2009

Maize to Milk: An Analysis of the Traceability Systems of Bulk Commodities

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Maize to milk: An analysis of the traceability systems of bulk commodities

by

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A thesis submitted to the graduate faculty

in partial fulfillment of requirements for the degree of

MASTER OF SCIENCE

Major: Industrial and Agricultural Technology

Program of Study Committee:
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Iowa State University

Ames, Iowa

2009

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ABSTRACT

Traceability is the ability to track any food, feed, food-producing animal or substance that will be used for consumption, through all the stages of production, processing, and distribution (European Union, 2002). In this study, an analysis of the traceability systems of three bulk commodities, corn, feed, and milk, was conducted to analyze the internal traceability system of each respective entity, the external traceability system among all entities, and the information exchange and communication between each entity. The objectives of this study were to create a model/map for tracing these commodities, to identify gaps in the internal and external traceability systems, and to provide quality control/quality management strategies to improve the external traceability system.

The first step of analysis involved comparing the ISO 22005 traceability standard to the current tracing and tracking system used by the dairy processor. Only 2 of the 9 design components of the Standard were met by the processor due to lack of specified objectives. A concept map was created using supplier/recipient records from the dairy processor and dairy farm. Using records from the processor, information gaps were identified in the traceability system. After identifying gaps, quality control and quality management strategies were developed to help close the gaps and strengthen the external traceability system. A product flow model was also created to determine the location of products from corn to processed milk and to determine what records are kept at each point in the chain.

The study showed that once the dairy processor has developed specific objectives to serve as the foundation for their traceability system, the established safety and quality programs that have been implemented and executed can be easily integrated into an ISO 22005 certified traceability system. Since making the decision to fully implement an ISO certified traceability system will require additional information such as risk and cost-benefit analyses, small changes that will yield timely results can be made in the area of quality control.

CHAPTER 1: INTRODUCTION

Introduction

In recent years, the food production industry has been plagued by frequent occurrence of deadly food safety scares in the meat, vegetable, and dairy industries. From the first confirmed case of Bovine Spongiform Encephalopathy in the United States in 2003, to the *Salmonella* scare in peanut butter in 2009, consumers question the quality and safety of the food they feed their families. These incidents have had an immense impact on our global society not only because of the negative economic impact they have caused (Fox, Coffey, Minert, Schroeder, & Valentin, 2005), losing up to $4.7 billion, but also because of the detrimental health effects including hospitalizations and death, these occurrences have caused in humans (Associated Press, 2008). The development and integration of a method to pinpoint the source of an outbreak is now a necessity.

Numerous countries have experienced the direct economic and human health effects of food outbreak occurrences. Within days of the 2003 BSE confirmation in Washington State, 53 countries including major importers such as Japan, Mexico, South Korea, and Canada banned imports of US beef. Although some important markets did partially reopen in 2004, exports for the year were 82% lower than in 2003. In fact, an analysis performed for the Kansas Department of Agriculture, suggested that the US beef industry losses from export restrictions during 2004 ranged from $3.2 billion to $4.7 billion (Fox et al., 2005). In China, in 2008, melamine, an industrial contaminant commonly used in coatings and laminates, wood adhesives, fabric coatings, ceiling tiles and flame retardants, was being used to produce dairy products by one of China's largest dairy processing companies. Several countries - Burundi, Gabon, Tanzania, Indonesia, Taiwan, Japan, Singapore, Malaysia, and others have banned the import of Chinese dairy products (Brice, 2008). Several children died, 53, 000 were sickened, and 13,000 were hospitalized (of which 80% were ages 2 or younger) (AP, 2008). These are only two examples of the economic and human health impacts that have occurred due to the occurrence of a food contamination.

It is clear that the global food production industry is in need of a method or system to mitigate food safety outbreaks. Food producers are in dire need of systems that will aid in the production of safe, quality products from farm to fork, and consumers demand it. The needs of the industry and demands of the public are being met with a system referred to as “traceability.”

Traceability

According to the European Union (2002), traceability is the ability to track any food, feed, food-producing animal or substance that will be used for consumption, through all the stages of production, processing, and distribution (Official Journal of the European Union, 2002). Once unaccepted in the vocabularies and glossaries of government and food producers alike, traceability has recently become a hot topic in the food production industry. Tracking products has now become a vital part of the way producers do business. As for government, enforcing and regulating traceability can no longer be ignored: immediate action must be taken to ensure that all food products are safe and wholesome.

The term traceability is often used interchangeably with other terms such as identity preserved production and marketing (IPPM) or segregation. This notion is misleading and incorrect. While IPPM and segregation focus on issues such as capturing premiums for grains and oilseeds and the prevention of hazardous crops entering the food chain, traceability employs a method that allows food producers and retailers to identify the source of contamination and initiate procedures to remedy the situation (Smyth & Phillips, 2002). Though each concept has its place in the food industry, traceability has become important because of the magnitude of recent events such as the *Salmonella* outbreak in tomatoes and peppers (Centers for Disease Control and Prevention, 2008) and *E.Coli* outbreak in spinach (Department of Health and Human Services, 2006).

Traceability has become important in all facets of food production. The United States government recognizes the importance of traceability, and has taken large steps to integrate its practices and principles into US food production and processing. In 2002, President George W. Bush signed the Public Health Security and Bioterrorism Preparedness Act which requires all food establishments to register with the Food and Drug Administration and to maintain documentation indicating the immediate previous source and immediate subsequent recipient of their product or ingredients. The European Union has passed two pieces of legislation on GM (genetically modified) food and feed and traceability and labeling. These laws require the labeling of all GM feed and food products and provide a system for identifying these products throughout the supply chain.

The food industry has also taken the initiative to improve traceability systems, not only to meet regulations, but for consumers. The Produce Marketing Association (PMA), United Fresh Produce Association, and several others have joined together to form the Produce Traceability Initiative in an effort to standardize and adopt consistent traceability practices across the supply chain, from farm to fork (Produce Marketing Association, 2007). Companies such as Sun-Opta produce and market non-GMO food products, only possible through the use of efficient traceability systems. Bryan Silbermann, president of the PMA, says, “Effective traceability must be a business imperative for everyone in our industry. Consumers and regulators expect it (PMA, 2007)."

ISO 22000 & 22005

While it is a step forward for government and industry to embrace traceability, this new found enthusiasm has made standardization very difficult. Numerous traceability systems have been developed with the same vision, yet how they achieve the means to this end is totally different. These systems have been tailored to fit the needs of each company, each industry, and each government as they see fit. Therefore, traceability has become a priority to the International Organization of Standardization (ISO), an organization that seeks to harmonize similar, but varying standards, rules, and policies. They have recently issued a quality management standard specifically geared toward food production, ISO 22000, Food Safety Management Systems – Requirements for any organization in the food chain. This standard specifies requirements for organizations to demonstrate ability to control food safety hazards in reference to their own policies and relevant food safety regulations, as well as, aim to boost customer satisfaction. ISO 22000 contains the quality management system requirements of ISO 9000 in addition too the more specific food safety requirements. The ISO has now issued a standard specifically for traceability in the feed and food chain, ISO 22005 (International Organization for Standardization, 2007).

Project Background and Description

Researchers argue that implementing traceability systems is beneficial. In addition, the effort to improve these systems is reflected by each new regulation, standard, and company policy of numerous organizations. The question remains, have these efforts been successful or is there yet still more work to be done?

A case study was performed to analyze the traceability systems of three major bulk commodities, from corn to milk. In this study, an attempt will be made to trace the path of a processed liquid milk product back to the original farm(s) where the corn was grown and provided to dairy cattle as feed. Documentation and methods developed by each entity will be used to evaluate the internal and external tracing capabilities of each of the entities involved.

Though this study could be conducted on many other food supply chains, this particular chain was selected for two specific reasons. First, dairy cattle diets are rich in corn and corn products, a bulk commodity and common breeding ground for aflatoxin which can be passed on to the milk. Second, milk and milk products, another bulk commodity, are especially crucial because they provide 73% of the calcium available in the food supply. In fact, of all foods, none surpasses milk as a single source of those dietary elements needed for the maintenance of proper health, especially in children and the elderly. (International Dairy Foods Association, 2007). Therefore, this supply chain contains bulk commodities that have large food safety implications.

Project Objectives

The objectives of this study were to develop a conceptual model/ map that can be used as a tool to trace and track the bulk commodities involved in the food chain selected for this case study, corn, feed, and milk; to identify gaps in these respective traceability systems with an emphasis on the processing operation; and to develop quality control and quality management strategies at the processing level that will effect each subsequent entity in the supply chain resulting in a more effective external traceability system.

Thesis Organization

This thesis is written in the alternative format. The General Introduction is Chapter one of this thesis. The second chapter is a general literature review. Chapter three is a manuscript for a journal article. Chapter four is the general conclusion. Chapter five is the suggested future research. The appendix contains a glossary and a final copy of ISO 22005: Traceability in the Feed and Food Chain.

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CHAPTER 2: LITERATURE REVIEW

Introduction

Traceability is the ability to follow any food item through all stages of production, processing, transport, and distribution (International Organization of Standardization, 2007). Traceability is also defined as the ability to track any food, feed, food-producing animal or substance that will be used for consumption, through all the stages of production, processing, and distribution. (Official Journal of the European Union, 2002). Can-Trace defines traceability as the ability to trace the history, application or location of that which is under consideration. (Can-Trace, 2004). Though a concept very familiar to all food production industries, traceability has not always been embraced and formally defined. In light of several recent outbreaks in the meat and vegetable industries, traceability has taken center stage in all food production.

This section contains a literature review that will present the standards and principles of traceability, as well as some objectives and benefits of traceability. The review will discuss very basic features of all traceability systems and the most recent government, international, and industry efforts geared toward improving traceability. The concluding information will describe research conducted to analyze the benefits of implementing traceability systems. Though research on traceability is growing, there has not been a reported study that analyzes the entire food supply chain across multiple bulk commodities.

Traceability: Principles, Regulations, and Standards

Various governments, industries, and initiatives have varying definitions for traceability. However, the concepts and goals of traceability are all the same, tracking and tracing food products from farm-to-fork, from start to finish.

Basic Principles

Though there are several definitions of traceability, there are some components that are common and essential to all traceability systems. All traceability systems are characterized by three primary traits, breadth, depth, and precision. Breadth describes the amount of information the traceability system records (Golan, Krissof, Kuchler, Calvin, Nelson & Price, 2004). It would be unreasonable and expensive to keep records for all attributes of a product because all attributes do not affect the quality and safety of the products being produced. The breadth of the system must coincide with the food producer's objectives identified in the design stages of the traceability system. In most cases, the breadth of traceability systems is more likely to include attributes that are important to regulators and consumers. Depth describes how far back or forward the system monitors relevant information (Golan et al., 2004). Depth is largely determined by the breadth of the system.

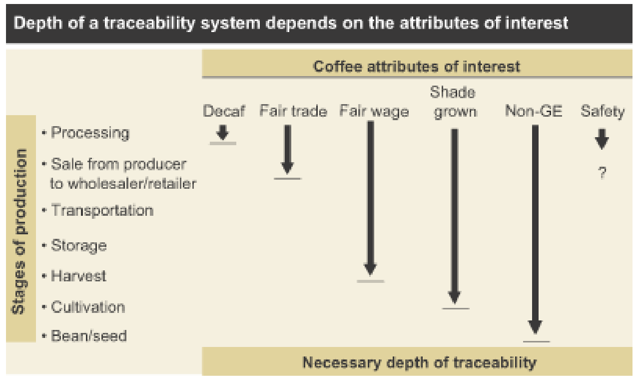

Figure 1. Depth of a Traceability System
(Source: Golan, Krissof, Kuchler, Calvin, Nelson & Price, 2004).

Precision reflects the degree of assurance with which the tracing system can pinpoint a particular food product's movement or characteristics (Golan et al., 2004). In some cases, the objectives of the system will dictate a precise system, while for other objectives a less precise system will suffice. For example, systems that trace larger units like whole animals are much more precise because they have the ability to track backward to identify where the animal was grown. Systems for grain are likely less precise because while they cannot be traced back to the farm, the grain can be traced to an elevator because it is sorted by quality attributes and stored in bulk, not by individual farm. Traceability does not allow one to trace back to a single lot of grain or single farm, however it does allow one to determine where the contamination is not, a very difficult task without a traceability system. Though 100% traceability is impossible, it is the aim of producers to implement systems that meet its individual objectives as efficiently as possible. Traceability systems are designed for specific information.

Internal/External Traceability

Internal and external traceability are separate, but closely related concepts. Internal traceability involves monitoring a product as it is delivered, processed, combined, and packaged within a facility. Advantages accrue from internal traceability within a step in the chain (Moe, 1998). (Figure 2) External traceability, also known as chain traceability, monitors product from raw ingredients through processing to the consumer. An external traceability system is therefore a collection of internal traceability systems. It can only be as good as the individual internal systems that it consists of. In “Perspectives on Traceability in Food Manufacture,” Moe argues that, “Many advantages can accrue from establishing chain (external) traceability, and when sub-descriptors concerning quality attributes are included, the advantages are increased (Figure 2). Internal and external traceability combine to create the capability of tracing the processing of multiple products as opposed to one single product (Table 1).

Advantages of Internal Traceability in the Production Step	Advantages of Chain Traceability
•Possibility for improved process control •Cause-and-effect indications when product does not conform to standards •Possibility of correlating product data with raw material characteristics and processing data •Better planning to optimize the use of raw material for each product type •Avoidance of uneconomic mixing of high-and low-quality raw materials •Ease of information retrieval in quality management audits •Better grounds for implementing IT solutions to control and managements systems (e.g. Computer based quality managements systems, Laboratory Information Managements Systems (LIMS), Manufacturing Execution Systems (MES) and others)	•Establishes the basis for efficient recall procedures to minimize losses •Information about the raw material can be sued for better quality and process control •Avoids unnecessary repetition of measurements in tow or more successive steps •Improves incentive for maintaining inherent quality of raw materials •Makes possible the marketing of special raw material or product features •Meets current and future government requirements (e.g. confirming country of origin)

Table 1. Advantages of Internal and External Traceability (Source: Moe, 1998).

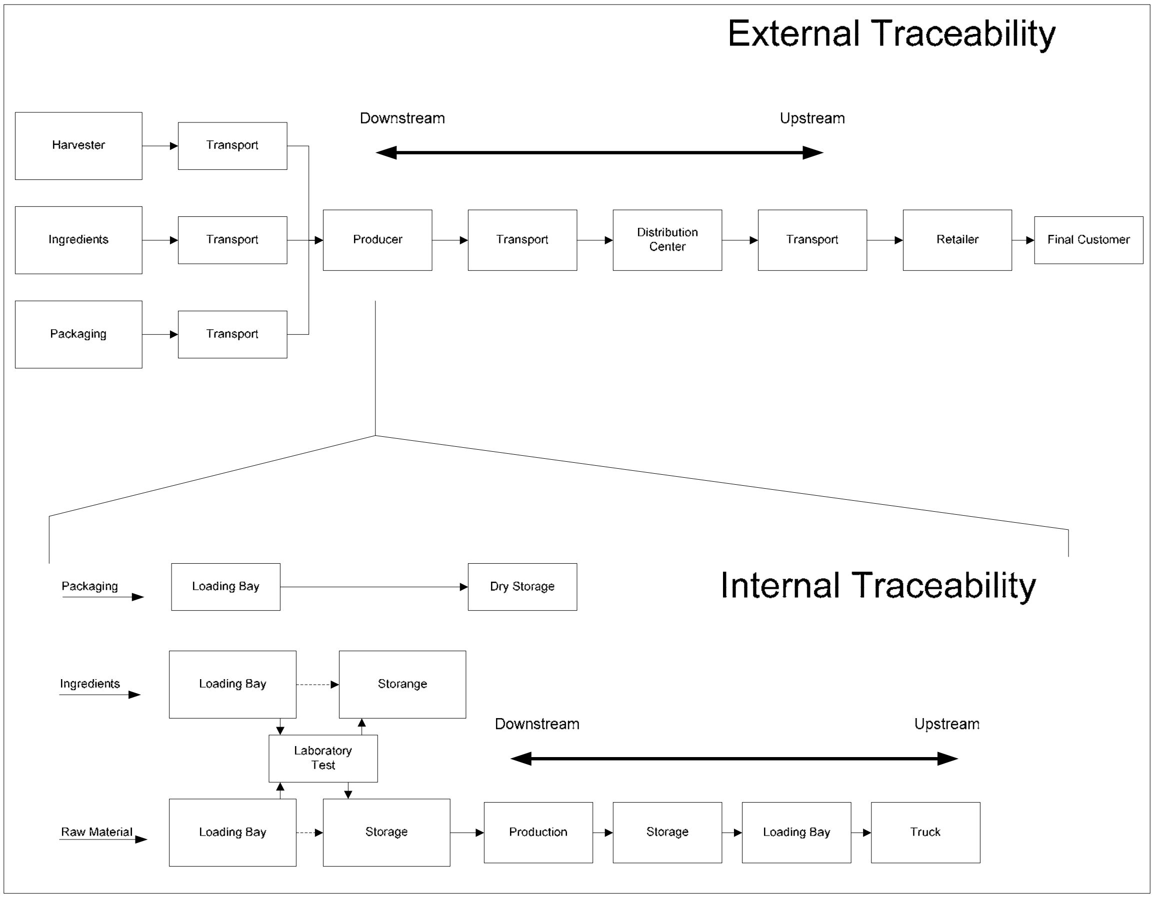

Figure 2. Internal/External Traceability (Source: DNTS, 2008).

United States: Public Health Security and Bioterrorism Preparedness Act of 2002

The September 11, 2001 attacks on the United States prompted legislators to evaluate the vulnerability of major infrastructure systems and significant supply sources which included United States food supply. As a direct result of these events, President George W. Bush signed the *Public Health Security and Bioterrorism Preparedness Act of 2002* also known as the Bioterrorism Act (http://www.fda.gov/oc/bioterrorism/bioact.html.). This Act is divided into five parts:

- Title I: National Preparedness for Bioterrorism and Other Public Health Emergencies

- Title II: Enhancing Controls on Dangerous Biological Agents and Toxins
- Title III: Protecting Safety and Security of Food and Drug Supply
- Title IV: Drinking Water Security and Safety
- Title V: Additional Provisions

The Food and Drug Administration is only responsible for carrying out Title III, Subtitle A: Protection of the Food Supply and Subtitle B: Protection of the Drug Supply. Domestic or foreign food facilities that manufacture, process, pack, transport, distribute, receive, hold or import food in the United States are required to register with FDA and prior notice must be made for any shipment of human or animal food being imported or offered for import. In addition, this Act established final regulations on the establishment and maintenance of records of all registered business and organizations. These records are required to identify the immediate previous source of all food or food products received, as well as, the immediate subsequent recipient of all food or food products. This is also referred to as the one up, one down principle. This principle also appears in EU Regulation EC 178/2002. (Official Journal of the European Union, 2002).

This Act gives FDA the authority to retrieve records on any article of human or animal food or food product which is believed to be adulterated and poses a threat of adverse health consequences or death. The entity must make these records readily available as soon as possible, not to exceed 24 hours. The facilities are not required to retain these records for longer than 2 years. The requirements are as follows:

Food having significant risk of spoilage, loss of value, or loss of palatability within . . .	**Non- transporter Records**	**Transporter Records**
60 days	6 months	6 months
> 60 days but within 6 months	1 year	1 year
> 6 months	2 years	1 year
All animal feed, including pet food	1 year	1 year

Exempt from the Act are:

- Farms
- Foreign entities that do not transport food in the United States
- Restaurants
- Restaurants/Retail Facilities if sales of food it prepares and sells to consumers for immediate consumption are >90% of its total food sales
- Entities performing covered activities with food regulated exclusively by the United States Department of Agriculture
- Entities who manufacture food for personal consumption
- Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food

European Union General Food Law

In 2003, the European government followed the United States in instituting regulations for traceability. Specifically, the EU instituted legislation for labeling and genetically modified feed and food products, in two parts: EC 1829/2003 on Genetically Modified Food and Feed and EC 1830/2003 on Traceability and Labeling of Genetically Modified Organisms.

EC 1829/2003 provides a uniform procedure for the scientific assessment and authorization of GMO’s and GM food and Feed. Authorizations apply to GMOs for food or feed use, food or feed containing or consisting of GMOs; and food or feed produced from or containing ingredients produced from GMOs. This regulation requires that all food and feed which consist of or contain GMO’s and are produced from or contain ingredients that are produced from GMO’s regardless of the percentage of GM material in the final food or feed product.

EC 1829/2003 provides two thresholds for the adventitious presence of GM material in non-GMO food and feed products. The threshold is set at 0.9% for GMO’s that have EU authorization and 0.5% for material not yet authorized by the EU, but have received a favorable risk assessment from the European Commission. Products that fall under these thresholds are not required to be tracked or labeled provided that the GM presence can be proven to be adventitious and unavoidable. There is no threshold allowance for the presence of GM material that has been neither authorized nor assessed.

EC 1830/2003 provides a uniform EU system for identifying GM food products throughout the supply chain. Its objective is to facilitate accurate labeling in accordance with the aforementioned regulation, EC 1829/2003. This regulation covers the following marketed products:

• Any products (including food or feed) consisting of or containing GMOs

• Food produced from GMOs

• Feed produced from GMOs

Documentation for food or feed products containing or consisting of GM material must begin at the first stage of placing it on the market. Written documentation is required to be transmitted throughout all stages of the supply chain stating that the product contains a GMO. This documentation must also provide the unique identifiers for the specific GMO, this is the most difficult part. All entities in the supply chain are required to maintain documentation for 5 years detailing the immediate provider of the product and the subsequent receiver of the product.

Documentation for food or feed products produced from GMO's must be transmitted to the operator receiving the product. For each transaction, information regarding all food ingredients, feed materials, and feed additives that were produced from GMO's must be included. For products that do not have an ingredient list, an indication that the product is produced from GMO's is required. All entities in the supply chain are required to maintain documentation for 5 years detailing the immediate provider of the product and the subsequent receiver of the product.

Can -Trace

The Canadian food industry came together in July of 2003 to develop a program to identify industry requirements to track food and food products through the food chain. Implemented in 2004, Can-Trace contains traceability standards for all food and food products sold in Canada. Unlike the 2002 Bioterrorism Act, participation in Can-Trace is voluntary and industry-led, with no government mandate that requires any organization or business to participate. However, Can-Trace has participation from over 25 national trade associations and government organizations. The goal of Can-Trace is to develop minimal standards that will still allow for traceability across the supply chain using the "one-up, one-down" principle (Can-Trace, 2005).

This principle is employed by GS1 in its global traceability standard. GS1 is a global, non-profit organization that designs and implements global standards, technologies and solutions to improve the efficiency of supply chains. Two technologies primarily used by GS1 are bar codes and Radio Frequency Identification (RFID) to initiate the tracing and tracking capabilities (GS1). According to GS1, standards are agreements that structure any activity or any industry and may be a way of measuring or describing, or classifying products or services (GS1). GS1 was formed from a merger between the European Article Numbering (EAN) International and the Uniform Code Council (UCC). GS1 has a line of products; GS1 Traceability is specifically for tracking and tracing items in the food and pharmaceutical supply chain. The GS1 Traceability Standard defines the traceability process, defines minimum traceability requirements for all sectors and products, and identifies pre-existing GS1 Standards. GS1 is proscriptive in that requirements are defined, rather than being user-specified.

In Can-Trace, tracking is the capability to follow the path of a specified unit and/or lot of trade items downstream through the supply chain as it moves between trading partners. Tracing is the capability to identify the origin of a particular unit located within the supply chain by reference to records held upstream in the supply chain. The Can-Trace system consists of three elements: Product Party Location Identification, Recording of Information, and Linking of Information. Collectively, product, party, and location identification is fundamental full chain traceability because every food component harvested from farm or sea and through every stage of its transformation/packaging to a finished consumer product must somehow be uniquely identified by an accepted protocol at each stage of transformation or possession. Recording of information ensures standardizing the information that needs to be recorded through each step of the food production and distribution chain. Linking of information ensures the continuity of the flow of traceability information; each partner must pass on information about the identified lot or product group to the next partner in the production chain.

Can-Trace is based on database principles, primarily for the animal industry. The developers believed that there are certain pieces of information that must be obtained, maintained and made available at certain points by the participants in the food supply chain (Can-Trace, 2005). Can-Trace Data Standard Version 1.0 establishes a list of mandatory and optional elements for animal tracing which include:

Mandatory Data

- Buyer Identifier
- Lot Number
- Product Description
- Product Identifier
- Quantity
- Shipment Identifier
- Unit of Measure
- Vendor/Supplier Identifier

Optional Data

- Animal Age
- Best Before Date
- Buyer Name
- Contact Information
- Country of Origin
- Date of Pack/Catch/Retirement
- Logistic Provider Information
- Receipt Date
- Ship Date
- Ship from Location Identifier
- Ship to Location Identifier
- Shipping Container Serial Number
- Supplier License Number (Seafood)
- Unit of Trade
- Vehicle Identifier
- Vendor/Supplier Name

These elements are generic and not all are specifically applicable to all participants in the supply chain. However, when all mandatory and optional data elements are tailored to their specific food product, an efficient flow of documentation will be the result (Figure 3).

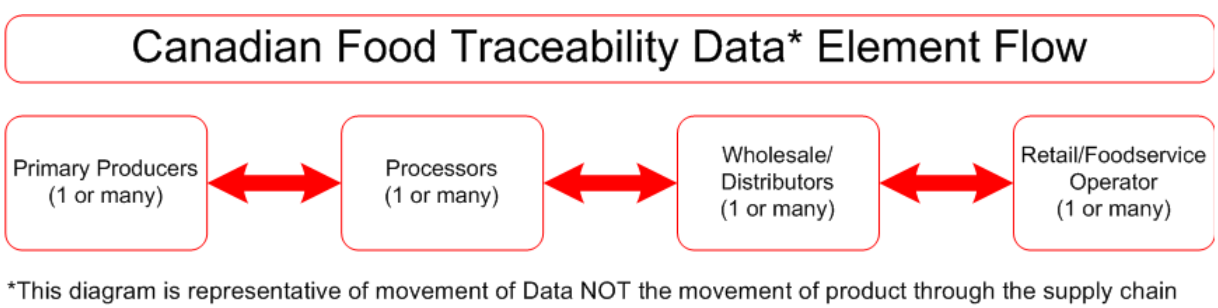

Figure 3. Successful Traceability Through an Efficient Flow of Data Elements. (Source: CanTrace, 2005).

Future initiatives for Can-Trace include a report for recommended best practices for documents, development of guidelines to integrate this system into existing regulatory food safety and quality control programs, and an overview for the challenges for applying this system to multi-ingredient products.

ISO: 22000

ISO is a worldwide federation of national standards bodies that make the development, manufacturing and supply of products more efficient, safer, and cleaner by developing consensus international standards in many areas. ISO 22000, introduced in 2005, is an international standard for food safety management systems. Because the ISO 9000 Quality Management System series does not specifically deal with food safety management systems, many countries developed separate forms of auditable documentation and national standards which caused large inconsistencies among trading countries. The ISO 22000 series was created to bring consistency and harmony to national standards on an international level.

This standard provides requirements for any organization in the food supply chain and is comparable specifically to ISO 9001:2000 which gives the requirements for an organizations quality management system in the manufacturing industry. In fact, ISO 22000 was designed to be fully compatible with ISO 9001:2000, making it easier for companies already ISO 9001 certified to extend certification to ISO 22000. ISO 22000 actually includes a table showing the correspondence of its requirements with that of ISO 9001:2000. No matter how simple or complex, this standard can be used by organizations that are either directly or indirectly involved in the food production chain. It covers all areas which include production, processing, distribution, storage, and handling of all food and food ingredients. ISO 22000 can be used by farms, dairies, feed processors, beverage manufacturers, and grocery stores. This standard aims to bring generally recognized key elements: effective communication, system management, and hazard analysis, together to ensure safety within all points in the food supply chain.

ISO 22005

The most recent addition to the ISO 22000 series is ISO 22005: Traceability in the feed and food chain - General principles and basic requirements for system design and implementation. This standard allows organizations operating at any step of the food chain to design systems for:

- tracing the flow of materials (feed, food, their ingredients and packaging),
- identify necessary documentation for each stage of production,
- ensure adequate coordination between the different actors involved,
- require that each party be informed of at least his direct suppliers and clients, preferably more.

Not only will this standard provide a sense of consistency for organizations that choose to implement it, it will also improve the use and reliability of information, the effectiveness, and the productivity of the organization. This is possible because the ISO 22005 standard is written in a manner that clearly outlines the tools needed to achieve traceability, but allows enough flexibility so that each user can tailor their traceability system to their specific needs.

ISO 22005 operates from many common principles shared by many variations of traceability systems. The standard says that traceability systems should be:

- verifiable,
- applied consistently and equitably,
- results oriented,
- cost effective,
- practical to apply,
- compliant with any applicable regulations or policy, and
- compliant with defined accuracy requirements.

Like many other traceability systems, the objectives must be individually tailored to each organization based on the product(s) produced and the needs and wants of the organization. Therefore, only the actions necessary to meet those objectives need to be included in the traceability system. The key to success is clear and numerical definition of specific case-based objectives and allowable tolerances for meeting the objectives.

Table 2. Comparison Table of Regulations and Standards

	Regulations and Standards			
Comparison Variables	**Bioterrorism Act**	**EU Regulations**	**Can-Trace**	**ISO 22005**
Traceability System/Chain of Custody System	Chain of Custody	Chain of Custody	Traceability System	Traceability System
Voluntary or Mandated by Law	Mandated	Mandated	Voluntary	Voluntary
Objective	Food Safety	Authenticity	User Specified	User Specified
Trace, Track, Both	Both	Both	Both	Both
Configurable/Defined	Defined	Defined	Defined	Configurable

Traceability: Objectives & Benefits

Researchers agree that traceability in the food industry has three major objectives, improved supply chain management, improved food safety and quality control, and differentiation and marketing of foods with credence attributes (Golan et al., 2004). The benefits associated with these objectives include lower cost distribution systems, reduced recall expenses, and expanded sales of products with attributes that are difficult to discern. In every case, the benefits of traceability can translate into larger net revenues for the firm.

Improved Supply Chain Management

Supply chain management represents the management of the entire set of production, manufacturing, transformations, distribution and marketing activities by which a consumer is supplied with a desired product (Opara & Mazaud, 2001). In 2000, American companies spent $1.6 trillion on supply-related activities, including the movement, storage, and control of products across the supply chain (State of Logistics Report, 2001). It is essential that businesses find efficient and effective ways to move products. Simchi-Levi and Kaminsky believe the "idea is to have an information trail that follows the product's physical trail" (Simchi-Levi & Kaminsky, 2003). In the past, companies tended to operate with "island mentality," trading very little information from link to link (Clause, 2003). Companies were only concerned about the activities that went on in their own facilities. As product life cycles decreased and product variety increased, supply chain management became a necessity, not an option. Today, companies have shifted focus from integrating within their companies to integrating across companies as a way to coordinate and improve supply (Kopczak & Johnson, 2003).

Though supply chain management alone has benefits such as reducing costs associated with outsourcing, globalization, and business fragmentation, there are additional benefits associated with the implementation of a traceability system. A very important component of a traceability system is the development of a flow chart which provides a pictorial view of all inputs, outputs, and interactions within the system. Because a traceability system is key to finding the most efficient ways to produce, assemble, warehouse, and distribute products, a flow chart will enhance the supply chain by allowing for the analysis of each intermediate step in the overall process and judge its importance to the process. (Golan, Krissof, & Kuchler, 2005). The flowchart facilitates the generation of supporting documentation that can be used to demonstrate integrity in the food supply chain, to meet regulatory compliance, and to validate and resolve consumer complaints. This can help to eliminate unnecessary or insignificant steps and to allocate funds and responsibility.

Researchers believe that while it is important to know the location of a product within the supply chain, simply knowing the location of a product does not improve supply management unless the traceability system is paired with a real-time delivery system or some inventory control system (Smith, Tatum, Belk, Scanga, Grandin, Sofos & 2005) . Recently, companies like Wal-Mart and Kimberly-Clark have required suppliers to use Radio Frequency Identification (RFID) systems to ship goods. So, for example, when Kimberly-Clark fulfills an order from Wal-Mart for diapers, an RFID scanner reads the codes in the tags on each case of diapers and sends them to the computer system as workers stack the cases on pallets containing the rest of the retailer’s order. The software verifies that the cases going on the pallet are indeed part of the order and uses the codes to create a digital picture of the warehouse (Koelsch, 2005). This technology improves the supply chain by reducing the number of charge backs to the seller and reducing the number of out of stocks at the retail store. In 2005, The United States Department of Defense and European retailers, Tesco and Metro were preparing for the introduction of their own respective RFID systems (Neff, 2005). Large volume buyers like RFID because of data management technology and, in the case of the US Department of Defense, the identification trail for the Department of Homeland Security, if need be. (Fordice, 2004)

These systems provide the real-time delivery component that differentiates minimal traceability from complete traceability.

Improved Food Safety and Quality Control

Much like its role in supply chain management, a traceability system alone can make no food safety guarantees. However, when implemented along with efficient food safety management systems and effective quality management systems, traceability enhances performance by reducing the occurrence of producing unsafe food products, and increasing consumer confidence through transparency.

Quality managements systems and traceability systems differ in that a QMS is a set of policies, processes, and procedures that define how to create products and services in an organization (Laux, 2007). Traceability is the ability to follow any food item through all stages of production, processing, transport, and distribution (International Organization of Standardization, 2007). Traceability aids a quality management system by identifying the location of products and facilitating their recall when safety and quality standards have been breached (Opara, 2003). In the United States, estimates of the total cost of illnesses related to foodborne disease range from $5-$10 billion per annum, but some studies have reported higher values in the range of $20-$30 billion annually (Opara & Mazaud, 2001). Traceability systems aid in reducing the distribution of unsafe or poor quality products, by providing information that expedites the process of locating and removing bad product from the market. Therefore, this reduces the cost incurred from distributing unsafe products and illness caused from those products. In addition, traceability systems reduce product liability and damage, minimize the risk of bad publicity, and help to decrease the number of recalls related to unsafe food production. Opara and Mazaud argue that traceability provides the communication linkage for identifying, verifying, and isolating sources of non-compliance to agreed standards and customer expectations, if and when those non-compliances occur (Opara & Mazaud, 2001). Therefore the financial impact of problems to a company or industry is reduced.

A study done on how consumers link traceability to food quality and safety found that 69% of respondents believe that safety and quality are directly linked to traceability (Rijswijk & Frewer, 2006). Thus, not only is it important for industries to implement traceability systems, but also it is important for them to make the information as transparent as possible. Traceability systems represent the most suitable tool for circulating information on product quality to end customers, and for making the manufacturing system and the whole supply chain more transparent. They also enable the identification of the parties responsible for the production of a given food and the transfer of this information to the consumers, who, as a consequence, may become more loyal customers (Bertolini, Bevilacqua, & Massini, 2006). It appears that transparency is a crucial factor in both establishing food safety and customer trust (Beulens, Broens, Folstar, & Hofstede, 2005). In recent years, as the occurrence of toxic food outbreaks have increased, consumers are becoming more and more informed about the food they feed their families. They are no longer more concerned about sale prices, they are looking for brand names that have “proven” that their products are safe and wholesome. Korthals (2008) believes that, “ …traceability should not be used as a purely administrative tool or as a safety system, …rather it should represent an instrument for establishing effective and responsive policies and institutions based on involvement via informed food choices by citizens/consumers."

In essence, traceability systems help firms isolate the source and extent of safety or quality control problems. Firms have an incentive to invest in traceability systems because they help minimize the production and distribution of unsafe or poor quality products, which in turn minimizes the potential for bad publicity, liability, and recalls (Golan et al., 2004).

Differentiation and Marketing of Foods with Credence Attributes

Traditionally, the United States grain market is known for producing homogenous bulk commodities based on quality. Increasingly, however, markets are signaling demand for differentiated products. Consumers are demanding verification for products with credence attributes (Clause, 2003). Credence attributes are content attributes and process attributes. Content attributes are defined as attributes that affect the physical properties of a product, although they can be difficult for consumers to perceive (Golan et al., 2004) For example, the origin of a red apple is a credence attribute. Process attributes are defined as attributes that do not affect the final product content, but refer to characteristics of the production process (Golan et al., 2004) For example, free range grown chicken or shade grown apples are process attributes. Though differentiation can happen at the product level and can be tested for, credence attributes are those that cannot be tested for, but only documented through traceability systems. The benefits of traceability for credence attributes are greater the more valuable the attribute is to processors or final customers (Golan et al., 2004).

The European Union is an example of why traceability for credence attributes is necessary. In 2003, legislation was passed that required the identification and labeling of all products produced from or containing 0.9 percent of genetically altered products. Since the U.S. is the largest producer of genetically altered products, it is necessary to employ traceability systems document the level of genetically altered material in final products in order to remain a primary producer to the EU (Rockwell Automation, 2008) The application of modern biotechnology in agriculture, particularly for genetically modified (GM) foods, has received considerable interest from the general public as well as from scientists and government. In a UK survey, GM foods were among the top consumer food concerns (Opara & Mazaud, 2001). In the U.S., a survey showed that 60% of all Americans were either consumers of organic foods or were interested in these products (Opara & Mazaud, 2001). These are just a few indicators that consumers are increasingly becoming more preferential about their food choices. Factors such as animal treatment, vaccination, and country-of-origin are also becoming important beyond safety and quality.

Overall, traceability systems improve the differentiation and marketing of foods with credence attributes because it verifies that food products are, in fact, what they claim to be. In addition, though traceability systems are not created to appease the political consumer, it is an added bonus that consumers have the option of making purchases based on the absence or presence of various characteristics.

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CHAPTER 3: DAIRY SUPPLY CHAIN CASE STUDY

Introduction

According to the Centers for Disease Control and Prevention (CDC), it is estimated that in the United States, foodborne diseases cause approximately 76 million illnesses, 325, 000 hospitalizations, and 5,000 deaths each year (Mead, Slutsker, Dietz, McCraig, Bresee, Shapior, Griffen & Tauxe, 1999).These statistics indicate that it is imperative that a tool or method be developed to assist industry and government in accurately tracing and tracking contaminated products to help lessen the risks to human health and financial burden to industries when recalls occur. That tool is called traceability and can be used in any food supply chain, in this case, the production of milk.

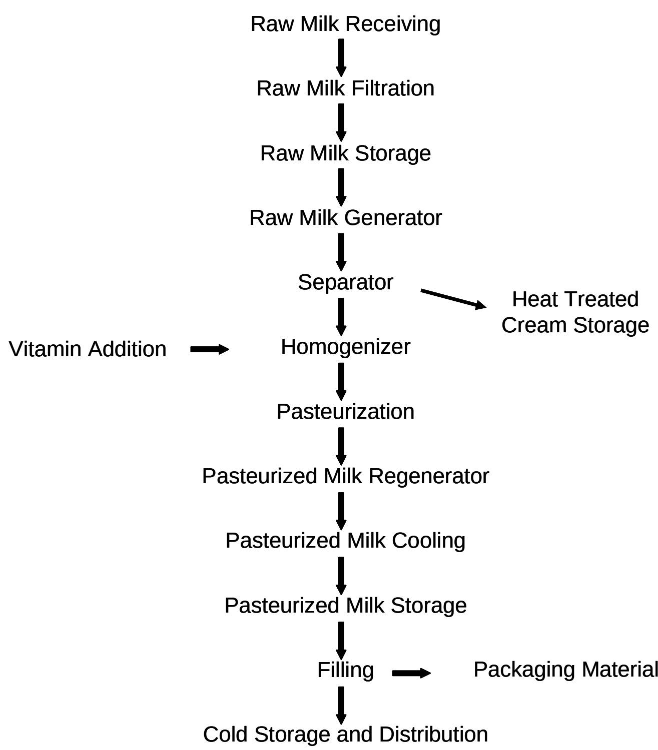
Traceability is not a new term to the dairy industry. In fact, farmers have recorded data on attributes like breed, vaccinations, weight, and lineage for years. However, as the need and demand for traceability in the food and feed chain increases, not only are physical and genetic attributes important, but equally as important is the raw milk that is being produced and processed to make milk and milk products. This is important because these products are good sources of vitamins and milk and milk products contribute about three quarters of the calcium available in the U.S. Food Supply (International Dairy Foods Association, 2007). Since milk plays such a large role in the food supply, it is important that producers ensure its safety and quality. Though this seems like an easy task due to state and federally mandated programs, pathogens that occur in milk and dangerous toxins that can appear in the supply chain make this feat quite difficult.

The Dairy Industry: Processing, Regulations & Standards, and Risks in the Feed Supply

Dairy Processing

Dairy processing is proven technology. With advances, the science of dairy farming and processing has become quite complex concerning methods of feeding, types of feed and best practices concerning quality and safety. Today, dairy processing begins with manually or mechanically milking cows, pumping the milk to bulk tank and cooling it immediately in preparation for transportation to a dairy processor. Once the milk arrives at the dairy processor, the processing continues as indicated by the diagram below (Figure 4).

Figure 4. Milk Processing Diagram



Pasteurized Milk Ordinance & Hazard Analysis and Critical Control Points

Of all foods, none surpasses milk as a single source of those dietary elements needed for the maintenance of proper health, especially in children and older citizens (FDA, 2007). For this reason, it is important that these products are produced with the highest level of both quality and safety. The FDA and state regulatory agencies have collaborated to enforce rules and programs that ensure that the dairy products that are produced are safe. Two of such programs are the Grade “A” Pasteurized Milk Ordinance (PMO) and Hazard Analysis and Critical Control Points (HACCP).

The Grade “A” Pasteurized Milk Ordinance (PMO) is the evolved version of the Standard Milk Ordinance passed by the United States Public Health Service in 1924. This ordinance is highly recommended by the USPHS and the United States Food and Drug Administration (FDA). It is not authored by the USPHS and FDA alone, but is also developed by federal, state, and local levels of milk regulatory and rating agencies including Health and Agriculture Departments, all facets of the dairy industry, educational and research institutions, and sanitarians. The National Conference on Interstate Milk Shipment (NCIMS) and FDA meet biennially to recommend changes and modifications to the ordinance. The current 2007 edition is the 27^{th} revision of the PMO.

The PMO provides the administrative and technical details to processing and producing safe milk and milk products and is recognized by public health agencies, the milk industry, and many others as a national standard for milk sanitation. In fact, it is the basic standard used in the voluntary Cooperative State-USPHS/FDA Program for the Certification of Interstate Milk Shippers. Many state governments have adopted the PMO as law and is therefore governed, regulated, and enforced by state agricultural or public health agencies.

Another program instituted to maintain and improve the safe production of milk and many other products is Hazard Analysis and Critical Control Points (HACCP). HACCP is a proactive food safety system designed to identify biological, chemical, and physical hazards and to prevent, eliminate, and reduce those hazards as best as possible within all stages of food production. First developed in the 1960's by The Pillsbury Company for the National Aeronautics and Space Administration (NASA), this system is now mandated by FDA and USDA in the seafood, juice and meat industries and is used voluntarily in many other food production industries as well.

Though HACCP is mandatory in the production of some food products such as juice, HACCP is currently in a pilot program in the dairy industry. Though the PMO is one of the primary standards of milk production, HACCP provides an alternative that is equivalent to the traditional PMO. Dairy HACCP is another tool that dairy processors can use to assure the safety of dairy and dairy products.

Risks in the Feed Supply

Aflatoxins are toxic metabolites produced by certain strains of the fungi *Aspergillus flavus* and *A. parasiticus*. Aflatoxin is commonly found on grains such as tree nuts, peanuts, and oilseeds including corn and cottonseed. M_1 is a unique type of aflatoxin as it is only found in milk. Dairy cattle produce milk with M1 after consuming feed contaminated with B_1 aflatoxin, the most toxic and most carcinogenic of all types. B_1 is metabolized by enzymes in the liver and shows up as M_1 in dairy cattle urine and milk, however the toxicity of B_1 is more potent than M_1. Though all aflatoxins pose a concern in the food supply, M_1 is of significant concern because of the carcinogenic effects it can cause in humans (Pennington, 2004) as a result of eating or drinking a product contaminated with M_1 aflatoxin. In fact, because infants and young children are likely to consume considerable quantities of milk products the U.S. Food and Drug Administration has established action levels for aflatoxin in animal feed and milk (Table 3). It is also notable to mention that the action level for foods intended for human consumption is 20 ppb (Food Process and Safety Technology, 2006).

Table 3. U.S. FDA action levels for aflatoxin in animal feeds and milk

Commodity	*Action Level (ppb)*[1,2,3]
Corn and peanut products intended for finishing (i.e. feedlot) beef cattle	300
Cottonseed meal intended for beef cattle, swine, or poultry (regardless of age or breeding status)	300
Corn and peanut products intended for finishing swine of 100 pounds or greater	200
Corn and peanut products intended for breeding beef cattle, breeding swine, or mature poultry	100
Corn, peanut products, and other animal feeds and feed ingredients but excluding cottonseed meal, intended for immature animals	20
Corn, peanut products, cottonseed meal, and other animal feed ingredients intended for dairy animals, for animal species or uses not specified above, or when the intended use is not known	20
Milk	0.5 (aflatoxin M_1)

[1]ppb = parts per billion
[2]Feed for the listed animals and uses MAY NOT exceed the applicable action levels.
[3]Blending aflatoxin-contaminated feed to reduce aflatoxin concentration is restricted. Contact Nebraska Department of Agriculture for further information (402) 471-2394.

(Source: NebFact, 2002)

While the FDA does have very stringent regulations on aflatoxin contaminated corn, it still has a few uses, one of which is ethanol production (Munkvold, Hurburgh, & Meyer, 2005). Though ethanol processors may not accept corn with high levels of aflatoxin, the possibility of acceptance still exists. In fact, there are many ethanol plants that don't test every load of corn for mycotoxins. In a study conducted by the Iowa Grain Quality Initiative, it was found that over 50% of ethanol plants test weekly for mycotoxins on selected loads, but only 9% tested all inbound loads. The managers of these plants, did however, say they would increase testing frequency if there was a suspected problem. (Hardy, Holz-Clause, Shepherd, & Hurburgh, 2006).

In the past 10 years, increased ethanol production has increased the availability of distillers grains for use as feed, especially distillers dried grains plus solubles (DDGS) (Figure 5).

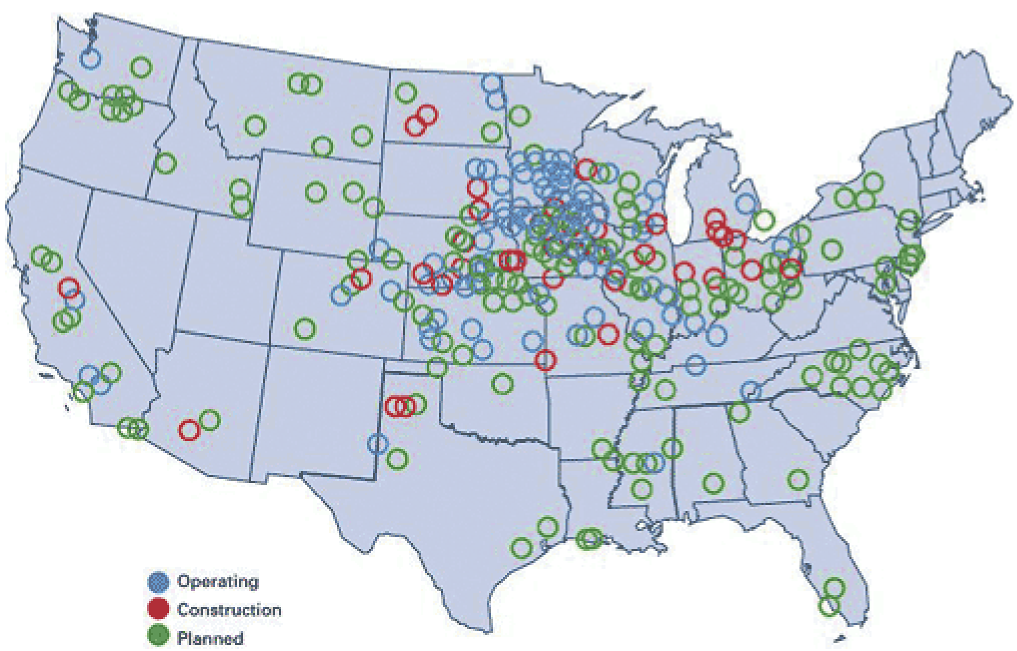


Figure 5. Existing and planned U.S. corn processing plants as of 8/30/06.
(Source: Integrated Crop Management, 2007)

For dairy farmers, this is great news because DDGS today are an even greater source of protein and energy than in the past. In fact, the quantity of distillers grains marketed for use in animal feed has increased from 1.89 million metric tons in 1999 to 8.35 million metric tons in 2005 (a 340 percent increase), and is expected to continue to increase in the future (Food and Drug Administration, 2006). From an economical point of view, this is also good news because DDGS can be stored for long periods of time, can be transported farther distances than wet distillers grain, can be easily blended with other dietary ingredients, and have a high percentage of dry matter therefore, increasing the milk production capacity of dairy cattle (Schingoethe, Kalscheur, & Garcia, 2002). From the milk processing point of view, however, this poses a concern because of the stability of aflatoxin.

During ethanol production, corn undergoes a process called fractionation to better prepare the corn for fermentation. It is broken down into three parts, endosperm, bran, and germ (Figure 6).

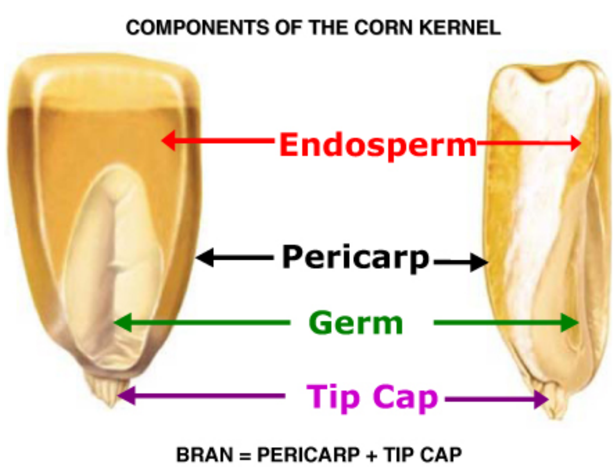


Figure 6. (Source: Cereal Process Technologies, 2009)

Only the starch, found in the endosperm, is used to produce ethanol. The remaining nutrients vitamins, minerals, protein, fat, and dangerous mycotoxins such as aflatoxin are concentrated into DDGS. Therefore, if an ethanol plant processes a bushel of corn contaminated with aflatoxin, the toxin concentrates in the distillers grains by up to three times. This poses a problem because many ethanol plants sell their resulting DDGS to dairy and other farmers as feed. Therefore, DDGS potentially contaminated with aflatoxin poses one of many serious risks to dairy cattle and the milk and milk products they produce.

Case Study Description & Objectives

This case study was conducted using a regional dairy processor, a dairy farm, and a network of farms and ethanol plants. The project focused on three bulk commodities corn, feed and milk. The study focused on analyzing the internal traceability systems of each individual bulk commodity, analyzing the external traceability system among the three bulk commodities, and analyzing the communication and information exchange between each of the entities. More emphasis was placed on the dairy processor because it has the most influence and most power to make decisions that would subsequently affect both the dairy farm and its feed suppliers in terms of product standards and supplier requirements. The objectives of this study were to create a model/map for tracing these commodities from corn to milk, to identify gaps in the internal and external traceability systems, and to provide quality control/quality management strategies and recommendations to improve the overall external traceability system.

Though the Public Health Security and Bioterrorism Preparedness Act mandates that all U.S. food production companies have some form of traceability, not all industries have fully embraced its practice. In this case, the dairy processor not only wants to meet government regulations as best as possible, but they are enthusiastic about using the results of this case study to help them improve their entire operation. In addition, they want to ensure the safety of the many customers that choose to purchase their products, and the thousands of children that consume their products as a part of their school lunch program. Company initiative coupled with consumer safety are two reasons why this company agreed to participate in this study. A confidentiality agreement was signed in the planning stages of the case study, therefore the company's identity cannot be revealed. Therefore, any subsequent associations with the dairy processor, including the dairy farm or feed suppliers, will not be revealed.

Methods and Materials

Participants

The company selected for this study was selected because it is small enough to intricately study the details of its processing operation and large enough to make a noticeable impact on regional and domestic dairy processing if the decision is made to develop a traceability system. The dairy processor is a regional company that produces over 300 varieties of both dairy and non-dairy fluid and frozen products and distributes as far as 400 miles spanning 4 states. They are a private, family-owned business and employ approximately 600 employees. They produce about 40 million pounds of milk monthly and receive up to 1,000,000 pounds of milk per day.

The dairy farm selected is one of many suppliers of the dairy processor. This farm supplies all of its raw milk exclusively to the selected dairy processor. The farm milks 2300 cows per day and supplies approximately 17,000 gallons of raw milk to the processor each day. The feed network discussed in the study is specific to this dairy farm and the feed ingredients and feed suppliers may or may not be included in the feed network of other suppliers to this processor.

The feed network in this study consists of farms in at least five states including Iowa, Nebraska, South Dakota, Colorado, and Wyoming. This network provides feed ingredients such as alfalfa hay, wheat straw, ground corn, wet corn gluten, corn silage, soybean meal, and DDGS. In addition to water, molasses, and nutritional additives, these ingredients make up the daily ration provided to the dairy cattle at the dairy farm included in this case study. Corn and corn products, the bulk commodity of interest in this study, account for over 60% of the daily feed ration at this farm.

Data Description and Collection

This project is a case study. The goal is to explore this operation in great depth and provide suggestions and recommendations specific to this operation. A large portion of the data was collected using the semi-structured interview style. The goal of semi-structured interview is to explore a topic more openly and to allow interviewees to express their opinions and ideas in their own words (Esterberg, 2002).When using this method, the research questions are not fixed and the interviewee is not limited to prescribed responses. In contrast, interviewees are encouraged to respond openly and in as much depth as desired. An interview of this type also requires an interviewer that is knowledgeable about the subject matter, rather than a surveyor that asks questions and records responses without further interpretation.

The questions developed for the series of interviews conducted at the dairy processor were intended to determine (Appendix B):

- The knowledge level of employee's regarding traceability, basic principles of traceability, United States legislation related to traceability, and ISO 22005 Standard for traceability in the feed and food chain.
- The presence of a defined system designed to trace and track product received and distributed by the processing company.
- The data management mechanisms used to collect data on tracking and tracing product throughout the operation.
- The mock recall procedure currently in place by the dairy processor.
- The product standard requirements for raw milk suppliers.
- Standard operating procedures conducted during milk processing and production.
- If present, estimates of any benefits associated with having a defined traceability system.
- Problem areas in the traceability system.

A separate set of similar questions were also developed for the interviews conducted at the dairy farm. These questions were intended to determine:

- The presence of a defined system designed to trace and track product received and distributed by the processing company.

- The data management mechanisms used to collect data on tracking and tracing product throughout the operation.
- The product standard requirements for feed suppliers.
- Identified problem areas in the traceability system.
- Feed ingredients, rations, and location and/or identity of source.
- Timeline and frequency for chemical analysis testing.

The dairy farm provided a significant amount of information concerning the feed network in terms of identifying the suppliers of the feed ingredients. However, for ingredients such as soybean meal and DDGS that are purchased from large processors, telephone interviews were conducted to determine:

- The approximate number of elevators and/or elevator complexes where feed was purchased.
- The approximate number of direct producers that sell feed to the agri-processor or ethanol plant.
- The approximate number of investors that sell feed to the agri-processor or ethanol plant.

Data was also gathered from site visits at the dairy processor and the dairy farm. This method was used, not to explore the behavior of the employees, but to gain a better understanding of the actual procedures that take place in the processing operation and on the farm. At the processor, this provided an opportunity to interact with and ask impromptu questions to individuals about their role in all areas of the processing operation, from raw milk receiving to cold storage. At the farm, this provided an opportunity to interact and ask impromptu questions to individuals about their role in all areas of dairy farms, from the nursery to the milking parlor. In addition, documentation was reviewed that describes how the dairy processor implements state, federal, and voluntary programs such as HACCP and the Pasteurized Milk Ordinance. Documentation that indicates how they track product throughout their facility, from initial delivery to retailer, was also reviewed.

ISO 22005 Assessment

A key step in this case study was first to conduct an assessment to determine the presence or absence of a defined traceability system in the dairy processing plant. It was also to determine, if there was a defined traceability system, was that system ISO 22005 certified. If not, what components are already in place that can be used to develop an ISO 22005 certified traceability system.

The collected data will be compared to the nine components required for the design of a traceability system as defined by the ISO 22005 Standard which include:

- Objectives
- Regulatory and policy requirements relevant to traceability
- Products and/or ingredients
- Position in the feed and food chain
- Flow of materials
- Information requirements
- Procedures

- Documentation
- Feed and food chain coordination

Objectives are the first design component of an ISO 22005 certified traceability system. The objectives are the most vital component of designing a traceability system because they serve as the foundation and each subsequent component is developed from the objectives. The objectives should take into consideration the principles as defined by the standard which include:

- Verifiable
- Applied consistently and equitably
- Results oriented
- Cost effective
- Practical to apply
- Compliant with any applicable regulations or policy
- Compliant with defined accuracy requirements.

At the time of analysis, the dairy processor and its suppliers had not developed specific objectives for a defined traceability system. The dairy processor does, however, house its own lab to test for physical characteristics and foodborne pathogens where the obvious objective is to produce safe, wholesome products from receipt to the “sell-by” date of the products. They have also implemented and successfully executed a HACCP plan, a Supplier Guarantee Program, Prerequisite Programs, and Good Manufacturing Practices where the objectives are to prevent and eliminate pathogens, contaminants, drug residues, allergens, foreign materials, etc. The dairy processor conducts weekly taste tests to critique old and new products as a means of monitoring and maintaining the high quality of its products. Though a defined set of objectives is not present, the development of a set of objectives for a traceability system will be a relatively simple task due to the objectives of the multiple safety and quality control programs already in place. Examples of objectives listed in the standard include supporting food safety and/or food quality objectives, meeting customer specifications, determining the history or origin of the products, and facilitating the withdrawal and/or recall of products to name a few.

The next design component of an ISO 22005 certified traceability system deals with regulatory and policy requirement relevant to traceability. As stated in the Standard, "The organization shall identify the relevant regulatory and policy requirements to be met by its traceability system." This component ensures that all local, state, and federal regulations and policies are being correctly executed. This processor is mandated by both state and federal regulations that include the Pasteurized Milk Ordinance and the Bioterrorism Act. The state that the processor resides in adopted the PMO as law, therefore, they are regulated by the state government and must adhere to its rules, regulations, and policies as enforced by the state government. This processor is also mandated by the federal government to maintain records of the immediate previous source and immediate subsequent recipient as written in the Bioterrorism Act. Since this processor has adhered to both state and federal regulations, this component is fulfilled.

The third design component of an ISO 22005 certified traceability system is identifying products and/or ingredients. The Standard states, "The organization shall identify the relevant products and/or ingredients for which the objectives of its traceability system apply. Though this processor produces and distributes over 300 dairy and frozen products, for the purpose of this case study the focus in on whole, white milk. However, since the processor has not developed a set of objectives for this traceability system, this component is not fully fulfilled.

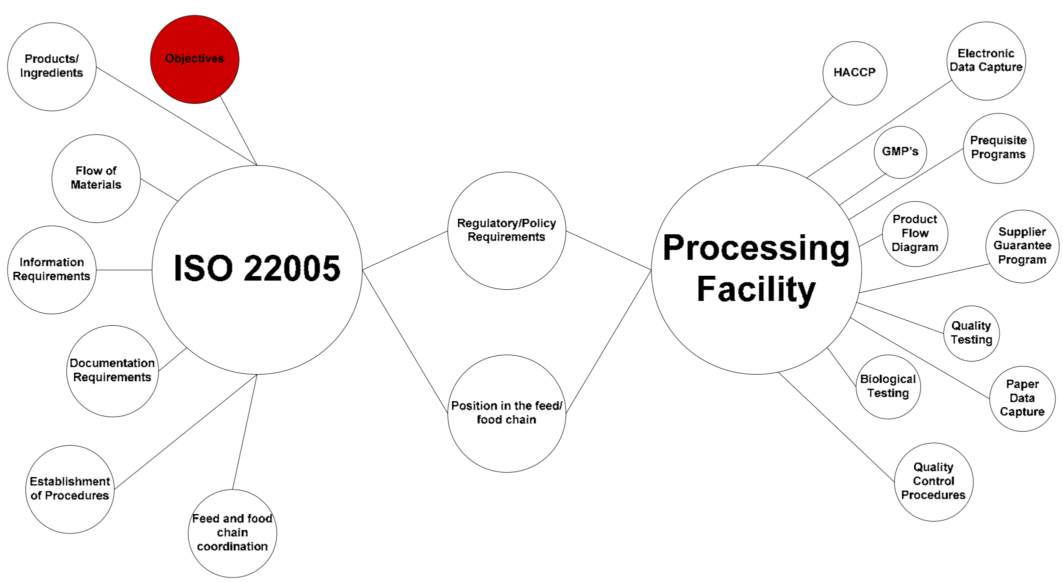
The next design component of an ISO 22005 certified traceability system is identifying the position in the feed and food chain. The Standard states, "The organization shall determine its position in the food chain by at least identifying its suppliers and customers." This information required to fulfill this component is also regulated by the Bioterrorism Act which states that an organization is required to document and maintain information that identifies the immediate previous source and immediate subsequent recipient of its products for no longer than two years. The processor identifies its immediate previous source by documenting every raw milk load that enters the facility. They record the date received, the supplier identification (name of dairy farm or cooperative), and the bill of lading identification code that will contain all identifying information. They identify their immediate recipients using pick tickets that include all details of customer orders. Though the processor maintains documentation concerning suppliers and recipients very well, there are some instances where bill of lading identification codes were missing in the documentation. Therefore, the processor does fulfill this component, but can be easily improved by enforcing quality control/quality management strategies concerning documentation and maintenance of data.

The next design component of an ISO 22005 certified traceability system is documentation indicating the flow of materials. The Standard states, "The organization shall determine and document the flow of materials within its control in a manner which meets the objectives of the traceability system.” Through a system of paper and electronic documents, the processor records information on its products from raw milk delivery to the retailer. Though most of the documentation is captured electronically by separate database systems, some data is recorded on paper by employees. Also, one of the two primary HTST (High Temperature Short Time) pasteurizers used for milk has the technological capability of electronically capturing vital information that could not be captured otherwise. Though the processor does have documentation to indicate its flow of materials, because there are no defined objectives this component is not fulfilled. Since they do have a very well established method of recordkeeping, fulfilling the component will not be a difficult task once objectives for the traceability system have been defined.

The last design component of an ISO 22005 certified traceability system is feed and food chain coordination. The Standard states, “If an organization participates in a traceability system with other organizations, the design elements shall be coordinated. Links in the feed and food chain are established as each organization identifies its immediate prior source(s) and immediate subsequent recipient(s).” Based on these criteria, it seems that the dairy processor fulfills the requirements of this design component because they do maintain documentation of suppliers and recipients. However, because the processor does not have defined objectives, therefore no traceability system, complete coordination with suppliers and recipients is not possible. As with most of the previous design components, the establishment of objectives will help the dairy processor fulfill the component.

Based on this assessment, the current system that the dairy processor uses to track and trace milk throughout its facility cannot be defined as a traceability system because it fails to fulfill seven of the nine design component in the ISO 22005 standard. However, the processor has successfully implemented and executed several safety and quality programs that can be integrated into an ISO 22005 certified traceability system once objectives have been defined (Figure 7) (Table 4). The current system in place by the processor can rather be defined as a chain of custody system which is systematic procedure for tracking a material or product from its origin to its final use (Mohawk Paper, 2006)[1]. It is clear that the lack of specific objectives is the primary determining factor on whether or not a traceability system is, in fact, present in this processing facility.

Figure 7. ISO 22005 Design Components vs. Quality Programs in Processing Facility



[1] In order to maintain consistency and to avoid confusion, the traceability system at the dairy processor will now be referred to as a chain of custody system for the remainder of the paper.

Table 4. ISO 22005 Design Components vs. Pre-existing Programs

ISO 22005 Design Components	**Pre-existing Programs**
Objectives	No pre-existing program
Regulatory and Policy Requirements	• Pasteurized Milk Ordinance (PMO) • Hazard Analysis and Critical Control Points (HACCP)
Products and/or ingredients	Product Description form, mandatory component of HACCP Program
Position in the feed and food chain	• Raw Milk Loads Data (FDA) • Customer Order Form (FDA)
Flow of materials	HACCP Flowchart
Information requirements	Bill of Lading from suppliers
Procedures	• Product Description form, mandatory component of HACCP Program • HACCP Flowchart
Documentation	• HACCP Hazard Analysis Summary Table
Feed and Food Chain Coordination	No pre-existing program

Results

The following information will discuss findings based on the three study objectives.

Traceability Modeling/Mapping

The supplier and recipient data collected from the dairy processor, the dairy farm, and the feed network were used to develop a map identifying the dairy processor, the dairy farm, and the feed ingredients and location of origin of all feed ingredients (Figure 8). This data identified the feed ingredients used at the dairy farm which include alfalfa hay, wheat straw, ground corn, wet corn gluten, corn silage, soybean meal, distillers dried grain with solubles, molasses, and nutritional additives. The daily rations are as follows:

Feed Ingredient	Daily Ration, lbs/day
Alfalfa Hay	11
Corn Silage	47
Ground Corn	9.75
Wet Corn Gluten	9.00
Wheat Straw	1.5
Molasses	2.0
Soybean Meal	3.65
DDGS	4.5
Calcium Supplement	0.4
Mineral Pre-mix	1.85
Water	10
Total	100.65 lbs/day

The data also identified that all of the corn products excluding the DDGS were grown within five miles of the dairy farm. The corn that produced the DDGS was produced in the same state as the dairy producer and was purchased from over 650 investors and 12 elevator complexes. The other ingredients are grown in Iowa, Colorado, Nebraska, South Dakota, and Wyoming. The soybean meal is purchased from a broker in Western Iowa and Eastern Nebraska, but grown in various regions of the United States.

Though the model is simplistic in nature, there are a few key points, details, and implications to be made about the elements in the traceability model and the activities that take place within the individual entities included in the model. This will assist in illustrating the true scope of this supply chain and the utility of the model.

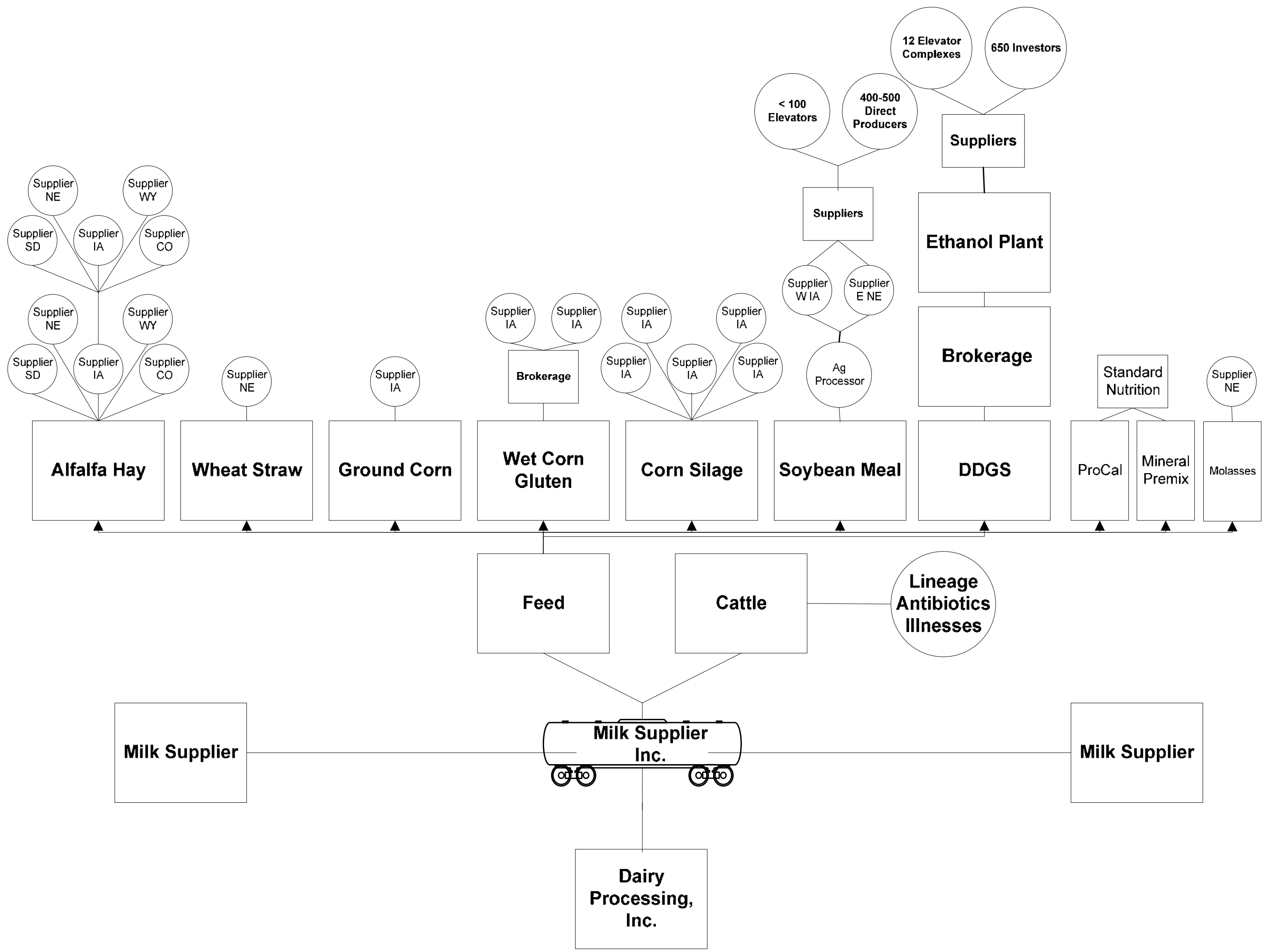
1. Key point #1: Though this model illustrates one raw milk supplier, approximately 7 dairy farms and 4 cooperatives provide raw milk to this operation, totaling well over 100 farms. They receive 25-30 tankers per day and approximately1 million lbs/day of milk. In addition, due to the PMO raw milk tanks are brought to empty every 72 hours. The raw milk silos have capacity of approximately 50,000 gallons and can hold the milk from up to 10 tanker trucks. This implies that the number and identity of suppliers to each raw milk silo can be readily identified within this time period in the event of a recall or food safety emergency.
2. Key Point #2: As previously stated, the dairy farm included in the case study provides the dairy processor with approximately 17,000 gallons of milk per day, equivalent to about 3 tanker trucks at approximately 6,000 gallons per tanker. Each raw milk silo at the processor has a capacity of 50,000 gallons. The implies that depending on the time of delivery, a single day supply of contaminated milk from this particular dairy farm could cause a product recall of 50,000-100,000 gallons of milk (15-20 tankers).
3. Key point #3: Currently, this dairy farm uses electronic RFID tags to determine the number and identity of the dairy cattle that have been milked and how much milk is produced per cow. In addition, all milk is directly pumped into the tanker that will transport it to the dairy processing facility. This implies that the actual

cows that contributed to a batch of milk delivered to the processor can be identified in the event of a recall or food safety emergency.

4. Key point #4: When feed ingredients are delivered to the dairy farm, they are stored individually in separate barns. The feed is then mixed using the rations previously mentioned and the feedstock is stored in a separate barn as well. Though not currently in practice, this indicates that the feed barns that house the individual ingredients can be emptied periodically to minimize the number of contributing suppliers and simplify the process of identifying those suppliers if necessary.
5. Key Point #5: Upon delivery of the feed to the dairy farm, the information provided to the dairy farmer from the feed supplier includes the supplier identification, ingredient, quantity, and occasionally a chemical analysis. In addition, the dairy farmers test its corn ingredients quarterly for aflatoxin.

These points, in addition to further information introduced later in the case study, demonstrate that, though large in scope, there are several established mechanisms in place in the supply chain that can be very useful when implementing a traceability system. The key to making this map useful will be to standardize, capture, and communicate the information appropriately.

Figure 8. Traceability Model



Gaps in the Internal Traceability System of the Processing Facility

In order to meet the second objective, data indicating product flow throughout the facility from delivery to retailer was required as well as a recall procedure to determine the capacity in which the processor could trace products. Since Simchi-Levi and Kiminsky believe the “idea is to have an information trail that follows the product’s physical trail,” the first task was to develop a product flow diagram and determine if the data being recorded coincided with the product location as it moved from the feed supplier to the dairy processing facility (Figure 9). After this diagram was developed, a diagram specific to the processing facility was developed as well (Figure 10). Also, a recall procedure would be used to identify the documents being used by the processor to conduct an actual recall or a mock recall.

Figure 9. Product Flow Model & Recorded Information of Entire Supply Chain

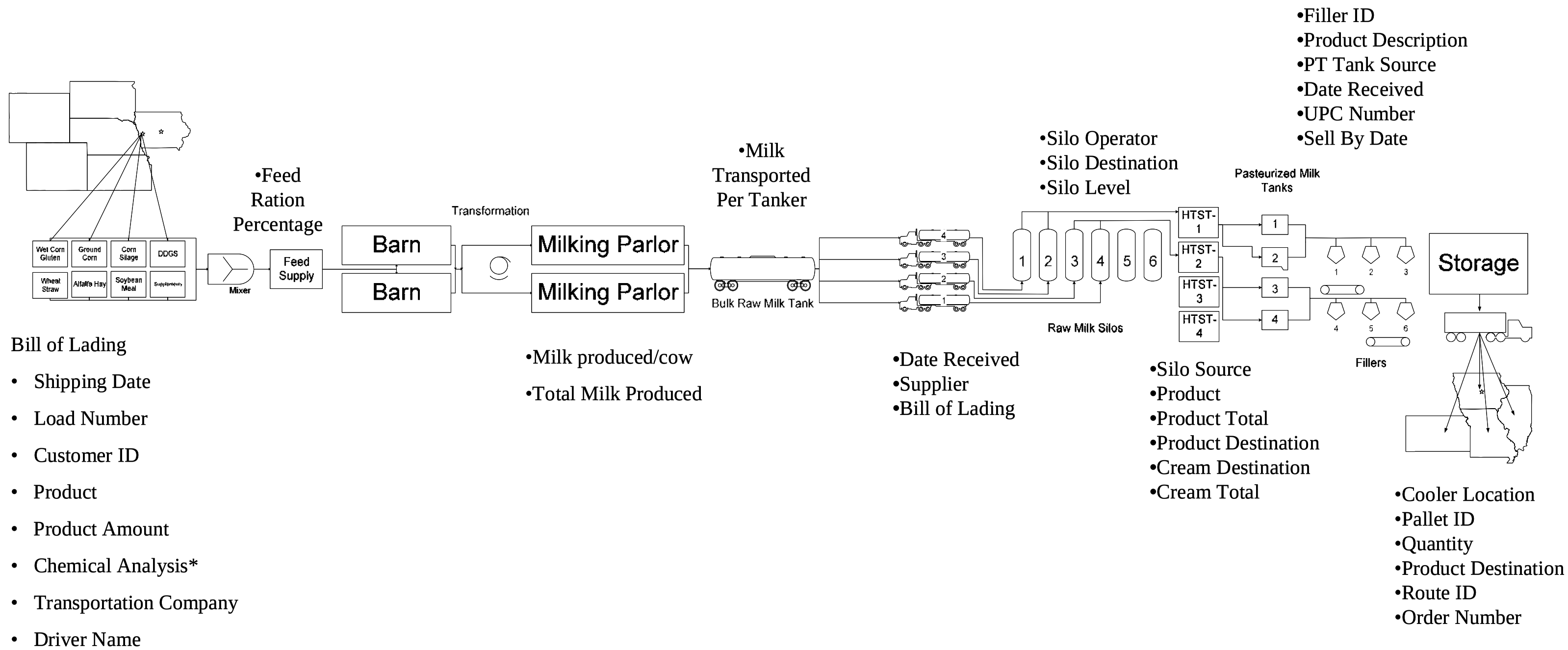
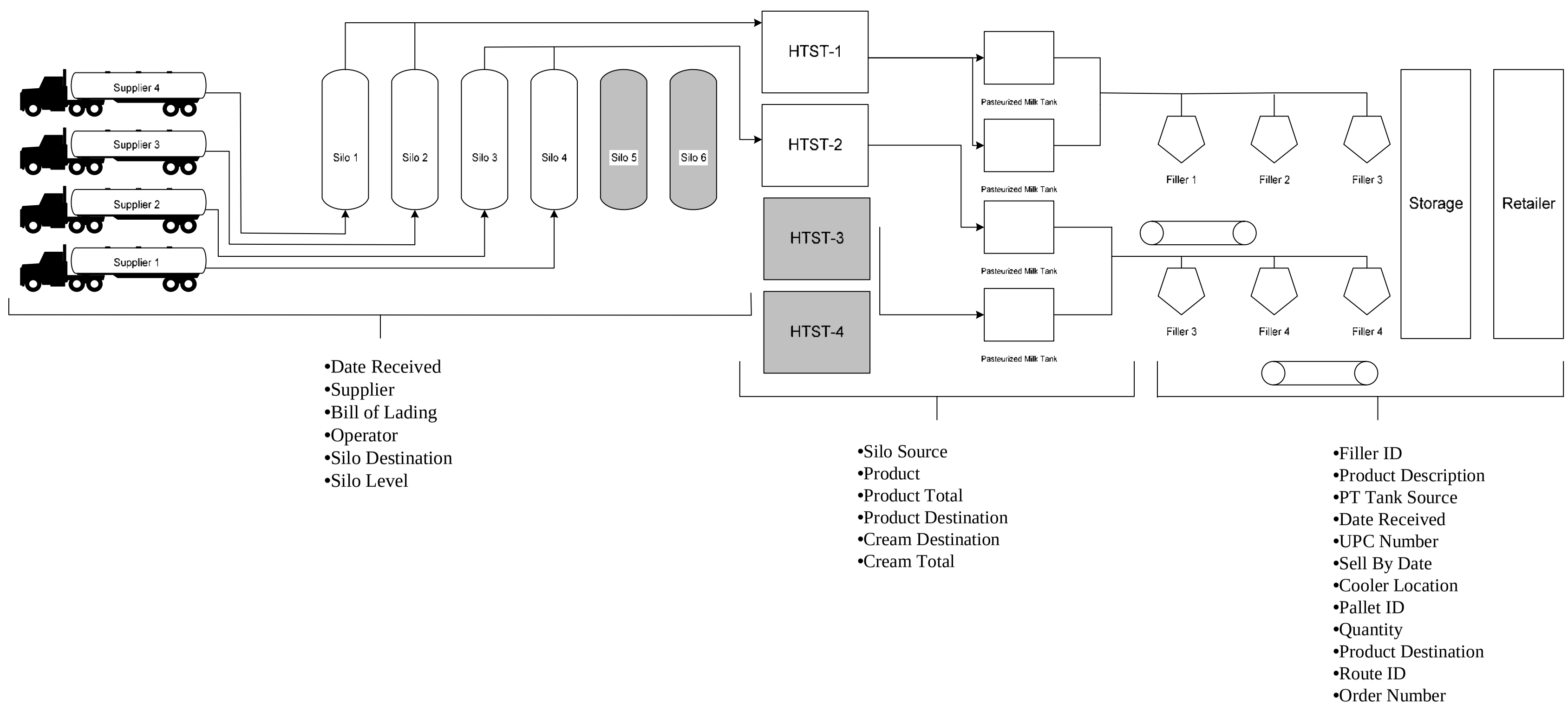


Figure 10. Product Flow Model & Recorded Information
at the Dairy Processor



The first identified gap in the processors chain of custody system is during raw milk delivery. During this stage the customary recorded data include:

- Date received
- Supplier
- Bill of Lading
- Operator
- Silo Destination
- Silo Level

After analyzing this set of data, it was found that often times the bill of lading identification number was unknown. Though the other pieces of data were there, the bill of lading is very important because it is the actual document that contains all of the original information agreed upon by both the supplier and the processor and contains signatures from both parties. In addition, the bill of lading is one physical document that still stands when other electronic documents are lost or destroyed and is also essential to other departments within the company such as accounting. When this document is lost, the information cannot be retrieved. Therefore, the capability of identifying suppliers that contributed to a specific silo is lost.

The second gap in the processors chain of custody system was found during pasteurization. As indicated by the diagram, information captured during this stage includes:

- Silo Source
- Product
- Product Total
- Cream Destination
- Cream Total

There are two issues with this step in processing. The first issue is that the listed information above can only be captured by 1 of 2 HTST units that pasteurize the milk and milk products. Without this information, a gaping hole is created in the system and the ability to trace the product is very difficult. Actually, it makes the possibility of tracing back to an actual raw milk silo virtually impossible. The processor does however pasteurize most of its milk and milk products on the tank with the ability to capture the desired information. The second issue with this step involves written documentation. When milk is pasteurized using HTST tank number 2, employees are responsible for recording on the pasteurization chart when one silo is emptied and the other one begins. Though this is a customary quality control practice, due to human error this information is not always recorded. The lack of this information again creates a hole and eliminates the ability to perform a trace back past pasteurization. Both of these issues create a very critical gap in the chain of custody system because this is the central step in the process and without data at this point there is no link between information collected at raw delivery and during filling through distribution.

The third gap identified in the chain of custody system is the absence of a documented recall procedure. Though the processor does perform mock recalls biennially and retrieves the entire mock recalled product, there is no written procedure that details the actions and items needed to conduct a recall. In addition, mock recalls are usually conducted on products that are produced in smaller quantities rather than mass quantities. These issues were identified as gaps for two reasons. First, without a documented written recall procedure it creates an opportunity for error in retrieving the correct information. In addition, a documented recall procedure is an imperative document in training new employees. Without it, the ability of a new employee to correctly perform a recall, mock or actual, is unlikely. Second, because mock recalls are conduced on products that are produced in smaller quantities, the technological and human capacity of conducting an actual recall is unknown.

The fourth gap was identified at the dairy farm, rather than within the processor's chain of custody system. This gap is associated with the feed storage method at the dairy farm. When feed is received, it is stored in separate barns as discussed previously, however as the feed is received it is simply added and mixed with the existing feed already in the barn. If there are a large number of suppliers of that particular ingredient, it makes it difficult to identify the contributors once mixed with other ingredients in the feed mixture.

The fifth and final gap was also identified at the dairy farm. This gap is associated with the feeding method. When distributing the feed to the dairy cattle, the feed is not measured or rationed individually per cow. Conversely, the feed is spread evenly in two rows on either side of the barn. This makes it difficult to determine from day to day the feed suppliers that contributed to the total feed mixture, therefore, making it difficult to identify problem areas or suppliers in the event of a recall.

Quality Control/Quality Management Strategies

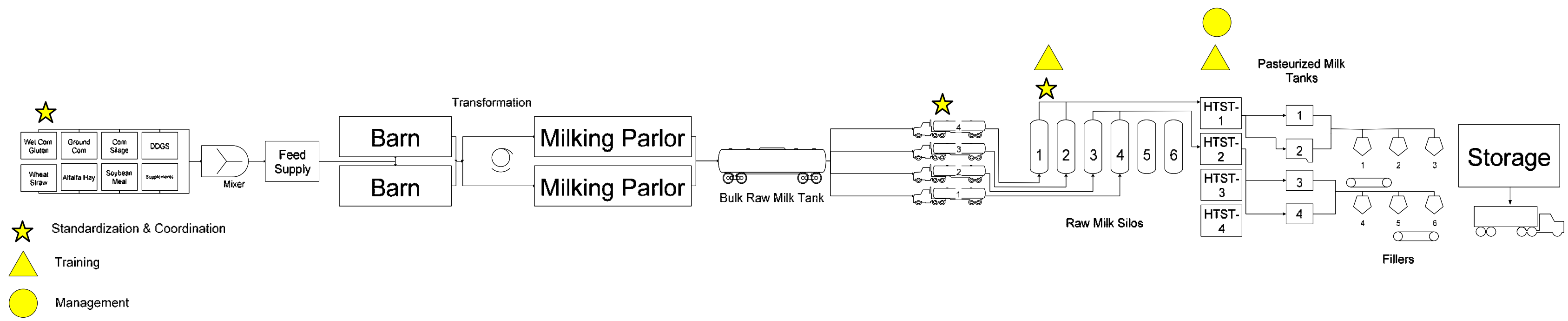
In order to fulfill the last and final objective of this study, the entire supply chain was analyzed, farm to distribution, and quality control and quality management strategies were developed to strengthen the entire supply chain in hopes of achieving feed and food chain coordination. Most of the strategies involve the processor implementing and mandating specific criteria from its suppliers.

The first strategy involves implementing product standards for suppliers and developing a monitoring and verification system to ensure that suppliers are adhering to product standards. Currently, when a load of raw milk enters the facility, it is tested for temperature, flavor, odor, added water, and antibiotics. They also ensure that the bill of lading indicates that the supplier is a Grade A farm, if the tanker is properly sealed to prevent tampering, and if the tanker has a proper wash ticket to ensure that it was washed properly. Though the battery of tests the processor conducts is extremely important, implementing product standards that require suppliers to regularly test for mycotoxins would further assure the safety of the milk and milk products produced. Currently, they only test during particular times of year or season when mandated by the state regulatory agency. In addition, employing product standards to the milk supplier would cause dairy farms and/or cooperatives to subsequently require product standards from their feed suppliers. Developing a monitoring and verification system would ensure that standards are being met. All in all, implementing product standards and developing a monitoring system would create a ripple effect of improvement throughout the entire supply chain.

The second strategy involves the processor requiring that all data is collected and recorded in a consistent format. Though data collection methods seem like a minor issue, capturing and colleting data in a consistent format allows for simple compilation. For example, the processor could consider purchasing the same software for HTST unit 2 that is already used on HTST unit 1. Therefore, all milk processing data, regardless of the processing unit, would be consistent and available in the event of a recall. Because this is a decision that would require capital, it must be made by management as indicated by the circle on the diagram (Figure 11). In addition, sharing information between entities becomes hassle free because none of the information has to be reformatted, deciphered, or re-entered by any of the parties in the supply chain. This is especially important at three points in the supply chain: as feed ingredients are sold to dairy farmers, as raw milk is transferred to the dairy processor, and at the reception of the raw milk at the processor as indicated by the stars on the diagram (Figure 11). This is a matter of standardization and coordination among all three entities in the supply chain.

The last and final strategy involves re-enforcing and implementing new information into employee training. While interviewing and interacting with various employees at the dairy processor, it seemed quite obvious that many of them were not familiar with the terminology, regulations, and standards related to traceability. It is important that employees have a basic knowledge of these terms in order to understand why it is important to efficiently collect data and perform tasks that will maintain a traceability system. From a quality control perspective, it is important that the processor emphasize and re-emphasize key tasks that would improve tracing and tracking such as recording bills of lading identification numbers and recording the change of raw milk silos on pasteurization charts, two areas indicated by the triangles on the diagram (Figure 11). This will not only improve efficiency, but will close gaps in the traceability system at the processor level.

Figure 11. Product Flow Model with Indicated Areas of Improvement



Conclusions

The objectives of this study were to create a model/map for tracing commodities from corn to milk, to identify gaps in the internal and external traceability systems, and to provide quality control/quality management strategies and recommendations to improve the overall external traceability system. This has been done through the case study conducted the dairy processor. This study demonstrated that currently the dairy processor does not have an ISO 22005 certified traceability system in place, but an efficient chain of custody system. With time, this chain of custody system can be easily transformed into a traceability system by integrating small additions and alterations to the existing safety and quality programs already in place. Through creating a product flow model, gaps in the chain of custody system were identified. The quality control and quality management strategies were based on identified gaps and components to achieve full feed and food chain coordination and eventually, traceability.

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CHAPTER 4: GENERAL CONCLUSIONS

Traceability is the ability to track any food or feed back to its place of origin. As the number of food recalls increase and as countries continue to import and export an increasing number of products across the globe, the food production industry is starting to welcome the idea of traceability. As the thought of a total food supply chain grows and island mentality slowly dissipates, the implementation and adoption of traceability systems in bulk commodities is expanding.

This research dealt with the tracing and tracking mechanisms employed by a dairy processing company and its comparison to the ISO 22005 traceability in the feed and food chain standard. Also, the data collected from the processor, dairy farm, and network of feed suppliers was used to develop a model for tracing bulk commodities from feed to milk. In addition, this study uncovered inconsistencies or gaps in the system in use by the processing facility and provided quality control/quality management strategies that would aid in strengthening the overall external traceability system.

When comparing the tracing and tracking mechanism in use by the facility to the ISO Standard, it was determined that the company had a very efficient chain of custody system, but did not have a traceability system due to lack of specific objectives, the foundation of a traceability system. A model to help identify feed ingredients and places of origin was developed as a tool that will aid this processor in identifying feed suppliers in the event of a recall. Moreover, this tool can be used to help them efficiently meet the 24 hour time limit on identifying the immediate previous source and subsequent recipient as mandated by the Bioterrorism Act in the event of a recall. Gaps such as missing data, inconsistent data capture, non-compliance of standard operating procedures, and lack of a recall procedure were identified and recommendations in the form of quality control/quality management strategies were suggested. These procedures included implementation of product standards, development of a monitoring and verification system, requiring all suppliers to collect data in consistent format, and altering employee training.

The results of this study have proven that through consistent data collection, communication, and coordination it is possible to identify the feed ingredients that contribute to a processed milk product found on a local grocery shelf. It also proves that there are significant gaps within this processing operation that have not yet been compromised, but are very vulnerable to predators like aflatoxin. Though this processor has successfully operated for many years without a recall, implementing a traceability system would only strengthen the integrity of their products. It would allow them to take a closer look at every aspect of the operation and uncover gaps and inconsistencies that would otherwise not be found until a problem occurs.

CHAPTER 5: RECOMMENDATIONS FOR FUTURE RESEARCH

Following are several recommendations to researchers that will continue studying the implementation of traceability system in bulk commodities:

1) Developing and implementing an ISO 22005 certified traceability system can be time consuming and sometimes very costly. The quality control/quality management strategies provided in this study were meant to improve the total supply chain by implementing practices that are not very large, and are inexpensive. The further development and implementation of a traceability system is recommended.
2) This study only dealt with the qualitative aspects of implementing a traceability system. A cost-benefit analysis for full development and implementation in this dairy processing facility is recommended.
3) The primary focus of this study was the dairy processor. In order to achieve feed and food chain coordination, all players in the food supply chain must have similar traceability systems. Further intricate analysis of the dairy farm and feed supply network is recommended.

APPENDIX A: GLOSSARY

1. Traceability: The ability to track any food, feed, food-producing animal or substance that will be used for consumption, through all the stages of production, processing, and distribution. (Official Journal of the European Union, 2002).

2. Traceability: The ability to follow the movement of a feed or food through specified stage(s) of production, processing, and distribution. (International Organization of Standardization, 2007).

3. Traceability: The ability to trace the history, application or location of that which is under consideration. (Can-Trace, 2004).

4. Traceability system: totality of data and operations that is capable of maintaining desired information about a product and its components through all or part of its production and utilization chain. (International Organization of Standardization, 2007).

5. Tracking: is the capability to follow the path of a specified unit and/or lot of trade items downstream through the supply chain as it moves between trading partners. (Can-Trace, 2004).

6. Tracing: is the capability to identify the origin of a particular unit located within the supply chain by reference to records help upstream in the supply chain. (Can-Trace, 2004).

APPENDIX B: DAIRY PROCESSOR AND DAIRY FARM QUESTIONS

Traceability Systems, Regulations, Standards, and Documentation Questions

1. Are you aware and relatively knowledgeable about the regulations regarding traceability which are spelled out in the 2004 Bioterrorism Act?
2. Are you aware and relatively knowledgeable about the standards regarding traceability which are spelled out in ISO 22005?
3. What is the definition of traceability according to your company, as written in your company policy/handbook?
4. Please give a brief description of the traceability system currently in use by your company.
5. Is record keeping as it relates to traceability an important function of your position?
6. Breadth, Depth, and Precision are terms often used to describe traceability systems. Are you familiar with these terms? If so, can you define them for me in your own words? If not, Breadth describes the amount of information the traceability system records. In other words, What attributes of your product are worth tracking? Depth describes how far back or forward the system tracks. Precision reflects the degree of assurance with which the tracing system can pinpoint a particular food product’s movement or characteristics. Can you describe how these terms relate to the traceability system that is currently in use by your company?

7. Does your company track the progress of your product only when it enters this facility and progresses forward to distribution or before it enters this facility, during it's progression through this facility, and forward to distribution?
8. Is your traceability system capable of tracing a product backward, from a finished product to its origin and from its origin to a finished product?
9. Is all or part of your company's traceability system maintained through your Quality Assurance/Quality Control procedures?
10. If not, how is the traceability system maintained?
11. Are the traceability records of your company electronic or paper?
12. If not, how is the traceability system documentation maintained?
13. What are the company standards as they relate to traceability?
14. The 2004 Bioterrorism Act states that establishments who manufacture, process, pack, transport, distribute, receive, hold, or import food or food products should maintain records and be able to identify the immediate previous sources and immediate subsequent recipients of the product. Based on this statement, would you consider your traceability system to be efficient and effective?
15. Does your company routinely conduct mock recalls?
16. If so, have the results met or exceeded company standards?
17. In your company, what is defined as a lot?

18. Does your company have product standards or policy standards that you require from suppliers of milk under quality control procedures?
19. Does your company have a policy on feed rations or feed ingredients?
20. How does your company track supplier policy requirements?

Questions 18-20 will only be asked to upper level management.

21. Based on the financial reports, consumer satisfaction reports, and cost benefit analyses of your company, what are the benefits of having a traceability system?
22. Where has your company encountered problems or loopholes in your traceability system?
23. If so, where does the breakdown occur most frequently?

Processing Questions

24. When being pumped into the raw milk silos, is the milk from one dairy farm mixed with raw milk from other dairy farms?
25. When beginning the pasteurization process, how do you differentiate between batches of milk being processed?
26. Are silos emptied one at a time, or simultaneously?
27. How do you identify which milk goes to which pasteurizers?
28. How does the coding on the labels relate to the actual milk being filled in the containers?

ACKNOWLEDGEMENTS

First, I would like to thank my major professor, Dr. Charles R. Hurburgh Jr., for his continuous support, guidance, and enthusiasm, as I completed this great endeavor. In addition, I would like to thank my committee members, Dr. Sam Beattie and Dr. D. Raj Raman for your support and encouragement. Thank you to the dairy processing company and dairy farm that so graciously and eagerly allowed me the opportunity to study and analyze your operations, for without you this project would not have been possible. I would also like to express my gratitude to my colleagues in the Iowa State University Grain Quality Lab, your companionship, willingness to answer questions and give advice, and encouraging words are appreciated more than you will ever know.

Also, I would like to thank the advisors and members of the Iowa State University Chapters of Minorities in Agriculture, Natural Resources, and Related Sciences and the Black Graduate Student Association, especially Mary de Baca, Aurelio Curbelo, and Thelma Harding. Enormous thanks to the members of the Ames Alumnae Chapter of Delta Sigma Sorority, Inc., especially Nicole Rembert and Nicole Bartolozzi, your unconditional love, support, and sisterhood mean the world to me. I would also like to thank my former advisors, mentors, and administrators at the University of Arkansas at Pine Bluff who believed in me, challenged me, and set me on the path to Iowa State University.

Most importantly, I would like to thank my family and my parents, Bobby and Dorothy Brown, and my brother, Jordan for your love, support, encouragement, and

prayers, and as I embarked upon and completed this journey. Thank you for preparing me and equipping me with the tools to do anything my hands undertake.