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Using Quality Management Systems for Food Traceability

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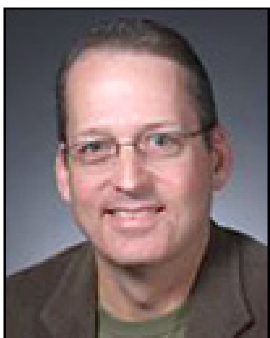

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Using Quality Management Systems for Food Traceability

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Abstract

Due to the events of 9/11, the US Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) requires that all companies involved in the food and feed industry to self register with the Food and Drug Administration (FDA) and maintain records and information for food traceability purposes. Farmers Cooperative, (FC) of Iowa, used a quality management system (QMS) to create a traceability system. Forty-one mock recalls at grain elevators were done and demonstrated that the company met the requirements for the Act. A traceability index was created that quantifies a lot size of grain in an elevator. The time duration of a recall event was impacted by the backward or forward information flow of the event. Commingling of large quantities of grain did not significantly impact the time required to meet the FDA 24-hour mandate. The quantity of grain of the recalled lot size did not have a significant impact upon lot size of suspected contaminated grain.

Introduction

The events of 9/11 have amplified concerns about safety of the food supply. Legislation requirements for food traceability presented special 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 was signed into law in June 2002 (Iowa Grain Quality Initiative, 2006). Specifically, sections 305 and 306 give the FDA responsibility for food protection and tracing to the source, incidents of food adulterated by terrorist groups or from naturally occurring events (Iowa Grain Quality Initiative, 2006).

The Act requires that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the FDA. This produced a database of all facilities engaged in food handling and processing activities (FDA, 2002a). Facilities handling raw agricultural commodities are included (Iowa Grain Quality Initiative, 2006). The Act also increased the need for traceability in US commodity production with the regulatory requirements noted on the FDA website listed in the end of the paper.

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 (FDA, 2002a). By connecting the records of suppliers and customers of suspected food product(s), a chain of evidence may allow the FDA to trace food forward or backward in the supply chain. To facilitate efficient traceback, the FDA requires that a location produce requested records within a 24-hour period (FDA, 2002a; 2002b).

Timeliness is important because limiting the scale of a product recall depends, in part, upon a prompt determination of what organizations are involved, or what lots contain suspect product, and those locations not affected. The Act allows for innovation in meeting the traceability requirements by not dictating how the one up and one down approach will be done.

Traceability has become the overall moniker applied to information flow of food processing in either direction. There are differences between tracking and traceability. In a tracing system, the information flow moves backward through the supply chain from consumer to supplier. Tracking is following the information forward from the source to the end user (Schwagle, 2005).

If a location has existing records which allows the FDA to identify the immediate supplier(s) and the subsequent recipient(s) of the food in question, then the organization does not need to create an entire new record system (FDA, 2002b). 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 grain traceability. When Karnal Bunt was found in American wheat in 1996, the Animal and Plant Health Inspection Service (APHIS) of the USDA spent over $60 million to contain and eradicate the disease in the small original area. The reduction of exports was estimated at $250 million even though area of actual infection was limited to a small portion of Arizona (Casagrande, 2000). In 2001, volunteer plants of genetically engineered corn, genetically engineered by Prodigene Co. for pharmaceutical purposes, grew among a field of soybeans in Nebraska, resulting in the soybeans to be considered adulterated. The 500 bushels of adulterated soybeans were delivered to an elevator and mixed with other soybeans that resulted in a total of 500,000 bushels of adulterated soybeans that had to be destroyed (BioTrek, 2002). Starlink corn, unapproved for human consumption, was planted on 0.5 % of the 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, Price, & Allen, 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. Most recent, the United State's largest salmonella outbreak tied to fresh produce demonstrated the difficulty of commodity food traceability under the guidance of the Act (Venkataraman, 2008). The grain commodity chain is based on a similar operating structure and the food industry will need to prepare to meet new traceability expectations of the FDA with better results.

Quality Management Systems and Traceability

The increased use of quality management systems (QMS) could meet these demands in an efficient way. While QMS have been widely adopted in other industries such as manufacturing and professional services, the agriculture sector has begun to understand the internal benefits that such initiatives bring.

A QMS focuses on the achievement of results, in relation to quality objectives, to satisfy customer needs and expectations. To create a coherent format for quality management requirements, the International Organization for Standardization (ISO) created the ISO 9001 series (American Society for Quality, 2000a).

Historically, ISO 9001:2000 was based on BS 5750, a quality management standard developed by the British Standards Institute co-released in 1987 as BS 5750/ ISO 9000 (BSI, 2006; Campany, Hooker, Ozuna, & Tilburgd, 2000; Zaibet & Brendahl, 1997). Since then, ISO 9001:2008 has been revised to promote a process management approach (ISO, 2009). Certification to the standard has become the demonstration that defines performance reached by an organization (Meuwissen, Velthuis, Hogeveen, & Huirne, 2003). As a result, the ISO standard has become the dominant QM system. Between 2000 and 2005, over 770,000 individual certificates have been issued, an 18-fold increase (ISO, 2005). Many other organizations use the standard but do not become certified.

There are some studies of ISO 9000 and food traceability. The ISO standard states that an organization, where appropriate, shall identify the product, and its components, by suitable means throughout production (American Society for Quality, 2000a; 2000b). A recent benchmarking study of international food companies found that most food processors focus on safety prevention through quality assurance (QA) systems which includes traceability (van der Vorst, 2006). Manning and Baines (2004) state that such QA schemes are based on company needs rather than on meeting mandatory requirements of traceability. Bailey, Jones, and Dickinson (2002) state that meeting traceability requirements will be most difficult for commodity handlers due the blending from multiple sources before processing.

According to Golan, Krissoff, Kuchler, Nelson, Price, and Calvin (2004), the grain supply chain is based on infrastructure built to move large flows of product based on a limited variety of attributes. Large-scale marketing affords elevators to minimize per-unit handling costs by aggregation of crops of smaller lot sizes into larger batches. Cereal crops are commingled from various producers upon receipt. During this process, a record of type of commodity sold, weight, price received, time of purchase, and any premiums and discounts is created by the elevator. This recordkeeping process typically ends here as the grain is blended to achieve a homogeneous quality level. In the overall supply chain, elevators are crucial in the system as they monitor and control product by transforming grain according to safety and quality characteristics (Golan et al., 2004). Hurburgh (2006; 2004) described how source verification may be achieved utilizing a certified quality management system, such as ISO 9001. Hurburgh and Sullivan (2004) showed 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.

The tracking unit defines the maximum possible precision and is typically referred to as a 'lot' in the system. A lot is typically defined by the amount of material that share unique and similar characteristics with a common process history (van der Vorst, 2006). Batch processing has higher precision because a batch is a unique unit in the view of traceability. Alternatively, in continuous flow processing, lot definition is more difficult since changes in conditions are not as easily identified (Moe, 1998). For the grain elevator example, the lot is typically defined as the bushel amount on a single scale ticket.

The basic traceability metric for a grain elevator is based upon a traceability index (Hurburgh, 2006). The Act only requires 24-hour reporting, not precision. To develop guidelines for the grain industry, the definition of a traceability index (TI) for quantitative measure is as follows:

Traceability Index = suspect volume / 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 smaller than the entire amount of grain within an elevator facility (Hurburgh, 2007; 2006). Explicitly, the traceability goal should be 1:1; one unit of suspected grain is narrowed down to one unit of tracked material. While this is unlikely in practice, TI provides a method of continuous improvement supported by an objective target.

Farmers Cooperative (FC) of Iowa implemented a quality management system to create additional opportunities for marketing grain. The objective was to have a universally recognized quality management system in place, so that as end-users (food processors) sought specialty grain origination, the company could present a program that would have 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 treating grain as a foodstuff (Sullivan & Hurburgh, 2002). The resources needed for food tracking were put in place with requirements such as standard operating procedures, discipline in process control and the documentation of responsibility throughout the production history (Hurburgh, 2004). Table 1 describes the relevant quality management system procedures that FC uses with regard to grain traceability.

Table 1. FC quality management system procedures

ISO Number	Relevant QM system Process	FC Procedure Objective
5.6.1	Management review	Provide a forum for personnel to discuss the quality management system, review information the system is generating, and continual improvement of the system
7.5.3	Grain identification and tracking	Provide a system and instruction to determine the location of grain lots within bulk storage across the elevator
7.5.3	Commodity grain receiving and storage assignment	Establish a process and authority for receipt and identification of inbound grain for storage by grade quality
7.5.4	Recalling commodity grain	Provide a system and responsibilities for conducting a mock recall to identify and isolate the origin of contaminated grain and any remaining suspect grain within the elevator

Table 2. FC mock recall data set

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

Methods

To demonstrate the effectiveness of procedures in Table 2, 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. 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. Some data was not available for every recall.

A forward recall is defined as 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).

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 events 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 and associated null hypotheses were:

1. Does the QMS-based traceability system meet the FDA guideline for 24 hours maximum recall duration under the Act?
   a. A grain elevator operating a QMS-based traceability system meets or is less the FDA requirement for reporting results within 24 hours.

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?
   a. There is no difference between forward or backward events in reporting recalls within grain elevators.
3. Is time duration of the mock recall event impacted by the level of precision of traceability (TI)?
   a. There is no relationship between the level of precision and the time duration in reporting recall events within a grain elevator.
4. Is grain traceability precision (TI) impacted by the forward or backward information flow?
   a. There is no relationship between the level of precision and information flow of recall event within a grain elevator.
5. Does the quantity of suspect material (lot size) impact the time duration of the recall event?
   a. There is no relationship between the lot size and the time duration in reporting recall events within a grain elevator.
6. Does the lot size of suspect material impact the traceability index of the recall event?
   a. There is no relationship between the lot size and level of precision of a recall event within a grain elevator.

Delimitations

This study had the following limits:

1. This research is a case study and represents an in-depth investigation of Farmers Cooperative of Iowa.
2. The commodities involved in this recall are limited to corn and soybeans.
3. The procedures included in this study are based upon a quality management system based upon the ISO 9001:2000 quality standard

Results

As shown in Table 3, the results show that most FC facilities met the 24-hour requirement. The average time was 13.42 hours with a standard deviation of 11.18 hours, well below the 24 maximum time limit. Overall, five locations did not meet the 24-hour requirement or 12% of all locations. Twenty-five percent of the elevators reported results within three hours. Thus, a quarter of locations only needed a few hours time to demonstrate results.

Table 3. Overall results of mock recall exercises at FC grain elevators locations

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

The summary results in Table 3 also demonstrate the variability of grain traceability precision through the TI. The mean TI was 180 with a wide standard deviation of 300. The range of TI results was of 8-942. While the range was large, a minimum of 8:1 demonstrates possibility of improved grain traceability using a QMS. At the other end, a large traceability index of 942 demonstrated a lack of grain traceability. This elevator location did not follow all the requirements of the QMS noted in Table 1. The operator reported that he had no idea where the grain came from, which made the entire inventory of the elevator suspect.

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 did not follow a normal distribution with a defined 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, the longer it takes to track grain. The Act requires an organization maintain records while the product is in the organization's custody. FC often transfers grain from one elevator location to another by truck. 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.

A sign test for medians was done to answer if a grain elevator operating a QMS-based traceability system meets the FDA requirement for reporting results within 24 hours. The one sample sign test was performed to examine if the actual median recall time was less than the null hypothesized test value of 24 hours. Based upon binomial distribution theory, the one sample sign test makes no assumptions about normality and may be used for testing asymmetric distributions (Lehmann & D'Abrea, 1975). This test compares the probability of observing the specific number of recalls (p=0.50) below the hypothesized value of 24. The results are shown in Table 4.

As shown above, the 41 total recalls, 36 locations reported below and 5 reported above the hypothesize value of 24. None reported at 24 hours. At 0.00, the probability that the population median was less than the test value was significant. Thus, a grain elevator operating a QMS-based traceability system meets or is less than the FDA requirement for reporting results within 24 hours.

To test the null hypothesis that there was no difference between forward or backward events in reporting recalls within grain elevators, a Kruskal-Wallis (KW) test was done. Since the distribution of results was skewed, the KW test is a nonparametric alternative to a one-way analysis of variance (ANOVA). It does not require the data to be normal, but instead uses the rank of the data values rather than the actual data values for the analysis (Minitab, 2007). The KW test of the recall time and information flow data was determine if the medians were significantly different from one another (Minitab, 2007).

Figure 1. Distribution of overall mock recall events

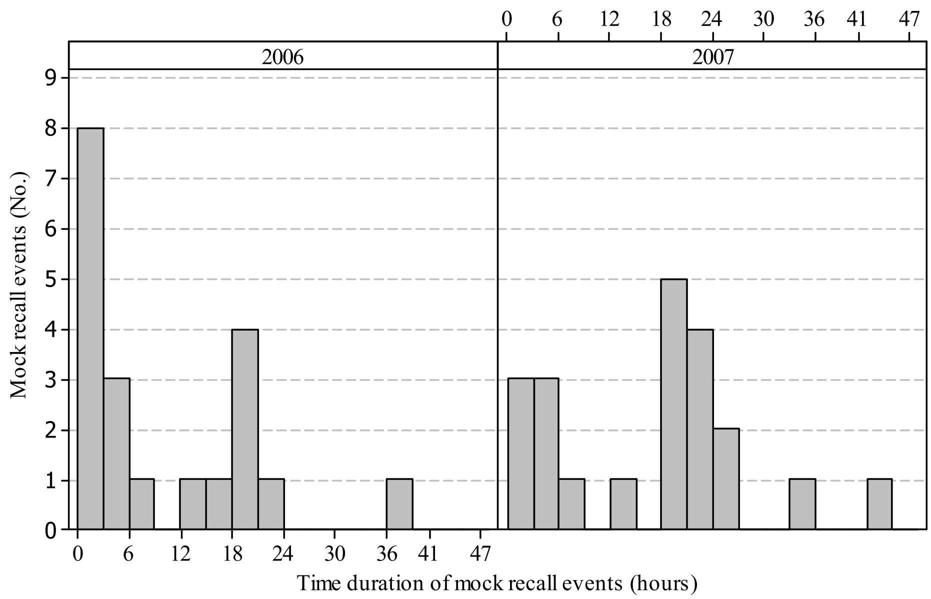


Table 4. Results of mock recall exercises for FDA 24 hour recall mandate

Mock recall description	Elevator Reporting (n)			
	Below	Equal	Above	Median Recall Time (hrs.)
Number of Locations	36	0	5	12.42a

[a]Median with different letter significantly different at p = 0.50

Table 5. Time duration of repeated mock recall exercises at FC elevator locations

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

[a,b]Medians with different letters significantly different from one another at p = 0.05

The results in Table 5 demonstrate that there was a significant difference in the amount of time required to report elevator recall results between the two medians of information flow (backward and forward) with a reported p value of 0.04. Of the 41 recalls, 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. Backward tracing also requires after-the-fact review or assembly of records not necessarily refined for this purpose.

To test for a relationship between the level of precision and the time duration in reporting recall events within a grain elevator, a scatterplot was created. 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). A pearson correlation coefficient tests the strength and direction of two variables in a linear relationship. The pearson value of this test is 0.162, further confirming the lack of a significant relationship between these variables.

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.

To answer the question if there is no relationship between the level of precision and information flow of recall event within a grain elevator, results were tabulated. As shown in Table 6, there was a small set of mock recalls forward (N=3) and backward (N=17) events to compare. For testing, comparison of events by flow is not feasible due to the low number of data points as shown below. Additionally, the mean difference in TI's were difficult to interpret because of the large standard deviations. Regardless, grain elevators should conduct both types of recalls to test a traceability system.

A scatterplot was created to test for a relationship between the lot size and the time duration in reporting recall events within a grain elevator. As shown in figure 3, there was a significant relationship between the suspect bushels being tracked (lot size) and the amount of time required to provide data. The person correlation coefficient is 0.365, indicating a slight, positive relationship with a reported p value of 0.02, less than the test value of 0.05. However, the presence of three recalls with bushel quantities above 2000 will influence this result. Regardless, the volume of recalled material was not arbitrarily assigned; mock recall events began with the amount of bushels that were on a single scale ticket, or load of

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

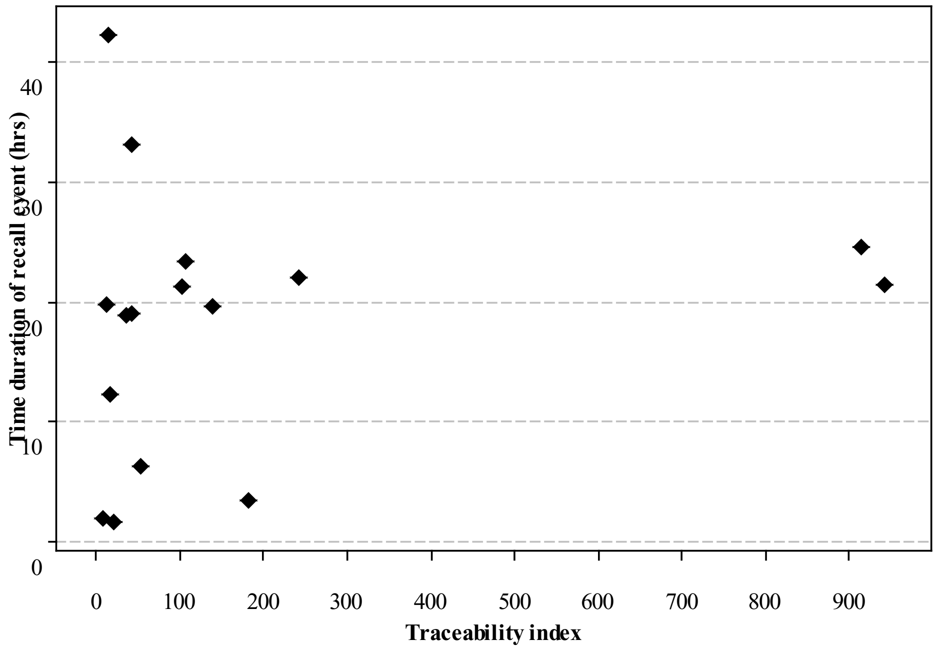
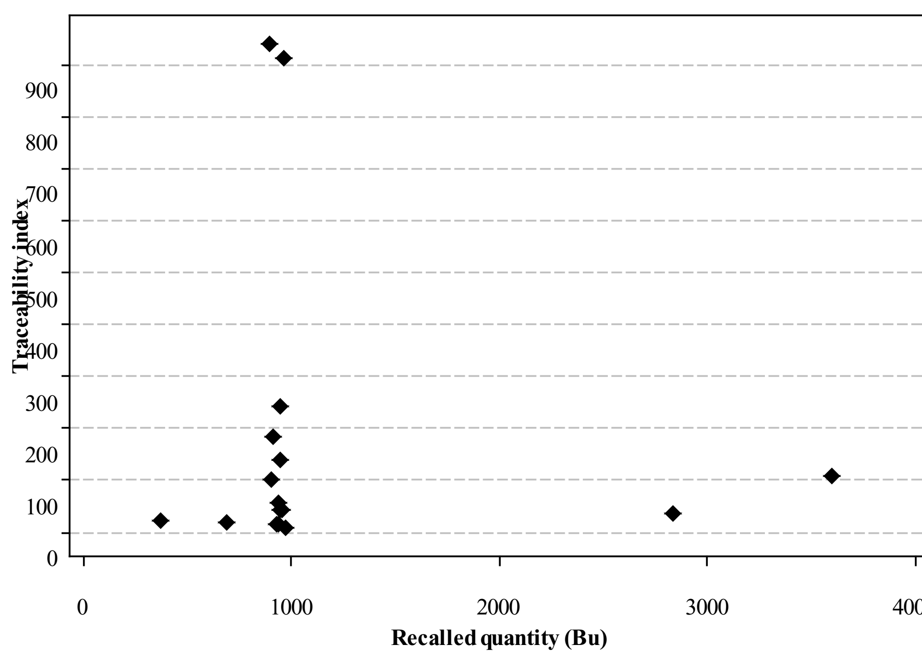


Table 6. Traceability index of 2007 mock recall exercises at FC elevator locations

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

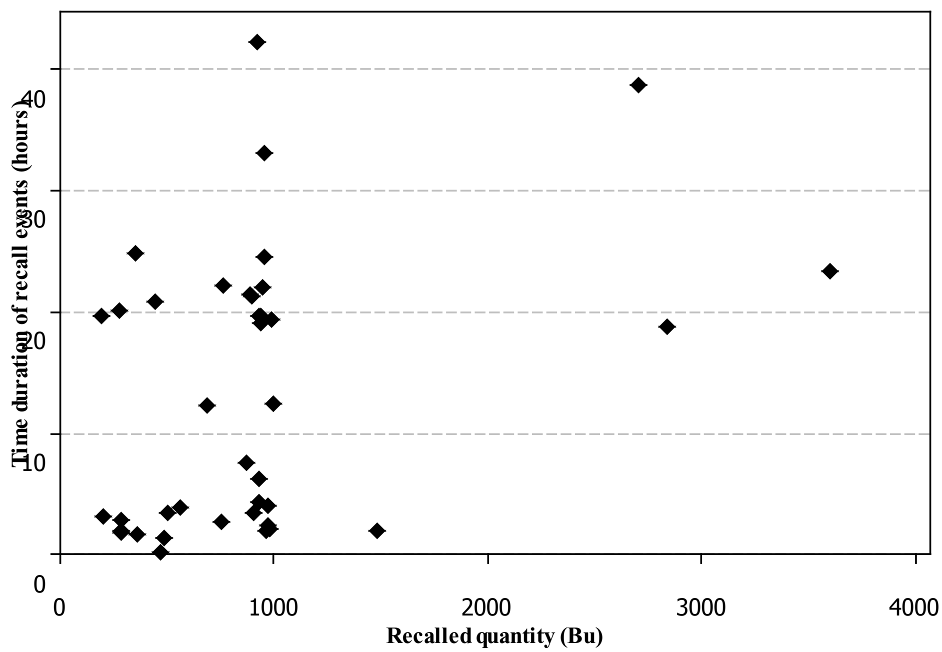
Figure 3. Time duration and lot size of mock recall events



grain. Minimizing the amount of suspect material should automatically be the goal of a commodity grain handler.

To test the last hypothesis of if there was a relationship between the lot size and level of precision of a recall event within a grain elevator, a final scatterplot was created. In figure 4, the amount of grain traced (lot size) did not have a significant impact upon the precision of the traceability index. A pearson correlation coefficient of -0.096 further confirms this result. The small sample size hinders answering this question. From figure 4, Most of the data were clustered together, with a few locations reporting large TI's. 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

FC 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. FC initially designed and implemented a QMS to meet external goals. FC's subsequent focus on internal improvements enabled the organization to meet new, unforeseen government regulations.

There were approximately six tests done to answer the research questions discussed above. The first question was if a QMS-based traceability system could meet the FDA mandate of 24 hours. This result was significant. The median of 12.42 hours was significantly less than the test value of 24 hours. This is the only mandate of the FDA Bioterrorism Act of 2002 and one which will guide industry best practices. Additionally, timeliness of recall could prevent the closing of an entire elevator operation in the event of an actual recall.

The flow of recall event was significant. There was a significant difference between forward or backward events in reporting recalls within grain elevators. A backward event took significantly longer than a forward event. The reported standard deviations were 8.2 for a forward event and 10.4 for a backward event. However, a KW medians test proved significant with a reported p value of 0.04. Although the process flow of an actual recall event is not within the control of the elevator, an FDA recall would be backward, tracing backward from a triggering event. Improving the ability to follow a backward event is an area of improvement within the quality management system.

Concerning a relationship between the level of precision (TI) and the time duration in reporting recall events within a grain elevator, no significant relationship was found by visual examination and correlation analysis. In the event of a recall, identification of suppliers and customers requires precision. More precise levels of grain traceability apparently may not require more time based upon these study results.

It was not feasible for a significance test between the level of precision and information flow of recall event due to a small sample size and large standard deviations. However, there were some interesting results: the reported TI's for forward and backward events were as low as 8 and 13. While not statistically significant, the practical result of such a small index is an important indicator of the utility of quality management systems for traceability in the commodity grain business. 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, suspected, lot size. This was demonstrated in the spinach recall of 2006 (Cuite, Condry, Nucci, & Hallman, 2007). Following the QMS traceability processes could minimize the need to destroy large amounts of suspect grain, contaminated or not.

The next research question was exploring for a relationship between the lot size and the time duration in reporting recall events. There was a significant relationship between the suspect bushels being tracked (lot size) and the amount of time required to provide data. The larger the amount of suspected contaminated material in the recall event, the longer it took to provide results. Grain elevator operations handle large volumes of grain and the commingling of different sources of grain can result in large lot sizes. Refining the QMS system for robustness to lot size would constitute continuous improvement to the QMS-based traceability system.

There was no relationship between the lot size and level of precision of a recall event within the grain elevators. With more evidence, managing backward events may prove to be more difficult, reinforcing the finding that backward events take longer to complete than forward events.

In summary, an organization that meets the ISO 9001 quality standard also incorporates traceability processes. QMS adoption by FC enabled this organization 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 and improvement of a quality management system. Some of these improvements are noted above. Other improvements would be found by future research: namely, the unique characteristics of forward and backward recall events, improvement in precision, and reduction in overall recall time. This study provides benchmark data on which to evaluate improvement and influence future research in the area.

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