

Using Quality Management Systems to Meet Food Traceability Requirements of the Bioterrorism Act of 2002 (*Best NAIT 2008 Conference Proceedings Paper*)

Dr. Chad Laux, CSIT

Purdue University - Anderson,
Anderson, IN 46013, (317) 648-2905,
claux@purdue.edu

Dr. Charles Hurburgh

Iowa State University
Dept. of Agriculture and Biosystems Engineering,
Ames, IA 50014, (515) 294-8649, tatry@iastate.edu

Ms. Gretchen Mosher

Iowa State University, Dept of Agriculture and Biosystems Engineering,
Ames, IA 50014, (515) 294-6358, gamosher@iastate.edu

Introduction

The events of 9/11 intensified concerns about the safety of food. Legislation requirements for food traceability present challenges for US grain handlers in meeting new regulations of the Food and Drug Administration (FDA) (Iowa Grain Quality Initiative, 2006). With the goal of protecting the US food supply, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (known as 'the Act').

The Act requires that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States register with the FDA. The Act also increased the need for traceability in US commodity production with the regulatory requirements of as noted on FDA's website: <http://www.fda.gov/oc/bioterrorism/bioact.html>. Section 306 of the Act requires that registered locations maintain records which identify the immediate previous sources and the immediate subsequent recipients of food, including packaging. Connecting the records of suppliers and customers may allow the FDA to trace backward or track forward suspect food product(s) in the supply chain. The FDA requires that a location produce records within 24 hours (FDA, 2002a; 2002b).

FDA will allow an organization to utilize existing records if the immediate supplier(s) and subsequent recipients(s) are identified. While this should reduce the overall cost of organizations in meeting the records requirements, the ability of a commodity grain handler to meet the Act will test that organization's management system.

A number of recall events concerning cereal grains highlight the difficulty of commodity grain traceability. The USDA spent over \$60 million to contain and eradicate Karnal Bunt in American wheat over a small origin area in Arizona. The reduction in exports was valued at over \$250 million (Casagrande, 2000). In 2001, 500,000 bushels of soybeans were destroyed at a Nebraska elevator after commingling with 500 bushels of soybeans containing engineering corn (BioTrek, 2002). In the most famous case, Starlink corn, unapproved for human consumption, was planted on one percent of total US corn acreage in 2000. Discovery of Starlink corn in the human food chain resulted in the recall of over 300 food products and caused major disruptions in the food chain (Lin et al., 2002). The commingled total of Starlink with other corn eventually reached 124 million bushels in 2000 (Lin et al., 2002). These events demonstrate the consequences of poor traceability. Considering these events, how will a commodity grain elevator be able to meet new traceability expectations of the Act?

Quality Management Systems and Traceability

The nature of grain handling makes food traceability difficult. The grain supply chain is based on infrastructure built to move large flows of product based on a limited variety of attributes (Golan et al., 2004). Cereal crops are commingled immediately upon receipt by a grain elevator based on quality attributes such as moisture, damage, or foreign material. Grain from different sources is blended together to achieve a homogeneous quality level. Bailey et al. (2002) note that meeting traceability requirements will be most difficult for commodity handlers due the blending from multiple sources before processing.



After peer-review, this paper was designated the Best Conference Proceedings Paper of the NAIT 2008 Conference, ranking the highest of all 38 papers submitted for review.

Hurburgh and Sullivan (2004) note that a large grain elevator cooperative should be able to track raw material through elevator operations based on the implementation of a quality management system certified to the ISO 9001 standard. Defining guidelines for the grain industry, the basic traceability metric for a grain elevator is based upon a traceability index (Hurburgh, 2004, 2006). The definition of a traceability index (TI) for quantitative measure is as follows:

$$\text{Traceability Index} = \text{suspect volume} / \text{volume being tracked}$$

By the process of elimination separating where problem grain could not have been located, the amount of possibly contaminated grain becomes progressively less than the entire amount of grain within an elevator facility (Hurburgh, 2006; 2007). TI provides a method of continuous improvement supported by an objective target for grain elevators.

Farmers Cooperative Elevator Co, Farnhamville, IA, (FC) implemented a quality management system to create additional opportunities for marketing grain. The objective was to have a universally recognized quality system in place, so that as end-users (food processors) sought specialty grain origination, the company could present a program that would have an immediately recognizable creditability. However, Hurburgh (2003) notes the benefits of the quality management system were through improvements to operations management such as systematic inventory management and grain accounting. In the context of food safety, adoption of a quality management system changed the mindset of the employees from handling a commodity product to grain as a foodstuff (Sullivan and Hurburgh, 2002). The resources needed for food traceability were put in place with requirements such as standard operating procedures, discipline in process control and documentation of responsibility throughout the production history (Hurburgh, 2004). To understand how a formal QMS met the Act requirements, a series of mock recalls were done at the elevator.

Methodology

To demonstrate the effectiveness of the QMS in food traceability, FC conducted a total of 41 mock recall events at 27 FC elevator locations in 2006 and 2007. Of the 41 total mock recalls in 2006 and 2007, 17 were forward and 24 were backward. A forward recall is defined following grain identity from a known supplier to an unknown customer and/or elevator location. A forward recall is typically used as a good business practice and would not be the method of recall initiated by FDA in the likelihood of a trigger event. In the event of an actual event, FDA would utilize a backward recall where suspect material in the hands of a known customer would be traced backward through the food supply chain to unknown sources and initial locations (FDA, 2002a; 2002b).

Of the 41, 14 elevator locations did repeated recalls: 1 forward event in 2006 and 1 backward event in 2007 for a total of 28 repeated recall events. The time duration was recorded in both 2006 and 2007 recalls. The traceability index was recorded in the 2007 recall events. The data for the study consisted of reports filed by the location managers. This meant that the some data (or quality of data) was not available for every recall. Table 1 displays the data sets for these mock recalls.

Mock Recalls by Year	Recall Events (n)
First Round (2006)	
Forward	21
Backward	0
Second Round (2007)	
Forward	3
Backward	17
New	3
Repeats	14

Table 1: Farmers Cooperative Co. mock recall data set

The forward recall process was initiated electronically by the Quality Management department with information concerning the suspected commodity (corn or soybeans), quantity, scale ticket number, and producer name. Scale tickets were chosen

randomly by the Quality Manager. The elevator management was to track the suspected lot of grain forward through the facility, identify the customer(s) of the grain, locate all possible storage bins that would still have contaminated material, and identify all bins that did not have possible contamination. A record of the recall time was kept.

The backward recall event included the lot size, amount of suspect material, and scale ticket number loaded out on a specific date. The elevator management was to trace backward the grain and identify all supplier(s), contaminated storage bins, and bins not contaminated. Again, the Quality Manager chose outbound lots randomly. All statistical analysis was done in Minitab® Release 14 statistical software.

With the QM system procedures in place, the principal research questions were:

1. Does the QMS-based traceability system meet the FDA guideline for 24 hours maximum recall duration under the Act? This is only mandatory requirement of the Bioterrorism Act at this time. Quality and acceptability of data are at the judgment of investigators should an event arise.
2. Does the forward or backward information flow impact the time duration of a recall?
3. Is time duration of the mock recall event impacted by the level of precision of traceability (TI)?
4. Is grain traceability precision (TI) impacted by the forward or backward information flow?
5. Does the quantity of suspect material (lot size) impact the time duration of the recall event?
6. Does the lot size of suspect material impact the traceability index of the recall event?

Results

As shown in Table 2, the results show that most FC facilities met the Act requirement. The average time was 13.42 hours with a standard deviation of 11.18 hours, well below the 24 maximum time limit. 25 percent of the elevators reported results within three hours. The summary results in Table 2 also demonstrate the variability of grain traceability precision through the TI. The mean TI was 180 with a wide standard deviation of 300. Fewer facilities reported sufficient data since elevator managers reported results. Since the traceability index is not a requirement of FDA, it is a guideline for future improvement in traceability for the grain handling industry. The range of TI results was of 8 - 942. While the range was large, a minimum of 8:1 demonstrates possibility of grain traceability using a QMS. At the maximum, a large traceability index of 942 demonstrated a lack of grain traceability. This elevator location did not follow all the requirements of the QMS and the operator reported that he had no idea where the grain came from, which made the entire inventory of the elevator suspect.

Mock recall description	Time Duration (hours)			TI (2007 only)		
	N	Mean	SD	n	Mean	SD
All elevator locations	41	13.42	11.18	16	180	300

Table 2: Overall results of mock recall exercises at FC grain elevator locations

Since the 24 hour limit is the single requirement of the Act, distributions of the results in 2006 and 2007 are displayed in figure 1. In the 2006 events, all of the mock recall events were forward and the distribution displayed a right skew.

One elevator location required 39 hours required to report results. This elevator location had the responsibility to follow grain through another FC elevator due to intra-company transfer of the tracked grain. The longer the grain flow in the cooperative, the longer it takes to track grain. FC often transfers grain from one elevator location to another by truck. The Act requires an organization maintain records while the product is in the organization's custody. Still having custody of the grain, significant time was added to the recall event.

In the 2007 mock recalls, the results displayed a more normal distribution of duration. In the 2007 set, four elevators did not meet the 24 hour rule. Two of these locations were new to FC, merged into the company from another elevator company within six months prior to the mock recalls. Three of the elevators that reported results past the 24 hour limit conducted backward recalls.

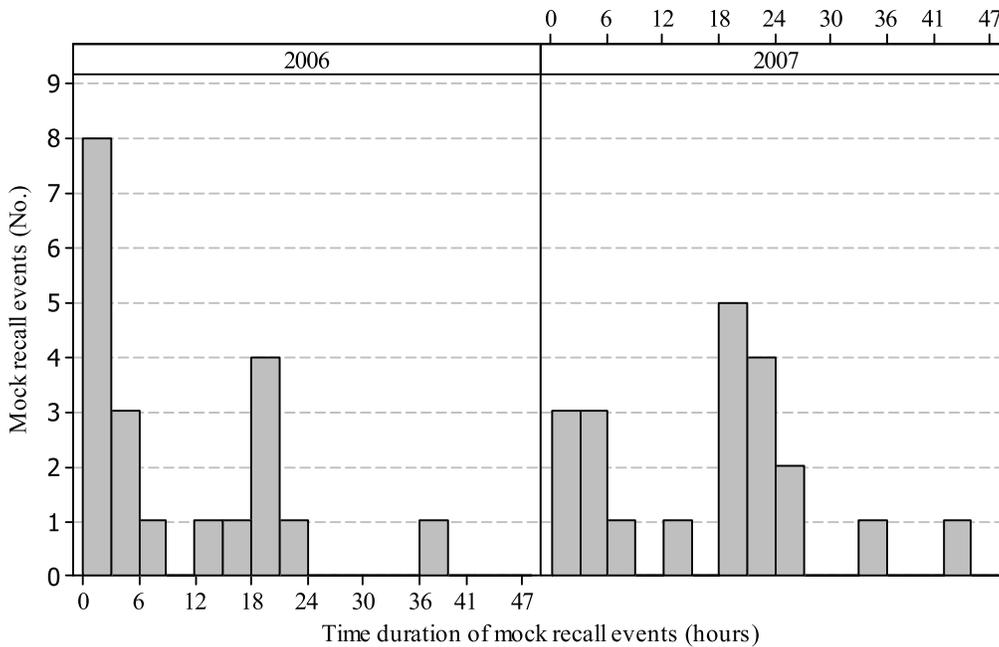


Figure 1: 2006 and 2007 distribution of time results

As shown in figure 2, there was no significant relationship between the time required for the recall event and the precision of grain traceability (TI). The length of time of the traceability processes was not impacted by their tracking precision. The majority of locations reported results no matter how well defined their inventory control. Since time is the only FDA requirement of grain elevators, then reporting results, no matter how accurate, would be expected. If grain handlers expect to manage an actual FDA event, specifying a level of traceability would be good practice. For example, simply presenting a list of suppliers and customers of an elevator cooperative to FDA upon request will not meet the requirement of the Act (FDA, 2002a; 2002b). FDA is letting the industry progressively set standards as it improves compliance.

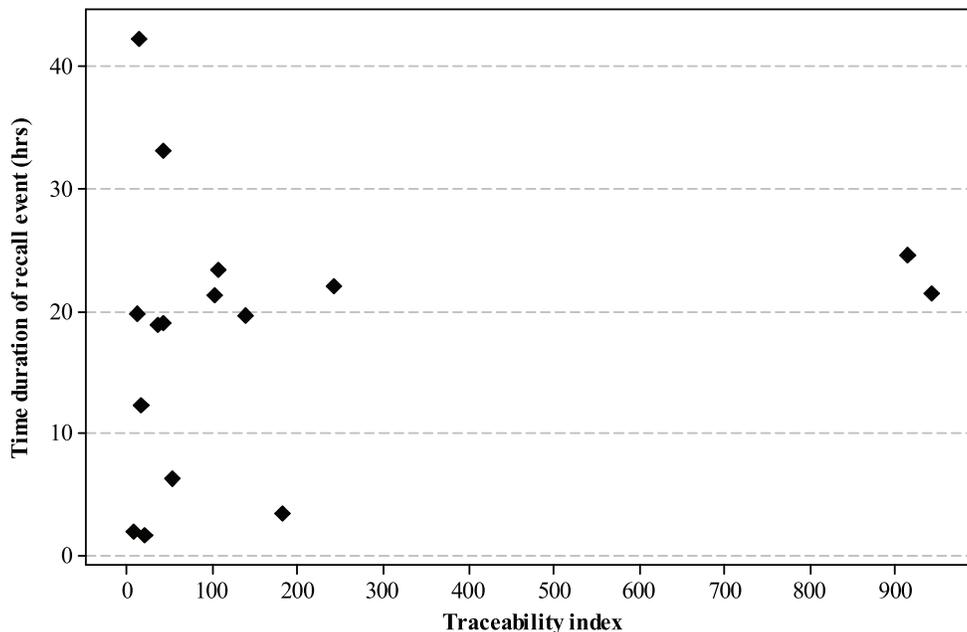


Figure 2: Traceability index and time duration of mock recall events

The results in Table 3 demonstrate that there was a significant difference in the amount of time required to report elevator recall results between the flows (backward and forward). Of the total 41 recalls accomplished, there were 14 elevator locations which did two recalls: one forward and one backward.

The time required to report results took significantly longer in a backward event. This is because tracing suspect material back to the origin also required tracking forward to identify where that material subsequently went. Both backward tracing and forward tracking were required in backward recall events.

Mock Recall Description	Time duration (hours)		
	n	Mean	SD
Forward (First recall)	14	7.9 ^a	8.4
Backward (Second recall)	14	18.4 ^b	10.2

^{a,b}Means with different letters significantly different at $p = 0.05$

Table 3: Time duration of repeated mock recall exercises at FC grain elevator locations

In 2007, the set of mock recalls included both forward (N=3) and backward (N=17) events. The backward events reported less precise TI's than locations doing forward events as shown in table 4. But the sample size of events is small and the precision of traceability (TI) was not significantly impacted by the flow of the event (backward or forward). The mean difference in TI's was lessened by the large standard deviation. Grain elevators should conduct both types of recalls to test a traceability system since forwards and backwards recalls are different in nature.

Mock recall description	Traceability Index				
	n	Mean	SD	Min	Max
Backward	17	215	324	8	942
Forward	3	25	15	13	42

Table 4: Traceability index of 2007 mock recall exercises at FC grain elevator locations

There was no relationship between the suspect bushels being tracked (lot size) and the amount of time required to provide data (figure 3). Minimizing the amount of suspect material should be the goal of a commodity grain handler because in the event of an actual FDA recall, suspected product could be destroyed per FDA regulations (FDA, 2002a). The tracking process is more important in response to an FDA event; not how large the triggering event was.

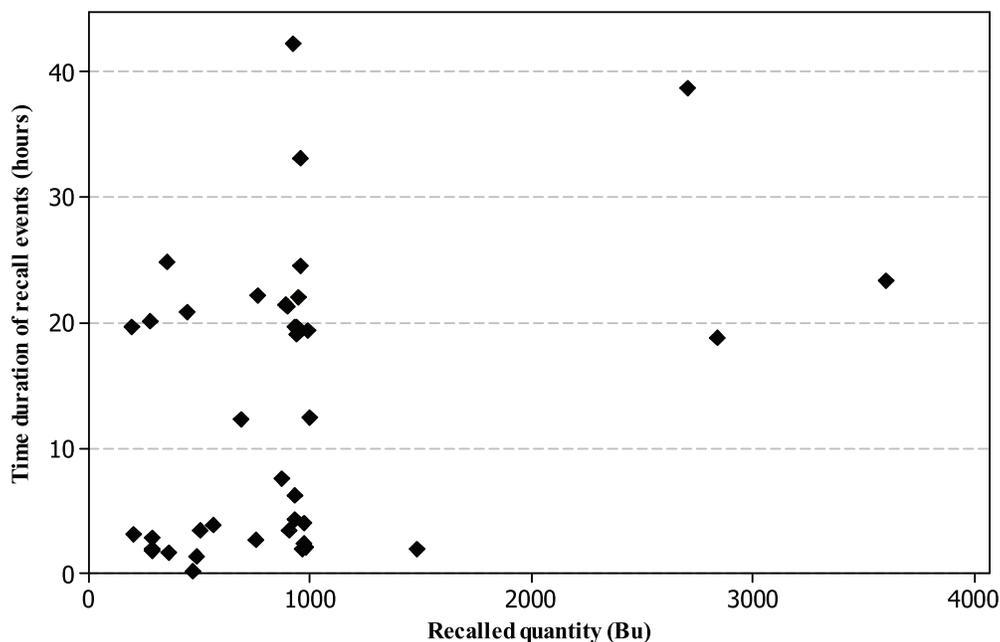


Figure 3. Time duration and lot size of 2006 and 2007 mock recall events

In figure 4, the amount of grain traced (lot size) did not have a significant impact upon the precision of the traceability index. Most of the data were clustered together with a few locations reporting large TI's. Both of the locations reporting the largest TI's conducted backward events. This could be evidence that backward events are harder to manage. There were also two elevators with larger than the average lot size (approximately 1,000 bu) and low TI's at 36 and 107. These elevators demonstrated average grain traceability precision, even though the lot sizes were larger. The process of traceability was more important than how much suspect material was at stake. This was also the second time that these elevators had done mock recalls. The impact of improvement from the first round of events is unknown.

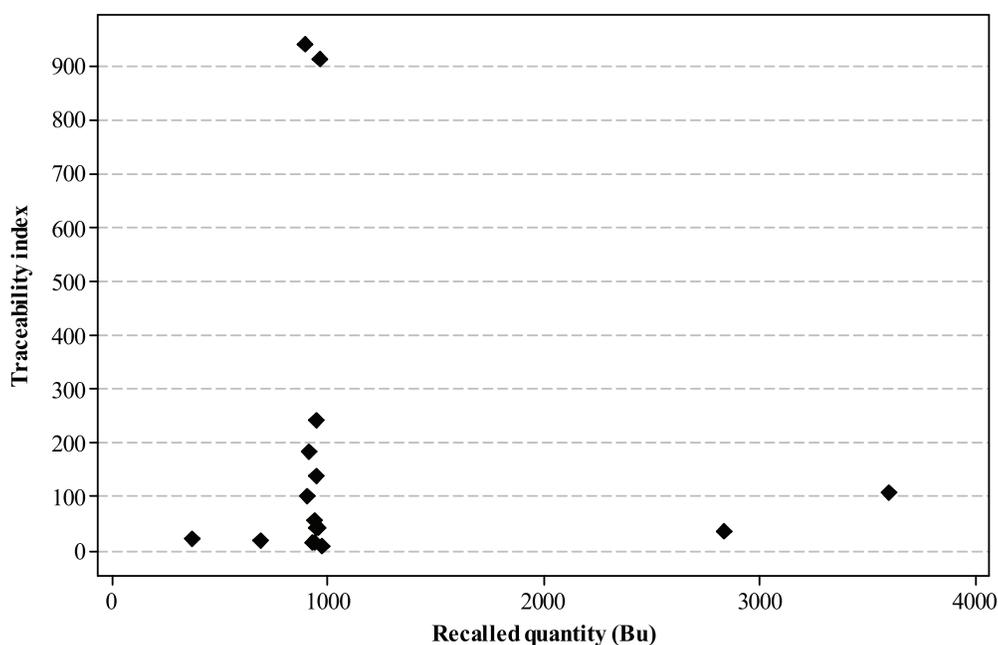


Figure 4. Traceability index and lot size of 2007 mock recall events

Discussion and Conclusions

Farmers Cooperative Co. implemented quality management system grain traceability processes at 27 elevator locations. The results of the mock recall study demonstrate that the QMS provided a benchmark for improvement. A traceability index (TI) was created for use as a guideline for the grain industry. FC initially designed and implemented a QMS to meet external goals. Its subsequent focus on internal improvements enabled the organization to meet new, unforeseen government regulations.

FC was able to produce results within the 24 hour timeframe required by FDA. Timeliness of recall could prevent the closing an entire elevator operation in the event of an actual recall. The flow of the recall event was significant. A backward event took significantly longer than a forward event. But the process flow of an actual recall event is not within the control of the grain industry. By definition, an FDA recall would be backward due to the nature of tracing backward from a triggering event.

The ability to meet the 24 hour deadline was not related to the lot size of grain traced in the facility, demonstrating that the QMS processes of traceability were robust. Grain elevator operations handle large volumes of grain and the commingling of different sources of grain can result in large lot sizes. The time required by FC to produce results was not affected by the lot size.

The precision level, or TI, of recall event was not related to the time required to produce results. In the event of a recall, identification of suppliers and customers requires precision. More precise levels of grain traceability apparently will not require more time.

The traceability index did not change significantly with regard to a backward or forward elevator recall event. While a backward event takes longer, the level of precision did not change significantly.

The interaction between lot size and the traceability index was not significant. During an actual event, the amount of suspect grain could be large. The FDA would likely quarantine suspect material at quantities greater than the original lot size. This was demonstrated in the spinach recall of 2006 by the FDA (Cuite et al., 2007). Following the QMS traceability processes could minimize the need to destroy large amounts of suspect grain.

An organization that meets the ISO 9001:2000 quality standard also incorporates traceability processes. QMS adoption by FC enabled the company to meet the unanticipated regulation of the Bioterror Act at nominal additional effort. A QMS system requires continuous improvement of quality related activities. It is possible that a more precise level of grain traceability will occur through the ongoing use of a quality management system. This study provides benchmark data on which to evaluate improvement.

References

- Bailey, D., E. Jones, and D. L. Dickinson. (2002). Knowledge management and comparative international strategies on vertical information flow in the global food system. *American Journal of Agricultural Economics*. 84, 5, 1337-1344.
- BioTrek. (2002). Nebraska crop contamination issue briefing. Available at: <http://biotech.wisc.edu/Education/prodigene.html> (Accessed June 26, 2007)
- Casagrande, R. 2000. Biological terrorism targeted at agriculture: the threat to US national security. *The Nonproliferation Review*. 7, 3, 92-105.
- Cuite, C. L., S. C. Condry, M. L. Nucci, and W. K. Hallman. (2007). Public response to the contaminated spinach recall of 2006. Food Policy Institute, Rutgers University: New Brunswick, New Jersey. Available at: http://foodpolicyinstitute.org/docs/reports/FPI_Spinich_Recall_Report.pdf (accessed June 27, 2007).
- Food and Drug Administration (FDA). (2002a). Establishment and maintenance of records under the public health security and bioterrorism preparedness and response act of 2002 (Docket No. 2002N-0277). Food and Drug Administration, U. S. Department of Health and Human Services: Washington DC. Available at: <http://www.fda.gov/oc/bioterrorism/bioact.html> (accessed October 26, 2006).

- Food and Drug Administration (FDA). (2002b). Questions and answers regarding establishment and maintenance of records (Edition 3). Food and Drug Administration, U. S. Department of Health and Human Services, CFSAN: Washington DC. Available at: <http://www.cfsan.fda.gov/~dms/recguid3.html> (accessed October 26, 2006).
- Golan, E., B. Krissoff, F. Kuchler, K. Nelson, G. Price, and L. Calvin. (2004). Traceability for food safety and quality assurance: mandatory systems miss the mark. *Current Agriculture, Food & Resource Issues*. 4, 27-35. Available at: <http://www.CAFRI.org>. (accessed October 23, 2006).
- Hurburgh, C. R. (2003). Quality management systems for agriculture: a case study. *Resource Magazine*. 10, 4, 13-17.
- Hurburgh, C. R. (2004). Source verification and certified quality management systems for the corn market. *Fourth Corn Utilization and Technology Conference*. Indianapolis, IN: National Corn Growers Association and Corn Refiners Association.
- Hurburgh, C. R. and T. J. Sullivan. (2004). An ISO-based system for quality management and traceability in the US grain handling industry. *International Quality Grains Conference: A Global Symposium on Quality-Assured Grains and Oilseeds for the 21st Century*. Indianapolis, IN: U.S. Grain Quality Research Consortium (NC-213).
- Hurburgh, C. R. (2006). The impact of FDA recordkeeping rules on grain handling. *GEAPS/NGFA Operations Management and Technology Seminar Series*. St. Louis, MO: GEAPS.
- Hurburgh, C. R. (2007). Traceability in bulk commodities. *2nd Annual IFSS Symposium: Food Safety and Public Health: Production, Distribution, and Policy*. Ames, IA: IFSS.
- Iowa Grain Quality Initiative. (2006). U.S. FDA registration and record maintenance review. Available at: <http://www.extension.iastate.edu/grain/> (Accessed August 10, 2006).
- Lin, W., G. K. Price, and E. Allen. (2002). Starlink: impacts on the U.S. corn market and world trade. In *USDA Feed Yearbook/FDS-2001*. Washington, D.C.
- Sullivan, T. J. and C. R. Hurburgh. (2002). A quality management system for grain facilities: an ongoing case study. *International Conference and Technical Exposition, Grain Elevator and Processing Society*. Vancouver, British Columbia: GEAPS.