range of Reported Results
T25	38	0.1	0.35	0.39	113%	247%	0.0 – 1.40
T25	14	1.5	1.37	0.45	33%	-9%	0.7 – 2.09
T25	14	5.0	4.55	1.59	35%	-9%	1.5 – 8.5
CBH351	9	0.1	0.11	0.06	50%	14%	0.01 – 0.2
CBH351	9	0.5	0.46	0.37	79%	-7%	0.07 – 1.1
CBH351	9	1.5	1.18	0.8	68%	-21%	0.38 – 3.0
MON810	18	0.1	0.10	0.06	64%	1%	0.0 – 0.50
MON810	20	0.5	0.47	0.50	108%	-7%	0.1 – 3.90
MON810	22	0.8	0.77	0.36	46%	-3%	0.10 – 1.40
MON810	22	3.0	1.71	0.62	36%	-43%	0.5 – 2.85
GA21	28	0.1	0.10	0.04	38%	4%	0.05 – 0.2
GA21	16	0.4	0.36	0.17	39%	19%	0.08 – 0.8
GA21	16	1.5	1.11	0.37	34%	-26%	0.4 – 2.1
E176	20	0.1	0.11	0.04	37%	10%	0.0 – 0.2
E176	20	0.5	0.36	0.17	46%	-28%	0.1 – 0.8
E176	20	3.0	2.18	0.75	35%	-27%	0.9 – 3.7
Bt11	15	0.1	0.16	0.10	63%	58%	0.05 – 3.60
Bt11	18	0.4	0.50	0.21	41%	24%	0.15 – 1.0
Bt11	18	0.5	0.43	0.17	38%	-14%	0.18 – 0.8
Bt11	18	1.5	1.20	0.62	52%	-20%	
NK603	16	0.1	0.09	0.03	40%	-13%	0.0 – 0.15
NK603	0.4	0.4	0.49	0.32	65%	23%	0.1 – 1.25
NK603	0.5	0.5	0.37	0.13	36%	-26%	0.2 – 1.8
NK603	0.8	0.8	0.86	0.46	53%	7%	0.3 -3.4
NK603	5.0	5.0	4.24	1.15	27%	-15%	2.08 – 10.61
Herculex	13	0.4	0.28	0.15	53%	-30%	0.1 – 1.00
Herculex	14	0.8	0.76	0.55	73%	-5%	0.1 – 1.98
MON863	13	0.4	0.46	0.20	42%	16%	0.20 – 0.80
RUR	33	1.5	1.33	0.43	32%	-11%	0.4 – 2.10
RUR	32	2.5	2.24	0.58	26%	-10%	0.92 – 5.0

Summary of Findings

Qualitative Sample Analysis

PCR: As evidenced by the "percentage correct scores" in Table 25 and Figure 1, participants were able to correctly identify most of the transgenic events in the corn test samples with greater than 91% accuracy through the use of conventional PCR. The best performance was observed for the detection of the RoundUp Ready (CP4 EPSPS) event while T25 had the highest percentage of false negatives (11.5%) and MON863 had the highest percentage of false positives (10.0%).

Protein: Detecting the presence or absence of the protein product of the various transgenes was done through the use of either lateral flow strips (LFS) or enzyme-linked immunosorbent assays (ELISA) (Tables 28 through 33). Detection by lateral flow strips displayed good overall accuracy. In most cases, a correct determination was made on the corn test samples (note that most of the performance scores were 100% correct). In the three soybean test samples all participants were able to detect the gene product of the RoundUp Ready insert with 100% accuracy.

Quantitative Sample Analysis

Since the discovery of the polymerase chain reaction in 1985, analytical methods for the detection of nucleic acids have advanced rapidly. Real-time PCR continues to be the method of choice for the analyses of transgenic events in grains. The USDA/GIPSA proficiency program is designed to allow participating laboratories the ability to assess their individual methods for the detection and quantification of transgenic events and to compare the values of their measurements with peer laboratories. The analysis of proficiency test samples also enables laboratories to develop and validate new methods, and participation in a proficiency program is mandatory for ISO17025 certification. Overall, the performance of the participants testing for transgenic events in corn and soy was very good. GIPSA collected data for the April 2007 distribution and performed statistical analysis including a mean, standard deviation, % coefficient of variation, range, % relative error, and z-scores. Outliers were identified and not included in the statistical analyses. Laboratories with z-scores above +2 or below -2 are advised to carefully review their procedures. Participants are encouraged to seek confidential advice from the GIPSA staff to assist with this review. There was a characteristic inverse relationship between precision (% RSD) of reported quantifications and event fortification level for most of the fortified samples. Reported quantifications were highly variable at the lowest fortification level (0.1%) while being less variable at higher fortification levels.

For the assessment of residue analytical methods in crops, food, feed and environmental samples, it is recommended that an analytical method have a % RSD below 20%. It should be noted however, that the % RSD for all transgenic events in this study was greater than 20%, and this high level of inter-laboratory variability is consistent with observations from previous studies. The lack of internationally recognized reference material for all events, genetics, matrix effects and lack of standardized methods may be contributing factors to this observed variability. Monitoring and improving the performance of laboratories that use PCR for the detection of transgenic events in grains will improve marketing and reliability of this commodity. The USDA/GIPSA proficiency testing program should be a complement to other quality assurance tools used by laboratories as they monitor their performance and improve their analytical capabilities.

Note: It is important to understand that there are no internationally recognized standard reference materials for all transgenic events. 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.

To obtain additional information on the USDA/GIPSA Proficiency Program, contact Mrs. Ganga Murthy, USDA/GIPSA Proficiency Program Manager, at US 816-891-0469, or by e-mail at Ganga.Murthy@usda.gov.

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