15) Ridley, W. R., M. A. Nemeth, J. D. Astwood, M. L. Breeze and R. Sorbet (2002). Amended report for MSL-17199: Compositional analyses of forage and grain collected from corn rootworm protected maize event MON 863 grown in 1999 U.S. field trials. MSL-17669, an unpublished study conducted by Monsanto Company.

Study Title

Amended Report for MSL-17199:
Compositional Analyses of Forage and Grain Collected From Corn Rootworm Protected Maize Event MON 863 Grown in 1999 U.S. Field Trials

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Study Completed on

Amendment 2
February 28, 2002

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Laboratory Project ID

MSL-17669
Monsanto Study No. 99-01-39-30
Covance Study No. 6103-243

Statement of No Data Confidentiality Claims

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 10(d)(1)(A), (B), or (C).

"We submit this material to the United States Environmental Protection Agency specifically under the requirements set forth in FIFRA as amended, and consent to the use and disclosure of this material by EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 86-5, we reserve and do not waive any rights involving this material that are or can be claimed by the company notwithstanding this submission to EPA."

Company: Monsanto Company

Company Agent: _____

Title: _____

Signature: _____ Date: _____

Statement of Compliance

This study meets GLP requirements of 40 CFR Part 160 (EPA) except for the following:

The reference standards used for compositional analysis were not characterized according to GLP standards. This exception had no effect on the integrity or quality of the study because the reference standards were obtained from reputable suppliers.

Submitter: _____ Date: _____

Sponsor: Ravinder S Sidhu Date: Feb 28, 2002

Study Director: William P. Ridley Date: Feb. 28, 2002

Quality Assurance Statement

Study Title: Amended Report for MSL-17199: Compositional Analyses of Forage and Grain Collected From Corn Rootworm Protected Maize Event MON 863 Grown in 1999 U.S. Field Trials

Study Number: 99-01-39-30

Reviews conducted by the Quality Assurance Unit confirm that the final report reflects the raw data.

The following is a list of the reviews conducted by Monsanto Regulatory Quality Assurance Unit on the study reported herein. Additional reviews conducted by the Quality Assurance Unit of Covance Laboratories are specified in the contract facility subreport which is archived.

Dates Of Inspection / Audit	Phase	Date Reported To: Study Director	Management
June 5, 2000	Raw Data/Draft Report	June 5, 2000	June 5, 2000
April 4, 2001	Amended Report Audit	April 9, 2001	April 9, 2001
February 20, 2002	Amended Report Audit	February 22, 2002	February 22, 2002

Kristen Berman

Quality Assurance Unit
Monsanto Regulatory, Monsanto Company

2/28/02

Date

Signatures of Approval

Study Number: 99-01-39-30

Title: Amended Report for MSL-17199: Compositional Analyses of Forage and Grain Collected From Corn Rootworm Protected Maize Event MON 863 Grown in 1999 U.S. Field Trials

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Covance Labs., Inc (Madison): Matthew L. Breeze (composition analysis)
Certus International, Inc (St. Louis): Roy Sorbet (statistical analysis)

Study Initiation Date: September 22, 1999

Completion Dates -
Original Study: June 8, 2000
Amendment 1 Report: April 10, 2001
Amendment 2 Report: February 28, 2002

Records Retention: All study specific raw data, protocols, final reports and facility records will be retained at Monsanto, St. Louis except for raw data and facility records maintained at Covance Laboratories, Inc., Wisconsin Facility.

Sample Storage: Any unused study samples that are not destroyed will be stored at Monsanto, St. Louis.

Signatures of Approval (continued)

Amendments to Report MSL-16590 (Completed April 10, 2001):

This amendment modifies the final report to reflect new Cry3Bb1 protein information. The following changes do not affect the quality or integrity of the data.

MSL-17199 Amendment 1 Report	MSL-16590 Original Report	Amendment
1. Title Page	1. Title Page	a. Added 'Amended Report For MSL-16590' in front of study title b. Added new line: "Amendment 1" after "Report Completed on" c. Added new report completion date
2. Page 4	2. Page 4	Added new line to QA Statement: "Amended Report Audit" to list of phases
3. Page 5	3. Page 5	Added "Original" to Study Completion Date Added "Amended Report Completion Date"
4. Page 6	4. Not included	List of Changes in Amended Report
5. Pages 7 and 8	5. Pages 6 and 7	Table of Contents - changed pagination
6. Page 10	6. Page 9	Reworded first paragraph to reflect new protein information
7. Page 12	7. Page 11	Reworded second paragraph to reflect new protein information
8. Page 24	8. Page 23	Inserted a new references: Hileman, R. E. and Astwood,, J.D., 2001 and Dudin et al., 2001.
9. Table 10, Page 57	9. Table 10, Page 56	Change footnote to read 'mean of sixteen replicates'
10. Table 11, Page 63	10. Table 11, Page 62	Change footnote to read 'mean of sixteen replicates'

Signatures of Approval (continued)

Amendments to Report MSL-17199:

This amendment modifies the final report to reflect revised statistical information for the combined site analysis. The following changes do not affect the quality or integrity of the data.

Item	MSL-17669 Amendment 2 Report	MSL-17199 Amendment 1 Report	Amendment
1.	Title Page	Title Page	Added 'Amended Report For MSL-17199' in front of study title, revised amendment number, completion date and addresses for Monsanto Co. and Certus International, Inc.
2.	Page 2	Page 2	Revised 'Statement of No Data Confidentiality Claims'
3.	Page 4	Page 4	Revised study title and added additional line to QA 'Dates of Audit'
4.	Page 5	Page 5	Revised study title, addresses of Monsanto Co. and Certus International, Inc., and 'Amended Report Completion Date'
5.	Page 6	Page 6	Revised title to clarify amended report/completion date
6.	Page 7	Not included	List of Changes in Amendment 2 Report
7.	Pages 8 and 9	Pages 7 and 8	Table of Contents - changed pagination
8.	Page 12	Page 11	Revised text to reflect new statistical information and new references for safety data
9.	Pages 15, 16, 21	Pages 14, 15, 20	Dudin *et al.*, 2000 corrected to Dudin *et al.*, 2001
10.	Page 22	Page 21	Revised text to reflect new statistical information
11.	Page 23	Page 22	Revised text to reflect new statistical information and new references for safety data
12.	Pages 24, 25	Pages 23, 24	New reference citations added
13.	Table 1, Page 29	Table 1, Page 28	Revised Table 1 to reflect new statistical information for combined site analysis
14.	Tables 10, 11 Pages 58 - 64	Tables 10, 11 Pages 57 - 63	Revised Tables 10 and 11 to reflect new statistical information for combined site analysis

William P. Ridley — Feb 28, 2002
Study Director — Date

Feb 28, 2002
Director Product Safety Center — Date

Ravinder S Sidhu — Feb-28, 2002
Sponsor Representative — Date

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Abbreviations

ADF	Acid detergent fiber
AA	Amino acid
AACC	American Association of Cereal Chemists
AOAC	Association of Official Analytical Chemists
AOCS	American Oil Chemists Society
APHIS	Animal and Plant Health Inspection Service
B.t.	*Bacillus thuringiensis*
CRW	Corn rootworm
Cry1	A class of Lepidopteran-specific *B.t.* Cry1 proteins that share >45% amino acid sequence identity
Cry2	A class of Lepidopteran- and Dipteran-specific *B.t.* Cry2 proteins that share >45% amino acid sequence identity
Cry3	A class of Coleopteran-specific *B.t.* Cry3 proteins that share > 45% amino acid sequence identity
Cry3Bb1	A natural isolate, and holotype, of the Cry3Bb class of *B.t.* Cry proteins, present in the microbial spray product, Raven®
cry3Bb1	The gene that encodes for the protein, Cry3Bb1
Cry3Bb1.11098	protein from *Bacillus thuringiensis* strain EG11098
Cry4	A class of Dipteran-specific *B.t.* Cry4 proteins that share >45% amino acid sequence identity
DW or dw	Dry weight
E. coli	*Escherichia coli*
FA	Fatty acid
FW or fw	Fresh weight
MN	Monmouth, Illinois
na	Not available
NDF or NDFE	Neutral detergent fiber
nptII	gene encoding neomycin phosphotransferase II
NPTII	protein for neomycin phosphotransferase II
ppm	parts per million (µg of analyte/g of sample)
RD	Richland, Iowa
SOP	Standard Operating Procedure
T/C	Test/Control
TIU	Trypsin inhibitor units
VH	Van Horne, Iowa
YK	York, Nebraska

[Standard abbreviations, e.g., units of measure, according to format described in 'Instructions to Authors' in the Journal of Biological Chemistry]

1.0 Summary

Monsanto Company has developed, through biotechnology techniques, maize event MON 863, which is protected from damage by the coleopteran insect pest, corn rootworm (*Diabrotica* spp.). A variant of the wild type *cry3Bb1* coding sequence (GenBank Accession No. M89794) was designed to encode a protein with enhanced insecticidal activity against corn rootworm. This *cry3Bb1* coding sequence was used to create recombinant *B.t.* strain EG11098. Expression of this gene in *Bacillus* results in the production of a protein, Cry3Bb1.11098. This gene was further modified to enhance expression in plants and placed into a vector used for the transformation of maize (*Zea mays*). Transformation event MON 863 produces a variant of the Cry3Bb1.11098 protein that differs from the wild type protein sequence by seven amino acids and from the *Bacillus*-produced Cry3Bb1.11098 protein by two amino acids (Hileman and Astwood, 2001a). Maize event MON 863 also contains the neomycin phosphotransferase II (*nptII*) gene encoding the NPTII protein that functions as a selectable marker.

The purpose of this study was to conduct compositional analyses of tissues collected from corn rootworm-protected maize event MON 863, the non-transgenic parental control line MON 846 and 18 commercial maize hybrids grown under field conditions. Field trials were conducted in the U.S. in 1999 at four replicated sites located in Monmouth, Illinois (MN); Richland, Iowa (RD); Van Horne, Iowa (VH); and York, Nebraska (YK). Maize event MON 863 and its control line, MON 846, were planted at all sites. Four different commercial reference hybrids (non-transgenic) were planted at two sites and five different commercial reference hybrids (non-transgenic) were planted at the remaining two sites to give a total of 18 different reference hybrids. Forage and grain were collected from all sites. Compositional analyses were conducted to measure proximates (protein, fat, ash, moisture), acid detergent fiber (ADF), neutral detergent fiber (NDF), amino acids, fatty acids, vitamin E, mineral (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc), phytic acid and trypsin inhibitor content of grain; and to measure proximate, ADF and NDF content of forage. In addition, the content of carbohydrates in forage and grain was determined by calculation. In all, 51 different components (7 in forage and 44 in grain) were evaluated as part of the safety and nutritional assessment of maize event MON 863.

Statistical analyses of the compositional data were conducted using a randomized complete block model analysis of variance for five sets of comparisons: analyses of data from each of the four replicated trials and data from a combination of all four trials. As there were a total of 51 components evaluated, a total of 255 comparisons were made: 51 comparisons for each of the five statistical analyses. The test event, MON 863, was compared to the control line, MON 846, to determine statistically significant differences at $p<0.05$. In addition, the comparison of MON 863 to the 95% tolerance interval for the commercial reference varieties was conducted to determine if the range of values for MON 863 fell within the population of commercial maize.

The results of compositional analyses showed that the 51 components measured in maize event MON 863 were within the range observed for commercial maize lines planted at the same U.S. sites in 1999. Futhermore, all 51 components were within published literature ranges (Jugenheimer, 1976; Watson, 1982; Watson, 1987), or historical ranges for non-transgenic maize varieties (Sanders and Patzer, 1995; Sanders *et al.*, 1996a,b; 1997a,b,c). There were no statistically significant differences in 224 of the 255 comparisons made between maize event MON 863 and the control line, MON 846, which included components in forage (fat, protein, ash, carbohydrate, ADF and NDF) and grain (ash, ADF, NDF, 12 of 18 amino acids, six of eight fatty acids, potassium, magnesium, and trypsin inhibitor).

Of the 31 comparisons found to be statistically different, 5% or approximately thirteen (0.05 × 255), were expected to be false positives based on chance alone. Differences that were observed for only one to three of these comparisons, and not consistently across all five comparisons, are unlikely to be of biological significance. The magnitude of the differences between the test event and the control line expressed as a percent of the control values ranged between 1.38%-15.52%. Furthermore, the range of values for those compositional components associated with the small statistical differences were found to all fall within the 95% tolerance interval for commercial varieties planted at the same U.S. sites in 1999. This demonstrates, with a confidence level of 95%, that the levels of key nutrients and other compositional components for MON 863 were within the same population as expected for non-transgenic commercial reference maize used in this study. Therefore, these minor differences are unlikely to be biologically meaningful, and the grain and forage from MON 863 are considered compositionally equivalent to that of conventional maize grain and forage.

These data, together with the safety of the Cry3Bb1 protein as demonstrated by rapid *in vitro* digestibility (Leach *et al.*, 2001; Hileman *et al.*, 2001), lack of homology to allergens and toxins (Hileman and Astwood., 2001b), lack of acute oral toxicity to mice (Bonnette and Pyla, 2001), the safety of registered *B.t.* formulations (e.g., Raven®) containing the Cry3Bb1 protein and the safe history of use of the host organism (maize) as a common source of animal feed and human food, support the conclusion that the corn rootworm protected maize event MON 863 is compositionally equivalent and as safe and nutritious as the maize varieties grown commercially today.

2.0 Introduction

2.1 Background

Bacillus thuringiensis (*B.t.*) is a gram-positive bacterium commonly present in soil. Many different strains of *B. thuringiensis* have been shown to produce crystal proteins or inclusion bodies which are specifically effective in controlling certain orders and species of insect pests. *B. thuringiensis*-based products have been widely used as microbial pesticides since 1961 (McClintock *et al.*, 1995). Microbial pesticides have been commercially available and used as

environmentally acceptable insecticides because they are specific for the targeted insect pests and are typically harmless to plants and other non-targeted organisms. *B.t.* proteins have been generally classified based on their insecticidal activity (*e.g.*, Cry1, Cry2, Cry3 and Cry4 proteins are toxic to lepidopteran, lepidopteran/dipteran, coleopteran and dipteran pests, respectively) (Bravo, 1997; Hofte and Whiteley, 1989). The Cry3 class protein, Cry3Bb1, has natural insecticidal activity against the coleopteran pest, corn rootworm, *Diabrotica* (Von Tersch *et al.*, 1994) a major North American corn pest.

The Cry3Bb1 protein was previously referred to as CryIIIB2 (or Cry3B2) as well as Cry3Bb or CryIIIC. This protein is now referred to as Cry3Bb1 protein according to the most recent and accepted nomenclature (Crickmore et al., 1998). A variant of the wild type *cry3Bb1* coding sequence (GenBank Access. No. M89794) was designed to encode a protein with enhanced insecticidal activity against corn rootworm. This *cry3Bb1* coding sequence was used to create recombinant *B.t.* strain EG11098. Expression of this gene in *Bacillus* results in the production of a protein, Cry3Bb1.11098, which contains a total of five amino acid differences from the wild type Cry3Bb1 protein sequence. This gene was further modified to enhance expression in plants and placed into a vector used for the transformation of maize (*Zea mays*). Transformation event MON 863 produces a variant of the Cry3Bb1.11098 protein that differs from the wild type protein sequence by seven amino acids and from the *Bacillus*-produced Cry3Bb1.11098 protein by two amino acids. The protein produced in MON 863 maize is hereafter referred to simply as a Cry3Bb1 variant protein (Hileman and Astwood, 2001a). In addition, the neomycin phosphotransferase II (*nptII*) gene was introduced as a selectable marker (Fraley et al., 1983).

2.2 Purpose

The purpose of this study was to conduct compositional analyses of tissues collected from corn rootworm-protected maize line MON 863 and the non-transgenic parental control line MON 846, grown under field conditions in the United States in 1999 at four replicated sites located in Monmouth, Illinois (MN); Richland, Iowa (RD); Van Horne, Iowa (VH); and York, Nebraska (YK). Eighteen different commercial hybrids (non-transgenic) were included as references and to provide data for the development of a 95% tolerance interval for each compositional component. Compositional analyses were conducted to measure proximates (protein, fat, ash, moisture), acid detergent fiber (ADF), neutral detergent fiber (NDF), amino acids, fatty acids, vitamin E, minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc), phytic acid and trypsin inhibitor content of grain; and to measure proximate, ADF and NDF content of forage. In addition, the content of carbohydrates in forage and grain was determined by calculation. Statistical evaluation of the composition data involved comparison of MON 863 to the control line, MON 846, to determine statistically significant differences at $p < 0.05$ and comparison of MON 863 to the 95% tolerance interval for the commercial reference varieties to determine if the range of values for MON 863 fell within the population of commercial maize.

3.0 Materials and Methods

3.1 Test Substance

The test substance was the corn rootworm (CRW) event MON 863. The seed source for MON 863 (Batch # 86310) was CRPR9801:1037. This seed was the progeny of a cross to A1 from an MTCY10412 x R0 derived plant that had been selfed and a homozygote identified CRW event MON 862 was also included at study initiation but was subsequently dropped from the study for commercial reasons (protocol amendments nos. 2 and 3). All data generated on MON 862 were archived with the final report.

3.2 Control Substance

The control substance for this study was maize line MON 846, which was not genetically modified, but has the background genetics representative of the test substance. The seed for MON 846 (Batch #84640) was progeny derived by crossing A1 × MTCY10412. MTCY10412 was the genotype into which MON 863 was transformed.

MON 847, the control line for event MON 862, was also included at study initiation but subsequently dropped from the study for commercial reasons (protocol amendment nos. 2 and 3). All data generated on MON 847 are included in the study files archived with the final report.

3.3 Reference Substances

There were 18 commercial maize lines (non-transgenic) used as reference substances for this study. The code number, source, single generation pedigree and seed lot numbers are included in the table below:

Reference Code #	Source	Pedigree	Seed Lot #
REF-1	Novartis	N7590	NA
REF-2	Golden H	H2493	NA
REF-3	Novartis	N7070	NA
REF-4	Pioneer	P3394	NA
REF-5	Holden's	198 X 277	B:361-2755845
REF-6	Holden's	228 X 283	B:142-2279727
REF-7	Holden's	HC33 X 185	B: 3 -2249694
REF-8	Holden's	198 X 172	B:225-1268724
REF-9	Holden's	277 X 218	B:155-1992724
REF-10	Holden's	200 X 185	B:304-1572744
REF-11	Holden's	228 X 184	B:341-2735837
REF-12	Holden's	HC34 X 172	B:172-2510824

(*continued*)

Reference Code #	Source	Pedigree	Seed Lot #
REF-13	Holden's	HC34 X 277	B:121-2867849
REF-14	Holden's	198 X 185	B:14 -1511633
REF-15	Holden's	197 X 273	B:296-2623733
REF-16	Holden's	200 X 277	B:321-2762717
REF-17	Holden's	198 X 284	B:168-2492824
REF-18	Holden's	HC33 X 283	B:170-2280844

NA = not available

Appropriate standards were used in each assay as reference standards for the analytical procedures. The analytical standards used for compositional analyses are described in Section 3.7

3.4 Characterization of the Test and Control Substances

The identity of each test and control substance was verified by the Study Director prior to its use in the study by verifying the chain-of-custody documentation supplied with the samples collected from the field. The test and control substances were characterized at the molecular level to distinguish between events by extracting DNA from leaf and grain tissue and analyzing the DNA by polymerase chain reaction or event-specific Southern blot analysis. The identity of all samples used in this study was confirmed and the data were summarized in study 99-01-39-22 (Dudin *et al.*, 2001).

3.5 Field Trials

The test and control substances were produced in 1999 U.S. field trials at four replicated sites (Production Plan 99-01-39-08). A detailed description of the results of the field trials is contained in the field report (Bhatti, 2000). The USDA's APHIS (Animal and Plant Health Inspection Service) requirements for the shipment, movement, environmental release and conduct of trials involving genetically-modified plants were followed in Production Plan 99-01-39-08. A brief summary of the conduct and results of these trials is included for reference.

The four replicated trials were conducted at the following sites (site code): Monmouth, Illinois (MN), Richland, Iowa (RD), Van Horne, Iowa (VH), and York, Nebraska (YK). These sites provided a variety of environmental conditions representative of regions where corn rootworm-protected maize lines would be grown as commercial products. At each site, test events, control lines and reference hybrids were planted as a Randomized Complete Block Design with four replications except for the reference lines which had only two replications. Four different commercial reference hybrids were planted at two sites and five different commercial reference hybrids were planted at the remaining two sites to give a total of eighteen different reference hybrids. Each row was clearly marked with its unique MON number or REF number and plot number for line identification. All plants of the test events, control lines and reference hybrids were self-pollinated.

Forage and grain were collected from all sites. In addition, the following samples were collected during the growing season: young leaf; overseason leaf (MN, RD and VH sites only); overseason whole plant (MN, RD and VH sites only); overseason root (MN, RD and VH sites only); silks (MN site only); and pollen (MN site only). All tissues were analyzed for the presence of the Cry3Bb1 protein using an ELISA assay (Dudin *et al.*, 2001). Compositional analyses were conducted on forage and grain in this study as described in Section 3.7. Forage was collected from whole plants (all above ground parts) at the early dent stage from each of the replications of test events, control lines and reference hybrids. The plants were cut into 4 to 6 inch segments, combined in uniquely labeled bags and frozen on dry ice. Ears were hand-harvested from all self-pollinated test, control and reference plants at normal kernel maturity, dried to a moisture level below 15%, shelled, and the kernels pooled to provide grain samples. Forage (on dry ice) and grain (at ambient temperature) samples were shipped to the Sponsor's facility where they were processed for compositional analyses according to Standard Operating Procedure (SOP) ES-93-ESOP-047-1.

3.6 Test System

There was no test system for this study. Analytical methods were used to evaluate the test event, control line and reference lines. Compositional analyses were performed by modifications of published methods that are currently used to evaluate the nutritional quality of maize (see Section 3.7).

3.7 Compositional Analytical Methods

Forage and grain samples for all replicates of the test and control lines and one replicate of each reference line for an individual site were shipped to Covance Laboratories, Inc., Madison, Wisconsin for compositional analyses. Grain samples were analyzed for proximates (protein, fat, ash, moisture), ADF, NDF, amino acids, fatty acids, vitamin E, minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc), phytic acid and trypsin inhibitor. Forage samples were analyzed for proximates, ADF and NDF. Carbohydrate levels in forage and grain were determined by calculation. The same methods were used for the proximate analysis of forage and grain except for the analysis of fat as described below. The analytical data generated by Covance Laboratories, Inc. was summarized in an Analytical Subreport (Covance study number 6103-243) that was archived with the study files.

Acid detergent fiber (ADF). The method used was based on a modified version of a USDA method (1970). The sample was placed in a fritted vessel and washed with an acidic boiling detergent solution that dissolved the protein, carbohydrate, and ash. An acetone wash was used to remove the fats and pigments. The lignocellulose fraction was collected on the frit and determined gravimetrically. The limit of detection of the method for this study was 0.1% fresh weight (fw).[1] There was no analytical reference substance for this analysis.

[1] % fw = (g/g fw) x 100

Amino acid composition (TAAP). The method used was based on a modified version of AOAC method 982.30 (1998) that estimates the levels of 18 amino acids in the sample: alanine, arginine, aspartic acid (including asparagine), cystine (including cysteine), glutamic acid (including glutamine), glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine. The sample was assayed by three methods to obtain the full profile. Tryptophan required a base hydrolysis using sodium hydroxide. Sulfur containing amino acids required an oxidation using performic acid prior to hydrolysis with hydrochloric acid. Analysis of the remaining amino acids was accomplished through direct hydrolysis with hydrochloric acid. The individual amino acids were quantitated using an automated amino acid analyzer. The limit of detection of the method for this study was 0.1 mg/g fw. The reference standards were: Beckman K18, 2.5 μmol/mL per constituent except cystine (1.25 μmol/mL), lot no. S901670; Aldrich L-tryptophan, 99%, lot no. 12729HS; Aldrich L-cysteic acid monohydrate, 98.0%, lot no. 04615MS; and Sigma L-methionine sulfone, 100%, lot no. 12H3349.

Ash (ASHM). The method used was based on a modified version of AOAC method 923.03 (1998). The sample was placed in an electric furnace at 550 °C and ignited to drive off volatile organic compounds. The nonvolatile matter remaining was quantitated gravimetrically and the percent ash was determined by calculation. The limit of detection of the method for this study was 0.1% fw. There was no analytical reference substance for this analysis.

Carbohydrates (CHO). The method used was based on a USDA method (1973). The limit of detection for this study was 1.0% and there was no reference standard. Carbohydrate values were calculated by difference using the fresh weight-derived data and the following equation:

$$\% \text{ carbohydrates} = 100\% - (\% \text{ protein} + \% \text{ fat} + \% \text{ ash} + \% \text{ moisture})$$

Fat by acid hydrolysis (FAAH). The method used was based on modified versions of AOAC methods 922.06 and 954.02 (1998). The forage sample was hydrolyzed with hydrochloric acid at an elevated temperature. The fat was extracted using diethyl ether followed by hexane. Extracts were washed with a dilute alkali solution and filtered through a sodium sulfate column. The extract was evaporated, dried and weighed. The limit of detection of this method for this study was 0.1% fw. There was no analytical reference substance for this analysis.

Fat by soxhlet extraction (FSOX). The method used was based on a modified version of AOAC method 960.39 (1998). The grain sample was weighed into a cellulose thimble containing sand or sodium sulfate and dried to remove excess moisture. Pentane was dripped through the sample to remove the fat. The extract was evaporated, dried and weighed. This method was used for grain sample analysis. The limit of detection of the method for this study was 0.1% fw. There was no analytical reference substance for this analysis.

Fatty acids (FAPM). The method used was based on a modified version of AOCS method Ce 1-62 (1997) that estimates the levels of 22 fatty acids in the sample: 8:0 caprylic acid, 10:0 capric acid, 12:0 lauric acid, 14:0 myristic acid, 14:1 myristoleic acid, 15:0 pentadecanoic acid, 15:1 pentadecenoic acid, 16:0 palmitic acid, 16:1 palmitoleic acid, 17:0 heptadecanoic acid, 17:1 heptadecenoic acid, 18:0 stearic acid, 18:1 oleic acid, 18:2 linoleic acid, 18:3 linolenic, 18:3 gamma linolenic acid, 20:0 arachidic acid, 20:1 eicosenoic acid, 20:2 eicosadienoic acid, 20:3 eicosatrienoic acid, 20:4 arachidonic acid and 22:0 behenic acid. Lipid in grain samples were extracted and saponified with 0.5 N sodium hydroxide in methanol. The saponification mixture was methylated with 14% (weight/volume) boron trifluoride:methanol. The resulting methyl esters were extracted with heptane containing an internal standard. The methyl esters of the fatty acids were analyzed by gas chromatography using external standards for quantitation. The limit of detection of this method for this study was 0.00400%. The analytical reference standards (purity 100%) were: Nu Chek Prep Hazelton special prep nos 1 (lot no. JA10-I), 2 (lot no. S10-G), 3 (lot no. F23-J), 4 (lot no. JY26-J); and Nu Chek Prep methyl gamma linolenate (lot nos. U-63M-F25-J).

Minerals/ICP emission spectrometry (ICPL). The method used was based on modified version of AOAC methods 984.27 and 985.01 (1998) and a literature method (Dahlquist *et al.*, 1978). This method was used to estimate the levels of nine minerals in the sample: calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc. Samples were dried, precharred and ashed overnight at 500° ± 50°C. Ashed samples were treated with hydrochloric acid, taken to dryness and dissolved in 5% (v/v) hydrochloric acid. The amount of each element was determined at appropriate wavelengths by comparing the emission of the unknown sample, using inductively coupled plasma, with the emission of the standard solutions described below.

Mineral	Lot Number	Concentration (ppm)	Limit of Detection (ppm)
Calcium	J5-111CA	10,000	20.0
Copper	6-137CU	1,000	0.500
Iron	9-172FE	1,000	2.00
Magnesium	K5-67MG	10,000	20.0
Manganese	6-201MN	1,000	0.300
Phosphorus	K6-54P	10,000	20.0
Potassium	M6-16K	10,000	100
Sodium	M6-41NA	10,000	100
Zinc	6-171ZN	1,000	0.400

Moisture (M100). The method used was based on a modified version of AOAC methods 926.08 and 925.09 (1998). Samples were dried in a vacuum oven at 100°C to a constant weight. The moisture loss was determined and converted to percent moisture. The limit of detection of this method for this study was 0.1% fw. There was no analytical reference substance for this analysis.

Neutral detergent fiber, enzyme method (NDFE). The method used was based on modified versions of an AACC method 32.20 (1998) and a USDA method (1970). Samples were placed in a fritted vessel and washed with a neutral boiling detergent solution to dissolve the protein, carbohydrate, enzyme and ash. Fats and pigments were removed using an acetone wash. The hemicellulose, cellulose and lignin fractions were collected on a frit and determined gravimetrically. The limit of detection of this method for this study was 0.1% fw. There was no analytical reference substance for this analysis.

Phytic acid (PHYT). The method used was based on modifications of two literature methods (Lehrfeld 1989, 1994). Samples were extracted using ultrasonication. Purification and concentration was performed using a silica based anion exchange (SAX) column. Sample analysis was conducted using a macroporous polymer high-performance liquid (HPLC) column [PRP-1, 5µm (150 x 4.1 mm)] connected to a refractive index detector. The limit of quantitation for this study was between 0.0500 and 0.0800% fw. The reference substance for this assay was Aldrich phytic acid, dodecasodium salt hydrate, 99%, lot no. 13529MS.

Protein (PGEN). The method used was based on modifications of AOAC methods 955.04 and 979.09 (1998) and literature methods (Bradstreet, 1965; Kalthoff and Sandell, 1948). Protein and other nitrogenous compounds in the sample were reduced to ammonia by digestion of the sample with sulfuric acid containing a mercury catalyst mixture. The acid digest was made alkaline, and the ammonia was distilled and titrated with a standard acid. The percent nitrogen was determined and converted to percent protein by multiplication with 6.25. The limit of detection of this method for this study was 0.1% fw. There was no analytical reference substance for this analysis.

Trypsin inhibitor (MIXX). The method used was based on a modified version of a AOCS method Ba 12-75 (1997). Trypsin inhibitor activity in the sample was determined by suspending the ground, defatted sample in dilute sodium hydroxide solution. An appropriate dilution of the suspension was made, and series of aliquots resulting in increased levels of the diluted suspension was mixed with trypsin and benzoyl-DL-arginine-p-nitroanilide. After 10 minutes, the action of the trypsin was stopped by the addition of acetic acid. The diluted suspension mixture was filtered or centrifuged and the absorbance of each filtered solution was measured at 410 nm. Trypsin inhibitor activity was calculated from the change in absorbance values due to the aliquot volume. The limit of detection for this study was 1.0 Trypsin Inhibitor Unit (TIU)/mg fw.

Vitamin E (LCAT). The method used was based on a modification of a literature method (Cort *et al.*, 1983, Speek *et al*, 1985 and McMurray, *et al*, 1980). Samples were saponified to break down fat and release vitamin E. The saponified mixture was extracted with ethyl ether and quantitated directly by HPLC on a silica column. The limit of quantitation for this study was approximately 0.005 mg/g fw. The reference substance for this assay was United States Pharmacopeia (USP) alpha tocopherol, 100%, lot number L1.

3.8 Control of Bias

The test and control lines were treated identically at each site. Corn forage and grain tissues were ground thoroughly before use to minimize tissue bias. The samples were analyzed by site and the order of samples was randomized to minimize assay bias.

3.9 Data Reduction and Statistical Analysis

Composition data from Covance, Inc., containing individual values for each analysis, were checked for accuracy at Monsanto Company and then transferred to Certus International for statistical analysis. The statistical results were summarized by Certus International in a subreport that was archived in the study files. The following fifteen analytes with >85% of observations at or below the LOD of the assay were excluded from statistical analysis: sodium, 8:0 caprylic acid, 10:0 capric acid, 12:0 lauric acid, 14:0 myristic acid, 14:1 myristoleic acid, 15:0 pentadecanoic acid, 15:1 pentadecenoic acid, 16:1 palmitoleic acid, 17:0 heptadecanoic acid, 17:1 heptadecenoic acid, 18:3 gamma linolenic acid, 20:2 eicosadienoic acid, 20:3 eicosatrienoic acid and 20:4 arachidonic acid. For 22:0 behenic acid and tyrpsin inhibitor there were 2 out of 50 observations below the LOD of these assays. To include a complete dataset for these two analytes in the statistical analysis, values equal to half the detection limit were assigned for the missing four datapoints.

Except for moisture, all component values were converted from a fresh weight to a dry weight basis and into their respective units described in Tables 2-11. Statistical analyses were conducted using a randomized complete block model analysis of variance for five sets of comparisons for each component in forage and grain: analyses for each of the four replicated trials, MN, RD, VH and YK, and for a combination of all four trials. There were a total of 51 components evaluated (7 in forage and 44 in grain). The 44 components in grain resulted from the difference between the initial 59 components minus the 15 components specified above that were excluded because their levels were below the LOD. A total of 255 comparisons were made: 51 comparisons for each of the five statistical analyses.

Individual replicated trial analyses used the model:

$$Y_{ij} = U + T_i + B_j + e_{ij},$$

where Y_{ij} = unique individual observation, U = overall mean, T_i = line effect, B_j = random block effect and e_{ij} = residual error.

Combined site analyses used the model:

$$Y_{ijk} = U + T_i + L_j + B(L)_{jk} + LT_{ij} + e_{ijk},$$

where Y_{ijk} = unique individual observation, U = overall mean, T_i = line effect, L_j = random location effect, $B(L)_{jk}$ = random block within location effect, LT_{ij} = random location by line interaction effect and e_{ijk} = residual error. The test event, MON 863, was compared to the non-transgenic control line, MON 846, to determine statistically significant differences at $p < 0.05$.

Compositional analysis data from the commercial reference lines were not included in the statistical analysis. However, a range of the reference values was determined for each compositional analysis component. Additionally, the commercial reference line data was used to develop population tolerance intervals. A tolerance interval is an interval with a specified degree of confidence, 100(1-α)%, which contains at least a specified proportion, p, of an entire sampled population for the parameter measured. For each compositional analysis component, tolerance intervals were calculated that are expected to contain, with 95% confidence, 99% of the values expressed in the population of commercial lines. Because negative quantities are not possible, calculated lower tolerance bounds that were negative, were set to zero.

SAS® software (SAS Institute, 1999) was used to generate all summary statistics and perform all analyses. Report tables present p-values from SAS® as either <0.001 or the actual value truncated to three decimal places.

4.0 Results and Discussion

4.1 Test and Control Substances Characterization

The characterization was performed under a separate study (Dudin, *et al.*, 2001). DNA from leaf and grain samples of MON 863 from all sites gave the expected molecular fingerprint indicating that event identity had been maintained. The MON 846 samples were confirmed as non-transgenic controls.

4.2 Compositional Analyses of Corn Tissues

The compositional analysis data and statistical evaluation are summarized in Tables 2-11. For each component, least-square means, standard errors and the range of observed values are presented for each line. In addition, mean differences between the test and control line, standard errors of the differences, the range of observed differences, 95% confidence intervals of the differences and the significance probabilities are presented for each comparison. Component values are expressed as follows: amino acids as % total amino acids; proximates (except moisture), ADF, NDF, calcium, magnesium, phosphorus, phytic acid and potassium

as % dry weight; moisture as % fresh wt.; fatty acids as % total fatty acids; copper, iron, manganese and zinc as mg/kg dw; vitamin E as mg/g dw; and trypsin inhibitor in TIU/mg dw.

Fifty-one different compositional components were evaluated as part of the safety and nutritional assessment of maize event MON 863. The values for all the compositional components assessed were either within the range observed for commercial maize lines planted at the same U.S. sites in 1999, published literature ranges (Jugenheimer, 1976; Watson, 1982; Watson, 1987) or historical ranges for non-transgenic corn varieties (Sanders and Patzer, 1995; Sanders *et al.*, 1996a,b; 1997a,b,c).

Data was developed and statistical analyses conducted for five sets of comparisons: analyses for each of four replicated trials (MN, RD, VH, YK) and for a combination of trials across all four field sites. Therefore, a total of 255 comparisons were made: 51 comparisons for each of these five statistical analyses. These evaluations showed that there were no statistically significant differences in 224 of the 255 comparisons made between MON 863 and the control line. Thus there were no statistically significant differences between MON 863 and the control line for the content of fat, protein, ash, carbohydrate, ADF and NDF in forage, and for the content of ash, ADF, NDF, 12 of 18 amino acids, six of eight fatty acids above the LOD, potassium, magnesium and trypsin inhibitor in grain.

As shown in Table 1, statistically significant differences ($p<0.05$) between MON 863 and control were seen for: cystine and leucine (three comparisons each); total fat, protein, moisture, zinc, iron, phytic acid and vitamin E (two comparisons each); tyrosine, phenylalanine, aspartic acid, arginine, carbohydrate, calcium, copper, manganese, phosphorus, 20:0 arachidic acid, 18:3 linolenic acid (one comparison each). Of the 31 comparisons found to be statistically different, 5% or approximately thirteen (0.05×255), were expected to be false positives based on chance alone. Differences which were observed for only one to three of these comparisons, and not consistently across all five comparisons, are unlikely to be of biological significance. The magnitude of the differences as a percent of the control values ranged between 1.38%-15.52%. Furthermore, the range of values for those compositional components associated with the small statistically significant differences were found to all fall within the 95% tolerance interval for commercial varieties planted at the same U.S. sites in 1999 (Table 1). This demonstrates with a 95% confidence level that the levels of key nutrients and other compositional components for MON 863 were within the same population as expected for non-transgenic corn. Therefore, these minor differences are unlikely to be biologically meaningful and the grain from MON 863 is considered compositionally equivalent to that of conventional corn grain.

5.0 Conclusions

The results of compositional analyses showed that the 51 components measured in maize event MON 863 were within the range observed for commercial maize lines planted at the same U.S. sites in 1999. Futhermore, all 51 components were within published literature

ranges (Jugenheimer, 1976; Watson, 1982; Watson, 1987), or historical ranges for non-transgenic maize varieties (Sanders and Patzer, 1995; Sanders *et al.*, 1996a,b; 1997a,b,c). There were no statistically significant differences in 224 of the 255 comparisons made between maize event MON 863 and the control line, MON 846, which included the levels of forage (fat, protein, ash, carbohydrate, ADF and NDF) and grain (ash, ADF, NDF, 12 of 18 amino acids, six of eight fatty acids, potassium, magnesium and trypsin inhibitor) components.

Of the 31 comparisons found to be statistically different, 5% or approximately thirteen (0.05 × 255), were expected to be false positives based on chance alone. Differences that were observed for only one to three of these comparisons, and not consistently across all five comparisons, are unlikely to be of biological significance. The differences between the test event and the control line expressed as a percent of the control values ranged between 1.38%-15.52%. Furthermore, the range of values for those compositional components associated with the small statistical differences were found to all fall within the 95% tolerance interval for commercial varieties planted at the same U.S. sites in 1999. This demonstrates, with a confidence level of 95%, that the levels of key nutrients and other compositional components for MON 863 were within the same population as expected for non-transgenic commercial reference maize used in this study. Therefore, these minor differences are unlikely to be biologically meaningful, and the grain and forage from MON 863 are considered compositionally equivalent to that of conventional maize grain and forage.

These data, together with the safety of the Cry3Bb1 protein as demonstrated by rapid *in vitro* digestibility (Leach *et al.*, 2001; Hileman *et al.*, 2001), lack of homology to allergens and toxins (Hileman and Astwood, 2001b), lack of acute oral toxicity to mice (Bonnette and Pyla, 2001), the safety of registered *B.t.* formulations (e.g., Raven®) containing the Cry3Bb1 protein and the safe history of use of the host organism (maize) as a common source of animal feed and human food, support the conclusion that the corn rootworm protected maize event MON 863 is compositionally equivalent and as safe and nutritious as the maize varieties grown commercially today.

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Table 1. Summary of Statistically Significant Differences for the Comparison of MON 863 to Control and Commercial Varieties

Tissue/ Component	Site Code	Mean MON 863[b]	Mean Control[b]	Mean Difference[b] (MON 863 minus Control)	Significance[b] (p-value)	Mean Difference[c] (% of Control Value)	MON 863[b] (Range)	Commercial[b] (95% T. I.[d] Lower, Upper)
Forage								
Moisture (% fw)	RD	70.23	71.43	-1.20	0.023	-1.68	(69.80 - 70.50)	(62.70, 77.69)
Grain								
Cystine (% Total AA)	MN	2.18	2.03	0.15	0.012	7.39	(2.15 - 2.21)	(1.59, 2.65)
Leucine (% Total AA)	MN	13.17	13.59	-0.42	0.013	-3.09	(12.88 - 13.42)	(11.30, 15.63)
Phenylalanine (% Total AA)	MN	4.99	5.09	-0.093	0.038	-1.83	(4.93 - 5.06)	(4.53, 5.66)
Zinc (mg/kg dw)	MN	20.51	22.79	-2.28	0.038	-10.00	(19.71 - 21.41)	(6.31, 37.95)
Total Fat (% dw)	MN	3.87	3.35	0.52	0.046	15.52	(3.59 - 4.06)	(1.68, 4.64)
Phytic Acid (% dw)	MN	1.15	1.33	-0.18	0.027	-13.53	(1.08 - 1.21)	(0.39, 1.33)
Leucine (% Total AA)	RD	13.44	13.67	-0.23	0.023	-1.68	(13.33 - 13.63)	(11.30, 15.63)
Protein (% dw)	RD	11.82	12.16	-0.34	0.039	-2.80	(11.63 - 11.97)	(5.47, 16.57)
Vitamin E (mg/g dw)	RD	0.013	0.015	-0.0023	0.011	-15.33	(0.012 - 0.014)	(0, 0.019)
18:3 linolenic (% Total FA)	RD	1.26	1.28	-0.020	0.043	-1.56	(1.23 - 1.29)	(0.75, 1.51)
Cystine (% Total AA)	VH	2.25	2.15	0.11	0.001	5.12	(2.22 - 2.29)	(1.59, 2.65)
20:0 Arachidic (% Total FA)	VH	0.43	0.41	0.022	0.001	5.37	(0.43 - 0.44)	(0.30, 0.51)
Iron (mg/kg dw)	VH	21.73	21.20	0.53	0.013	2.50	(21.13 - 23.05)	(12.52, 35.06)
Total Fat (% dw)	VH	3.08	3.42	-0.34	0.037	-9.94	(3.00 - 3.24)	(1.68, 4.64)
Moisture (% fw)	VH	9.86	10.37	-0.51	0.039	-4.92	(9.38 - 10.30)	(5.09, 18.62)
Aspartic Acid (% Total AA)	YK	6.44	6.36	0.088	0.040	1.38	(6.42 - 6.47)	(5.54, 7.65)
Tyrosine (% Total AA)	YK	3.67	3.48	0.19	0.026	5.46	(3.59 - 3.74)	(2.15, 4.65)
Calcium (% dw)	YK	0.0044	0.0047	-0.00023	0.035	-4.89	(0.0041 - 0.0047)	(0.0022, 0.0073)
Copper (mg/kg dw)	YK	1.85	1.69	0.16	0.002	9.47	(1.72 - 2.01)	(0.25, 2.70)

(continued over)

Table 1. Summary of Statistically Significant Differences for the Comparison of MON 863 to Control and Commercial Varieties (continued)

Tissue/ Component[a]	Site Code	Mean MON 863[b]	Mean Control[b]	Mean Difference[b] (MON 863 minus Control)	Significance[b] (p-value)	Mean Difference[c] (% of Control Value)	MON 863[b] (Range)	Commercial[b] (95% Tolerance Int. Lower, Upper)
Grain								
Iron (mg/kg dw)	YK	24.87	27.45	-2.58	0.013	-9.40	(23.99 - 25.42)	(12.52, 35.06)
Manganese (mg/kg dw)	YK	7.17	7.91	-0.75	0.012	-9.48	(6.94 - 7.40)	(0, 12.84)
Phosphorus (% dw)	YK	0.39	0.43	-0.036	0.037	-8.37	(0.37 - 0.41)	(0.21 - 0.47)
Zinc (mg/kg dw)	YK	24.20	27.16	-2.96	0.013	-10.90	(23.54 - 25.25)	(6.31, 37.95)
Carbohydrate (% dw)	YK	82.56	81.28	1.28	0.046	1.57	(81.83 - 83.13)	(78.97, 90.36)
Protein (% dw)	YK	12.44	13.62	-1.18	0.009	-8.66	(12.19 - 12.82)	(5.47, 16.57)
Arginine (% Total AA)	All	4.43	4.33	0.10	0.030	2.31	(4.21 – 4.68)	(3.38 – 5.22)
Cystine (% Total AA)	All	2.20	2.09	0.11	<0.001	5.26	(1.98 - 2.40)	(1.59, 2.65)
Leucine (% Total AA)	All	13.36	13.65	-0.29	0.039	-2.12	(12.88 - 13.65)	(11.30, 15.63)
Phytic Acid (% dw)	All	1.11	1.23	-0.12	0.001	-9.76	(0.92 - 1.28)	(0.39, 1.33)
Vitamin E (mg/g dw)	All	0.011	0.013	-0.0015	0.002	-11.54	(0.0062 - 0.014)	(0, 0.019)

[a] dw = dry wt., fw = fresh wt.; AA = amino acids, FA = fatty acids.

[b] Data obtained from Tables 2-11.

[c] Calculated using the following expression: [Mean Difference = (MON 863 minus Control)/Mean Control * 100].

[d] T.I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.

Table 2. Replicated Trial (MN, Illinois): Fiber and Proximate Content of Forage and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Historical[g] Range
Ash (% dw)	4.50 ± 0.32 (3.62 - 5.28)	4.81 ± 0.32 (4.19 - 5.56)	-0.32 ± 0.45 (-1.01 - 1.09)	0.530	-1.74, 1.11	3.74 - 5.02 (3.04, 5.58)	2.9 - 5.1
Carbohydrates (% dw)	84.86 ± 076 (83.46 - 86.32)	84.36 ± 0.76 (82.71 - 86.02)	0.51 ± 0.93 (-2.01 - 2.52)	0.626	-2.47, 3.48	82.59 - 87.10 (81.22, 88.97)	84.6 - 89.1
ADF (% dw)	26.53 ± 0.88 (24.06 - 28.57)	30.46 ± 0.88 (28.15 - 32.08)	-3.93 ± 1.25 (-6.96 - 0.42)	0.051	-7.91,0.045	19.78 - 39.00 (9.33, 45.44)	21.4 - 29.2
NDF (% dw)	45.05 ± 1.90 (41.04 - 48.70)	46.15 ± 1.90 (43.96 - 51.85)	-1.10 ± 2.68 (-10.81 - 3.90)	0.709	-9.64, 7.44	30.30 - 47.75 (22.71, 56.02)	39.9 - 46.6
Moisture (% fw)	71.48 ± 0.67 (69.30 - 73.10)	72.80 ± 0.67 (72.10 - 73.40)	-1.33 ± 0.94 (-3.70 - 1.00)	0.253	-4.32,1.67	67.00 - 74.10 (62.70, 77.69)	68.7 - 73.5
Protein (% dw)	8.04 ± 0.60 (6.91 - 9.52)	8.56 ± 0.60 (7.20 - 9.78)	-0.51 ± 0.82 (-2.54 - 1.31)	0.576	-3.13,2.10	6.45 - 10.14 (4.94, 11.97)	4.8 - 8.4
Total fat (% dw)	2.57 ± 0.17 (2.10 - 3.08)	2.26 ± 0.17 (1.94 - 2.58)	0.30 ± 0.24 (-0.48 - 1.14)	0.303	-0.48,1.08	1.39 - 2.62 (1.03, 3.24)	1.4 - 2.1

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt.
[b]The mean of four replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]The range of sample values for commercial lines grown at the same U.S. sites in 1999.
[f]T.I = tolerance interval, specified to contain 99% of commercial line population, negative limits set to zero.
[g]Range for control lines analyzed in Monsanto Company trials conducted in 1994 and 1995 (Sanders *et al.*, 1996b; 1997a)

Table 3. Replicated Trial (MN, Illinois): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Amino acids (% of total)								
Alanine	7.71 ± 0.064 (7.65 - 7.76)	7.70 ± 0.064 (7.46 - 7.88)	0.014 ± 0.087 (-0.15 - 0.24)	0.885	-0.26,0.29	7.30 - 8.06 (6.94, 8.46)	6.4-9.9	7.2-8.8
Arginine	4.55 ± 0.052 (4.47 - 4.68)	4.54 ± 0.052 (4.37 - 4.63)	0.016 ± 0.074 (-0.16 - 0.19)	0.844	-0.22,0.25	3.86 - 4.83 (3.38, 5.22)	2.9-5.9	3.5-5.0
Aspartic acid	6.64 ± 0.064 (6.53 - 6.72)	6.54 ± 0.064 (6.31 - 6.67)	0.097 ± 0.043 (0.050 - 0.23)	0.107	-0.039,0.23	6.05 - 7.14 (5.54, 7.65)	5.8-7.2	6.3-7.5
Cystine	2.18 ± 0.020 (2.15 - 2.21)	2.03 ± 0.020 (1.99 - 2.10)	0.15 ± 0.027 (0.075 - 0.20)	0.012	0.061,0.23	1.84 - 2.35 (1.59, 2.65)	1.2-1.6	1.8-2.7
Glutamic acid	19.26 ± 0.12 (19.08 - 19.40)	19.32 ± 0.12 (18.97 - 19.66)	-0.067 ± 0.17 (-0.43 - 0.24)	0.726	-0.62,0.49	18.31 - 20.25 (17.55, 21.25)	12.4-19.6	18.6-22.8
Glycine	3.68 ± 0.062 (3.63 - 3.74)	3.57 ± 0.062 (3.32 - 3.70)	0.11 ± 0.068 (0.0063 - 0.31)	0.191	-0.10,0.33	3.20 - 4.13 (2.81, 4.46)	2.6-4.7	3.2-4.2
Histidine	2.84 ± 0.020 (2.78 - 2.89)	2.88 ± 0.020 (2.85 - 2.90)	-0.039 ± 0.020 (-0.075 - 0.0036)	0.141	-0.10,0.024	2.60 - 3.20 (2.37, 3.35)	2.0-2.8	2.8-3.4
Isoleucine	3.66 ± 0.067 (3.53 - 3.89)	3.72 ± 0.067 (3.64 - 3.83)	-0.061 ± 0.063 (-0.21 - 0.056)	0.406	-0.26,0.14	3.47 - 3.94 (3.20, 4.17)	2.6-4.0	3.2-4.3
Leucine	13.17 ± 0.14 (12.88 - 13.42)	13.59 ± 0.14 (13.27 - 14.07)	-0.42 ± 0.080 (-0.65 - -0.27)	0.013	-0.67,-0.16	11.94 - 14.47 (11.30, 15.63)	7.8-15.2	12.0-15.8

(*continued over*)

Table 3. Replicated Trial (MN, Illinois): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Lysine	3.07 ± 0.052 (2.95 - 3.26)	2.99 ± 0.052 (2.93 - 3.06)	0.079 ± 0.063 (-0.057 - 0.24)	0.296	-0.12,0.28	2.40 - 3.52 (1.87, 3.89)	2.0-3.8	2.6-3.5
Methionine	2.12 ± 0.070 (1.89 - 2.32)	2.08 ± 0.070 (1.96 - 2.15)	0.038 ± 0.056 (-0.069 - 0.20)	0.552	-0.14,0.22	1.61 - 2.29 (1.34, 2.74)	1.0-2.1	1.3-2.6
Phenylalanine	4.99 ± 0.042 (4.93 - 5.06)	5.09 ± 0.042 (4.97 - 5.23)	-0.093 ± 0.026 (-0.17 - -0.043)	0.038	-0.18,-0.0094	4.80 - 5.35 (4.53, 5.66)	2.9-5.7	4.9-6.1
Proline	8.72 ± 0.095 (8.58 - 8.98)	8.77 ± 0.095 (8.64 - 9.05)	-0.050 ± 0.024 (-0.091 - 0.020)	0.130	-0.13,0.027	8.57 - 9.61 (8.04, 10.35)	6.6-10.3	8.7-10.1
Serine	4.74 ± 0.20 (3.93 - 5.08)	4.82 ± 0.20 (4.70 - 4.89)	-0.087 ± 0.23 (-0.77 - 0.23)	0.732	-0.83,0.65	4.24 - 4.99 (3.76, 5.69)	4.2-5.5	4.9-6.0
Threonine	3.45 ± 0.073 (3.16 - 3.55)	3.42 ± 0.073 (3.31 - 3.49)	0.029 ± 0.062 (-0.15 - 0.12)	0.672	-0.17,0.23	3.19 - 3.59 (2.93, 3.83)	2.9-3.9	3.3-4.2
Tryptophan	0.66 ± 0.0072 (0.65 - 0.68)	0.66 ± 0.0072 (0.66 - 0.68)	0.00049 ± 0.0073 (-0.013 - 0.019)	0.950	-0.023,0.024	0.54 - 0.82 (0.37, 0.90)	0.5-1.2	0.4-1.0
Tyrosine	3.64 ± 0.18 (3.55 - 3.76)	3.41 ± 0.18 (2.71 - 3.82)	0.24 ± 0.23 (-0.065 - 0.92)	0.390	-0.51,0.98	2.60 - 3.73 (2.15, 4.65)	2.9-4.7	3.7-4.3
Valine	4.92 ± 0.085 (4.78 - 5.13)	4.88 ± 0.085 (4.64 - 5.05)	0.044 ± 0.12 (-0.24 - 0.50)	0.737	-0.34,0.43	4.49 - 5.30 (4.15, 5.63)	2.1-5.2	4.2-5.3

(continued over)

Table 3. Replicated Trial (MN, Illinois): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fatty acids (% of total)								
16:0 palmitic acid	11.86 ± 0.051 (11.77 - 11.94)	11.93 ± 0.051 (11.85 - 12.10)	-0.072 ± 0.056 (-0.19 - 0.070)	0.284	-0.25,0.10	9.07 - 12.14 (7.74, 13.87)	7-19	9.9-12.0
18:0 stearic acid	1.68 ± 0.011 (1.64 - 1.70)	1.66 ± 0.011 (1.64 - 1.68)	0.021 ± 0.012 (-0.015 - 0.038)	0.184	-0.018,0.059	1.44 - 2.40 (1.04, 2.68)	1-3	1.4-2.2
18:1 oleic acid	21.73 ± 0.12 (21.60 - 21.90)	21.48 ± 0.12 (21.21 - 21.86)	0.25 ± 0.096 (0.042 - 0.44)	0.079	-0.055,0.56	21.26 - 32.06 (13.28, 36.31)	20-46	20.6-27.5
18:2 linoleic acid	62.62 ± 0.13 (62.35 - 62.81)	62.80 ± 0.13 (62.45 - 63.16)	-0.18 ± 0.083 (-0.36 - 0.0051)	0.113	-0.45,0.080	54.15 - 63.64 (50.21, 70.86)	35-70	55.9-66.1
18:3 linolenic acid	1.22 ± 0.012 (1.21 - 1.23)	1.22 ± 0.012 (1.18 - 1.26)	0.0054 ± 0.017 (-0.037 - 0.045)	0.764	-0.047,0.058	0.97 - 1.36 (0.75, 1.51)	0.8-2	0.8-1.1
20:0 arachidic acid	0.41 ± 0.0042 (0.40 - 0.42)	0.41 ± 0.0042 (0.40 - 0.42)	-0.0042 ± 0.0044 (-0.017 - 0.0026)	0.405	-0.018,0.0098	0.35 - 0.45 (0.30, 0.51)	0.1-2	0.3-0.5
20:1 eicosenoic acid	0.31 ± 0.0078 (0.30 - 0.31)	0.32 ± 0.0078 (0.30 - 0.35)	-0.0067 ± 0.011 (-0.039 - 0.0090)	0.582	-0.042,0.028	0.25 - 0.39 (0.18, 0.42)	na	0.2-0.3
22:0 behenic acid	0.18 ± 0.0026 (0.17 - 0.18)	0.19 ± 0.0026 (0.18 - 0.20)	-0.012 ± 0.0037 (-0.023 - -0.0063)	0.051	-0.023,0.00010	0.089 - 0.21 (0.055, 0.30)	na	0.1-0.3

(continued over)

Table 3. Replicated Trial (MN, Illinois): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Minerals								
Calcium (% dw)	0.0052 ± 0.00016 (0.0049 - 0.0055)	0.0055 ± 0.00016 (0.0052 - 0.0060)	-0.00025 ± 0.00022 (-0.00081 - 0.00032)	0.346	-0.00095, 0.00046	0.0039 - 0.0060 (0.0022, 0.0073)	0.01-0.1	0.003-0.006
Copper (mg/kg dw)	2.18 ± 0.069 (2.04 - 2.34)	2.22 ± 0.069 (2.11 - 2.45)	-0.040 ± 0.086 (-0.25 - 0.17)	0.675	-0.32,0.24	1.03 - 2.15 (0.25, 2.70)	0.9-10	na
Iron (mg/kg dw)	22.01 ± 0.51 (21.17 - 23.21)	23.30 ± 0.51 (21.69 - 24.19)	-1.29 ± 0.72 (-2.30 - 1.52)	0.169	-3.57,0.99	16.74 - 28.69 (12.52, 35.06)	1-100	na
Magnesium (% dw)	0.13 ± 0.0036 (0.13 - 0.14)	0.14 ± 0.0036 (0.14 - 0.16)	-0.010 ± 0.0048 (-0.018 - 0.0031)	0.120	-0.026,0.0050	0.091 - 0.14 (0.082, 0.17)	0.09-1.0	na
Manganese (mg/kg dw)	5.06 ± 0.21 (4.37 - 5.48)	5.48 ± 0.21 (5.11 - 5.77)	-0.41 ± 0.28 (-0.94 - 0.37)	0.234	-1.30,0.47	3.51 - 9.80 (0, 12.84)	0.7-54	na
Phosphorus (% dw)	0.39 ± 0.0099 (0.37 - 0.41)	0.43 ± 0.0099 (0.40 - 0.46)	-0.040 ± 0.014 (-0.068 - 0.0013)	0.064	-0.084,0.0045	0.27 - 0.41 (0.21, 0.47)	0.26-0.75	0.288-0.363
Potassium (% dw)	0.42 ± 0.011 (0.40 - 0.44)	0.45 ± 0.011 (0.42 - 0.48)	-0.029 ± 0.014 (-0.046 - 0.014)	0.133	-0.075,0.016	0.33 - 0.43 (0.28, 0.48)	0.32-0.72	na
Zinc (mg/kg dw)	20.51 ± 0.46 (19.71 - 21.41)	22.79 ± 0.46 (21.35 - 23.96)	-2.28 ± 0.65 (-3.36 - 0.064)	0.038	-4.34,-0.22	12.84 - 31.22 (6.31, 37.95)	12-30	na

(continued over)

Table 3. Replicated Trial (MN, Illinois): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fiber and Proximates								
Ash (% dw)	1.47 ± 0.044 (1.34 - 1.56)	1.57 ± 0.044 (1.50 - 1.67)	-0.092 ± 0.041 (-0.17 - -0.011)	0.110	-0.22,0.038	0.62 - 1.53 (0.26, 2.06)	1.1-3.9	1.2-1.8
Carbohydrates (% dw)	83.17 ± 0.30 (82.64 - 84.12)	82.94 ± 0.30 (82.45 - 83.43)	0.23 ± 0.42 (-0.78 - 1.67)	0.628	-1.12,1.57	82.51 - 87.84 (78.97, 90.36)	na	81.7-86.3
ADF (% dw)	4.62 ± 0.31 (4.23 - 5.23)	4.26 ± 0.31 (3.62 - 5.08)	0.37 ± 0.35 (-0.47 - 1.16)	0.368	-0.74,1.47	3.65 - 6.09 (1.98, 6.62)	3.3 - 4.3	3.1 - 5.3
NDF (% dw)	11.96 ± 0.54 (9.94 - 13.47)	11.34 ± 0.54 (10.96 - 11.70)	0.62 ± 0.76 (-1.75 - 1.84)	0.476	-1.80,3.03	9.50 - 14.95 (6.51, 16.28)	8.3-11.9	9.6 - 15.3
Moisture (% fw)	10.90 ± 0.13 (10.70 - 11.20)	11.05 ± 0.13 (10.70 - 11.40)	-0.15 ± 0.13 (-0.50 - 0.10)	0.339	-0.57,0.27	8.75 - 15.70 (5.09, 18.62)	7-23	9.4 - 15.8
Total fat (% dw)	3.87 ± 0.11 (3.59 - 4.06)	3.35 ± 0.11 (3.05 - 3.61)	0.52 ± 0.16 (-0.018 - 1.02)	0.046	0.015, 1.03	2.18 - 3.86 (1.68, 4.64)	3.1-5.7, 2.9-6.1	2.4-4.2
Protein (% dw)	11.51 ± 0.23 (10.86 - 11.78)	12.14 ± 0.23 (11.57 - 12.64)	-0.63 ± 0.32 (-1.52 - 0.086)	0.145	-1.65, 0.39	7.95 - 13.83 (5.47, 16.57)	6.0 - 12.0, 9.7 - 16.1	9.0 - 13.6

(continued over)

Table 3. Replicated Trial (MN, Illinois): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Miscellaneous								
Phytic Acid (% dw)	1.15 ± 0.032 (1.08 - 1.21)	1.33 ± 0.032 (1.25 - 1.37)	-0.18 ± 0.045 (-0.28 - -0.048)	0.027	-0.32,-0.037	0.73 - 1.17 (0.39, 1.33)	to 0.9%	na
Trypsin Inhibitor (TIU/mg dw)	1.79 ± 0.32 (0.56 - 2.65)	2.19 ± 0.32 (2.02 - 2.26)	-0.40 ± 0.45 (-1.70 - 0.63)	0.446	-1.84, 1.05	0.58 - 3.05 (0, 4.25)	na	na
Vitamin E (mg/g dw)	0.013 ± 0.00052 (0.013 - 0.014)	0.014 ± 0.00052 (0.012 - 0.015)	-0.00059 ± 0.00073 (-0.0020 - 0.00090)	0.480	-0.0029, 0.0017	0.0041 - 0.014 (0, 0.019)	0.017-0.047	0.008-0.015

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt; TIU = trypsin inhibitor units.
[b]The mean of four replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]Comm. = commercial. The range of sample values for commercial lines grown at the same U.S. sites in 1999.
[f]T. I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.
[g]Lit. = literature. For amino and fatty acids, Watson, 1982; for all other components, Watson, 1987; protein and fat second values from Jugenheimer, 1976.
[h]Hist. = historical. Range for control lines analyzed in Monsanto trials conducted between 1993 and 1995 (Sanders and Patzer, 1995; Sanders *et al.*, 1996a,b; 1997a,b,c).

Table 4. Replicated Trial (RD, Iowa): Fiber and Proximate Content of Forage and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Historical[g] Range
Ash (% dw)	4.83 ± 0.18 (4.63 - 5.26)	5.32 ± 0.18 (4.95 - 5.93)	-0.50 ± 0.26 (-1.23 - -0.017)	0.149	-1.32,0.33	3.74 - 5.02 (3.04, 5.58)	2.9 - 5.1
Carbohydrates (% dw)	83.97 ± 0.59 (82.45 - 85.76)	83.89 ± 0.59 (82.86 - 84.48)	0.078 ± 0.82 (-1.35 - 1.71)	0.930	-2.54,2.69	82.59 - 87.10 (81.22, 88.97)	84.6 - 89.1
ADF (% dw)	24.99 ± 1.33 (21.74 - 27.09)	25.60 ± 1.33 (23.39 - 29.64)	-0.61 ± 1.88 (-7.90 - 3.43)	0.766	-6.58,5.36	19.78 - 39.00 (9.33, 45.44)	21.4 - 29.2
NDF (% dw)	41.35 ± 2.07 (37.97 - 49.67)	39.90 ± 2.07 (37.32 - 41.79)	1.45 ± 2.93 (-2.86 - 12.34)	0.654	-7.88,10.79	30.30 - 47.75 (22.71, 56.02)	39.9 - 46.6
Moisture (% fw)	70.23 ± 0.20 (69.80 - 70.50)	71.43 ± 0.20 (71.00 - 72.00)	-1.20 ± 0.28 (-1.80 - -0.50)	0.023	-2.09,-0.31	67.00 - 74.10 (62.70, 77.69)	68.7 - 73.5
Protein (% dw)	8.78 ± 0.51 (7.08 - 10.40)	8.32 ± 0.51 (7.76 - 8.86)	0.47 ± 0.65 (-0.67 - 2.26)	0.523	-1.59,2.52	6.45 - 10.14 (4.94, 11.97)	4.8 - 8.4
Total fat (% dw)	2.47 ± 0.22 (1.87 - 3.16)	2.49 ± 0.22 (2.08 - 2.78)	-0.020 ± 0.31 (-0.91 - 1.09)	0.954	-1.02,0.98	1.39 - 2.62 (1.03, 3.24)	1.4 - 2.1

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt.
[b]The mean of four replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]The range of sample values for commercial lines grown at the same U.S. sites in 1999.
[f]T. I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.
[g]Range for control lines analyzed in Monsanto Company trials conducted in 1994 and 1995 (Sanders *et al.*, 1996b; 1997a).

Table 5. Replicated Trial (RD, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Amino acids (% of total)								
Alanine	7.76 ± 0.025 (7.71 - 7.82)	7.82 ± 0.025 (7.76 - 7.88)	-0.065 ± 0.028 (-0.12 - 0.0082)	0.100	-0.15,0.023	7.30 - 8.06 (6.94, 8.46)	6.4-9.9	7.2-8.8
Arginine	4.43 ± 0.051 (4.34 - 4.59)	4.31 ± 0.051 (4.19 - 4.40)	0.12 ± 0.070 (-0.00066 - 0.30)	0.190	-0.11,0.34	3.86 - 4.83 (3.38, 5.22)	2.9-5.9	3.5-5.0
Aspartic acid	6.41 ± 0.021 (6.38 - 6.45)	6.36 ± 0.021 (6.30 - 6.41)	0.057 ± 0.030 (-0.030 - 0.11)	0.153	-0.039,0.15	6.05 - 7.14 (5.54, 7.65)	5.8-7.2	6.3-7.5
Cystine	2.21 ± 0.065 (2.08 - 2.40)	2.12 ± 0.065 (2.01 - 2.29)	0.096 ± 0.091 (-0.11 - 0.39)	0.372	-0.20,0.39	1.84 - 2.35 (1.59, 2.65)	1.2-1.6	1.8-2.7
Glutamic acid	19.45 ± 0.064 (19.36 - 19.67)	19.58 ± 0.064 (19.43 - 19.68)	-0.13 ± 0.060 (-0.25 - -0.0032)	0.124	-0.32,0.064	18.31 - 20.25 (17.55, 21.25)	12.4-19.6	18.6-22.8
Glycine	3.56 ± 0.025 (3.47 - 3.62)	3.49 ± 0.025 (3.45 - 3.51)	0.069 ± 0.035 (-0.026 - 0.17)	0.147	-0.044,0.18	3.20 - 4.13 (2.81, 4.46)	2.6-4.7	3.2-4.2
Histidine	2.79 ± 0.018 (2.74 - 2.84)	2.79 ± 0.018 (2.76 - 2.81)	0.0076 ± 0.024 (-0.058 - 0.059)	0.773	-0.070,0.085	2.60 - 3.20 (2.37, 3.35)	2.0-2.8	2.8-3.4
Isoleucine	3.61 ± 0.034 (3.50 - 3.68)	3.66 ± 0.034 (3.61 - 3.75)	-0.053 ± 0.048 (-0.24 - 0.029)	0.347	-0.20,0.099	3.47 - 3.94 (3.20, 4.17)	2.6-4.0	3.2-4.3
Leucine	13.44 ± 0.066 (13.33 - 13.63)	13.67 ± 0.066 (13.50 - 13.78)	-0.23 ± 0.054 (-0.39 - -0.16)	0.023	-0.40,-0.058	11.94 - 14.47 (11.30, 15.63)	7.8-15.2	12.0-15.8

(continued over)

Table 5. Replicated Trial (RD, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Lysine	2.79 ± 0.045 (2.65 - 2.88)	2.74 ± 0.045 (2.67 - 2.85)	0.056 ± 0.064 (-0.19 - 0.21)	0.448	-0.15,0.26	2.40 - 3.52 (1.87, 3.89)	2.0-3.8	2.6-3.5
Methionine	2.31 ± 0.060 (2.23 - 2.39)	2.37 ± 0.060 (2.26 - 2.58)	-0.058 ± 0.066 (-0.20 - 0.12)	0.443	-0.27,0.15	1.61 - 2.29 (1.34, 2.74)	1.0-2.1	1.3-2.6
Phenylalanine	4.97 ± 0.022 (4.93 - 5.04)	5.00 ± 0.022 (4.95 - 5.04)	-0.031 ± 0.014 (-0.072 - -0.0059)	0.122	-0.076,0.015	4.80 - 5.35 (4.53, 5.66)	2.9-5.7	4.9-6.1
Proline	8.69 ± 0.050 (8.61 - 8.78)	8.75 ± 0.050 (8.64 - 8.86)	-0.054 ± 0.059 (-0.20 - 0.087)	0.429	-0.24,0.13	8.57 - 9.61 (8.04, 10.35)	6.6-10.3	8.7-10.1
Serine	4.92 ± 0.038 (4.83 - 5.06)	4.90 ± 0.038 (4.85 - 4.94)	0.022 ± 0.053 (-0.11 - 0.15)	0.711	-0.15,0.19	4.24 - 4.99 (3.76, 5.69)	4.2-5.5	4.9-6.0
Threonine	3.43 ± 0.017 (3.36 - 3.47)	3.39 ± 0.017 (3.37 - 3.40)	0.041 ± 0.024 (-0.018 - 0.092)	0.184	-0.035,0.12	3.19 - 3.59 (2.93, 3.83)	2.9-3.9	3.3-4.2
Tryptophan	0.69 ± 0.035 (0.62 - 0.83)	0.66 ± 0.035 (0.63 - 0.68)	0.027 ± 0.047 (-0.043 - 0.17)	0.601	-0.12,0.18	0.54 - 0.82 (0.37, 0.90)	0.5-1.2	0.4-1.0
Tyrosine	3.67 ± 0.14 (3.63 - 3.77)	3.54 ± 0.14 (2.97 - 3.78)	0.13 ± 0.20 (-0.14 - 0.81)	0.559	-0.50,0.75	2.60 - 3.73 (2.15, 4.65)	2.9-4.7	3.7-4.3
Valine	4.86 ± 0.037 (4.71 - 4.95)	4.87 ± 0.037 (4.86 - 4.88)	-0.0036 ± 0.053 (-0.17 - 0.090)	0.949	-0.17,0.16	4.49 - 5.30 (4.15, 5.63)	2.1-5.2	4.2-5.3

(continued over)

Table 5. Replicated Trial (RD, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fatty acids (% of total)								
16:0 palmitic acid	11.68 ± 0.038 (11.61 - 11.73)	11.74 ± 0.038 (11.66 - 11.88)	-0.056 ± 0.040 (-0.15 - 0.026)	0.258	-0.18,0.072	9.07 - 12.14 (7.74, 13.87)	7-19	9.9-12.0
18:0 stearic acid	1.72 ± 0.0091 (1.71 - 1.73)	1.75 ± 0.0091 (1.71 - 1.77)	-0.027 ± 0.013 (-0.059 - 0.014)	0.126	-0.068,0.014	1.44 - 2.40 (1.04, 2.68)	1-3	1.4-2.2
18:1 oleic acid	22.29 ± 0.055 (22.20 - 22.52)	22.36 ± 0.055 (22.33 - 22.42)	-0.070 ± 0.054 (-0.14 - 0.091)	0.286	-0.24,0.10	21.26 - 32.06 (13.28, 36.31)	20-46	20.6-27.5
18:2 linoleic acid	62.20 ± 0.076 (61.94 - 62.36)	62.03 ± 0.076 (61.87 - 62.13)	0.17 ± 0.083 (-0.061 - 0.32)	0.126	-0.089,0.44	54.15 - 63.64 (50.21, 70.86)	35-70	55.9-66.1
18:3 linolenic acid	1.26 ± 0.011 (1.23 - 1.29)	1.28 ± 0.011 (1.26 - 1.30)	-0.020 ± 0.0060 (-0.034 - -0.0052)	0.043	-0.039,-0.0011	0.97 - 1.36 (0.75, 1.51)	0.8-2	0.8-1.1
20:0 arachidic acid	0.39 ± 0.0027 (0.39 - 0.40)	0.40 ± 0.0027 (0.39 - 0.40)	-0.0036 ± 0.0025 (-0.0073 - 0.0036)	0.238	-0.012,0.0042	0.35 - 0.45 (0.30, 0.51)	0.1-2	0.3-0.5
20:1 eicosenoic acid	0.28 ± 0.0021 (0.28 - 0.29)	0.29 ± 0.0021 (0.28 - 0.29)	-0.0017 ± 0.0029 (-0.0095 - 0.0039)	0.604	-0.011,0.0076	0.25 - 0.39 (0.18, 0.42)	na	0.2-0.3
22:0 behenic acid	0.17 ± 0.0034 (0.17 - 0.17)	0.17 ± 0.0034 (0.15 - 0.17)	0.0051 ± 0.0048 (-0.0069 - 0.021)	0.369	-0.010,0.020	0.089 - 0.21 (0.055, 0.30)	na	0.1-0.3

(continued over)

Table 5. Replicated Trial (RD, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Minerals								
Calcium (% dw)	0.0049 ± 0.00012 (0.0047 - 0.0050)	0.0047 ± 0.00012 (0.0043 - 0.0050)	0.00027 ± 0.00010 (0 - 0.00043)	0.064	-0.00003,0.00057	0.0039 - 0.0060 (0.0022, 0.0073)	0.01-0.1	0.003-0.006
Copper (mg/kg dw)	2.43 ± 0.041 (2.35 - 2.56)	2.33 ± 0.041 (2.28 - 2.41)	0.10 ± 0.057 (-0.0043 - 0.28)	0.174	-0.081,0.28	1.03 - 2.15 (0.25, 2.70)	0.9-10	na
Iron (mg/kg dw)	25.61 ± 0.60 (24.91 - 26.36)	24.78 ± 0.60 (23.75 - 27.09)	0.82 ± 0.62 (-0.73 - 1.83)	0.274	-1.14,2.79	16.74 - 28.69 (12.52, 35.06)	1-100	na
Magnesium (% dw)	0.14 ± 0.0014 (0.13 - 0.14)	0.14 ± 0.0014 (0.14 - 0.14)	0.00044 ± 0.0015 (-0.0031 - 0.0042)	0.789	-0.0043,0.0052	0.091 - 0.14 (0.082, 0.17)	0.09-1.0	na
Manganese (mg/kg dw)	6.93 ± 0.17 (6.46 - 7.36)	6.96 ± 0.17 (6.68 - 7.38)	-0.029 ± 0.24 (-0.92 - 0.58)	0.911	-0.80,0.74	3.51 - 9.80 (0, 12.84)	0.7-54	na
Phosphorus (% dw)	0.42 ± 0.0059 (0.41 - 0.45)	0.43 ± 0.0059 (0.42 - 0.44)	-0.0017 ± 0.0075 (-0.015 - 0.019)	0.835	-0.026,0.022	0.27 - 0.41 (0.21, 0.47)	0.26-0.75	0.288-0.363
Potassium (% dw)	0.45 ± 0.0065 (0.44 - 0.48)	0.45 ± 0.0065 (0.44 - 0.45)	0.0085 ± 0.0092 (-0.0058 - 0.037)	0.424	-0.021,0.038	0.33 - 0.43 (0.28, 0.48)	0.32-0.72	na
Zinc (mg/kg dw)	24.81 ± 0.16 (24.25 - 25.13)	24.64 ± 0.16 (24.29 - 24.85)	0.17 ± 0.11 (-0.040 - 0.48)	0.233	-0.19,0.52	12.84 - 31.22 (6.31, 37.95)	12-30	na

(continued over)

Table 5. Replicated Trial (RD, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fiber/Proximates								
Ash (% dw)	1.48 ± 0.055 (1.41 - 1.47)	1.43 ± 0.055 (1.21 - 1.53)	-0.00097 ± 0.078 (-0.12 - 0.27)	0.990	-0.25,0.25	0.62 - 1.53 (0.26, 2.06)	1.1-3.9	1.2-1.8
Carbohydrates (% dw)	82.68 ± 0.16 (82.36 - 83.06)	82.61 ± 0.16 (82.09 - 82.91)	0.072 ± 0.23 (-0.55 - 0.57)	0.773	-0.66,0.80	82.51 - 87.84 (78.97, 90.36)	na	81.7-86.3
ADF (% dw)	4.13 ± 0.22 (3.49 - 4.63)	4.14 ± 0.22 (3.83 - 4.64)	-0.017 ± 0.21 (-0.45 - 0.47)	0.941	-0.68,0.65	3.65 - 6.09 (1.98, 6.62)	3.3 - 4.3	3.1 - 5.3
NDF (% dw)	10.85 ± 0.52 (9.21 - 12.68)	10.58 ± 0.52 (10.31 - 10.93)	0.27 ± 0.74 (-1.10 - 2.30)	0.740	-2.08,2.62	9.50 - 14.95 (6.51, 16.28)	8.3-11.9	9.6 - 15.3
Moisture (% fw)	8.81 ± 0.073 (8.54 - 8.94)	8.70 ± 0.073 (8.60 - 8.82)	0.11 ± 0.076 (-0.10 - 0.26)	0.243	-0.13,0.35	8.75 - 15.70 (5.09, 18.62)	7-23	9.4 - 15.8
Total fat (% dw)	4.07 ± 0.097 (3.94 - 4.26)	3.84 ± 0.097 (3.55 - 4.08)	0.23 ± 0.14 (0.0066 - 0.71)	0.195	-0.21,0.66	2.18 - 3.86 (1.68, 4.64)	3.1-5.7, 2.9-6.1	2.4-4.2
Protein (% dw)	11.82 ± 0.094 (11.63 - 11.97)	12.16 ± 0.094 (12.04 - 12.48)	-0.34 ± 0.098 (-0.56 - -0.094)	0.039	-0.65,-0.031	7.95 - 13.83 (5.47, 16.57)	6.0 - 12.0, 9.7 - 16.1	9.0 - 13.6

(continued over)

Table 5. Replicated Trial (RD, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Miscellaneous								
Phytic Acid (% dw)	1.15 ± 0.057 (0.97 - 1.28)	1.23 ± 0.057 (1.15 - 1.31)	-0.081 ± 0.076 (-0.28 - 0.086)	0.365	-0.32,0.16	0.73 - 1.17 (0.39, 1.33)	to 0.9%	na
Trypsin Inhibitor (TIU/mg dw)	2.51 ± 0.09 (2.33 - 2.66)	2.43 ± 0.093 (2.13 - 2.60)	0.080 ± 0.076 (-0.10 - 0.21)	0.373	-0.16,0.32	0.58 - 3.05 (0, 4.25)	na	na
Vitamin E (mg/g dw)	0.013 ± 0.00031 (0.012 - 0.014)	0.015 ± 0.00031 (0.015 - 0.016)	-0.0023 ± 0.00041 (-0.0032 - -0.0013)	0.011	-0.0036, -0.00095	0.0041 - 0.014 (0, 0.019)	0.017-0.047	0.008-0.015

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt; TIU = trypsin inhibitor units.
[b]The mean of four replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]Comm. = commercial. The range of sample values for commercial lines grown at the same U. S. sites in 1999.
[f]T. I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.
[g]Lit. = literature. For amino and fatty acids, Watson, 1982; for all other components, Watson, 1987; protein and fat second values from Jugenheimer, 1976.
[h]Hist. = historical. Range for control lines analyzed in Monsanto trials conducted between 1993 and 1995 (Sanders and Patzer, 1995; Sanders *et al.*, 1996a,b; 1997a,b,c).

Table 6. Replicated Trial (VH, Iowa): Fiber and Proximate Content of Forage and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Historical[g] Range
Ash (% dw)	4.43 ± 0.24 (3.95 - 5.16)	4.38 ± 0.24 (3.81 - 4.79)	0.048 ± 0.17 (-0.41 - 0.37)	0.788	-0.48,0.57	3.74 - 5.02 (3.04, 5.58)	2.9 - 5.1
Carbohydrates (% dw)	84.76 ± 0.32 (84.51 - 85.47)	86.12 ± 0.32 (85.52 - 87.21)	-1.36 ± 0.45 (-2.70 - -0.20)	0.056	-2.78,0.068	82.59 - 87.10 (81.22, 88.97)	84.6 - 89.1
ADF (% dw)	34.62 ± 2.47 (28.31 - 43.30)	28.69 ± 2.47 (26.73 - 29.76)	5.93 ± 3.30 (-1.45 - 14.03)	0.170	-4.57,16.43	19.78 - 39.00 (9.33, 45.44)	21.4 - 29.2
NDF (% dw)	44.29 ± 1.41 (41.78 - 46.39)	43.86 ± 1.41 (40.33 - 47.24)	0.44 ± 1.99 (-5.47 - 5.00)	0.841	-5.90,6.77	30.30 - 47.75 (22.71, 56.02)	39.9 - 46.6
Moisture (% fw)	70.80 ± 0.35 (69.60 - 71.60)	70.28 ± 0.35 (69.80 - 71.00)	0.53 ± 0.50 (-1.40 - 1.30)	0.371	-1.07,2.12	67.00 - 74.10 (62.70, 77.69)	68.7 - 73.5
Protein (% dw)	7.94 ± 0.31 (7.30 - 8.49)	6.72 ± 0.31 (5.99 - 7.50)	1.22 ± 0.44 (0.043 - 2.42)	0.068	-0.18,2.62	6.45 - 10.14 (4.94, 11.97)	4.8 - 8.4
Total fat (% dw)	2.79 ± 0.21 (2.54 - 3.01)	2.85 ± 0.21 (2.37 - 3.33)	-0.052 ± 0.18 (-0.41 - 0.35)	0.794	-0.63,0.58	1.39 - 2.62 (1.03, 3.24)	1.4 - 2.1

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt.
[b]The mean of four replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]The range of sample values for commercial lines grown at the same U.S. sites in 1999.
[f]T. I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.
[g]Range for control lines analyzed in Monsanto Company trials conducted in 1994 and 1995 (Sanders *et al.*, 1996b; 1997a).

Table 7. Replicated Site (VH, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower,Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Amino acids (% of total)								
Alanine	7.74 ± 0.035 (7.70 - 7.78)	7.75 ± 0.035 (7.63 - 7.85)	-0.0041 ± 0.029 (-0.072 - 0.069)	0.896	-0.097,0.088	7.30 - 8.06 (6.94, 8.46)	6.4-9.9	7.2-8.8
Arginine	4.35 ± 0.065 (4.21 - 4.56)	4.29 ± 0.065 (4.17 - 4.40)	0.059 ± 0.092 (-0.10 - 0.39)	0.563	-0.23,0.35	3.86 - 4.83 (3.38, 5.22)	2.9-5.9	3.5-5.0
Aspartic acid	6.55 ± 0.034 (6.47 - 6.64)	6.55 ± 0.034 (6.48 - 6.58)	0.0022 ± 0.043 (-0.11 - 0.092)	0.962	-0.13,0.14	6.05 - 7.14 (5.54, 7.65)	5.8-7.2	6.3-7.5
Cystine	2.25 ± 0.013 (2.22 - 2.29)	2.15 ± 0.013 (2.12 - 2.17)	0.11 ± 0.0096 (0.094 - 0.14)	0.001	0.076,0.14	1.84 - 2.35 (1.59, 2.65)	1.2-1.6	1.8-2.7
Glutamic acid	19.17 ± 0.079 (18.99 - 19.29)	19.22 ± 0.079 (19.03 - 19.45)	-0.046 ± 0.11 (-0.47 - 0.16)	0.706	-0.40,0.31	18.31 - 20.25 (17.55, 21.25)	12.4-19.6	18.6-22.8
Glycine	3.66 ± 0.029 (3.58 - 3.72)	3.67 ± 0.029 (3.62 - 3.72)	-0.013 ± 0.030 (-0.069 - 0.072)	0.689	-0.11,0.084	3.20 - 4.13 (2.81, 4.46)	2.6-4.7	3.2-4.2
Histidine	2.91 ± 0.018 (2.86 - 2.95)	2.90 ± 0.018 (2.86 - 2.94)	0.0031 ± 0.013 (-0.031 - 0.034)	0.834	-0.040,0.046	2.60 - 3.20 (2.37, 3.35)	2.0-2.8	2.8-3.4
Isoleucine	3.73 ± 0.076 (3.45 - 3.86)	3.77 ± 0.076 (3.62 - 3.85)	-0.044 ± 0.10 (-0.33 - 0.15)	0.692	-0.36,0.27	3.47 - 3.94 (3.20, 4.17)	2.6-4.0	3.2-4.3
Leucine	13.36 ± 0.081 (13.10 - 13.58)	13.45 ± 0.081 (13.31 - 13.57)	-0.084 ± 0.11 (-0.47 - 0.13)	0.513	-0.45,0.28	11.94 - 14.47 (11.30, 15.63)	7.8-15.2	12.0-15.8

(continued over)

Table 7. Replicated Site (VH, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower,Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Lysine	2.92 ± 0.053 (2.79 - 3.00)	2.98 ± 0.053 (2.83 - 3.08)	-0.064 ± 0.028 (-0.14 - -0.0071)	0.104	-0.15,0.024	2.40 - 3.52 (1.87, 3.89)	2.0-3.8	2.6-3.5
Methionine	2.30 ± 0.048 (2.17 - 2.45)	2.22 ± 0.048 (2.13 - 2.30)	0.080 ± 0.068 (-0.095 - 0.25)	0.323	-0.14,0.30	1.61 - 2.29 (1.34, 2.74)	1.0-2.1	1.3-2.6
Phenylalanine	5.00 ± 0.022 (4.93 - 5.06)	5.02 ± 0.022 (4.99 - 5.08)	-0.012 ± 0.029 (-0.095 - 0.041)	0.699	-0.11,0.080	4.80 - 5.35 (4.53, 5.66)	2.9-5.7	4.9-6.1
Proline	8.87 ± 0.11 (8.61 - 9.21)	8.92 ± 0.11 (8.83 - 9.04)	-0.043 ± 0.16 (-0.32 - 0.38)	0.799	-0.54,0.45	8.57 - 9.61 (8.04, 10.35)	6.6-10.3	8.7-10.1
Serine	4.53 ± 0.16 (4.29 - 5.09)	4.54 ± 0.16 (4.31 - 4.91)	-0.0084 ± 0.23 (-0.56 - 0.55)	0.972	-0.74,0.72	4.24 - 4.99 (3.76, 5.69)	4.2-5.5	4.9-6.0
Threonine	3.41 ± 0.049 (3.29 - 3.60)	3.39 ± 0.049 (3.35 - 3.43)	0.019 ± 0.057 (-0.062 - 0.18)	0.760	-0.16,0.20	3.19 - 3.59 (2.93, 3.83)	2.9-3.9	3.3-4.2
Tryptophan	0.68 ± 0.013 (0.63 - 0.71)	0.65 ± 0.013 (0.63 - 0.67)	0.026 ± 0.018 (-0.025 - 0.077)	0.241	-0.031,0.082	0.54 - 0.82 (0.37, 0.90)	0.5-1.2	0.4-1.0
Tyrosine	3.53 ± 0.087 (3.33 - 3.64)	3.49 ± 0.087 (3.30 - 3.69)	0.044 ± 0.080 (-0.12 - 0.26)	0.618	-0.21,0.30	2.60 - 3.73 (2.15, 4.65)	2.9-4.7	3.7-4.3
Valine	5.03 ± 0.054 (4.83 - 5.13)	5.05 ± 0.054 (4.93 - 5.12)	-0.021 ± 0.074 (-0.23 - 0.13)	0.792	-0.26,0.22	4.49 - 5.30 (4.15, 5.63)	2.1-5.2	4.2-5.3

(continued over)

Table 7. Replicated Site (VH, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower,Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fatty acids (% of total)								
16:0 palmitic acid	12.34 ± 0.082 (12.17 - 12.41)	12.03 ± 0.082 (11.74 - 12.20)	0.31 ± 0.12 (-0.030 - 0.64)	0.076	-0.060,0.68	9.07 - 12.14 (7.74, 13.87)	7-19	9.9-12.0
18:0 stearic acid	1.43 ± 0.033 (1.40 - 1.45)	1.42 ± 0.033 (1.33 - 1.52)	0.0014 ± 0.044 (-0.087 - 0.078)	0.976	-0.14,0.14	1.44 - 2.40 (1.04, 2.68)	1-3	1.4-2.2
18:1 oleic acid	21.08 ± 0.060 (20.97 - 21.18)	21.16 ± 0.060 (21.00 - 21.35)	-0.078 ± 0.053 (-0.16 - 0.073)	0.236	-0.25,0.090	21.26 - 32.06 (13.28, 36.31)	20-46	20.6-27.5
18:2 linoleic acid	63.03 ± 0.11 (62.88 - 63.21)	63.23 ± 0.11 (62.92 - 63.60)	-0.20 ± 0.16 (-0.72 - 0.29)	0.285	-0.71,0.30	54.15 - 63.64 (50.21, 70.86)	35-70	55.9-66.1
18:3 linolenic acid	1.16 ± 0.054 (1.15 - 1.17)	1.23 ± 0.054 (1.09 - 1.45)	-0.072 ± 0.076 (-0.30 - 0.071)	0.415	-0.31,0.17	0.97 - 1.36 (0.75, 1.51)	0.8-2	0.8-1.1
20:0 arachidic acid	0.43 ± 0.0037 (0.43 - 0.44)	0.41 ± 0.0037 (0.41 - 0.42)	0.022 ± 0.0021 (0.016 - 0.027)	0.001	0.015,0.029	0.35 - 0.45 (0.30, 0.51)	0.1-2	0.3-0.5
20:1 eicosenoic acid	0.34 ± 0.0053 (0.33 - 0.35)	0.33 ± 0.0053 (0.31 - 0.33)	0.011 ± 0.0074 (-0.0027 - 0.040)	0.235	-0.013,0.035	0.25 - 0.39 (0.18, 0.42)	na	0.2-0.3
22:0 behenic acid	0.20 ± 0.0058 (0.19 - 0.21)	0.19 ± 0.0058 (0.17 - 0.21)	0.011 ± 0.0082 (-0.014 - 0.029)	0.283	-0.015,0.037	0.089 - 0.21 (0.055, 0.30)	na	0.1-0.3

(continued over)

Table 7. Replicated Site (VH, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower,Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Minerals								
Calcium (% dw)	0.0062 ± 0.00061 (0.0059 - 0.0064)	0.0065 ± 0.00061 (0.0051 - 0.0089)	-0.00031 ± 0.00082 (-0.0027 - 0.00081)	0.733	-0.0029, 0.0023	0.0039 - 0.0060 (0.0022, 0.0073)	0.01-0.1	0.003-0.006
Copper (mg/kg dw)	2.59 ± 0.20 (2.16 - 3.18)	2.50 ± 0.20 (2.08 - 2.88)	0.089 ± 0.28 (-0.58 - 1.10)	0.775	-0.81,0.99	1.03 - 2.15 (0.25, 2.70)	0.9-10	na
Iron (mg/kg dw)	21.73 ± 0.46 (21.13 - 23.05)	21.20 ± 0.46 (20.57 - 22.61)	0.53 ± 0.10 (0.29 - 0.73)	0.013	0.21,0.85	16.74 - 28.69 (12.52, 35.06)	1-100	na
Magnesium (% dw)	0.12 ± 0.0026 (0.12 - 0.13)	0.13 ± 0.0026 (0.12 - 0.13)	-0.0024 ± 0.0031 (-0.010 - 0.0049)	0.496	-0.012,0.0075	0.091 - 0.14 (0.082, 0.17)	0.09-1.0	na
Manganese (mg/kg dw)	4.07 ± 0.11 (3.75 - 4.41)	4.23 ± 0.11 (4.01 - 4.39)	-0.16 ± 0.12 (-0.43 - 0.046)	0.263	-0.53,0.21	3.51 - 9.80 (0, 12.84)	0.7-54	na
Phosphorus (% dw)	0.40 ± 0.0085 (0.39 - 0.42)	0.41 ± 0.0085 (0.39 - 0.43)	-0.0084 ± 0.0039 (-0.020 - -0.0022)	0.120	-0.021,0.0041	0.27 - 0.41 (0.21, 0.47)	0.26-0.75	0.288-0.363
Potassium (% dw)	0.41 ± 0.012 (0.40 - 0.44)	0.41 ± 0.012 (0.39 - 0.46)	0.0044 ± 0.0075 (-0.016 - 0.017)	0.599	-0.019,0.028	0.33 - 0.43 (0.28, 0.48)	0.32-0.72	na
Zinc (mg/kg dw)	19.08 ± 0.51 (17.95 - 20.28)	20.14 ± 0.51 (18.77 - 20.94)	-1.06 ± 0.73 (-2.77 - 0.90)	0.241	-3.37,1.25	12.84 - 31.22 (6.31, 37.95)	12-30	na

(continued over)

Table 7. Replicated Site (VH, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower,Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fiber and Proximates								
Ash (% dw)	1.52 ± 0.11 (1.39 - 1.71)	1.56 ± 0.11 (1.24 - 1.89)	-0.036 ± 0.16 (-0.45 - 0.31)	0.834	-0.53,0.46	0.62 - 1.53 (0.26, 2.06)	1.1-3.9	1.2-1.8
Carbohydrates (% dw)	84.78 ± 0.30 (84.39 - 85.00)	84.21 ± 0.30 (83.07 - 84.80)	0.58 ± 0.41 (0.14 - 1.81)	0.255	-0.73,1.89	82.51 - 87.84 (78.97, 90.36)	na	81.7-86.3
ADF (% dw)	4.56 ± 0.18 (4.10 - 5.11)	4.78 ± 0.18 (4.50 - 4.96)	-0.21 ± 0.14 (-0.44 - 0.15)	0.215	-0.64,0.22	3.65 - 6.09 (1.98, 6.62)	3.3 - 4.3	3.1 - 5.3
NDF (% dw)	12.68 ± 0.46 (12.33 - 13.04)	12.92 ± 0.46 (11.51 - 14.08)	-0.24 ± 0.54 (-1.29 - 0.82)	0.681	-1.95,1.46	9.50 - 14.95 (6.51, 16.28)	8.3-11.9	9.6 - 15.3
Moisture (% fw)	9.86 ± 0.27 (9.38 - 10.30)	10.37 ± 0.27 (9.58 - 11.20)	-0.51 ± 0.15 (-0.90 - -0.20)	0.039	-0.97,-0.048	8.75 - 15.70 (5.09, 18.62)	7-23	9.4 - 15.8
Total fat (% dw)	3.08 ± 0.11 (3.00 - 3.24)	3.42 ± 0.11 (3.15 - 3.84)	-0.34 ± 0.095 (-0.60 - -0.14)	0.037	-0.64, -0.038	2.18 - 3.86 (1.68, 4.64)	3.1-5.7, 2.9-6.1	2.4-4.2
Protein (% dw)	10.63 ± 0.21 (10.43 - 10.82)	10.84 ± 0.21 (10.45 - 11.69)	-0.21 ± 0.27 (-1.00 - 0.12)	0.487	-1.06, 0.64	7.95 - 13.83 (5.47, 16.57)	6.0 - 12.0, 9.7 - 16.1	9.0 - 13.6

(continued over)

Table 7. Replicated Site (VH, Iowa): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower,Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Miscellaneous								
Phytic Acid (% dw)	1.08 ± 0.056 (0.92 - 1.20)	1.16 ± 0.056 (1.01 - 1.24)	-0.084 ± 0.080 (-0.31 - 0.19)	0.371	-0.34,0.17	0.73 - 1.17 (0.39, 1.33)	to 0.9%	na
Trypsin Inhibitor (TIU/mg dw)	2.55 ± 0.26 (1.91 - 3.10)	2.72 ± 0.26 (2.06 - 3.23)	-0.17 ± 0.19 (-0.65 - 0.30)	0.442	-0.79, 0.45	0.58 - 3.05 (0, 4.25)	na	na
Vitamin E (mg/g dw)	0.0087 ± 0.00031 (0.0083 - 0.0089)	0.0097 ± 0.00031 (0.0088 - 0.010)	-0.0010 ± 0.00044 (-0.0020 - -0.00024)	0.102	-0.0024, 0.00038	0.0041 - 0.014 (0, 0.019)	0.017-0.047	0.008-0.015

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt; TIU = trypsin inhibitor units.
[b]The mean of four replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]Comm. = commercial. The range of sample values for commercial lines grown at the same U.S. sites in 1999.
[f]T.I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.
[g]Lit. = literature. For amino and fatty acids, Watson, 1982; for all other components, Watson, 1987; protein and fat second values from Jugenheimer, 1976.
[h]Hist. = historical. Range for control lines analyzed in Monsanto trials conducted between 1993 and 1995 (Sanders and Patzer, 1995; Sanders *et al.*, 1996a,b; 1997a,b,c).

Table 8. Replicated Trial (YK, Nebraska): Fiber and Proximate Content of Forage and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Historical[g] Range
Ash (% dw)	5.16 ± 0.25 (4.79 - 5.65)	5.49 ± 0.25 (4.93 - 6.27)	-0.32 ± 0.35 (-1.29 - 0.31)	0.419	-1.43,0.78	3.74 - 5.02 (3.04, 5.58)	2.9 - 5.1
Carbohydrates (% dw)	83.36 ± 0.64 (82.29 - 84.56)	82.93 ± 0.64 (80.78 - 84.33)	0.44 ± 0.91 (-2.05 - 2.49)	0.663	-2.46,3.34	82.59 - 87.10 (81.22, 88.97)	84.6 - 89.1
ADF (% dw)	28.52 ± 1.16 (26.31 - 31.44)	28.87 ± 1.16 (26.48 - 32.03)	-0.35 ± 1.07 (-3.26 - 1.59)	0.765	-3.76,3.06	19.78 - 39.00 (9.33, 45.44)	21.4 - 29.2
NDF (% dw)	42.29 ± 1.96 (38.25 - 46.49)	41.85 ± 1.96 (37.67 - 46.15)	0.44 ± 2.77 (-7.91 - 8.83)	0.884	-8.38,9.25	30.30 - 47.75 (22.71, 56.02)	39.9 - 46.6
Moisture (% fw)	71.88 ± 0.71 (71.30 - 72.90)	72.20 ± 0.71 (70.00 - 74.50)	-0.33 ± 1.01 (-3.20 - 2.90)	0.768	-3.54,2.89	67.00 - 74.10 (62.70, 77.69)	68.7 - 73.5
Protein (% dw)	9.73 ± 0.32 (8.98 - 10.11)	9.71 ± 0.32 (8.73 - 10.55)	0.014 ± 0.45 (-0.91 - 1.23)	0.976	-1.43,1.46	6.45 - 10.14 (4.94, 11.97)	4.8 - 8.4
Total fat (% dw)	1.78 ± 0.28 (0.92 - 2.35)	1.80 ± 0.28 (1.30 - 2.37)	-0.021 ± 0.27 (-0.61 - 0.54)	0.943	-0.89,0.85	1.39 - 2.62 (1.03, 3.24)	1.4 - 2.1

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt.
[b]The mean of four replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]The range of sample values for commercial lines grown at the same U.S. sites in 1999.
[f]T. I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.
[g]Range for control lines analyzed in Monsanto Company trials conducted in 1994 and 1995 (Sanders *et al.*, 1996b; 1997a).

Table 9. Replicated Trial (YK, Nebraska): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Amino acids (% of total)								
Alanine	7.77 ± 0.039 (7.65 - 7.85)	7.89 ± 0.039 (7.81 - 7.98)	-0.12 ± 0.055 (-0.23 - 0.038)	0.109	-0.30,0.051	7.30 - 8.06 (6.94, 8.46)	6.4-9.9	7.2-8.8
Arginine	4.39 ± 0.080 (4.25 - 4.67)	4.18 ± 0.080 (4.09 - 4.35)	0.21 ± 0.11 (-0.090 - 0.51)	0.160	-0.15,0.57	3.86 - 4.83 (3.38, 5.22)	2.9-5.9	3.5-5.0
Aspartic acid	6.44 ± 0.018 (6.42 - 6.47)	6.36 ± 0.018 (6.30 - 6.39)	0.088 ± 0.025 (0.027 - 0.16)	0.040	0.0074,0.17	6.05 - 7.14 (5.54, 7.65)	5.8-7.2	6.3-7.5
Cystine	2.16 ± 0.051 (1.98 - 2.30)	2.06 ± 0.051 (2.00 - 2.14)	0.10 ± 0.072 (-0.15 - 0.25)	0.247	-0.13,0.33	1.84 - 2.35 (1.59, 2.65)	1.2-1.6	1.8-2.7
Glutamic acid	19.67 ± 0.11 (19.33 - 19.91)	20.10 ± 0.11 (19.89 - 20.26)	-0.43 ± 0.15 (-0.76 - 0.026)	0.062	-0.91,0.043	18.31 - 20.25 (17.55, 21.25)	12.4-19.6	18.6-22.8
Glycine	3.52 ± 0.036 (3.45 - 3.57)	3.40 ± 0.036 (3.33 - 3.53)	0.12 ± 0.051 (-0.075 - 0.23)	0.107	-0.046,0.28	3.20 - 4.13 (2.81, 4.46)	2.6-4.7	3.2-4.2
Histidine	2.82 ± 0.038 (2.70 - 2.95)	2.74 ± 0.038 (2.72 - 2.79)	0.073 ± 0.054 (-0.082 - 0.24)	0.269	-0.099,0.25	2.60 - 3.20 (2.37, 3.35)	2.0-2.8	2.8-3.4
Isoleucine	3.71 ± 0.054 (3.56 - 3.81)	3.80 ± 0.054 (3.67 - 3.87)	-0.097 ± 0.055 (-0.26 - -0.027)	0.175	-0.27,0.078	3.47 - 3.94 (3.20, 4.17)	2.6-4.0	3.2-4.3
Leucine	13.46 ± 0.11 (13.15 - 13.65)	13.90 ± 0.11 (13.64 - 14.17)	-0.44 ± 0.15 (-0.75 - 0.0057)	0.066	-0.93,0.055	11.94 - 14.47 (11.30, 15.63)	7.8-15.2	12.0-15.8

(continued over)

Table 9. Replicated Trial (YK, Nebraska): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Lysine	2.90 ± 0.054 (2.73 - 3.06)	2.80 ± 0.054 (2.74 - 2.88)	0.098 ± 0.076 (-0.15 - 0.32)	0.288	-0.14,0.34	2.40 - 3.52 (1.87, 3.89)	2.0-3.8	2.6-3.5
Methionine	2.38 ± 0.048 (2.23 - 2.49)	2.31 ± 0.048 (2.20 - 2.39)	0.075 ± 0.068 (-0.16 - 0.18)	0.353	-0.14,0.29	1.61 - 2.29 (1.34, 2.74)	1.0-2.1	1.3-2.6
Phenylalanine	5.00 ± 0.020 (4.97 - 5.03)	5.06 ± 0.020 (5.00 - 5.12)	-0.055 ± 0.028 (-0.15 - 0.033)	0.148	-0.14,0.035	4.80 - 5.35 (4.53, 5.66)	2.9-5.7	4.9-6.1
Proline	8.63 ± 0.096 (8.30 - 8.85)	8.70 ± 0.096 (8.60 - 8.88)	-0.063 ± 0.11 (-0.30 - 0.24)	0.618	-0.43,0.30	8.57 - 9.61 (8.04, 10.35)	6.6-10.3	8.7-10.1
Serine	4.60 ± 0.21 (4.20 - 5.09)	4.40 ± 0.21 (4.20 - 4.92)	0.20 ± 0.23 (-0.068 - 0.89)	0.449	-0.53,0.93	4.24 - 4.99 (3.76, 5.69)	4.2-5.5	4.9-6.0
Threonine	3.34 ± 0.048 (3.24 - 3.45)	3.23 ± 0.048 (3.16 - 3.33)	0.11 ± 0.045 (0.012 - 0.23)	0.098	-0.037,0.25	3.19 - 3.59 (2.93, 3.83)	2.9-3.9	3.3-4.2
Tryptophan	0.61 ± 0.0065 (0.60 - 0.63)	0.61 ± 0.0065 (0.60 - 0.62)	-0.00070 ± 0.0071 (-0.018 - 0.015)	0.927	-0.023,0.022	0.54 - 0.82 (0.37, 0.90)	0.5-1.2	0.4-1.0
Tyrosine	3.67 ± 0.051 (3.59 - 3.74)	3.48 ± 0.051 (3.29 - 3.57)	0.19 ± 0.047 (0.097 - 0.30)	0.026	0.043,0.35	2.60 - 3.73 (2.15, 4.65)	2.9-4.7	3.7-4.3
Valine	4.93 ± 0.068 (4.72 - 5.06)	4.99 ± 0.068 (4.84 - 5.08)	-0.056 ± 0.096 (-0.36 - 0.061)	0.602	-0.36,0.25	4.49 - 5.30 (4.15, 5.63)	2.1-5.2	4.2-5.3

(continued over)

Table 9. Replicated Trial (YK, Nebraska): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fatty acids (% of total)								
16:0 palmitic acid	12.16 ± 0.13 (11.88 - 12.56)	11.84 ± 0.13 (11.69 - 12.09)	0.31 ± 0.19 (-0.21 - 0.79)	0.195	-0.29,0.92	9.07 - 12.14 (7.74, 13.87)	7-19	9.9-12.0
18:0 stearic acid	1.82 ± 0.015 (1.77 - 1.86)	1.79 ± 0.015 (1.77 - 1.81)	0.023 ± 0.021 (-0.040 - 0.067)	0.367	-0.046,0.091	1.44 - 2.40 (1.04, 2.68)	1-3	1.4-2.2
18:1 oleic acid	22.90 ± 0.20 (22.32 - 23.55)	22.47 ± 0.20 (22.41 - 22.53)	0.42 ± 0.26 (-0.085 - 1.05)	0.209	-0.42,1.26	21.26 - 32.06 (13.28, 36.31)	20-46	20.6-27.5
18:2 linoleic acid	61.09 ± 0.33 (60.02 - 61.95)	61.80 ± 0.33 (61.55 - 62.03)	-0.72 ± 0.46 (-1.83 - 0.17)	0.220	-2.19,0.76	54.15 - 63.64 (50.21, 70.86)	35-70	55.9-66.1
18:3 linolenic acid	1.17 ± 0.017 (1.13 - 1.23)	1.24 ± 0.017 (1.23 - 1.24)	-0.063 ± 0.024 (-0.11 - 0.00026)	0.079	-0.14,0.014	0.97 - 1.36 (0.75, 1.51)	0.8-2	0.8-1.1
20:0 arachidic acid	0.41 ± 0.0029 (0.40 - 0.42)	0.40 ± 0.0029 (0.40 - 0.40)	0.0065 ± 0.0033 (-0.0010 - 0.014)	0.137	-0.0038,0.017	0.35 - 0.45 (0.30, 0.51)	0.1-2	0.3-0.5
20:1 eicosenoic acid	0.29 ± 0.0043 (0.28 - 0.30)	0.29 ± 0.0043 (0.28 - 0.30)	0.0019 ± 0.0060 (-0.0085 - 0.013)	0.766	-0.017,0.021	0.25 - 0.39 (0.18, 0.42)	na	0.2-0.3
22:0 behenic acid	0.17 ± 0.0030 (0.17 - 0.18)	0.16 ± 0.0030 (0.15 - 0.16)	0.013 ± 0.0043 (0.0028 - 0.022)	0.057	-0.00072,0.027	0.089 - 0.21 (0.055, 0.30)	na	0.1-0.3

(continued over)

Table 9. Replicated Trial (YK, Nebraska): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Minerals								
Calcium (% dw)	0.0044 ± 0.00010 (0.0041 - 0.0047)	0.0047 ± 0.00010 (0.0045 - 0.0048)	-0.00023 ± 0.00006 (-0.00037 - -0.00007)	0.035	-0.00043, -0.00003	0.0039 - 0.0060 (0.0022, 0.0073)	0.01-0.1	0.003-0.006
Copper (mg/kg dw)	1.85 ± 0.058 (1.72 - 2.01)	1.69 ± 0.058 (1.60 - 1.84)	0.16 ± 0.017 (0.12 - 0.20)	0.002	0.11,0.21	1.03 - 2.15 (0.25, 2.70)	0.9-10	na
Iron (mg/kg dw)	24.87 ± 0.34 (23.99 - 25.42)	27.45 ± 0.34 (26.49 - 28.16)	-2.58 ± 0.49 (-3.92 - -1.46)	0.013	-4.12,-1.03	16.74 - 28.69 (12.52, 35.06)	1-100	na
Magnesium (% dw)	0.13 ± 0.0023 (0.13 - 0.14)	0.14 ± 0.0023 (0.14 - 0.14)	-0.0074 ± 0.0032 (-0.016 - 0.00049)	0.105	-0.018,0.0029	0.091 - 0.14 (0.082, 0.17)	0.09-1.0	na
Manganese (mg/kg dw)	7.17 ± 0.13 (6.94 - 7.40)	7.91 ± 0.13 (7.69 - 8.28)	-0.75 ± 0.14 (-0.89 - -0.33)	0.012	-1.19,-0.30	3.51 - 9.80 (0, 12.84)	0.7-54	na
Phosphorus (% dw)	0.39 ± 0.0071 (0.37 - 0.41)	0.43 ± 0.0071 (0.42 - 0.43)	-0.036 ± 0.010 (-0.070 - -0.0086)	0.037	-0.068,-0.0039	0.27 - 0.41 (0.21, 0.47)	0.26-0.75	0.288-0.363
Potassium (% dw)	0.43 ± 0.0091 (0.40 - 0.45)	0.44 ± 0.0091 (0.43 - 0.46)	-0.013 ± 0.013 (-0.056 - 0.025)	0.389	-0.054,0.028	0.33 - 0.43 (0.28, 0.48)	0.32-0.72	na
Zinc (mg/kg dw)	24.20 ± 0.39 (23.54 - 25.25)	27.16 ± 0.39 (26.09 - 28.14)	-2.96 ± 0.56 (-4.60 - -2.01)	0.013	-4.73,-1.18	12.84 - 31.22 (6.31, 37.95)	12-30	na

(continued over)

Table 9. Replicated Trial (YK, Nebraska): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fiber and Proximates								
Ash (% dw)	0.98 ± 0.077 (0.84 - 1.12)	1.10 ± 0.077 (0.89 - 1.32)	-0.13 ± 0.082 (-0.32 - 0.055)	0.217	-0.39,0.13	0.62 - 1.53 (0.26, 2.06)	1.1-3.9	1.2-1.8
Carbohydrates (% dw)	82.56 ± 0.28 (81.83 - 83.13)	81.28 ± 0.28 (80.70 - 81.86)	1.28 ± 0.39 (-0.031 - 2.43)	0.046	0.041,2.52	82.51 - 87.84 (78.97, 90.36)	na	81.7-86.3
ADF (% dw)	4.47 ± 0.33 (4.12 - 4.75)	4.81 ± 0.33 (3.96 - 5.89)	-0.34 ± 0.46 (-1.77 - 0.79)	0.515	-1.80,1.13	3.65 - 6.09 (1.98, 6.62)	3.3 - 4.3	3.1 - 5.3
NDF (% dw)	11.08 ± 0.77 (10.50 - 11.51)	13.22 ± 0.77 (10.96 - 15.82)	-2.14 ± 1.05 (-4.32 - 0.10)	0.135	-5.50,1.22	9.50 - 14.95 (6.51, 16.28)	8.3-11.9	9.6 - 15.3
Moisture (% fw)	10.55 ± 0.079 (10.30 - 10.80)	10.80 ± 0.079 (10.70 - 10.90)	-0.25 ± 0.096 (-0.40 - 0)	0.079	-0.55,0.055	8.75 - 15.70 (5.09, 18.62)	7-23	9.4 - 15.8
Total fat (% dw)	4.07 ± 0.20 (3.52 - 4.56)	3.97 ± 0.20 (3.57 - 4.29)	0.11 ± 0.28 (-0.77 - 0.67)	0.726	-0.79,1.01	2.18 - 3.86 (1.68, 4.64)	3.1-5.7, 2.9-6.1	2.4-4.2
Protein (% dw)	12.44 ± 0.14 (12.19 - 12.82)	13.62 ± 0.14 (13.21 - 13.80)	-1.18 ± 0.20 (-1.51 - -0.39)	0.009	-1.81, -0.56	7.95 - 13.83 (5.47, 16.57)	6.0 - 12.0, 9.7 - 16.1	9.0 - 13.6

(continued over)

Table 9. Replicated Trial (YK, Nebraska): Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Miscellaneous								
Phytic Acid (% dw)	1.05 ± 0.052 (0.97 - 1.16)	1.19 ± 0.052 (1.01 - 1.28)	-0.14 ± 0.074 (-0.25 - 0.15)	0.156	-0.37,0.096	0.73 - 1.17 (0.39, 1.33)	to 0.9%	na
Trypsin Inhibitor (TIU/mg dw)	2.37 ± 0.27 (2.04 - 2.89)	2.60 ± 0.27 (1.91 - 3.45)	-0.23 ± 0.38 (-1.42 - 0.59)	0.582	-1.44, 0.97	0.58 - 3.05 (0, 4.25)	na	na
Vitamin E (mg/g dw)	0.011 ± 0.0012 (0.0062 - 0.013)	0.013 ± 0.0012 (0.013 - 0.014)	-0.0023 ± 0.0016 (-0.0077 - 0.00056)	0.254	-0.0075, 0.0029	0.0041 - 0.014 (0, 0.019)	0.017-0.047	0.008-0.015

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt; TIU = trypsin inhibitor units.
[b]The mean of four replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]Comm. = commercial. The range of sample values for commercial lines grown at the same U.S. sites in 1999.
[f]T.I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.
[g]Lit. = literature. For amino and fatty acids, Watson, 1982; for all other components, Watson, 1987; protein and fat second values from Jugenheimer, 1976.
[h]Hist. = historical. Range for control lines analyzed in Monsanto trials conducted between 1993 and 1995 (Sanders and Patzer, 1995; Sanders *et al.*, 1996a,b; 1997a,b,c).

Table 10. All Sites Combined: Fiber and Proximate Content of Forage and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Historical[g] Range
Ash (% dw)	4.73 ± 0.22 (3.62 - 5.65)	5.00 ± 0.22 (3.81 - 6.27)	-0.27 ± 0.16 (-1.29 - 1.09)	0.106	-0.61,0.066	3.74 - 5.02 (3.04, 5.58)	2.9 - 5.1
Carbohydrates (% dw)	84.24 ± 0.53 (82.29 - 86.32)	84.32 ± 0.53 (80.78 - 87.21)	-0.084 ± 0.43 (-2.70 - 2.52)	0.859	-1.47,1.30	82.59 - 87.10 (81.22, 88.97)	84.6 - 89.1
ADF (% dw)	28.67 ± 1.66 (21.74 - 43.30)	28.41 ± 1.66 (23.39 - 32.08)	0.26 ± 2.06 (-7.90 - 14.03)	0.907	-6.29,6.81	19.78 - 39.00 (9.33, 45.44)	21.4 - 29.2
NDF (% dw)	43.25 ± 1.26 (37.97 - 49.67)	42.94 ± 1.26 (37.32 - 51.85)	0.31 ± 1.25 (-10.81 - 12.34)	0.807	-2.25,2.87	30.30 - 47.75 (22.71, 56.02)	39.9 - 46.6
Moisture (% fw)	71.09 ± 0.46 (69.30 - 73.10)	71.68 ± 0.46 (69.80 - 74.50)	-0.58 ± 0.43 (-3.70 - 2.90)	0.269	-1.95,0.79	67.00 - 74.10 (62.70, 77.69)	68.7 - 73.5
Protein (% dw)	8.62 ± 0.53 (6.91 - 10.40)	8.33 ± 0.53 (5.99 - 10.55)	0.30 ± 0.37 (-2.54 - 2.42)	0.478	-0.87,1.47	6.45 - 10.14 (4.94, 11.97)	4.8 - 8.4
Total fat (% dw)	2.40 ± 0.23 (0.92 - 3.16)	2.35 ± 0.23 (1.30 - 3.33)	0.053 ± 0.15 (-0.91 - 1.14)	0.721	-0.26,0.36	1.39 - 2.62 (1.03, 3.24)	1.4 - 2.1

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt.
[b]The mean of sixteen replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]The range of sample values for commercial lines grown at the same U.S. sites in 1999.
[f]T.I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.
[g]Range for control lines analyzed in Monsanto Company trials conducted in 1994 and 1995 (Sanders *et al.*, 1996b; 1997a

Table 11. All Sites Combined: Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Amino acids (% of total)								
Alanine	7.74 ± 0.032 (7.65 - 7.85)	7.79 ± 0.032 (7.46 - 7.98)	-0.045 ± 0.031 (-0.23 - 0.24)	0.247	-0.14,0.055	7.30 - 8.06 (6.94, 8.46)	6.4-9.9	7.2-8.8
Arginine	4.43 ± 0.062 (4.21 - 4.68)	4.33 ± 0.062 (4.09 - 4.63)	0.10 ± 0.044 (-0.16 - 0.51)	0.030	0.0099,0.19	3.86 - 4.83 (3.38, 5.22)	2.9-5.9	3.5-5.0
Aspartic acid	6.51 ± 0.053 (6.38 - 6.72)	6.45 ± 0.053 (6.30 - 6.67)	0.061 ± 0.021 (-0.11 - 0.23)	0.064	-0.0070,0.13	6.05 - 7.14 (5.54, 7.65)	5.8-7.2	6.3-7.5
Cystine	2.20 ± 0.027 (1.98 - 2.40)	2.09 ± 0.027 (1.99 - 2.29)	0.11 ± 0.029 (-0.15 - 0.39)	<0.001	0.054,0.17	1.84 - 2.35 (1.59, 2.65)	1.2-1.6	1.8-2.7
Glutamic acid	19.39 ± 0.16 (18.99 - 19.91)	19.56 ± 0.16 (18.97 - 20.26)	-0.17 ± 0.090 (-0.76 - 0.24)	0.157	-0.46,0.12	18.31 - 20.25 (17.55, 21.25)	12.4-19.6	18.6-22.8
Glycine	3.60 ± 0.048 (3.45 - 3.74)	3.53 ± 0.048 (3.32 - 3.72)	0.072 ± 0.030 (-0.075 - 0.31)	0.100	-0.025,0.17	3.20 - 4.13 (2.81, 4.46)	2.6-4.7	3.2-4.2
Histidine	2.84 ± 0.032 (2.70 - 2.95)	2.83 ± 0.032 (2.72 - 2.94)	0.011 ± 0.023 (-0.082 - 0.24)	0.665	-0.063,0.085	2.60 - 3.20 (2.37, 3.35)	2.0-2.8	2.8-3.4
Isoleucine	3.67 ± 0.033 (3.45 - 3.89)	3.74 ± 0.033 (3.61 - 3.87)	-0.064 ± 0.033 (-0.33 - 0.15)	0.072	-0.13,0.0065	3.47 - 3.94 (3.20, 4.17)	2.6-4.0	3.2-4.3
Leucine	13.36 ± 0.081 (12.88 - 13.65)	13.65 ± 0.081 (13.27 - 14.17)	-0.29 ± 0.084 (-0.75 - 0.13)	0.039	-0.56,-0.026	11.94 - 14.47 (11.30, 15.63)	7.8-15.2	12.0-15.8

(continued over)

Table 11. All Sites Combined: Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Lysine	2.92 ± 0.061 (2.65 - 3.26)	2.88 ± 0.061 (2.67 - 3.08)	0.042 ± 0.036 (-0.19 - 0.32)	0.328	-0.073,0.16	2.40 - 3.52 (1.87, 3.89)	2.0-3.8	2.6-3.5
Methionine	2.28 ± 0.060 (1.89 - 2.49)	2.24 ± 0.060 (1.96 - 2.58)	0.034 ± 0.035 (-0.20 - 0.25)	0.348	-0.040,0.11	1.61 - 2.29 (1.34, 2.74)	1.0-2.1	1.3-2.6
Phenylalanine	4.99 ± 0.015 (4.93 - 5.06)	5.04 ± 0.015 (4.95 - 5.23)	-0.048 ± 0.017 (-0.17 - 0.041)	0.052	-0.096,0.0010	4.80 - 5.35 (4.53, 5.66)	2.9-5.7	4.9-6.1
Proline	8.73 ± 0.054 (8.30 - 9.21)	8.78 ± 0.054 (8.60 - 9.05)	-0.052 ± 0.046 (-0.32 - 0.38)	0.267	-0.15,0.045	8.57 - 9.61 (8.04, 10.35)	6.6-10.3	8.7-10.1
Serine	4.70 ± 0.11 (3.93 - 5.09)	4.67 ± 0.11 (4.20 - 4.94)	0.031 ± 0.094 (-0.77 - 0.89)	0.743	-0.17,0.23	4.24 - 4.99 (3.76, 5.69)	4.2-5.5	4.9-6.0
Threonine	3.41 ± 0.035 (3.16 - 3.60)	3.36 ± 0.035 (3.16 - 3.49)	0.049 ± 0.024 (-0.15 - 0.23)	0.056	-0.0016,0.099	3.19 - 3.59 (2.93, 3.83)	2.9-3.9	3.3-4.2
Tryptophan	0.66 ± 0.015 (0.60 - 0.83)	0.65 ± 0.015 (0.60 - 0.68)	0.013 ± 0.012 (-0.043 - 0.17)	0.295	-0.013,0.039	0.54 - 0.82 (0.37, 0.90)	0.5-1.2	0.4-1.0
Tyrosine	3.63 ± 0.057 (3.33 - 3.77)	3.48 ± 0.057 (2.71 - 3.82)	0.15 ± 0.078 (-0.14 - 0.92)	0.073	-0.016,0.32	2.60 - 3.73 (2.15, 4.65)	2.9-4.7	3.7-4.3
Valine	4.94 ± 0.043 (4.71 - 5.13)	4.94 ± 0.043 (4.64 - 5.12)	-0.0091 ± 0.043 (-0.36 - 0.50)	0.833	-0.097,0.079	4.49 - 5.30 (4.15, 5.63)	4.1-5.2	4.2-5.3

(continued)

Table 11. All Sites Combined: Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fatty acids (% of total)								
16:0 palmitic acid	12.01 ± 0.11 (11.61 - 12.56)	11.88 ± 0.11 (11.66 - 12.20)	0.12 ± 0.11 (-0.21 - 0.79)	0.337	-0.22,0.47	9.07 - 12.14 (7.74, 13.87)	7-19	9.9-12.0
18:0 stearic acid	1.66 ± 0.083 (1.40 - 1.86)	1.66 ± 0.083 (1.33 - 1.81)	0.0044 ± 0.013 (-0.087 - 0.078)	0.738	-0.023,0.032	1.44 - 2.40 (1.04, 2.68)	1-3	1.4-2.2
18:1 oleic acid	22.00 ± 0.36 (20.97 - 23.55)	21.87 ± 0.36 (21.00 - 22.53)	0.13 ± 0.12 (-0.16 - 1.05)	0.365	-0.26,0.52	21.26 - 32.06 (13.28, 36.31)	20-46	20.6-27.5
18:2 linoleic acid	62.23 ± 0.38 (60.02 - 63.21)	62.47 ± 0.38 (61.55 - 63.60)	-0.23 ± 0.18 (-1.83 - 0.32)	0.293	-0.81,0.35	54.15 - 63.64 (50.21, 70.86)	35-70	55.9-66.1
18:3 linolenic acid	1.20 ± 0.020 (1.13 - 1.29)	1.24 ± 0.020 (1.09 - 1.45)	-0.037 ± 0.021 (-0.30 - 0.071)	0.079	-0.080,0.0047	0.97 - 1.36 (0.75, 1.51)	0.8-2	0.8-1.1
20:0 arachidic acid	0.41 ± 0.0068 (0.39 - 0.44)	0.40 ± 0.0068 (0.39 - 0.42)	0.0052 ± 0.0062 (-0.017 - 0.027)	0.460	-0.014,0.025	0.35 - 0.45 (0.30, 0.51)	0.1-2	0.3-0.5
20:1 eicosenoic acid	0.30 ± 0.011 (0.28 - 0.35)	0.30 ± 0.011 (0.28 - 0.35)	0.0011 ± 0.0037 (-0.039 - 0.040)	0.783	-0.011,0.013	0.25 - 0.39 (0.18. 0.42)	na	0.2-0.3
22:0 behenic acid	0.18 ± 0.0068 (0.17 - 0.21)	0.18 ± 0.0068 (0.15 - 0.21)	0.0043 ± 0.0056 (-0.023 - 0.029)	0.498	-0.013,0.022	0.089 - 0.21 (0.055, 0.30)	na	0.1-0.3

(continued over)

Table 11. All Sites Combined: Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Minerals								
Calcium (% dw)	0.0052 ± 0.00041 (0.0041 - 0.0064)	0.0053 ± 0.00041 (0.0043 - 0.0089)	-0.00013 ± 0.00020 (-0.0027 - 0.00081)	0.538	-0.00056,0.00031	0.0039 - 0.0060 (0.0022, 0.0073)	0.01-0.1	0.003-0.006
Copper (mg/kg dw)	2.26 ± 0.17 (1.72 - 3.18)	2.19 ± 0.17 (1.60 - 2.88)	0.078 ± 0.076 (-0.58 - 1.10)	0.315	-0.078,0.23	1.03 - 2.15 (0.25, 2.70)	0.9-10	na
Iron (mg/kg dw)	23.55 ± 1.16 (21.13 - 26.36)	24.18 ± 1.16 (20.57 - 28.16)	-0.63 ± 0.80 (-3.92 - 1.83)	0.490	-3.18,1.92	16.74 - 28.69 (12.52, 35.06)	1-100	na
Magnesium (% dw)	0.13 ± 0.0034 (0.12 - 0.14)	0.14 ± 0.0034 (0.12 - 0.16)	-0.0049 ± 0.0024 (-0.018 - 0.0049)	0.135	-0.013,0.0028	0.091 - 0.14 (0.082, 0.17)	0.09-1.0	na
Manganese (mg/kg dw)	5.81 ± 0.78 (3.75 - 7.40)	6.15 ± 0.78 (4.01 - 8.28)	-0.34 ± 0.16 (-0.94 - 0.58)	0.122	-0.84,0.17	3.51 - 9.80 (0, 12.84)	0.7-54	na
Phosphorus (% dw)	0.40 ± 0.0068 (0.37 - 0.45)	0.42 ± 0.0068 (0.39 - 0.46)	-0.022 ± 0.0094 (-0.070 - 0.019)	0.065	-0.045,0.0020	0.27 - 0.41 (0.21, 0.47)	0.26-0.75	0.288-0.363
Potassium (% dw)	0.43 ± 0.0088 (0.40 - 0.48)	0.44 ± 0.0088 (0.39 - 0.48)	-0.0074 ± 0.0087 (-0.056 - 0.037)	0.457	-0.035,0.020	0.33 - 0.43 (0.28, 0.48)	0.32-0.72	na
Zinc (mg/kg dw)	22.15 ± 1.44 (17.95 - 25.25)	23.68 ± 1.44 (18.77 - 28.14)	-1.53 ± 0.69 (-4.60 - 0.90)	0.112	-3.73, 0.66	12.84 - 31.22 (6.31, 37.95)	12-30	na

(continued over)

Table 11. All Sites Combined: Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Fiber/Proximates								
Ash (% dw)	1.35 ± 0.12 (0.84 - 1.71)	1.41 ± 0.12 (0.89 - 1.89)	-0.064 ± 0.047 (-0.45 - 0.31)	0.196	-0.17,0.037	0.62 - 1.53 (0.26, 2.06)	1.1-3.9	1.2-1.8
Carbohydrates (% dw)	83.30 ± 0.56 (81.83 - 85.00)	82.76 ± 0.56 (80.70 - 84.80)	0.54 ± 0.27 (-0.78 - 2.43)	0.138	-0.32,1.40	82.51 - 87.84 (78.97, 90.36)	na	81.7-86.3
ADF (% dw)	4.45 ± 0.15 (3.49 - 5.23)	4.50 ± 0.15 (3.62 - 5.89)	-0.050 ± 0.18 (-1.77 - 1.16)	0.778	-0.43,0.33	3.65 - 6.09 (1.98, 6.62)	3.3 - 4.3	3.1 - 5.3
NDF (% dw)	11.64 ± 0.54 (9.21 - 13.47)	12.02 ± 0.54 (10.31 - 15.82)	-0.37 ± 0.61 (-4.32 - 2.30)	0.585	-2.33,1.58	9.50 - 14.95 (6.51, 16.28)	8.3-11.9	9.6 - 15.3
Moisture (% fw)	10.03 ± 0.50 (8.54 - 11.20)	10.23 ± 0.50 (8.60 - 11.40)	-0.20 ± 0.13 (-0.90 - 0.26)	0.216	-0.61,0.21	8.75 - 15.70 (5.09, 18.62)	7-23	9.4 - 15.8
Total fat (% dw)	3.77 ± 0.20 (3.00 - 4.56)	3.64 ± 0.20 (3.05 - 4.29)	0.13 ± 0.18 (-0.77 - 1.02)	0.520	-0.44,0.70	2.18 - 3.86 (1.68, 4.64)	3.1-5.7, 2.9-6.1	2.4-4.2
Protein (% dw)	11.60 ± 0.48 (10.43 - 12.82)	12.19 ± 0.48 (10.45 - 13.80)	-0.59 ± 0.22 (-1.52 - 0.12)	0.071	-1.28,0.097	7.95 - 13.83 (5.47, 16.57)	6.0 - 12.0, 9.7 - 16.1	9.0 - 13.6

(continued over)

Table 11. All Sites Combined: Amino Acid, Fatty Acid, Fiber, Mineral, Proximate, Phytic Acid, Trypsin Inhibitor and Vitamin E Content of Grain and Statistical Summary

Component[a]	MON 863 Mean[b] ± S.E.[c] (Range)	Control Mean[b] ± S.E.[c] (Range)	Difference (MON 863 minus Control) Mean ± S.E.[c] (Range)	p-value	95% C.I.[d] (Lower, Upper)	Comm. Range[e] (95% T.I.[f] Lower, Upper)	Lit.[g] Range	Hist.[h] Range
Miscellaneous								
Phytic Acid (% dw)	1.11 ± 0.033 (0.92 - 1.28)	1.23 ± 0.033 (1.01 - 1.37)	-0.12 ± 0.034 (-0.31 - 0.19)	0.001	-0.19,-0.050	0.73 – 1.17 (0.39, 1.33)	0.9%	na
Trypsin Inhibitor (TIU/mg dw)	2.30 ± 0.16 (0.56 - 3.10)	2.48 ± 0.16 (1.91 - 3.45)	-0.18 ± 0.16 (-1.70 - 0.63)	0.288	-0.53,0.17	0.58 - 3.05 (0, 4.25)	na	na
Vitamin E (mg/g dw)	0.011 ± 0.0012 (0.0062 - 0.014)	0.013 ± 0.0012 (0.0088 - 0.016)	-0.0015 ± 0.00047 (-0.0077 - 0.00090)	0.002	-0.0025, -0.00058	0.0041 - 0.014 (0, 0.019)	0.017-0.047	0.008-0.015

[a]ADF = acid detergent fiber; NDF = neutral detergent fiber; dw = dry wt.; fw = fresh wt; TIU = trypsin inhibitor units.
[b]The mean of sixteen replicate values.
[c]S.E. = standard error of the mean.
[d]C.I. = confidence interval.
[e]Comm. = commercial. The range of sample values for commercial lines grown at the same U.S. field sites in 1999.
[f]T.I. = tolerance interval, specified to contain 99% of the commercial line population, negative limits set to zero.
[g]Lit. = literature. For amino and fatty acids, Watson, 1982; for all other components, Watson, 1987; protein and fat second values from Jugenheimer, 1976.
[h]Hist. = historical. Range for control lines analyzed in Monsanto trials conducted between 1993 and 1995 (Sanders and Patzer, 1995; Sanders *et al.*, 1996a,b; 1997a,b,c).

APPENDIX

Protocol and Protocol Amendments

Monsanto Study Number: 99-01-39-30

Covance Project Number: 6103-243

Study Title: Compositional Analyses of Forage and Grain Samples Collected from Corn Rootworm Protected Corn Lines MON 862 and MON 863 Grown in the 1999 U.S. Field Trials

Sponsor:
Monsanto Company
Biotechnology Regulatory Sciences
700 Chesterfield Parkway North
St. Louis, MO 63198

Primary Testing Facility:
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700 Chesterfield Parkway North
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Study Director:
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Compositional Analysis Testing Facility:
Covance Laboratories Inc.
Wisconsin Facility
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Covance Principal Investigator:
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[redacted]

Approved By:

Sponsor/ Testing Facility Management Rep:

Date: 9/22/99

Patrick Weston
Monsanto Company

Study Director:

Pat Sanders

Date: 9-22-99

Patricia R. Sanders
Monsanto Company

Reviewed By:

Covance Principal Investigator:

Matt R. Breeze

Date: 9-23-99

Matt Breeze
Covance Laboratories, Inc.

[redacted]

1.0 Purpose

The purpose of this study is to estimate the levels of the major nutritional components in forage and grain collected from corn rootworm protected corn lines MON 862 and MON 863. Compositional parameters will be compared between the test lines and the control lines.

This study is designed to estimate the levels of proximates (moisture, protein, fat and ash), acid detergent fiber, neutral detergent fiber, amino acid composition, fatty acid profile, vitamin E, phytic acid, trypsin inhibitor and minerals in grain. Forage will be analyzed for proximates (moisture, protein, fat and ash), acid detergent fiber and neutral detergent fiber. The carbohydrate levels in forage and grain will be calculated.

2.0 Timelines

2.1 Proposed experimental start date: September 27, 1999

2.2 Proposed experimental termination date: February 1, 2000

3.0 Experimental design

3.1 Test, Control and Reference Substances

3.1.1 Test Substances

The test substances are the transgenic corn lines MON 862 and MON 863. Any of the test lines may be deleted at any time during this study. The deletion and reason(s) for the deletion of a line will be documented by amendment to the study protocol.

3.1.2 Control Substances

The control substances are the non-transgenic corn lines MON 846 and MON 847. MON 847 is the control line for test line MON 862; MON 846 is the control line for test line MON 863.

3.1.3 Reference Substances

The reference substances are the eighteen commercial hybrids (Appendix 2). Appropriate standards will be used in each assay as reference standards for the analytical procedures or calibration of equipment.

3.2 Test and Control Substance Characterization

The identity of the test and control substances will be determined by the Study Director prior to their use in the study by verifying the chain of custody documentation supplied with the corn samples. The identity of each corn line from each site will be confirmed by molecular analysis as part of Study 99-01-39-22.

[redacted]

3.3 Test System

There is no test system. This study uses analytical methods to assess the compositional parameters of the test, control and reference substances. Compositional analysis methods are validated assays which are currently used to evaluate nutritional parameters in corn products for commercial purposes. All methods have been validated according to Covance Standard Operating Procedures (SOPs) or industry standards.

3.4 Justification of Test System

There is no test system.

3.5 Procedure for Identification of Test System

There is no test system. The analytical methods to be used for the analysis of forage and grain samples are documented as Standard Operating Procedures (SOPs) or equivalent.

3.6 Description of Experimental Design

Forage and grain samples of each test, control and reference line were collected at each of the four field sites as detailed in Production Plan 99-01-39-08. Each sample was processed and stored at approximately -20°C. A subsample of each processed tissue sample will be shipped on dry ice to Covance for analysis. Covance will complete the compositional analyses and provide an analytical subreport to the Sponsor.

3.7 Proposed Statistical Methods

Statistical analysis of the compositional data will be performed at Monsanto or by a contract facility using a SAS statistical program (SAS Institute, 1990). Means and ranges will be computed across sites for each combination of tissue, component, and test and control substance. Mean component values will be evaluated for statistically significant differences between the control lines and the test lines. The mean, minimum and maximum across sites will be reported for each analyte. The reference substance data will be reported as ranges across hybrids across all sites. The statistical analysis will be discussed as part of the study final report.

3.8 Control of Bias

Samples will be collected from multiple field sites. The test lines and control lines were grown under identical conditions at each site. The samples will be analyzed by site. The samples will be analyzed, when appropriate, in the order designated on the Sample Transfer Form.

[redacted]

4.0 Compositional Analyses

4.1 Samples

There are two test lines and two control lines in this study. The lines were planted in four replicates at each site. There will be a forage and grain sample from each of the eighteen reference hybrids. The labels on the processed forage and grain samples will include: study number, date, storage conditions and the unique sample identifier (Appendix 1).

An aliquot of each processed forage sample will be shipped. A grain sample is a sub-sample of approximately 400 g of processed grain from each test, control or reference substance. Processed samples will be shipped on dry ice to Covance. Covance may perform additional processing if necessary. Samples will be stored at Covance at approximately -20°C until analyzed.

4.2 Analytical Methods

4.2.1 Forage Samples

The following analyses will be performed on the forage samples: proximates [moisture (M100), protein (PGEN), fat (FAAH), ash (ASHM)], acid detergent fiber (ADF) and neutral detergent fiber (NDFE). Carbohydrates (CHO) will be determined by calculation.

4.2.2 Grain Samples

The following analyses will be performed on the grain samples: proximates [moisture (M100), protein (PGEN), fat (FSOX), ash (ASHM)], acid detergent fiber (ADF), neutral detergent fiber (NDFE), amino acid composition (TAAP), fatty acid profile (FAC), vitamin E (LCAT), phytic acid (PHYT), trypsin inhibitor (MIXX), and minerals (ICPL) [calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc]. Carbohydrates (CHO) will be determined by calculation.

4.2.3 Any additional analyses or re-analyses will be approved by the study director, documented and justified in the raw data file. Not all analyses will necessarily be performed on all samples from all lines.

5.0 Records to be Maintained

5.1 Monsanto Facility

Records will be retained of all sample transfers, analysis, the protocol and all deviations and amendments thereto, and copies of all letters, memoranda, and other correspondence related to this study. Excess samples will be retained until notified of final disposition by the Sponsor.

[redacted]

5.2 Covance Facility

Original data or copies will be available at Covance to facilitate auditing the study during its progress and before acceptance of the final subreport. When the final subreport is completed, original study documentation, such as: paper data, computer printouts, chromatographs, worksheets, data sheets, notes by investigators, forms specified by SOP and magnetically encoded records, will be retained in the archives of Covance in accordance with 40 CFR Part 160.

Supporting facility records will be retained at Covance but will not be archived with the study data: refrigerator and freezer temperature records, instrument calibration and maintenance records.

5.3 Covance Final Subreport

A quality control checked and Quality Assurance accepted analytical subreport generated by the Covance Principal Investigator will be submitted to the Monsanto Study Director to be used in preparation of the final report. A final subreport including a data summary spreadsheet, reference standards (where applicable) for each assay and Method Summaries will be submitted to the Study Director. The raw data and final subreport will be audited by the Quality Assurance Unit of Covance in accordance with Covance Standard Operating Procedures (SOPs). One copy of the draft report and two copies of the final subreport will be provided. One year after signing of the final subreport excess frozen sample will be returned to the sponsor with transfer costs to be incured by sponsor. All other data maintained at room temperature will be returned at sponsor expense costs after 10 years.

6.0 Study Conduct Statement

6.1 Monsanto Facility

This study shall be conducted in accordance with the protocol. Any change, revision, or deviation from this protocol should be documented promptly according to the current version of SOP #GEN-POL-005 and communicated to the Study Director as soon as possible. All data and information will be recorded directly and promptly in indelible ink. The exceptions are electronically captured data, for which a printout will be generated and included with other study data. All entries will be dated on the day of entry and signed or initialed by the person entering the information. Computer printouts will be signed and dated by the person responsible for their generation. All data sheets must contain the Study number. Any change in entries will be made so as not to obscure the original entry, must indicate the reason for the change and must be dated and signed (or initialed) at the time of the change.

[redacted]

6.2 Covance

This experiment shall be conducted in accordance with the protocol and Covance SOPs. Any change, revision, or deviation from this protocol shall be documented promptly and communicated to the Study Director immediately. Covance Quality Assurance Unit will monitor the study conduct and audit the final subreport.

7.0 Confidentiality

No raw data, worksheets or other information summaries, reports, or other information related to this study may be revealed or released to any third party without prior notification and authorization of Monsanto.

8.0 GLP Compliance

This experiment will be conducted in compliance with the United States EPA FIFRA Good Laboratory Practice Regulations (40 CFR Part 160).

9.0 Reference

SAS Institute, Inc. 1990. SAS/STAT® User's Guide, Version 6, Fourth Edition, Volumes 1 and 2; SAS Procedures Guide®, Version 6, Third Edition; Cary, NC.

APPENDIX 1

SAMPLE IDENTIFIERS

Corn Line	11 RD	12 VH	13 YK	14 MN
Test samples:				
MON 862	86211-1	86212-1	86213-1	86214-1
	86211-2	86212-2	86213-2	86214-2
	86211-3	86212-3	86213-3	86214-3
	86211-4	86212-4	86213-4	86214-4
MON 863	86311-1	86312-1	86313-1	86314-1
	86311-2	86312-2	86313-2	86314-2
	86311-3	86312-3	86313-3	86314-3
	86311-4	86312-4	86313-4	86314-4
Control samples:				
MON 846	84641-1	84642-1	84643-1	84644-1
	84641-2	84642-2	84643-2	84644-2
	84641-3	84642-3	84643-3	84644-3
	84641-4	84642-4	84643-4	84644-4
MON 847	84751-1	84752-1	84753-1	84754-1
	84751-2	84752-2	84753-2	84754-2
	84751-3	84752-3	84753-3	84754-3
	84751-4	84752-4	84753-4	84754-4
Reference samples:				
	R14-11-1 or 2	R10-12-1 or 2	R5-13-1 or 2	R1-14-1 or 2
	R15-11-1 or 2	R11-12-1 or 2	R7-13-1 or 2	R2-14-1 or 2
	R16-11-1 or 2	R12-12-1 or 2	R8-13-1 or 2	R3-14-1 or 2
	R17-11-1 or 2	R13-12-1 or 2	R9-13-1 or 2	R4-14-1 or 2
	R18-11-1 or 2			R6-14-1 or 2

[redacted]

Study #: 99-01-39-30

Amendment #: 1

Compositional Analyses of Forage and Grain Samples Collected from Corn Rootworm Protected Corn Lines MON 862 and MON 863 Grown in the 1999 U.S. Field Trials

Date Change Implemented: 11-5-99

Page No/s. &/or Section/s: Pg 1, Study Director

Plan originally stated:

Study Director

Patricia R. Sanders
Monsanto Company-BB5F
Biotechnology Regulatory Sciences
700 Chesterfield Parkway North
St. Louis, MO 63198
Phone (314) 737-6412
FAX (314) 737-6189

Amended as follows:

Study Director

William P. Ridley
Monsanto Company-BB5I
Biotechnology Regulatory Sciences
700 Chesterfield Parkway North
St. Louis, MO 63198
Phone (636) 737-5594
FAX (636) 737-6189

Reason for Amendment and what impact will result from this change: Patricia Sanders is no longer employed at Monsanto Company. William Ridley has over twenty years of experience as study director and principal investigator for regulatory studies. Therefore this change should have no effect on the conduct of this study.

Signature of Approval

Testing Facility Management:

P. Weston **Date:** 11/3/99

Study Director:

William P. Ridley

W. Ridley **Date:** 11/3/99

Signature of Acknowledgment

Covance Principal Investigator:

Matt Breeze

Matt Breeze **Date:** 11-8-99

Study #: 99-01-39-30

Amendment #: 2

Compositional Analyses of Forage and Grain Samples Collected from Corn Rootworm Protected Corn Lines MON 862 and MON 863 Grown in the 1999 U.S. Field Trials

Date Changes Implemented: 12-1-99

Page No/s. &/or Section/s: Pg 3/ Sec 3.1.1 Test Substances

Plan originally stated: The test substances are the transgenic corn lines MON 862 and 863.

Amended as follows: The test substance is the transgenic corn line MON 863.

Page No/s. &/or Section/s: Pg 3/ Sec 3.1.2 Control Substances

Plan originally stated: The control substances are the non-transgenic corn lines MON 846 and MON 847. MON 847 is the control line for test line MON 862; MON 846 is the control line for test line MON 863.

Amended as follows: The control substance is a non-transgenic corn line MON 846.

Reason for Amendment and what impact will result from this change: A business decision to not pursue MON 862 as a commercial product has eliminated the need to analyze plant material from MON 862 and its control non-transgenic corn line, MON 847, for compositional components.

Signature of Approval

Testing Facility Management:

P. Weston **Date:** 11/30/99

Study Director:

W. Ridley **Date:** 12/1/99

Signature of Acknowledgment

Covance Principal Investigator:

Matt Breeze **Date:** 12-3-99

Study #: 99-01-39-30

Amendment #: 3

Compositional Analyses of Forage and Grain Samples Collected from Corn Rootworm Protected Corn Lines MON 862 and MON 863 Grown in the 1999 U.S. Field Trials

Date Changes Implemented: 12-17-99

Page No/s. &/or Section/s: Pg 1/ Study Title

Plan originally stated: Compositional Analyses of Forage and Grain Samples Collected from Corn Rootworm Protected Corn Lines MON 862 and MON 863 Grown in the 1999 U.S. Field Trials

Amended as follows: Compositional Analyses of Forage and Grain Samples Collected from Corn Rootworm Protected Corn Line MON 863 Grown in the 1999 U.S. Field Trials

Page No/s. &/or Section/s: Pg 3/ Sec 1.0 Purpose

Plan originally stated: The purpose of this study is to estimate the levels of the major nutritional components in forage and grain collected from corn rootworm protected corn lines MON 862 and MON 863.

Amended as follows: The purpose of this study is to estimate the levels of the major nutritional components in forage and grain collected from corn rootworm protected corn line MON 863.

Page No/s. &/or Section/s: Pg 5/ Sec 4.1 Samples

Plan originally stated: There are two test lines and two control lines in this study.

Amended as follows: There one test line and one control line in this study

Study #: 99-01-39-30 **Amendment #: 3**

Page No/s. &/or Section/s: **APPENDIX 1**

Plan originally stated: **SAMPLE IDENTIFIERS**

Corn	**11**	**12**	**13**	**14**
Line	**RD**	**VH**	**YK**	**MN**
Test samples:				
MON 862	86211-1	86212-1	86213-1	86214-1
	86211-2	86212-2	86213-2	86214-2
	86211-3	86212-3	86213-3	86214-3
	86211-4	86212-4	86213-4	86214-4
MON 863	86311-1	86312-1	86313-1	86314-1
	86311-2	86312-2	86313-2	86314-2
	86311-3	86312-3	86313-3	86314-3
	86311-4	86312-4	86313-4	86314-4
Control samples:				
MON 846	84641-1	84642-1	84643-1	84644-1
	84641-2	84642-2	84643-2	84644-2
	84641-3	84642-3	84643-3	84644-3
	84641-4	84642-4	84643-4	84644-4
MON 847	84751-1	84752-1	84753-1	84754-1
	84751-2	84752-2	84753-2	84754-2
	84751-3	84752-3	84753-3	84754-3
	84751-4	84752-4	84753-4	84754-4
Reference samples:				
	R14-11-1 or 2	R10-12-1 or 2	R5-13-1 or 2	R1-14-1 or 2
	R15-11-1 or 2	R11-12-1 or 2	R7-13-1 or 2	R2-14-1 or 2
	R16-11-1 or 2	R12-12-1 or 2	R8-13-1 or 2	R3-14-1 or 2
	R17-11-1 or 2	R13-12-1 or 2	R9-13-1 or 2	R4-14-1 or 2
	R18-11-1 or 2			R6-14-1 or 2

Study #: 99-01-39-30

Amendment #: 3

Amended as follows:

	SAMPLE IDENTIFIERS			
Corn	**11**	**12**	**13**	**14**
Line	**RD**	**VH**	**YK**	**MN**
Test samples:				
MON 863	86311-1	86312-1	86313-1	86314-1
	86311-2	86312-2	86313-2	86314-2
	86311-3	86312-3	86313-3	86314-3
	86311-4	86312-4	86313-4	86314-4
Control samples:				
MON 846	84641-1	84642-1	84643-1	84644-1
	84641-2	84642-2	84643-2	84644-2
	84641-3	84642-3	84643-3	84644-3
	84641-4	84642-4	84643-4	84644-4
Reference samples:				
	R14-11-1 or 2	R10-12-1 or 2	R5-13-1 or 2	R1-14-1 or 2
	R15-11-1 or 2	R11-12-1 or 2	R7-13-1 or 2	R2-14-1 or 2
	R16-11-1 or 2	R12-12-1 or 2	R8-13-1 or 2	R3-14-1 or 2
	R17-11-1 or 2	R13-12-1 or 2	R9-13-1 or 2	R4-14-1 or 2
	R18-11-1 or 2			R6-14-1 or 2

Reason for Amendment and what impact will result from this change: As noted in Amendment 2, a business decision to not pursue MON 862 as a commercial product eliminated the need to analyze plant material from MON 862 and its control non-transgenic corn line, MON 847, for compositional components. Sections 3.1.2 and 3.1.3 were amended in Amendment 2. The additional sections noted above were amended to avoid any misinterpretation of the protocol.

Study #: 99-01-39-30

Amendment #: 3

Page No/s. &/or Section/s: Pg. 4/ Sec. 3.8 Control of Bias

Plan originally stated: The samples will be analyzed, when appropriate, in the order designated on the Sample Transfer Form.

Amended as follows: The samples will be analyzed, when appropriate, in the order designated on the Sample Transfer Form or on a separate form provided by the Study Director.

Reason for Amendment and what impact will result from this change: The primary purpose of the Sample Transfer Form is sample inventory and chain-of-custody. Order of analysis can be specified by a separate randomized list provided by the Study Director.

Page No/s. &/or Section/s: Pg. 5/ Sec. 4.1 Samples

Plan originally stated: The labels on the processed forage and grain samples will include: study number, date, storage conditions and the unique sample identifier (Appendix 1).

Amended as follows: The labels on the processed forage and grain samples will include: study number, date, storage conditions and the unique LIMS/sample ID # .

Reason for Amendment and what impact will result from this change: The sample identifiers listed in Appendix 1 are used for both forage and grain and help in organizing the data by line number, site and plot for reporting. The LIMS/sample ID # is the unique number for an individual sample and should be included on the label.

Page No/s. &/or Section/s: Pg. 5/ Sec. 4.2.2 Grain Samples

Plan originally stated: The following analyses will be performed on the grain samples: proximates [moisture (M100), protein (PGEN), fat (FSOX), ash (ASHM)], acid detergent fiber (ADF), neutral detergent fiber (NDFE), amino acid composition (TAAP), fatty acid profile (FAC), vitamin E (LCAT), phytic acid (PHYT), trypsin inhibitor (MIXX), and minerals (ICPL) [calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc].

Amended as follows: The following analyses will be performed on the grain samples: proximates [moisture (M100), protein (PGEN), fat (FSOX), ash (ASHM)], acid detergent fiber (ADF), neutral detergent fiber (NDFE), amino acid composition (TAAP), fatty acid profile (FAPM), vitamin E (LCAT), phytic acid (PHYT), trypsin inhibitor (MIXX), and minerals (ICPL) [calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc]

Reason for Amendment and what impact will result from this change: The fatty acid profile mnemonic was changed from FAC to FAPM for ease of reporting the data.

Signature of Approval

Testing Facility Management:

P. Weston **Date:** 12/17/99

Study Director:

William P. Ridley

W. Ridley **Date:** 12/17/99

Signature of Acknowledgment

Covance Principal Investigator:

Matt Breeze

Matt Breeze **Date:** 1-4-00

Protocol Amendment Form **Amendment #: 4**

Monsanto Study #: **99-01-39-30**

Covance Study #: **6103-243**

Date changes implemented: February 14, 2002

The following is added to the protocol as Addendum 1. All requirements of the protocol are in effect unless otherwise specified. The addendum describes the re-opening of study 99-01-39-30, which has previously been completed. The statistical analyses of the compositional data are to be performed again.

Addition to the Protocol:

ADDENDUM 1 to Protocol 99-01-39-30

Proposed Experimental Start Date (Addendum): February, 2002

Proposed Experimental Termination Date (Addendum): March, 2002

Description of Additional Analyses:

The statistical analysis of the compositional data will be repeated. The revised analysis will contain the correct error term for the comparison of the test maize event, MON 863, to the control line, MON 846, for the combined site analysis. All other statistical analyses will remain the same as those conducted previously. Revised statistical analysis will be conducted by Certus International, Inc. using SAS software (SAS Institute, Inc., SAS *OnlineDoc*™, *Version 8*, Cary, NC: SAS Institute Inc., 1999).

Reason for the amendment and what impact will result for this change:

During a review of the analysis of variance for this study it was discovered that the SAS program had not correctly accounted for the site variability in the combined site analysis. The correction of this error will lead to the proper incorporation of site to site variability in the combined site statistical analysis. All other statistical analyses will remain the same.

[redacted]

Protocol Amendment Form **Amendment #: 4**

Approved By:

Patrick T. Weston
Testing Facility Management Representative
Feb 12, 2002
Date

William P. Ridley
Study Director
Feb. 14, 2002
Date

Ravinder S Sidhu
Ravinder S. Sidhu
Sponsor Representative
Feb-13, 2002
Date

Reviewed By:

Paula A Price
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Statistician
2/12/02
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