CHAPTER II

LITERATURE REVIEWS

2.1 Maize Industry

Maize has always been a second-priority crop in Asia after rice. Recently however population growth and rising consumption of livestock products (in turn fueled by rising per capita incomes) have led to increased demand for maize (Gerpacio, 2007). To serve this increased demand, Asian maize farmers are gradually shifting to higher yielding maize varieties and using more modern production technologies. In response, maize research and development (R&D) agencies in the region are aligning their research strategies to better serve the changing production and market requirements.

Worldwide, maize ranks first in terms of production among cereals, just ahead of wheat and significantly ahead of paddy rice. In developing economies, maize ranks first in Latin America and Africa, but only third in Asia after rice and wheat (FAO 2001). Globally, 561 million tons (m t) of maize were harvested in 1995-1997 from just under 140 million hectares (m h). Seventy-six percent of this area was located in developing countries (CIMMYT[1], 1999). During the same period, around 151 million tons of maize grains (27% of world production) were harvested in Asian countries from 42 million hectares (30% of global maize area) (Table 2.1). This level of production represented a significant increase from 1983-1985, when 94 million tons of maize were produced annually from 35 million hectares. Asia's contribution to worldwide harvested maize area and maize production also increased markedly between the two periods (Table 2.1).

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[1] CIMMYT® (www.cimmyt.org) is an inter nationally funded, not-for-profit organization that conducts research and training related to maize and wheat throughout the developing world.

Table 2.1: Average annual maize area, yield and production, Asia and the world, 1983-85 and 1995-97 (Gerpacio, 2007)

	1983-85			1995-97		
	Area (m ha)	Yield (t/ha)	Production (m t)	Area (m ha)	Yield (t/ha)	Production (m t)
Asia	35.6	2.7	96.6	41.9	3.6	151.7
South	7.5	1.3	10.0	8.0	1.5	12.3
Southeast	8.2	1.6	13.4	8.5	2.2	19.1
East	18.9	3.7	70.8	24.3	4.8	117.0
West[a]	1.0	2.3	2.4	1.1	3.1	3.3
World	126.7	3.4	429.9	136.7	4.1	561.5
Asia as percentage of world	28.1	79.4	22.5	30.7	87.8	27.0

Source: CIMMYT (1987, 1999).
[a] Data for West Asia, 1983-85, computed from FAOSTAT database, Production Domain, May 2000.

It is projected that by 2020 demand for maize in developing countries will surpass the demand for both wheat and rice. Globally, maize demand is projected to increase by 50% from its 1995 level of 558 million tons to 837 million tons by 2020 (IFPRI, 2000 cited in Gerpacio, 2007). Therefore study involved with maize industry is interesting. In developing countries, rising incomes and the consequent growth in meat and poultry consumption have resulted in a rapid increase in the demand for maize as livestock feed. This trend is particularly evident in East and Southeast Asia, where maize demand is projected to increase from 150 million tons in 1995 to 280 million tons in 2020 (IFPRI, 2000 cited in Gerpacio, 2007). Unabated population growth and the persistence of poverty have also kept food maize demand high in poor countries, as in some parts of South Asia. To cope with increasing demand for maize industry, therefore, efficient maize processing is necessary.

The major maize producers in Asia are China and Korea (D.P.R.) in East Asia; Indonesia, Thailand and Philippines in Southeast Asia; India, Nepal and Pakistan in South Asia; and Turkey, Iran and Afghanistan in West Asia. The major maize consumers in the region are Jordan, Lebanon, Sri Lanka, Malaysia and the Republic of Korea (Gerpacio, 2007).

2.1.1 Maize Industry in Thailand

Maize is a crop recently introduced in Thailand and is largely produced commercially (there is very little subsistence production). Over the last 30 years, the growth of maize production in the country has been the result of intensive R&D (Ekasingh et al., 2007). In close collaboration with CIMMYT, public-sector research in Thailand developed several locally adapted and disease resistant OPVs (open pollinated varieties) of maize, which dominated the market and area under maize until 1990. The nearly 2 m ha planted to maize (out of about 4 m ha planted to major field crops) and an annual production of 4 m ha attested to the success of these OPVs (Ekasingh et al., 2007). In the 1990s, total output of maize grain has continued to increase steadily, while the average area planted to maize has fallen somewhat and stabilized at around 1.4 m ha.

Beginning around 1990, there was a fundamental shift in the maize seed industry of Thailand, marked by substantial changes in production technology and market outlets. Several private multinational and national companies started to produce maize hybrids that began to dominate in farmers' fields (Ekasingh et al., 2007). Active promotion of hybrids by the public and private sectors helped farmers rapidly learn to use the new hybrids and were one indication of productive collaboration between the two sectors.

Maize in Thailand is predominantly used for animal feed, with 80-100% production being sold to commercial poultry and livestock feed mills (Ekasingh et al., 2004). It is a highly commercial crop, handled by an extensive network of merchants. Maize sold as animal feed is mainly used domestically, and only a small fraction is exported. Meanwhile, about 5-20% of all maize grown in Thailand is consumed as food, either as white corn or sweet corn. Among the survey areas, traditional maize consumers were reported in Pop Pra district, Tak province and Chiang Dao district, Chiang Mai province (Upper North), and in Pak Chong district, Nakorn Ratchaseema province (Lower Northeast).

2.1.1.1 Infrastructure of Maize Industry in Thailand

(1) Accessibility and irrigation facilities

Maize farmers have good access to product markets because transportation infrastructure and systems are good in Thailand. In remote maize production areas, difficult road situations have forced farmers to harvest and sell their maize in the dry season, even if the output is ready for harvest in the rainy season. This is a rare situation, and occurs primarily because farmers cannot sell their rainy season grains for a good price after harvest. Most farmers have access to reasonable roads, and merchant services are readily available (Ekasingh et al., 2004).

Most maize in Thailand is cultivated in the uplands, making the need for irrigation minimal. Only baby corn and sweet corn are normally planted in irrigated fields after the main season wet-rice cultivation, and only selected maize-producing areas in Phichit and Chiang Rai have access to irrigation facilities (Ekasingh et al., 2004).

(2) Post-harvest facilities

Maize farmers in Thailand store their output in sacks inside storage barns. Storage facilities are often quite basic, usually composed of farm sheds. Most farmers sell their output after milling in their fields, for which they contract a milling machine from merchants. The machine is brought to the village, and milling is normally done on wet grains right after harvesting (Ekasingh et al., 2004).

(3) Markets and marketing practices

The 1999 RRA survey found that about 55% of maize farmers sold their output immediately after harvest. About 25% kept the output for a month or two before selling, 15% kept it for two to three months, and about 5% kept it for more than three months. The longest time farmers stored the output while waiting for better market prices was five months (Ekasingh et al., 2004).

In all sites except Sra Kaew (Central Plains) and Nakorn Ratchaseema (Lower Northeast), small merchants would come into the villages and offer to buy farmers' maize production. If the farmers provided threshing labor, the small merchants would thresh the grain at no extra cost. Most merchants who came to the villages had lent farmers some capital for household or farm production use; the farmers were therefore obliged to sell their output to the merchant-financiers. In a few cases, farmers themselves performed the merchants' task of assembling the outputs for delivery. In some cases, merchants from other districts would come and trade in the villages. Small pick-ups or large trucks transported the maize grain after assembly. In Sra Kaew and Nakorn Ratchaseema, the normal practice was for farmers to use carts fixed to small tractors to transport their maize grain to the merchants. Some maize farmers in Uthai Thani (Lower North) sold their output to BAAC, and those in Nakorn

Ratchaseema (Lower Northeast) sold their grain to cooperatives (Ekasingh et al., 2004).

2.2 Drying Process in Agricultural Industries

Drying refers to the process of removing water from any substance, even a liquid (which then becomes a "dry" liquid) (Carranza, 2001). Drying also applies to gases and solids. The chemical industry uses drying in sectors ranging from agricultural products and fine chemicals through plastics and paints. Methods vary with material and application.

2.2.1 Gas drying

A popular form of gas drying is air drying. Dry gas is essential in chemical processing because it precludes ice from forming in instrument air lines. In the past, ice formation in instrumentation has caused plant shutdowns and emergency venting, both of which are very costly. An example of gas drying is membrane dryer which removes water vapor from gas streams by the selective permeation of water molecules through polymers. Since gas drying is not the type of drying used in this research, only short description is presented here.

2.2.2 Liquid drying

Liquid drying is another important unit operation in the chemical industry. One way to dry liquids is spray drying. The objective, however, is not necessarily water or solvent evaporation, but powder formation. Spray drying usually takes place in a cyclone-shaped vessel as shown in Figure 2.1. The liquid enters the cyclone through a spray nozzle called an atomizer. This rotary or pressure unit atomizes it into very small droplets. Dry air is forced into contact with the fine liquid droplets, which have a high ratio of surface area to volume. The extra surface area enhances the evaporation process, and the powder precipitates quickly. Since maize drying is not the type of liquid drying, only short description of liquid drying is presented here.

Figure 2.1: Spray dryer, a type of liquid drying

2.2.3 Solid drying

The chemical and agricultural industries use solid drying to remove water from solid objects such as fruits, seeds, detergents, polymers and other fine powders, granules, and pellets. There are several types of solid dryer such as fluidized bed dryer, vacuum dryer. However these dryers use hot air as a medium to carry heat for drying. Therefore air-drying is the most frequently used in agricultural industry.

According to Hofsetz et al. (2007), Vega et al. (2007), air-drying is the most common drying method employed for foodstuffs and conservation of food on a global scale. The main attribute of this method is the decrease in the water activity in the product by decreasing its water content, inhibiting the development of microorganisms and decreasing spoilage reactions, thus prolonging the shelf life of the product. An important advantage of dehydrated products is that their costs of packing, storage and transportation are reduced due to the comparatively smaller volume and mass of the dried product (Okos et al., 1992). Furthermore, products with low moisture content can be stored for long periods of time at room temperature (Jarayaman and Das Gupta, 1995).

Example of dryers used the concept of hot air drying is shown in Figure 2.2 and 2.3. The dryer in Figure 2.3 has a fan and a control panel that monitors the air flow and temperature of drying air, which is heated as it flows between closely spaced Nichrome electrical resistance heating bars. Hot air goes perpendicularly through the sample placed as a thin layer in a stainless steel basket, which hangs on a balance by a nylon thread, interconnected by an interface system to a computer where the data on mass changes are continuously recorded and stored in real time at programmed time intervals. Similarly the dryer in Figure 2.3 has a blower to distribute hot air to the sample. However the sample is organized in trays.

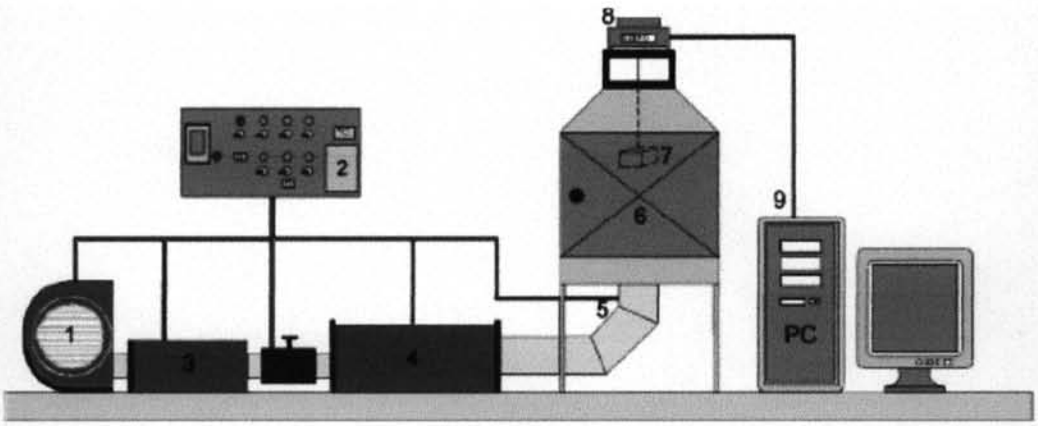


Figure 2.2: Schematic diagram of drying equipment. (1) Blower air-filterer; (2) control panel; (3) pre-heating air section; (4) heating air section; (5) thermocuple; (6) oven; (7) sample; (8) digital balance and RS232; (9) PC (Vega et al., 2007)

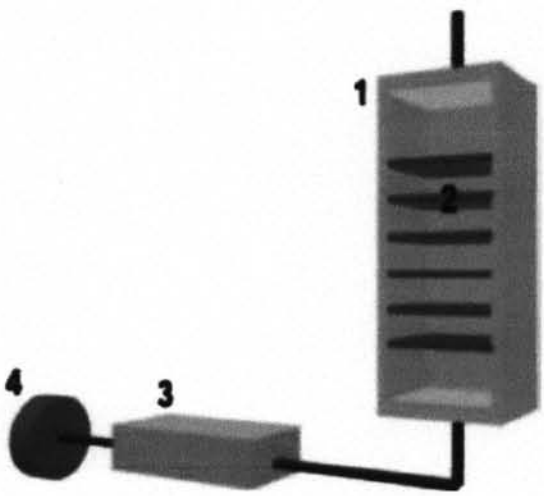


Figure 2.3: Air-drying: (1) fixed bed dryer; (2) shelves with the samples; (3) heating box and (4) blower (Souza et al., 2007)

Although air drying offers dehydrated products that can have an extended shelf life, but the quality of a conventionally dried product is often reduced as compared to that of the original foodstuff, with an impact in quality in terms of colour, rehydration ratio, texture and other characteristics (Ratti, 2001). Recently, microwave drying has appeared as a rapid and efficient drying method as compared to conventional hot air-drying. However, due to its high cost, microwave drying cannot compete with conventional air-drying. Therefore, essentially for economic reasons, it has been suggested that it should be applied only in the last stages of air-drying (Maskan, 2000). Despite many advantages, such as good rehydration properties, high quality products and little or no shrinkage, freeze drying has always been recognized as the most expensive process for manufacturing dehydrated products (Ratti,2001; Saca and Lozano, 1992). Another cheaper alternative to produce materials with similar qualities to those of freeze-dried products is called puffing. A puffing process involves the release or expansion of vapour or gas within the product, either to create an internal structure or to expand and/or rupture an existing one (Payne et al., 1989). Some puffing methods include explosion puffing (Saca and Lozano, 1992), high temperature fluidized beds (Kim and Toledo, 1987), the application of vacuum dehydration (Krokida et al., 1997), and a high temperature and short time drying pulse (Schultz et al., 2007; Varnalis et al., 2001).

2.2.3.1 Air-drying of maize

According to Davidson et al. (2000), maize usually has to be dried with heated air in order to achieve a safe moisture level for long-term storage. In the design of maize dryers and their control systems, a compromise must be made between drying conditions which give a rapid moisture removal rate (*i.e.* high grain throughput) and those which preserve quality of the dried product. Quality factors of maize include physical properties (test weight, stress cracks, colour) as well as chemical characteristics (starch gelatinization and solubility, fat acidity). Kernel stress cracks increase the susceptibility of maize kernels to breakage during mechanical handling, and the fines created increase material losses in all milling operations and promote mould growth during storage. Chemical damage resulting from overheating reduces both purity and yield of starch and the other products of maize wet milling. Both types of damage are deleterious to maize dry milling, causing reduced quality and yield of grits and oil. Therefore a proper dryer for maize drying should preserve quality at a user-defined level, and permits the highest moisture removal rate and energy efficiency given those operational constraints.

Regulation of heated-air grain dryers can be accomplished by adjusting the temperature, flow rate or humidity (through exhaust-air recycle) of the drying air as well as the grain flow rate (Davidson et al., 2000). Most designs only allow the operator to change the air temperature and the grain flow rate. Normally, small adjustments in grain flow rate are made automatically to compensate for small variations in the discharge moisture content, and the drying air temperature is changed only if there is a large deviation in the initial moisture content. However, most cross-flow dryers are now designed to recycle all of the exhaust cooling air and a part of the exhaust drying air in order to maximize energy efficiency. Recycling the moisture-laden exhaust air also increases the humidity of the drying air. With all other parameters constant, fuel consumption and the rate of moisture removal both will decrease as the proportion of exhaust drying air recycled increases. For a set airflow and recycle rate, reducing the drying temperature simultaneously decreases throughput and energy efficiency. The problem of quality-based dryer control is, therefore, multi-objective and highly interactive (Davidson et al., 2000).

2.3 Failure mode and effects analysis (FMEA)

Failure mode and effects analysis (FMEA) was first developed for systems engineering as a formal design methodology in the 1960s by the aerospace industry with their obvious reliability and safety requirements (Seyed-Hosseini, Safaei and Asharpour, 2006). It represents a powerful and documented method for engineers to present in a structural and formalized manner with their subjective thinking and experience in terms of three main questions (Sankar and Prabhu, 2001): what might go wrong? What might cause it to wrong? And what effect would it have?

Theoretically FMEA is a method that examines potential failures in products or processes, the effects of the failures, and the criticality of these effects on the product functionality. It is a powerful technique that allows companies to anticipate problems in product design or manufacturing processes, and avoid the potential consequences by taking corrective actions and implementing effective control plans. It may be used to determine risk management priorities for mitigating known threat-vulnerabilities.

According to BS 5760 Part 5, "FMEA is a method of reliability analysis intended to identify failures, which have consequences affecting the functioning of a system within the limits of a given application, thus enabling priorities for action to be set" (BS 5760 Part 5, 1991). The institute of Healthcare Improvement has defined FMEA as "a systematic, proactive method for evaluating a process to identify where and how it may fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change" (Reid, 2005). General Motors (GM) has defined FMEA as "an analytical tool that uses a disciplined technique to identify and help eliminate product and process potential failure modes (General Motor Co., 2002, cited in Reid (2005). In addition, The DaimlerChrysler, Ford and GM FMEA reference manual has described FMEA as a systematic group of activities intended to do the following (Daimler Chrysler, Ford Motor Co. and General Motors cited in Reid, 2005):

- Recognize and evaluate the potential failure of a product/process and the effects of that failure;
- Identify actions that could eliminate or reduce the chance of the potential failure modes occurring;
- Document the entire process.

In conclusion, FMEA is a tool to list possible failure modes of a product, service or process and give a rating so that improvement efforts can focus on the most important features or characteristics.

2.3.1 Importance of FMEA

When an FMEA was performed properly, it actually quantifies design or process risk so high risk can be easily identified. This is important because in the field of quality, the right thing to do is not always intuitive-in fact, it can actually be counterintuitive (Reid, 2005). This is particularly true with characteristic management, dealing with selection of the characteristics to be controlled (Reid, 2003). Once an FMEA is completed, the result is usually the evaluation of some high risk characteristics that would not have otherwise been identified. Using this information, the organization can and should take corrective and preventive action to escape the potential failures in the subject design or process.

These actions should be deployed across the organization to similar products, services and processes and the result should be improvements in quality, safety and cost, which should also positively impact customer satisfaction (Reid, 2005). In addition, the FMEA also give process documentation and organizational memory.

Like other quality tools, FMEA is more effective when completed by a team of subject matter experts or interested stakeholders. In clause 7.3.1.1, the automotive industry international technical specification ISO TS 16949 actually requires automotive organizations to use multidisciplinary teams to prepare FMEAs (Reid, 2005).

Although an FMEA can be completed by a subject matter expert, but it would then be limited to that person's own knowledge, experience and bias. A process FMEA will likely involve several disciplines within an organization, so ideally each should be represented.

2.3.2 Classification of FMEA

Although FMEA now tends to go by different names, i.e. machinery FMEA, system FMEA, and healthcare FMEA, but in general, FMEA can be classified into two main types: (i) Design FMEA and (ii) Process FMEA.

2.3.2.1 Design FMEA

Design FMEA involves design activities, for example, product design, machine or tooling design. It deals with the steps of breaking down the product into smaller parts such as sub-assemblies, sub-systems or components; identifying the potential failure modes and potential causes for each of the parts; determining the current controls (or solutions) to the causes; followed by the failure effects to the product assembly and end users; finally, the risks of the effects are assessed (Teoh and Case, 2004).

In the design process there are four phases (Pahl and Beitz, 1996):

• *Design specification*: Problem recognition, establishing the requirements, the requirement specifications and the functions needed to achieve the requirements.
• *Conceptual design*: Find the possible concepts that can be used to perform the functions defined in the functional structure.
• *Embodiment design*: Produce design layout, schematic, draft or configuration drawing of the design.
• *Detail design*: Establish detail dimensions using proper engineering drawings, and drawing release for fabrication.

Among these four phases, traditional FMEA is suitable for use in the detail design phase where the design solutions have been firmed up since traditional FMEA will not be able to cope with frequent design changes. In addition the information required for FMEA is relatively easier to obtain when detail design has been established. Nowadays, however, FMEA has been used further upstream to conceptual design by using knowledge modeling approach (Teoh and Case, 2004).

In the past design FMEA was carried out manually in hard copy or spread sheet format. As the knowledge in the FMEA grows, however, it gets harder and harder to perform manual FMEA system. To date several researches have been carried out automatically in design FMEA, for example, FLAME for the electrical design of automobile systems (Price et al., 1995), GENMech for mechanical design (Hughes et al., 1999), and hydraulic systems design (Atkinson et al., 1992; Hogan et al., 1992). However, only a handful of automatic FMEA generation techniques for specific domain applications have reached the shop floor (Teoh and Case, 2004). Most of the mechanical, electromechanical and manufacturing process designs still depends on the conventional method of FMEA.

2.3.2.2 Process FMEA

Process FMEA is used to solve problems due to manufacturing processes. It starts with a process flow chart that represents each of the manufacturing steps of a product. The potential failure modes and potential causes for each of the process steps are identified, then the current controls are determined, followed by the effects of failures on the manufacturing line operators and product end users (Teoh and Case, 2004). The risks of these effects are then evaluated accordingly. The automotive industry uses this type of FMEA to evaluate how a car is assembles. For example, a process FMEA would prompt evaluators to ask weather an operator outs the parts together correctly and whether a technician installs the air bag properly.

Owing to that the overall objective of this research is to improve the efficiency and productivity of an existing drying process, therefore, it is directly involved with process FMEA.

2.3.3 Procedure of FMEA analysis

According to Johnson (2002), an effective FMEA can be carried out as follows:

(1) Reviewing the process: A cross-functional team with various job responsibilities and levels of experiences should be formed. Then a copy of the products' blueprint should be given to each member of the team.

(2) Brainstorming potential failure modes: The team analyses each component and subsystem of the product for the failure modes by identifying ways it could potentially fail.

(3) Listing potential effects of each failure mode: The team lists the potential effects of each failure next to the failure. If a failure has more than one effect, each effect should be written in a separate row.

(4) Assigning a severity rating for each effect: The team gives each effect its own severity rating (i.e. from 1 to 10, with 10 being the most severe). If the team cannot agree on a rating, a vote has to be carried out.

(5) Assigning an occurrence rating for each failure mode: The team collects data on the failure of the product's competition. By using this information, the team can determine how likely it is for a failure to occur and assign an appropriate rating (i.e. from 1 to 10, with 10 being the most likely)

(6) Assigning a detection rating for each failure mode and effect: The team lists all controls currently in place to prevent each effect of a failure from occurring and assign a detection rating for each item (i.e. from 1 to 10, with 10 being a low likelihood of detection)

(7) Calculating the risk priority number (RPN) for each effect: The team multiplies the severity rating by the occurrence rating by the detection rating. RPN is a decision factor based on the product of three ratings: severity, occurrence, and detection.

(8) Prioritizing the failure modes for action: The team decides which items need to be worked on right away. Any improvement plan would be based on the indications from the RPN. Failure modes with high RPN values are selected. For example, if the team ends up with RPNs ranging from 20 to 200, the team might want to work first on those with RPN of 100 or higher.

(9) Taking action to eliminate or reduce the high risk failure modes: The team determines what action to take with each high risk failure and assign a person to implement the action. The corresponding current controls (i.e. the solutions) are implemented for these high RPNs.

(10) Calculating the resulting RPN as the failure modes are reduced or eliminated: The team is reassembled after completing the initial corrective actions and calculates a new RPN for each failure. Finally the tem will decide they have taken enough action or they want to work on another set of failures.

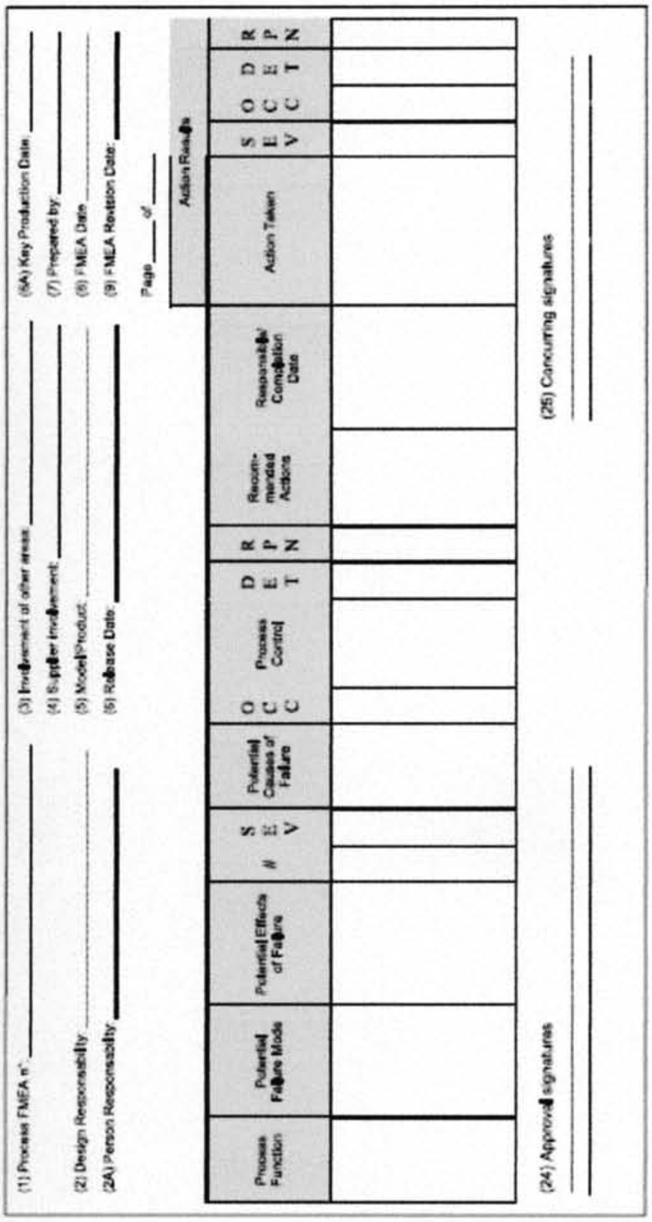
2.3.4 Researches on FMEA

A lot of research has been carried out to enhance the performance of FMEA. It is mainly applied in industrial production of machinery, motor cars, mechanical and electronic components.

The introduction of FMEA in a food company can be considered as a step in a new direction as in the study in Scipioni et al. (2002). The design and subsequent implementation of FMEA in Elledi SpA company has permitted to detect which were the most probable and serious failures that can occur on wafer production lines. The team consisted of the Production Manager, the Quality Assurance Manager, the Mechanical Manager, the Maintenance Operators and the Group Leads, and one external member, the FMEA expert, with the task of coordinate team activities based on the implementation of FMEA theory and the data collected during the work. Failures in the production line were evaluated with failure registration forms filled by FMEA operators. An example of a failure registration form is shown in Figure 2.4. Once the FMEA team obtained all the information available about known and/or potential failures of the system, it moved the operative phase of risk evaluation through the definition of the FMEA form. An example of the form used in this research is shown in Figure 2.5. It reported the detected failure typologies and some additional information associated with them: potential causes, failure effects, description of line controls that detect the failure and the evaluation of the three risk parameters (severity, occurrence, and detection).

FAILURE REGISTRATION FORM			
WAFER CUTTING / PACKAGING			
Date ...../...../......			Time ....
Production line n° 1☐ 2☐ 4☐ 5☐			Item...............................
WAFER CUTTING	☐	Broken blade	
	☐	Problems with dragging belt engine	
	☐	Loosed transfer wafer chain	
	☐	Improper wafer dragging	
	☐	Other..	
PRIMARY PACKAGING	Jammed machinery	☐	Unrolled wrapping paper reel
		☐	Incorrect position wrapping paper reel
		☐	Broken / imperfect wrapping paper
	☐	Broken photo-electric cell	
	☐	Broken welding resistance wires	
	☐	Other..	
☐	Problems transparent film packaging		
FINAL	☐	Improper machinery start	
	☐	Jammed machinery	
	☐	Broken / Imperfect cardboard	
	☐	Idle time for glue tank / sticking nozzles cleaning	
	☐	Other..	
Notes..			
Signature..			

Figure 2.4: Example of failure registration form (Scipioni et al., 2002)


(1) Process FMEA n°
(2) Design Responsibility
(2A) Person Responsibility
(3) Involvement of other areas
(4) Supplier Involvement
(5) Model/Product
(6) Release Date
(6A) Key Production Date
(7) Prepared by
(8) FMEA Date
(9) FMEA Revision Date
Page ___ of ___

Process Function	Potential Failure Mode	Potential Effects of Failure	#	SEV	Potential Causes of Failure	OCC	Process Control	DET	RPN	Recom-mended Actions	Responsible/ Completion Date	Action Results: Action Taken	SEV	OCC	DET	RPN

(24) Approval signatures
(25) Concurring signatures

Figure 2.5: Example of FMEA form (Scipioni et al., 2002)

Severity rating was based upon the failure description adopted by the manufacturer, such as any possible problem that causes a production interruption or a stop of the plants. For example, the greater is the stop time of the plant, the more serious is the failure. A criterion of occurrence rating was based upon daily or hourly failure rates. In this case, like in many others companies of Food Industry, a computerised monitoring system was not implemented and a statistical database was not available, therefore, occurrence was evaluated in a qualitative way based on direct experience on the production lines. Detection rating was evaluated using a visual control, made by line operators, on production chain or final product. After three ratings were evaluated, RPN was calculated and the FMEA team decide to intervene in the system when the RPN was equal to or greater than a threshold value of 50, or when the Severity of the failure was considered too high to permit the potential occurrence of the failure. Since the process FMEA did not permit to modify the process, product, or machinery design, so for every failure the Severity value have remained fixed and the recommended actions have permitted to reduce only the values of Occurrence and Detection. Therefore the intervention was based on the identification of a list of ''Recommended Actions'' that could prevent the failures, reducing the rate of Occurrence and Detection. The results revealed that the ''incorrect stamp position'' in primary package phase is the greatest RPN failure individuated in the production cycle by FMEA team due to high values of Occurrence and Detection (the damage could be detected only by visual control of the operator on final package), and high value of Severity (due to the fact that the production of a defected final package was a violation of a compulsory regulation). This failure then could be easily prevented through the execution of the recommended action such as the periodic replacement of the stamp (Scipioni et al., 2002).

The healthcare system has also begun using FMEA as a process improvement tool (Reid, 2005; Reiling, Knutzen, and Stoecklein, 2003; Spath, 2003). The three rating criterion in healthcare FMEA suggested by Reid (2005) are shown in Figure 2.6-2.8. The severity rating is based on how serious the impact would be if the potential failure were to occur. The occurrence rating is based on the probability of the potential failure occurring while the detection rating is based on how easily the potential failure could be detected prior to occurrence (Reid, 2005).

Rating	Criteria	During care	After care	Example
10	Failure may seriously endanger patient.			Failure could cause patient or staff death.
9	Failure involves regulatory noncompliance.			Failure could cause long-term patient or staff disability.
8	Failure causes patient high dissatisfaction.			Patient health seriously impacted.
7	Failure causes patient dissatisfaction.			Patient health impacted.
6	Failure causes disruption of patient ADL.*			Patient has to return for major correction.
5	Inconvenience for patient and multiple providers.			Failure caught at subsequent healthcare provider organization.
4	Inconvenience at subsequent function; minor rework.			Failure caught and corrected at subsequent in-house function.
3	Slight inconvenience at next function; minor rework.			Failure caught and corrected at next in-house function.
2	Slight inconvenience at delivery; minor rework.			Failure caught and corrected at delivery.
1	Patient will probably not notice.			No effects.

*Activities of daily living.

Figure 2.6: Criteria for Severity rating in Healthcare FMEA (Reid, 2005)

Rating	Failure probability	IPTO*	IPMO**
10	Very high	>500	>500,000
9	Very high	333	333,333
8	High	125	125,000
7	High	50	50,000
6	Moderate	12.5	12,500
5	Moderate	2.5	2,500
4	Moderate	0.5	500
3	Low	0.067	67
2	Very low	0.0067	7
1	Remote	0.00067	<1

* Incidents per thousand opportunities
** Incidents per million opportunities

Figure 2.7: Criteria for Occurrence rating in Healthcare FMEA (Reid, 2005)

Rating	Detection	Criteria*	Error proofed	Gauged	Manual inspection	Example
10	Almost impossible	Almost certainty of nondetection				Can not detect or is not checked
9	Very remote	Controls will probably not detect				Control achieved with indirect or random checks only
8	Remote	Control as have a poor chance of detection				Control achieved with visual inspection only
7	Very Low	Controls have a low chance of detection				Control achieved with multiple visual checks only
6	Low	Controls may detect				Control achieved with charting methods, such as statistical process control
5	Moderate	Controls may detect				Control based on variable gauging after delivery or 100% go-no go gauging after service delivery
4	Moderately high	Controls have a good chance of detection				Error detection in subsequent operations; gauging performed at service delivery
3	High	Controls have a very good chance of detection				Error detection at delivery or in subsequent operations by multiple layers of acceptance; cannot accept failure
2	Very high	Controls almost certain to detect				Error detection in delivery, such as automatic gauging with automatic stop feature; failure cannot pass
1	Almost certain	Controls will detect				Error proofed—failure cannot occur

*Process controls from failure mode effects analysis.

Figure 2.8: Criteria for Detection rating in Healthcare FMEA (Reid, 2005)

McCain (2006) has successfully introduced FMEA in a service setting (Compuware Contract Employee Process). An example of FMEA template used for Compuware Contract Employee Process is shown in Figure 2.9. As a result, the uses of FMEA allowed Compuware to meet the ISO 9001 requirement for preventive action.

Prepared by: Project team:								Owner: Responsibility:						
								FEMA date:	Original: Revision:					
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Service or process feature	Potential failure mode	Potential effects of failure	SEV	Potential cause of failure	OCC	DET	RPN	Recommended action	Who acts and target completion date	Action taken	SEV	OCC	DET	RPN
Implement and manage on-site recruiting process	On-site recruiting process not implemented	Insufficient number of employees available	8	No one available to conduct on-site recruiting	8	3	192	Cross train all recruiters on the on-site recruiting process	Branch managers 11/15/2006	Recruiters cross trained	8	2	2	32

SEV = severity rating
OCC = occurrence rating
DET = detection rating
RPN = rating priority number

Figure 2.9 FMEA template used for Compuware Contract Employee Process (McCain, 2006).

2.3.5 Limitation of FMEA

Johnson and Khan (2003) have studied the concerns and inhibitors that process FMEA (PFMEA) users have by evaluating a sample of suppliers to an automotive manufacturing company in the UK. The result showed that 'Team' and 'Teamwork' emerged as the most important topic in terms of the successful implementation of a PFMEA, followed by 'Technical'. 'Technical' issues created the greatest number of concerns, with the fundamental understanding of the practical aspects of PFMEA being the root concerns. The PFMEA process management and general management aspects were also found to be important and needed improvement and focus. However the PFMEA technique has limitations, caused by issues such as the understanding of cause and effect and the practical aspects of managing the data and keeping it up to date. It was indicated that the suppliers of automotive industry found it difficult to quantify the true benefits of the PFMEA technique, in terms of costs, reliability improvements and problem prevention.

Reiling, Knutzen and Stoecklein (2003) have reported that the potential for bias in users of FMEA. For example, what one person considers a high Severity, another might consider medium or low. What is a failure to one person might not be a failure to others.