

USDA/GIPSA Proficiency Program
Testing for the Presence of Biotechnology Events in Corn and Soybeans
October 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 qualitative 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, MON863, Herculex RW, and MIR 604; 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 0.1%, 0.5, 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.

- Fifteen participants submitted **qualitative** results only,
- Five participants submitted **quantitative** results only, and
- Twenty-nine 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 CBH351 with for all participants (DNA-based assays).
- Table 8: Percentage of correct results 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: Percentage of correct results 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: Percentage of correct results in qualitative reports for GA21 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 Herculex RW for all participants (DNA-based assays).
- Table 24: Percentage of correct results in qualitative reports for Herculex RW for all participants.
- Table 25: Qualitative results for soybeans fortified with MIR604 for all participants (DNA-based assays).
- Table 26: Percentage of correct results in qualitative reports for MIR604 for all participants.
- Table 27: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays).
- Table 28: Percentage of correct results in qualitative reports for CP4 EPSPS for all participants.
- Table 29: Percentage of correct results in qualitative reports for each transgenic event for all participants (DNA-based assays).
- Figure 1: Summary data of all participants for each event combined with the number of results submitted for that particular event (DNA-based assays).
- Table 30: Qualitative results for corn fortified with Cry1Ab for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).
- Table 31: Percentage of correct results in qualitative reports for Cry1Ab for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).
- Table 32: Qualitative results for corn fortified with T25 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).
- Table 33: Percentage of correct results in qualitative reports for T25 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).

- Table 34: Qualitative results for corn fortified with NK603 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).
- Table 35: Percentage of correct results in qualitative reports for NK603 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).
- Table 36: Qualitative results for corn fortified with MON863 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).
- Table 37: Percentage of correct results in qualitative reports for MON863 for all participants using Lateral Flow Strip (LFS) Testing (Protein-based testing).
- Table 38: Qualitative results for soybeans fortified with CP4EPSPS for all participants using Lateral Flow Strip (LFS) Testing and/or Enzyme-Linked Immunosorbent Assay (ELISA) Testing (Protein-based testing).
- Table 39: Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Lateral Flow Strip (LFS) Testing and/or Enzyme-Linked Immunosorbent Assay (ELISA) Testing (Protein-based testing).

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

- 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 E176 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 for soybeans fortified with CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) Testing (Protein-based testing).
- Table 52: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS for all participants (DNA-based assays).
- Table 53: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays.
- Appendix I: List of organizations who wished to be identified as a participant in the GIPSA October 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 #	N	P	P	P	P	P
1752	N	P	P	P	P	P
1754	N	P	P	P	P	P
1764	N	P	P	P	P	P
1770	N	P	P	P	P	P
1773	N	P	P	P	P	P
1778	N	P	P	P	P	P
1781	N	P	P	P	P	P
1785	N	P	P	P	P	P
1844	N	P	P	P	P	P
1854	N	P	P	P	P	P
1858	N	P	P	P	P	P
1859	N	P	P	P	P	P
1862	N	P	P	P	P	P
1865	N	P	P	P	P	P
1870	N	P	P	P	P	P
1871	N	P	P	P	P	P
1875	N	P	P	P	P	P
1892	N	P	P	P	P	P
2031	N	P	P	P	P	P
2032	N	P	P	P	P	P
2039	N	P	P	P	P	P
2057	N	P	P	P	P	P
2076	N	P	P	P	P	P
2112	N	P	P	P	P	P
2132	N	P	P	N	N	P
2678	N	P	P	P	P	P
2692	N	P	P	P	P	P
2705	N	P	P	P	P	P
2707	N	P	P	P	P	P
2716	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

n	33	33	33	33	33	33
# Neg	33	0	0	1	1	0
# Pos	0	33	33	32	32	33
% Correct	100.0%	100.0%	100.0%	97.0%	97.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	3.0%	3.0%	0.0%

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	198
# Reported Incorrect	2
% Correct	99.0%
# of Provided Positives (P)	163
# of False Negatives	2
%False Negative	1.2%
# of Provided Negatives (N)	35
# of False Positives	0
%False Positive	0.0%

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

NOS	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	N	P	P	P	P	P
1752	N	P	P	P	P	P
1754	N	P	P	P	P	P
1764	N	P	P	P	P	P
1770	N	P	P	P	P	P
1773	N	P	P	P	P	P
1778	N	P	P	P	P	P
1781	N	P	P	P	P	P
1785	N	P	P	P	P	P
1844	N	P	P	P	P	P
1854	N	P	P	P	P	P
1858	N	P	P	P	P	P
1859	N	P	P	P	P	P
1865	N	P	P	P	P	P
1870	N	P	P	P	P	P
1871	N	P	P	P	P	P
1875	N	P	P	P	P	P
1892	N	P	P	P	P	P
2031	N	P	P	P	P	P
2032	N	P	P	P	P	P
2039	N	P	P	P	P	P
2057	N	P	P	P	P	P
2076	N	P	P	P	P	P
2112	N	P	P	P	P	P
2132	N	P	P	P	P	P
2678	N	P	P	P	P	P
2692	N	P	P	P	P	P
2705	N	P	P	P	P	P
2707	N	P	P	P	P	P
2716	N	P	P	P	P	P
2724	N	P	P	P	P	P
2732	N	P	P	P	P	P

n	31	31	31	31	31	31
# Neg	31	0	0	0	0	0
# Pos	0	31	31	31	31	31
% Correct	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 4: 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	186
# Reported Incorrect	0
% Correct	100.0%
# of Provided Positives (P)	155
# of False Negatives	0
%False Negative	0.0%
# of Provided Negatives (N)	31
# of False Positives	0
%False Positive	0.0%

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 #	0.0%	0.1%	0.0%	0.8%	0.0%	0.5%
1752	N	P	N	P	N	P
1773	N	P	N	P	N	P
1781	N	P	N	P	N	P
1785	N	P	N	P	N	P
1787	N	P	N	P	N	P
1788	N	P	P	P	N	P
1844	N	P	P	P	N	P
1854	N	P	P	P	N	P
1859	N	P	N	P	N	P
1865	N	P	N	P	N	P
1892	N	P	P	P	N	P
2032	N	P	N	P	N	P
2060	N	P	P	P	N	P
2089	N	P	P	P	N	P
2132	N	P	P	P	N	P
2692	N	P	N	P	N	P
2694	N	P	N	P	N	P
2705	N	P	P	P	N	P
2707	N	P	N	P	N	P
2732	N	P	N	P	N	P
2808	P	P	N	P	P	P

n	21	21	21	21	21	21
# Neg	20	0	13	0	20	0
# Pos	1	21	8	21	1	21
% Correct	95.2%	100.0%	61.9%	100.0%	95.2%	100.0%
% Incorrect	4.8%	0.0%	38.1%	0.0%	4.8%	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	10
% Correct	92.1%
# of Provided Positives (P)	73
# of False Negatives	0
%False Negative	0.0%
# of Provided Negatives (N)	53
# of False Positives	10
%False Positive	15.9%

Table 7: Qualitative results for corn fortified with CBH351 for all participants (DNA-based assays). (N=negative, P=positive)

CBH351 Participant #	Sample 1 0.0%	Sample 2 0.0%	Sample 3 0.0%	Sample 4 0.0%	Sample 5 5.0%	Sample 6 0.1%
1752	N	N	N	N	P	P
1770	N	N	N	N	P	P
1773	N	N	P	P	P	P
1785	N	N	N	N	P	P
1788	N	N	N	N	P	P
1844	N	N	N	N	P	P
1854	P	P	N	P	P	P
1859	N	N	N	N	P	P
1892	N	N	N	N	P	P
2032	N	N	N	P	P	P
2692	N	N	N	N	P	P
2694	N	N	N/R	N	P	P
2707	N	N	N	N	P	P
2732	N	N	N	N	P	P

n	14	14	13	14	14	14
# Neg	13	13	12	11	0	0
# Pos	1	1	1	3	14	14
% Correct	92.9%	92.9%	92.3%	78.6%	100.0%	100.0%
% Incorrect	7.1%	7.1%	7.7%	21.4%	0.0%	0.0%

Table 8: 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	83
# Reported Incorrect	6
% Correct	92.8%
# of Provided Positives (P)	34
# of False Negatives	0
%False Negative	0.0%
# of Provided Negatives (N)	49
# of False Positives	6
%False Positive	10.9%

Table 9: Qualitative results for corn fortified with MON810 for all participants (DNA-based assays). (N=negative, P=positive)

MON810 Participant #	Sample 1 0.0%	Sample 2 0.8%	Sample 3 0.0%	Sample 4 0.1%	Sample 5 1.5%	Sample 6 0.0%
1752	N	P	N	P	P	P
1785	N	P	N	P	P	N
1788	N	P	N	P	P	N
1844	N	P	N	P	P	N
1854	P	N	P	N	P	P
1859	N	P	N	P	P	P
1862	N	P	N	P	P	N
1892	N	P	N	P	P	N
2032	N	P	N	P	P	N
2039	N	P	N	P	P	N
2089	N	P	N	N	P	N
2132	N	P	N	P	P	N
2692	N	P	N	P	P	N
2705	N	P	N	P	P	N
2707	N	P	N	P	P	N
2724	N	P	N	P	P	N
2808	N	P	P	N	P	P

n	17	17	17	17	17	17
# Neg	16	1	15	3	0	13
# Pos	1	16	2	14	17	4
% Correct	94.1%	94.1%	88.2%	82.4%	100.0%	76.5%
% Incorrect	5.9%	5.9%	11.8%	17.6%	0.0%	23.5%

Table 10: 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	102
# Reported Incorrect	11
% Correct	89.2%
# of Provided Positives (P)	54
# of False Negatives	4
%False Negative	6.9%
# of Provided Negatives (N)	48
# of False Positives	7
%False Positive	12.7%

Table 11: 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 #	0.0%	0.4%	0.8%	0.4%	0.5%	5.0%
1752	N	P	P	P	P	P
1785	N	P	P	P	P	P
1787	N	P	P	P	P	P
1788	N	P	P	P	P	P
1844	N	P	P	P	P	P
1854	P	P	P	P	P	P
1859	N	P	P	P	P	P
1862	N	P	P	P	N	P
1865	N	P	P	P	P	P
1892	N	P	P	P	P	P
2032	N	P	P	P	P	P
2089	N	P	P	P	P	P
2112	N	P	P	P	P	P
2678	N	N	P	P	P	P
2692	N	P	P	P	P	P
2705	N	P	P	P	P	P
2707	N	P	P	P	P	P
2727	N	N	N	N	N	P

n	18	18	18	18	18	18
# Neg	17	2	1	1	2	0
# Pos	1	16	17	17	16	18
% Correct	94.4%	88.9%	94.4%	94.4%	88.9%	100.0%
% Incorrect	5.6%	11.1%	5.6%	5.6%	11.1%	0.0%

Table 12: 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	108
# Reported Incorrect	7
% Correct	93.5%
# of Provided Positives (P)	85
# of False Negatives	6
%False Negative	6.6%
# of Provided Negatives (N)	23
# of False Positives	1
%False Positive	4.2%

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 #	0.0%	0.0%	0.8%	0.1%	0.1%	1.5%
1752	N	N	P	P	P	P
1773	N	N	P	P	P	P
1785	N	N	P	P	P	P
1787	N	N	P	P	P	P
1788	N	N	P	P	P	P
1844	N	N	P	P	P	P
1854	N	N	P	P	P	N
1858	N	N	P	P	P	P
1859	N	N	P	P	P	P
1862	N	N	P	P	P	P
1865	N	N	P	P	P	P
1892	N	N	P	P	P	P
2032	N	N	P	P	P	P
2089	N	N	P	P	N	P
2112	N	N	P	P	P	P
2132	N	N	P	P	P	P
2692	N	N	P	P	P	P
2705	N	N	P	P	P	P
2707	N	N	P	P	P	P
2724	N	N	P	N/A	N/A	P
2727	N	N	P	N/A	N/A	P
2808	P	P	P	P	P	P

n	22	22	22	20	20	22
# Neg	21	21	0	0	1	1
# Pos	1	1	22	20	19	21
% Correct	95.5%	95.5%	100.0%	100.0%	95.0%	95.5%
% Incorrect	4.5%	4.5%	0.0%	0.0%	5.0%	4.5%

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	128
# Reported Incorrect	4
% Correct	96.9%
# of Provided Positives (P)	84
# of False Negatives	2
%False Negative	2.3%
# of Provided Negatives (N)	44
# of False Positives	2
%False Positive	4.3%

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

Bt11 Participant #	Sample 1 0.0%	Sample 2 0.5%	Sample 3 0.4%	Sample 4 0.0%	Sample 5 0.1%	Sample 6 5.0%
1752	N	P	P	N	P	P
1773	N	P	P	N	P	P
1785	N	P	P	N	P	P
1787	N	P	P	N	P	P
1788	N	P	P	N	P	P
1844	N	P	P	N	P	P
1854	P	P	P	P	P	P
1858	N	P	P	N	P	P
1859	N	P	P	N	P	P
1862	N	P	P	N	P	P
1865	N	P	P	N	P	P
1892	N	P	P	N	P	P
2032	N	P	P	N	P	P
2089	N	P	P	N	N	P
2132	N	P	P	N	P	P
2692	N	P	P	N	P	P
2705	N	P	P	N	P	P
2707	N	P	P	N	P	P
2724	N	P	P	N	P	P
2727	N	P	P	N	N	P
2808	P	P	N	P	P	P

n	21	21	21	21	21	21
# Neg	19	0	1	19	2	0
# Pos	2	21	20	2	19	21
% Correct	90.5%	100.0%	95.2%	90.5%	90.5%	100.0%
% Incorrect	9.5%	0.0%	4.8%	9.5%	9.5%	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	126
# Reported Incorrect	7
% Correct	94.4%
# of Provided Positives (P)	85
# of False Negatives	3
%False Negative	3.4%
# of Provided Negatives (N)	41
# of False Positives	4
%False Positive	8.9%

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 #	0.0%	0.1%	0.4%	0.0%	0.0%	1.5%
1752	N	P	P	N	N	P
1773	N	P	P	N	N	P
1785	N	P	P	N	N	P
1788	N	N	P	N	N	P
1844	N	P	P	N	N	P
1854	N	P	P	N	N	P
1859	N	P	P	N	N	P
1862	N	P	P	N	N	P
1865	N	P	P	N	N	P
2032	N	P	P	N	N	P
2089	N	N	P	N	N	P
2692	N	P	P	N	P	P
2705	N	P	P	N	N	P
2707	N	P	P	N	N	P
2727	N	P	P	N	P	P

n	15	15	15	15	15	15
# Neg	15	2	0	15	13	0
# Pos	0	13	15	0	2	15
% Correct	100.0%	86.7%	100.0%	100.0%	86.7%	100.0%
% Incorrect	0.0%	13.3%	0.0%	0.0%	13.3%	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	90
# Reported Incorrect	4
% Correct	95.6%
# of Provided Positives (P)	45
# of False Negatives	2
%False Negative	4.3%
# of Provided Negatives (N)	45
# of False Positives	2
%False Positive	4.3%

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%	0.5%	0.0%	0.8%	0.0%	0.0%
1752	N	P	N	P	N	N
1773	N	P	N	P	N	N
1785	N	P	N	P	N	N
1844	N	P	N	P	N	N
1854	N	P	P	P	N	N
1859	N	P	N	P	N	N
1865	N	P	N	P	N	N
2032	N	P	N	P	N	N
2060	N	P	N	P	N	N
2089	N	P	N	P	N	N
2692	N	P	N	P	N	N
2707	N	P	N	P	N	N

n	12	12	12	12	12	12
# Neg	12	0	11	0	12	12
# Pos	0	12	1	12	0	0
% Correct	100.0%	100.0%	91.7%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	8.3%	0.0%	0.0%	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	72
Reported Incorrect	1
% Correct	98.6%
# of Provided Positives (P)	25
# of False Negatives	0
%False Negative	0.0%
# of Provided Negatives (N)	47
# of False Positives	1
%False Positive	2.1%

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%	0.5%	1.5%	0.4%	0.0%	0.0%
1752	N	P	P	P	N	N
1773	N	P	P	P	N	N
1785	N	P	P	P	N	N
1788	N	P	P	P	N	N
1844	N	P	P	P	N	N
1854	P	P	P	P	P	P
1859	N	P	P	P	N	N
1865	N	P	P	P	N	N
2032	N	P	P	P	N	N
2039	N	P	P	P	N	N
2089	N	P	P	P	N	N
2692	N	P	P	P	N	N
2705	N	P	P	P	N	N
2707	N	P	P	P	N	N
2727	N	P	P	P		N

n	15	15	15	15	14	15
# Neg	14	0	0	0	13	14
# Pos	1	15	15	15	1	1
% Correct	93.3%	100.0%	100.0%	100.0%	92.9%	93.3%
% Incorrect	6.7%	0.0%	0.0%	0.0%	7.1%	6.7%

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	89
# Reported Incorrect	3
% Correct	96.6%
# of Provided Positives (P)	48
# of False Negatives	0
%False Negative	0.0%
# of Provided Negatives (N)	41
# of False Positives	3
%False Positive	6.8%

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 #	0.0%	0.5%	0.8%	0.1%	0.0%	0.0%
1752	N	P	P	P	N	N
1785	N	P	P	P	N	N
1844	N	P	P	P	N	N
1859	N	P	P	P	N	N
2032	N	P	P	P	P	N
2039	N	P	P	P	N	N
2060	N	P	P	P	N	N

n	7	7	7	7	7	7
# Neg	7	0	0	0	6	7
# Pos	0	7	7	7	1	0
% Correct	100.0%	100.0%	100.0%	100.0%	85.7%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%	14.3%	0.0%

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

Total # of Reported Results	42
# Reported Incorrect	1
% Correct	97.6%
# of Provided Positives (P)	22
# of False Negatives	0
%False Negative	0.0%
# of Provided Negatives (N)	20
# of False Positives	1
%False Positive	4.8%

Table 25: Qualitative results for corn fortified with MIR 604 for all participants (DNA-based assays). (N=negative, P=positive)

MIR 604	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.0%	0.1%	0.5%	1.5%	0.0%	0.0%
1752	N	P	P	P	N	N
1773	N	P	P	P	N	N
1785	N	P	P	P	N	N
1787	N	P	P	P	N	N
1844	N	P	P	P	N	N
1859	N	P	P	P	N	N
2032	N	P	P	P	N	N
2060	N	P	P	P	N	N
2089	N	N	P	P	N	N

n	9	9	9	9	9	9
# Neg	9	1	0	0	9	9
# Pos	0	8	9	9	0	0
% Correct	100.0%	88.9%	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	11.1%	0.0%	0.0%	0.0%	0.0%

Table 26: Percentage of correct results in qualitative reports for MIR 604 for all participants. Table 26 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	54
# Reported Incorrect	1
% Correct	98.1%
# of Provided Positives (P)	26
# of False Negatives	1
%False Negative	3.7%
# of Provided Negatives (N)	28
# of False Positives	0
%False Positive	0.0%

Table 27: 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
	0.10	0.50	2.50
1752	P	P	P
1788	P	P	P
1844	P	P	P
1851	P	P	P
1854	P	P	P
1858	P	P	P
1859	P	P	P
2076	N	P	P
2089	P	P	P
2692	P	P	P
2707	P	P	P
2724	P	P	P

n	11	11	11
# Neg	1	0	0
# Pos	10	11	11
% Correct	90.9%	100.0%	100.0%
% Incorrect	9.1%	0.0%	0.0%

Table 28: Percentage of correct results in qualitative reports for CP4 EPSPS for all participants. Table 28 also includes % False Negative for this event.

Total # of Reported Results	33
# Reported Incorrect	1
% Correct	97.0%
# of Provided Positives (P)	32
# of False Negatives	1
%False Negative	3.0%

Table 29: Percentage of correct results in Qualitative reports for each transgenic event for all participants. N = number of results submitted. Table 29 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
N	198	186	126	83	102	108	128
Reported Incorrect	2	0	10	6	11	7	4
% Correct	99.0%	100.0%	92.1%	92.8%	89.2%	93.5%	96.9%
Provided (+)	163	155	73	34	54	85	84
False Negatives	2	0	0	0	4	6	2
%False Negative	1.2%	0.0%	0.0%	0.0%	6.9%	6.6%	2.3%
Provided (-)	35	31	53	49	48	23	44
False Positives	0	0	10	6	7	1	2
%False Positive	0.0%	0.0%	15.9%	10.9%	12.7%	4.2%	4.3%

Event	Bt11	NK603	Herculex	MON863	Herculex RW	MIR 604	RUR
N	126	90	72	89	42	54	33
Reported Incorrect	7	4	1	3	1	1	1
% Correct	94.4%	95.6%	98.6%	96.6%	97.6%	98.1%	97.0%
Provided (+)	85	45	25	48	22	26	32
False Negatives	3	2	0	0	0	1	1
%False Negative	3.4%	4.3%	0.0%	0.0%	0.0%	3.7%	3.0%
Provided (-)	41	45	47	41	20	28	
False Positives	4	2	1	3	1	0	
%False Positive	8.9%	4.3%	2.1%	6.8%	4.8%	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 MIR 604 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).

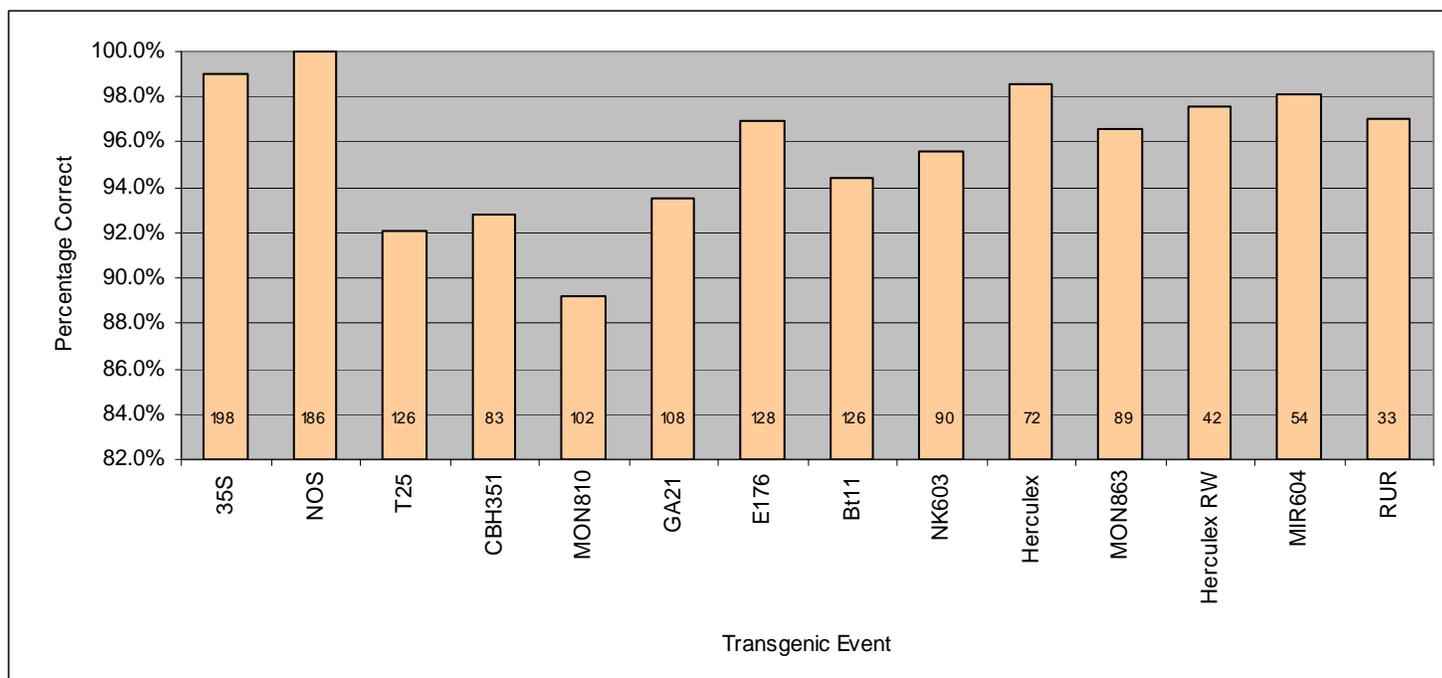


Table 30: Qualitative results for corn fortified with Cry1Ab - (Lateral Flow Strip) (Protein-based assays). (N=negative, P=positive)

Cry1Ab	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #						
1843	N	N	N	N	N	P
2133	N	N	N	N	N	P

n	2	2	2	2	2	2
# Neg	2	2	2	2	2	0
# Pos	0	0	0	0	0	2
% Correct	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%

Table 31: Percentage of correct results in qualitative reports for Cry1Ab for all participants.

Total # of Reported Results	12
Reported Incorrect	0
% Correct	100.0%
# of Provided Positives (P)	2
# of False Negatives	0
% False Negative	0.0%
# of Provided Negatives (N)	10
# of False Positives	0
% False Positive	0.0%

Table 32: Qualitative results for corn fortified with T25 - (Lateral Flow Strip) (Protein-based assays). (N=negative, P=positive)

T25	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.0	0.1	0.0	0.8	0.0	0.5
1843	N	N	N	N	N	N

n	1	1	1	1	1	1
# Neg	1	1	1	1	1	1
# Pos	0	0	0	0	0	0
% Correct	100.0%	0.0%	100.0%	0.0%	0.0%	0.0%
% Incorrect	0.0%	100.0%	0.0%	100.0%	100.0%	100.0%

Table 33: Percentage of correct results in qualitative reports for T25 for all participants.
Table 33 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	6
Reported Incorrect	3
% Correct	50.0%
# of Provided Positives (P)	0
# of False Negatives	3
% False Negative	100.0%
# of Provided Negatives (N)	6
# of False Positives	0
% False Positive	0.0%

Table 34: Qualitative results for corn fortified with NK603 - (Lateral Flow Strip) (Protein-based assays). (N=negative, P=positive)

NK603	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.0	0.1	0.4	0.0	0.0	1.5
1843	N	N	P	N	N	P
2133	N	N	N	N	N	P

n	2	2	2	2	2	2
# Neg	2	2	1	2	2	0
# Pos	0	0	1	0	0	2
% Correct	100.0%	0.0%	50.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	100.0%	50.0%	0.0%	0.0%	0.0%

Table 35: Percentage of correct results in qualitative reports for NK603 for all participants. Table 35 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	12
Reported Incorrect	3
% Correct	75.0%
# of Provided Positives (P)	3
# of False Negatives	3
% False Negative	50.0%
# of Provided Negatives (N)	9
# of False Positives	0
% False Positive	0.0%

Table 36: Qualitative results for corn fortified with MON863 - (Lateral Flow Strip) (Protein-based assays). (N=negative, P=positive)

MON863	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant #	0.0	0.5	1.5	0.4	0.0	0.0
1843	N	P	P	P	N	N
2133	N	N	P	P	N	N

n	2	2	2	2	2	2
# Neg	2	1	0	0	2	2
# Pos	0	1	2	2	0	0
% Correct	100.0%	50.0%	0.0%	0.0%	100.0%	100.0%
% Incorrect	0.0%	50.0%	100.0%	100.0%	0.0%	0.0%

Table 37: Percentage of correct results in qualitative reports for NK603 for all participants. Table 37 also includes % False Positive and % False Negative for this event.

Total # of Reported Results	12
Reported Incorrect	1
% Correct	91.7%
# of Provided Positives (P)	5
# of False Negatives	1
% False Negative	16.7%
# of Provided Negatives (N)	7
# of False Positives	2
% False Positive	22.2%

Table 38: Qualitative results for soybeans fortified with CP4 EPSPS for all participants (Lateral Flow Strip/Plate) and/or Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based assays). (N=negative, P=positive)

CP4 EPSPS Participant #	Sample 1 0.10	Sample 2 0.50	Sample 3 2.50
1764 LFS	P	P	P
1843 LFS	P	P	P
1843 Plate	P	P	P
1858 LFS	P	P	P
2133 LFS	N	P	P

n	5	5	5
# Neg	1	0	0
# Pos	4	5	5
% Correct	80.0%	100.0%	100.0%
% Incorrect	20.0%	0.0%	0.0%

Table 39: Percentage of correct results in qualitative reports for CP4 EPSPS for all participants.

Total # of Reported Results	15
# Reported Incorrect	1
% Correct	93.3%
# of Provided Positives (P)	14
# of False Negatives	1
%False Negative	6.7%

Table 40: Quantitative Results and z-Scores for Corn Fortified with T25 using DNA-based Assays

Event: T25													
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.8 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.5 (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	Reported Result (w/w%)	z-Score	
1754	0.0	0.0	0.2	0.1	0.0	0.0	1.3	0.9	0.0	0.0	0.8	1.6	
1764	0.0	0.0	1.3	1.8	0.8	1.7	0.9	0.2	0.0	0.0	0.4	-0.5	
1770	0.0	0.0	2.0	2.8	1.3	2.8	2.0	2.2	0.0	0.0	0.6	0.5	
1778	0.0	0.0	0.1	0.0	0.0	0.0	1.4	1.1	0.0	0.0	0.5	0.0	
1780	0.0	0.0	0.11	0.0	0.0	0.0	0.82	0.0	0.0	0.0	0.46	-0.2	
1870	0.0	0.0	0.1	0.0	0.0	0.0	0.7	-0.2	0.0	0.0	0.6	0.5	
1871	0.0	0.0	0.1	0.0	0.0	0.0	0.3	-0.9	0.0	0.0	0.2	-1.6	
1875	0.0	0.0	0.05	-0.1	0.0	0.0	0.28	-0.9	0.0	0.0	0.21	-1.6	
2057	0.0	0.0	0.88	1.2	0.63	1.3	1.50	1.3	0.0	0.0	0.37	-0.7	
2716	0.0	0.0	0.19	0.1	0.0	0.0	0.67	-0.2	0.0	0.0	0.37	-0.7	

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

Event: CBH351												
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 5.0 (w/w%)		Fortified @ 0.1 (w/w%)							
Participant Number	Reported Result (w/w%)	z-Score										
1754	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.8	-0.8	0.1	0.0
1778	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.5	-1.0	0.1	0.0
1781	0.0	0.0	0.0	0.0	P		P		5.3	-0.8	0.05	-0.4
1870	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.8	-0.8	0.07	-0.2
1875	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.54	-0.3	0.10	0.0
2057	0.0	0.0	0.0	0.0	0.13		0.0	0.0	4.70	-0.2	*0.39	1.6

Table 42: Quantitative Results and z-Scores for Corn Fortified with MON810 using DNA-based Assays

Event: MON810												
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.8 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 1.5 (w/w%)		Fortified @ 0.0 (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	Reported Result (w/w%)	z-Score
1754	0.0	0.0	0.5	-1.4	0.0	0.0	0.1	0.0	0.9	-1.4	0.0	0.0
1763	0.0	0.0	0.2	-2.6	0.0	0.0	0.1	-0.9	0.7	-1.9	0.0	0.0
1764	0.0	0.0	0.7	-0.5	0.0	0.0	0.1	0.0	1.5	0.0	0.0	0.0
1770	0.0	0.0	0.9	0.5	0.0	0.0	0.1	0.0	1.8	0.7	0.0	0.0
1773	0.0	0.0	0.4	-1.9	0.0	0.0	0.0	-2.3	0.7	-1.8	0.0	0.0
1778	0.0	0.0	0.3	-2.4	0.0	0.0	0.1	0.0	0.5	-2.3	0.0	0.0
1780	0.0	0.0	0.56	-1.1	0.0	0.0	0.10	0.0	1.43	-0.2	0.0	0.0
1781	0.0	0.0	0.35	-2.1	0.0	0.0	0.03	-1.6	0.7	-1.8	0.0	0.0
1788	0.0	0.0	0.62	-0.8	0.0	0.0	0.1	0.0	0.75	-1.7	0.0	0.0
1847	0.0	0.0	0.22	-2.7	0.0	0.0	0.0	-2.3	0.63	-2.0	0.0	0.0
1865	0.0	0.0	0.4	-1.9	0.0	0.0	0.1	0.0	0.7	-1.8	0.0	0.0
1870	0.0	0.0	0.2	-2.8	0.0	0.0	0.06	-0.9	0.8	-1.6	0.0	0.0
1871	0.0	0.0	0.5	-1.4	0.0	0.0	0.1	0.0	0.7	-1.8	0.0	0.0
1875	0.0	0.0	0.19	-2.9	0.00	0.0	0.0	-2.3	0.36	-2.6	0.0	0.0
2031	0.0	0.0	0.85	0.2	0.0	0.0	0.17	1.6	1.8	0.7	0.0	0.0
2057	0.0	0.0	0.62	-0.8	*0.17	4.5	0.10	0.0	1.15	-0.8	1.00	4.5
2060	0.0	0.0	0.27	-2.5	0.0	0.0	0.04	-1.4	0.69	-1.9	0.0	0.0
2694	0.00	0.0	0.24	-2.6	0.0	0.0	0.08	-0.5	0.52	-2.3	0.0	0.0
2716	0.0	0.0	0.34	-2.2	0.0	0.0	0.10	0.0	0.87	-1.4	0.0	0.0
2727	0.0	0.0	0.5	-1.4	0.0	0.0	0.1	0.0	0.9	-1.4	0.0	0.0

(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 and z-Scores for Corn Fortified with GA21 using DNA-based Assays

Event: GA21													
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.4 (w/w%)		Fortified @ 0.8 (w/w%)		Fortified @ 0.4 (w/w%)		Fortified @ 0.5 (w/w%)		Fortified @ 5.0 (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	Reported Result (w/w%)	z-Score	
1754	0.0	0.0	0.8	2.0	*1.3	1.4	0.5	0.6	0.7	1.0	7.0	1.5	
1764	0.0	0.0	0.4	0.0	0.7	-0.3	0.3	-0.6	0.5	0.0	5.0	0.0	
1770	0.0	0.0	0.5	0.5	0.8	0.0	0.3	-0.6	0.3	-1.0	3.4	-1.2	
1773	0.0	0.0	0.6	1.0	0.9	0.3	0.5	0.6	0.6	0.5	4.9	-0.1	
1778	0.0	0.0	0.4	0.0	0.6	-0.6	0.2	-1.3	0.5	0.0	4.5	-0.4	
1780	0.0	0.0	0.26	-0.7	0.52	-0.8	0.27	-0.8	0.34	-0.8	3.79	-0.9	
1781	0.0	0.0	0.2	-1.0	0.4	-1.1	0.2	-1.3	0.3	-1.1	2.6	-1.8	
1870	0.0	0.0	0.3	-0.5	0.5	-0.8	0.25	-0.9	0.3	-1.0	3.5	-1.2	
1871	0.0	0.0	0.3	-0.5	0.6	-0.6	0.2	-1.3	0.3	-1.0	4.2	-0.6	
1875	0.0	0.0	0.15	-1.2	0.56	-0.7	0.32	-0.5	0.28	-1.1	3.99	-0.8	
2057	0.0	0.0	0.61	1.0	0.84	0.1	0.70	1.9	0.70	1.0	5.10	0.1	
2060	0.0	0.0	0.19	-1.0	0.42	-1.1	0.14	-1.6	0.20	-1.4	3.63	-1.1	
2694	0.0	0.0	0.26	-0.7	P		P		0.34	-0.8	P		
2716	0.0	0.0	0.30	-0.5	0.79	0.0	0.20	-1.3	0.39	-0.5	2.87	-1.6	
2720	0.0	0.0	0.04	-1.8	*1.71	2.5	0.48	0.5	0.03	-2.3	1.60	-2.6	

Table 44: Quantitative Results and z-Scores for Corn Fortified with E176 using DNA-based Assays

Event: E176													
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.8 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 1.5 (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	Reported Result (w/w%)	z-Score	
1754	0.0	0.0	0.0	0.0	0.4	-2.2	0.1	0.0	0.1	0.0	1.2	-0.7	
1764	0.0	0.0	0.0	0.0	1.0	1.1	*0.2	2.0	0.1	0.0	1.3	-0.5	
1770	0.0	0.0	0.0	0.0	0.5	-1.6	0.1	0.0	0.1	0.0	0.9	-1.4	
1778	0.0	0.0	0.0	0.0	0.7	-0.5	0.1	0.0	0.1	0.0	1.2	-0.7	
1780	0.0	0.0	0.0	0.0	0.47	-1.8	0.08	-0.4	0.10	0.0	1.00	-1.2	
1781	0.0	0.0	0.0	0.0	0.4	-2.2	0.03	-1.4	0.01	-3.2	1.0	-1.2	
1788	0.0	0.0	0.0	0.0	0.59	-1.2	0.1	0.0	0.1	0.0	1.1	-0.9	
1870	0.0	0.0	0.0	0.0	0.7	-0.5	0.1	0.0	0.1	0.0	1.5	0.0	
1871	0.0	0.0	0.0	0.0	0.4	-2.2	0.06	-0.8	0.06	-2.0	0.9	-1.4	
1875	0.0	0.0	0.0	0.0	0.53	-1.5	0.10	0.0	0.09	-0.5	1.50	0.0	
2057	0.0	0.0	0.0	0.0	0.56	-1.3	*0.22	2.4	0.10	0.0	2.35	2.0	
2060	0.0	0.0	0.0	0.0	0.44	-2.0	0.05	-1.0	0.05	-2.5	1.08	-1.0	
2694	0.0	0.0	0.0	0.0	0.52	-1.5	0.09	-0.2	0.06	-2.0	1.00	-1.2	
2716	0.0	0.0	0.0	0.0	0.24	-3.1	0.11	0.2	0.10	0.0	0.41	-2.5	

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

Event: Bt11													
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.5 (w/w%)		Fortified @ 0.4 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 5.0 (w/w%)		
Participant Number	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score									
1754	0.0	0.0	0.3	-1.2	0.2	-1.5	0.0	0.0	0.1	0.0	3.3	-1.0	
1764	0.0	0.0	0.3	-1.2	0.3	-0.7	0.0	0.0	0.1	0.0	4.2	-0.5	
1770	0.0	0.0	0.6	0.6	0.4	0.0	0.0	0.0	0.1	0.0	6.4	0.8	
1778	0.0	0.0	0.3	-1.2	0.2	-1.5	0.0	0.0	0.1	0.0	3.6	-0.8	
1780	0.0	0.0	0.41	-0.5	0.25	-1.1	0.0	0.0	0.09	-0.1	4.76	-0.1	
1781	0.0	0.0	0.8	1.7	0.5	0.7	0.0	0.0	0.06	-2.0	P		
1788	0.0	0.0	0.47	-0.2	0.57	1.3	0.0	0.0	0.1	0.0	5.7	0.4	
1870	0.0	0.0	0.4	-0.6	0.3	-0.7	0.0	0.0	0.15	0.3	4.3	-0.4	
1871	0.0	0.0	0.4	-0.6	0.2	-1.5	0.0	0.0	0.1	0.0	4.3	-0.4	
1875	0.0	0.0	0.27	-1.3	0.23	-1.3	0.0	0.0	0.09	-0.1	3.98	-0.6	
2057	0.0	0.0	0.39	-0.6	0.19	-1.6	0.0	0.0	0.10	0.0	3.70	-0.8	
2060	0.0	0.0	0.29	-1.2	0.21	-1.4	0.0	0.0	*0.6	3.3	4.07	-0.6	
2692	0.0	0.0	0.82	1.9	0.57	1.3	0.0	0.0	*0.42	2.1	8.4	2.0	
2694	0.0	0.0	0.44	-0.3	0.24	-1.2	0.0	0.0	0.07	-0.2	3.86	-0.7	
2716	0.0	0.0	0.47	-0.2	0.30	-0.7	0.0	0.0	0.11	0.1	0.97	-2.4	

Table 46: Quantitative Results and z-Scores for Corn Fortified with NK603 using DNA-based Assays

Event: NK603													
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 0.4 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 1.5 (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	Reported Result (w/w%)	z-Score	
1754	0.0	0.0	0.1	0.0	0.3	-1.2	0.0	0.0	0.0	0.0	1.2	-1.4	
1764	0.0	0.0	0.1	0.0	0.3	-1.2	0.0	0.0	0.0	0.0	0.9	-2.8	
1770	0.0	0.0	0.1	0.0	0.2	-2.5	0.0	0.0	0.0	0.0	0.7	-3.8	
1778	0.0	0.0	0.1	0.0	0.3	-1.2	0.0	0.0	0.0	0.0	0.8	-3.3	
1780	0.0	0.0	0.10	0.0	0.36	-0.5	0.0	0.0	0.0	0.0	1.32	-0.8	
1781	0.0	0.0	0.09	-0.5	0.2	-2.5	0.0	0.0	0.0	0.0	0.8	-3.3	
1847	0.0	0.0	0.07	-1.8	0.28	-1.5	0.0	0.0	0.0	0.0	1.23	-1.3	
1870	0.0	0.0	0.08	-1.0	0.3	-1.2	0.0	0.0	0.0	0.0	1.0	-2.3	
1871	0.0	0.0	0.1	0.0	0.4	0.0	0.0	0.0	0.0	0.0	1.3	-0.9	
1875	0.0	0.0	0.08	-1.0	0.24	-2.0	0.0	0.0	0.0	0.0	1.03	-2.2	
2057	0.0	0.0	0.10	0.0	0.13	-3.3	0.0	0.0	0.0	0.0	1.00	-2.3	
2060	0.0	0.0	0.06	-2.1	0.22	-2.2	0.0	0.0	0.0	0.0	1.19	-1.5	
2694	0.0	0.0	0.04	-3.1	0.24	-2.0	0.0	0.0	0.0	0.0	0.99	-2.4	
2716	0.0	0.0	0.10	0.0	0.11	-3.6	0.0	0.0	0.0	0.0	1.37	-0.6	

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

Event: Herculex												
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.5 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.8 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.0 (w/w%)	
Participant Number	Reported Result (w/w%)	z-Score										
1754	0.0	0.0	0.3	-0.8	0.0	0.0	0.4	-1.2	0.0	0.0	0.0	0.0
1770	0.0	0.0	0.3	-0.8	0.0	0.0	0.5	-0.9	0.0	0.0	0.0	0.0
1778	0.0	0.0	0.3	-0.8	0.0	0.0	0.3	-1.5	0.0	0.0	0.0	0.0
1780	0.0	0.0	0.39	-0.4	0.0	0.0	0.55	-0.7	0.0	0.0	0.0	0.0
1781	0.0	0.0	0.1	-1.6	0.0	0.0	0.3	-1.5	0.0	0.0	0.0	0.0
1847	0.0	0.0	0.19	-1.2	0.0	0.0	0.41	-1.1	0.0	0.0	0.0	0.0
1870	0.0	0.0	0.2	-1.2	0.0	0.0	0.3	-1.5	0.0	0.0	0.0	0.0
1871	0.0	0.0	0.2	-1.2	0.0	0.0	0.4	-1.2	0.0	0.0	0.0	0.0
1875	0.0	0.0	0.17	-1.3	0.0	0.0	0.32	-1.4	0.0	0.0	0.0	0.0
2057	0.0	0.0	*1.00	2.0	0.0	0.0	*1.50	2.0	0.0	0.0	0.0	0.0
2694	0.0	0.0	P		0.0	0.0	0.25	-1.6	0.0	0.0	0.0	0.0
2716	0.0	0.0	0.11	-1.6	0.0	0.0	0.21	-1.7	0.0	0.0	0.0	0.0

Table 48: Quantitative Results and z-Scores for Corn Fortified with MON863 using DNA-based Assays

Event: MON863												
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.5 (w/w%)		Fortified @ 1.5 (w/w%)		Fortified @ 0.4 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.0 (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	Reported Result (w/w%)	z-Score
1754	0.0	0.0	0.5	0.0	1.0	-0.5	0.3	-0.4	0.0	0.0	0.0	0.0
1764	0.0	0.0	1.0	2.1	*3.6	2.2	*1.2	3.3	0.0	0.0	0.0	0.0
1770	0.0	0.0	0.8	1.3	1.6	0.1	0.6	0.8	0.0	0.0	0.0	0.0
1778	0.0	0.0	0.4	-0.4	1.5	0.0	0.5	0.4	0.0	0.0	0.0	0.0
1780	0.0	0.0	0.57	0.3	1.72	0.2	0.45	0.2	0.0	0.0	0.0	0.0
1781	0.0	0.0	0.90	1.7	*3.6	2.2	0.7	1.2	0.0	0.0	0.0	0.0
1870	0.0	0.0	0.5	0.0	1.5	0.0	0.5	0.4	0.0	0.0	0.0	0.0
1871	0.0	0.0	0.8	1.3	1.9	0.4	0.6	0.8	0.0	0.0	0.0	0.0
1875	0.0	0.0	0.10	-1.7	0.08	-1.5	0.29	-0.5	0.0	0.0	0.0	0.0
2057	0.0	0.0	0.73	1.0	1.18	-0.3	0.33	-0.3	0.0	0.0	0.0	0.0
2060	0.0	0.0	0.68	0.8	1.91	0.4	0.54	0.6	0.0	0.0	0.0	0.0
2112	0.0	0.0	0.54	0.2	1.06	-0.5	0.29	-0.5	0.0	0.0	0.0	0.0
2694	0.0	0.0	0.51	0.0	1.44	-0.1	0.41	0.0	0.0	0.0	0.0	0.0
2716	0.0	0.0	0.39	-0.5	1.12	-0.4	0.29	-0.5	0.0	0.0	0.0	0.0

(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 49: Quantitative Results and z-Scores for Corn Fortified with Herculex RW using DNA-based Assays

Event: Herculex RW													
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.5 (w/w%)		Fortified @ 0.8 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.0 (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	Reported Result (w/w%)	z-Score	
1754	0.0	0.0	0.7	0.3	1.0	0.3	0.3	1.5	0.0	0.0	0.0	0.0	
1773	0.0	0.0	1.0	0.7	1.4	1.0	0.3	1.5	0.0	0.0	0.0	0.0	
1778	0.0	0.0	1.1	0.8	1.1	0.5	0.1	0.0	0.0	0.0	0.0	0.0	
1780	0.0	0.0	0.70	0.3	0.96	0.3	0.10	0.0	0.0	0.0	0.0	0.0	
1781	0.0	0.0	0.9	0.6	1.0	0.3	0.2	0.7	0.0	0.0	0.0	0.0	
1847	0.0	0.0	0.42	-0.1	0.56	-0.4	0.10	0.0	0.0	0.0	0.0	0.0	
1865	0.0	0.0	1.1	0.8	2.0	1.9	0.2	0.7	0.0	0.0	0.0	0.0	
1870	0.0	0.0	0.8	0.4	1.4	1.0	0.1	0.0	0.0	0.0	0.0	0.0	
1871	0.0	0.0	0.8	0.4	1.3	0.8	0.1	0.0	0.0	0.0	0.0	0.0	
1875	0.0	0.0	0.80	0.4	1.26	0.7	0.16	0.4	0.0	0.0	0.0	0.0	
2057	0.0	0.0	*3.10	3.7	2.90	3.4	0.53	3.2	0.0	0.0	0.0	0.0	

Table 50: Quantitative Results and z-Scores for Corn Fortified with MIR604 using DNA-based Assays

Event: MIR604													
Fortification Level (w/w%)	Fortified @ 0.0 (w/w%)		Fortified @ 0.1 (w/w%)		Fortified @ 0.5 (w/w%)		Fortified @ 1.5 (w/w%)		Fortified @ 0.0 (w/w%)		Fortified @ 0.0 (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	Reported Result (w/w%)	z-Score	
1754	0.0	0.0	0.1	0.0	0.4	-1.1	1.1	-1.9	0.0	0.0	0.0	0.0	
1778	0.0	0.0	0.1	0.0	0.4	-1.1	1.0	-2.4	0.0	0.0	0.0	0.0	
1780	0.0	0.0	0.10	0.0	0.33	-1.9	0.80	-3.4	0.0	0.0	0.0	0.0	
1781	0.0	0.0	0.05	-2.4	0.2	-3.3	1.20	-1.5	0.0	0.0	0.0	0.0	
1865	0.0	0.0	0.1	0.0	0.2	-3.3	0.6	-4.4	0.0	0.0	0.0	0.0	
1870	0.0	0.0	0.09	-0.5	0.4	-1.1	1.2	-1.5	0.0	0.0	0.0	0.0	
1871	0.0	0.0	0.1	0.0	0.2	-3.3	0.8	-3.4	0.0	0.0	0.0	0.0	
1875	0.0	0.0	0.05	-2.4	0.24	-2.9	0.72	-3.8	0.0	0.0	0.0	0.0	
2057	0.0	0.0	0.10	0.0	0.20	-3.3	0.90	-2.9	0.0	0.0	0.0	0.0	
2694	0.0	0.0	0.07	-1.4	0.28	-2.4	1.04	-2.2	0.0	0.0	0.0	0.0	

(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 51: 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 @ 0.1 (w/w%)	Fortified @ 0.5 (w/w%)	Fortified @ 2.5 (w/w%)
Participant Number	Reported Result (w/w%)		Reported Result (w/w%)
1754	0.1	0.2	1.8

Table 52: Quantitative Results and z-Scores for Soybeans Fortified with RUR using DNA-based Assays

Event: RUR						
Fortification Level (w/w%)	Fortified @ 0.1 (w/w%)		Fortified @ 0.5 (w/w%)		Fortified @ 2.5 (w/w%)	
Participant Number	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score	Reported Result (w/w%)	z-Score
	1754	0.10	0.0	0.50	0.0	1.70
1770	0.2	1.5	0.6	0.5	2.3	-0.2
1773	0.1	0.0	0.6	0.5	2.4	-0.1
1778	0.1	0.0	0.4	-0.5	2.2	-0.3
1780	0.11	0.2	0.53	0.1	2.16	-0.3
1781	0.3	3.0	0.9	2.0	3.8	1.2
1783	0.10	0.0	0.31	-0.9	2.12	-0.4
1785	0.08	-0.3	0.44	-0.3	1.7	-0.8
1788	0.27	2.6	0.5	0.0	4.9	2.3
1847	0.197	1.5	0.923	2.1	3.31	0.8
1858	0.10	0.0	0.86	1.8	1.89	-0.6
1862	0.13	0.5	0.60	0.5	2.63	0.1
1865	0.2	1.5	0.7	1.0	4.1	1.5
1870	0.1	0.0	0.4	-0.5	1.8	-0.7
1871	0.16	0.9	0.70	1.0	2.60	0.1
1875	0.12	0.3	0.47	-0.1	2.19	-0.3
1892	0.2	1.5	0.9	2.0	3.7	1.1
2031	0.1	0.0	1.1	3.0	3.0	0.5
2032	0.10	0.0	0.50	0.0	1.70	-0.8
2039	0.10	0.0	0.60	0.5	2.80	0.3
2057	0.15	0.8	0.50	0.0	1.45	-1.0
2060	0.10	0.0	0.48	-0.1	2.28	-0.2
2132	0.30	3.0	0.82	1.6	5.13	2.5
2692	0.11	0.2	0.34	-0.8	1.36	-1.1
2694	0.10	0.0	0.41	-0.4	1.47	-1.0
2705	0.1	0.0	0.4	-0.5	3.5	0.9
2716	0.14	0.6	0.97	2.3	2.13	-0.3
2719	0.15	0.8	0.58	0.4	2.10	-0.4
2720	0.01	-1.4	0.65	0.7	4.83	2.2
2725	0.07	-0.5	0.59	0.4	2.49	0.0
2727	0.2	1.5	0.8	1.5	2.5	0.0
2808	0.1	0.0	0.6	0.5	1.0	-1.4

(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 53: Descriptive statistics for 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	10	0.1	0.50	0.67	133%	403%	0.1 -2.0
T25	10	0.5	0.45	0.18	41%	-10%	0.2 – 0.8
T25	10	0.8	0.99	0.55	56%	23%	0.3 – 2.0
CBH351	5	0.1	0.09	0.02	16%	-8%	0.07 – 0.5
CBH351	5	5.0	4.27	0.69	16%	-15%	0.7 – 4.7
MON810	20	0.1	0.1	0.04	57%	-23%	0.0 – 0.17
MON810	20	0.8	0.4	0.2	48%	-44%	0.19 – 0.9
MON810	20	1.5	0.9	0.4	57%	-23%	0.3 – 1.8
GA21	29	0.4	0.34	0.18	53%	-15%	0.04 – 0.8
GA21	15	0.5	0.38	0.19	50%	-24%	0.01 – 0.7
GA21	12	0.8	0.64	0.17	26%	-21%	0.4 – 1.71
GA21	14	5.0	4.01	1.30	33%	-20%	1.60 – 7.0
E176	26	0.1	0.08	0.03	31%	-16%	0.03 – 0.22
E176	14	0.8	0.53	0.18	34%	-33%	0.24 – 1.0
E176	14	1.5	1.17	0.43	37%	-22%	0.41 – 2.35
Bt11	13	0.1	0.1	0.03	35%	-7%	0.00 – 0.6
Bt11	15	0.4	0.3	0.1	43	-22%	0.19 – 0.57
Bt11	15	0.5	0.4	0.2	39%	-11%	0.27 – 0.82
Bt11	14	5.0	4.40	1.68	38%	-12%	0.97 – 8.4
NK603	14	0.1	0.09	0.02	22%	-13%	0.04 – 0.10
NK603	14	0.4	0.26	0.08	32%	-36%	0.11 – 0.4
NK603	14	1.5	1.06	0.21	20%	-29%	0.7 – 1.37
Herculex	10	0.5	0.23	0.09	41%	-55%	0.1 - 1.00
Herculex	11	0.8	0.36	0.10	29%	-55%	0.21 – 1.50
MON863	13	0.4	0.45	0.14	31%	12%	0.29 – 1.2
MON863	12	0.5	0.60	0.24	39%	20%	0.10 – 1.0
MON863	14	1.5	1.33	0.50	38%	-11%	0.08 – 3.6
Herculex RW	11	0.1	0.20	0.13	67%	99%	0.10 – 0.53
Herculex RW	10	0.5	0.83	0.20	25%	66%	0.42 – 3.10
Herculex RW	11	0.8	1.35	0.67	46%	69%	0.56 – 2.90
MIR604	10	0.1	0.09	0.02	25%	-14%	0.05 – 0.10
MIR604	10	0.5	0.29	0.09	32%	-43%	0.20 – 0.4
MIR604	10	1.5	0.94	0.21	22%	-38%	0.6 – 1.20
RUR	32	0.1	0.14	0.07	48%	37%	0.01 – 0.30
RUR	32	0.5	0.61	0.20	33%	23%	0.31 – 1.1
RUR	32	2.5	2.6	1.06	41%	4%	1.00 – 5.13

Summary of Findings

Qualitative Sample Analysis

PCR: As evidenced by the “percentage correct scores” in Table 29 and Figure 1, participants were able to correctly identify most of the transgenic events in the corn test samples with greater than 92% accuracy through the use of conventional PCR. The best performance was observed for the detection of the NOS event while MON810 had the highest percentage of false negatives (6.9%) and T25 had the highest percentage of false positives (15.9%).

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 30 through 39). 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 93% 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 October 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 33%. 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. 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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