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IMPLEMENTING FMEA (FAILURE MODE AND EFFECT ANALYSIS) IN A CANNED CORN MANUFACTURING INDUSTRY: A CASE STUDY

IMPLEMENTAÇÃO DE FMEA (FAILURE MODE AND EFFECT ANALYSIS) EM UMA INDÚSTRIA DE FABRICAÇÃO DE MILHO EM CONSERVA: UM ESTUDO DE CASO

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ABSTRACT

Assuring quality and food safety is challenging for many companies, as they affect the sustainability of the business. it was identified lack of studies focused on applying risk assessment tools in the food industry by reviewing the literature. This study aims to describe the implementation of Failure Mode and Effect Analysis (FMEA) to identify potential risks and how to prevent them, to assure quality requirements in a corn food plant. This paper follows a case study approach, based on a qualitative methodology. During the execution of FMEA, the hazards and mitigation controls were identified. The results provide evidences of how FMEA can be effective by showing the vulnerabilities of production flow, controls to implement and how to prioritize actions. FMEA contributed to managing risks found for the company where the case study was conducted. This case study can be followed by other companies and different processing technologies, extrapolating the food industry.

Key words: FMEA; quality; hazard; corn; food industry.

RESUMO

Garantir a qualidade e a segurança alimentar é um desafio para muitas empresas, pois isto afeta a sustentabilidade do negócio. Foi identificada a falta de estudos focados na aplicação de ferramentas de avaliação de risco na indústria alimentícia por meio da revisão da literatura. Este estudo tem como objetivo descrever a implementação da Análise de Modo e Efeito de Falha (FMEA) para identificar riscos potenciais e como preveni-los, para garantir os requisitos de qualidade em uma planta de alimentos de milho. Este artigo segue uma abordagem de estudo de caso, com base em uma metodologia qualitativa. Durante a execução da FMEA, os perigos e controles de mitigação foram identificados. Os resultados fornecem evidências de

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como a FMEA pode ser eficaz, mostrando as vulnerabilidades do fluxo de produção, controles a serem implementados e como priorizar as ações. A FMEA contribuiu para o gerenciamento dos riscos encontrados para a empresa onde o estudo de caso foi conduzido. Este estudo de caso pode ser seguido por outras empresas e diferentes tecnologias de processamento, extrapolando a indústria alimentícia.

Palavras-chave: FMEA; qualidade; perigo; milho; indústria alimentícia.

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1 INTRODUCTION

Nowadays, it is usual to face a huge competition between companies that offer the same products or services. Therefore, the pursuit for high productivity and quality is a key factor of influence in customers' decision. It remains clear that there is less tolerance for defects, wastes and inefficiency at manufacturing processes [1]. The definition of quality is directly connected with attending the expectation of a stakeholder, guarantying full compliance of requirements, besides the fact of being a competitive differential. In addition, it can be highlighted that the increase of competitiveness starts a rise of expectation in the stakeholders, making the companies be even more pressed about their productive chain and at the evaluation of their intrinsic and extrinsic risks. The terms "quality" and "competitiveness" are being truly imposed beyond the organizations to keep them active on the market [2, 3].

Quality management has an important role at the consolidation of production sector, because its goal is to reduce the number or rate of failures, consequently, affecting in an optimal use of productive resources of an organization. Some kinds of failures can have drastic impacts for the customers, for example the aviation and automobile industry. In their context, a bad working can be equal to a life risk to the final user [2,4].

The quality in the food industry context is directly related to customers' safety once a food cannot cause damage to the user. Besides the competitiveness issue, quality assumes a decisive role at the food production, mainly when it is about products

with raw materials prevenient from animals or vegetables. In these cases, the worrying about quality must be higher once some failures can cause lethal damage to customer's health [2]. Data collected by Brazilian Ministry of Justice and Public Security in 2016 [5] shows that an amount of 9.651.519 products were involved in 138 recall campaigns in 2016, 2.9% of this amount only in the food industry. Although recall is a protection tool for the customer, it is a tool that can contribute negatively for a brand reputation.

The risk assessment in the food industry is very important because it has a preventive and predictive aspect in a global context of competitiveness. Quality management focused on preventing non compliances is also very important to reduce inspection practices and costs [6]. Between a huge quantity of tools to evaluate risks, Failure Mode and Effect Analysis (FMEA) is constantly used. This method has a goal of identifying potential failures and indicating possible defects caused by these failures, focused on minimize the risk of them [7]. Nowadays, FMEA application is focused on automobile, mechanical, electronic and machinery industry. In the food scenario, FMEA is an innovative tool [8].

Researchers have shown some successful cases of application of Failure Mode and Effect Analysis at the food industry. FMEA model have been applied in a ready to eat vegetables plant, allowing the business to propose corrective actions for high risks steps at the process [9]. It was applied also for salmon production [10], octopus and snails [11], with the objective to reduce contamination risks during production. Another case study demonstrates the effective application of FMEA in a potato chips manufacturing, allowing the business to define their critical control points and how to prevent failures on them [12].

Thus, this paper aims to demonstrate an empirical implementation of FMEA in a canned corn industry located in Brazil, as an opportunity to check the efficiency of the tool in a specific context, as it was evidenced in previous resources. First, a general context about the canned corn sector will be presented, followed by a background on FMEA and its steps of implementation. During the exposition of the results, it will be discussed some benefits and challenges of the FMEA implementation.

2 THEORETICAL BACKGROUND

2.1 CANNED CORN SECTOR

Canned corn is considered as one of the most relevant foods for humanity, because it has a large productivity, versatility, and nutritional value. It is part of the basic nutrition in Latin America, Asia and Africa [13]. United States and China were the main growers of corn in the world. Brazil is the third biggest grower in the world [14]. Besides it is observed an increasing in the cultivation of this product in Brazil; it can be explained by the added value of this vegetable and its derivatives [15].

The canned corn is categorized as a “food processed in hermetical package, stable in environmental temperature with a pH higher than 4.5” according to Brazilian regulatory requirements [16]. This scenario is favorable to the growing of Clostridium botulinum. For this reason, the product must be sterilized.

Clostridium botulinum is a microorganism that can lead to botulism. This is a serious illness, with a high rate of lethality. For this reason, it must be treated as a medical emergency. It is very important that the diagnostic be made as soon as possible, reducing the risk of lethality. In Brazil, the report of botulism cases started to be done in 1990’s. In the most part of the cases, botulinical toxin comes from canned foods [17].

2.2 FAILURE MODE AND EFFECT ANALYSIS (FMEA)

There are several methods that assure quality during the production. Failure Mode and Effect Analysis (FMEA) is one of them. This tool consists in qualitative analyses, which helps on identifying and solve vulnerabilities in products or processes [2]. Some examples of benefits can be mentioned, for example: improving quality and reliability; improving the competitiveness of an organization; reducing time and cost for developing products [6]. FMEA is a tool with the basic function of avoiding that failures happen in the process. There is an increasing in the reliability on a product or process by reducing the chance of a failure to occur or having the acknowledge of which actions perform in case of failures [18]. The first application of FMEA in a formal way happened in 1960’s, in a context of innovation into the aerospace industry. In this context, FMEA

is classified as an analysis method for products or process, used to identify every possible reason of failure and define the impact of each of the failure modes. It does not demand a sophisticated analysis, it is a simple tool and it is able to bring a complete approach [2]. FMEA includes some basic steps, for example: the organization (forming teams and defining milestones), process evaluation and process mapping, risk assessment, critical analysis of results, implementing corrective actions and monitoring the process [8].

The organization step is decisive for the execution of FMEA. Planning activities is fundamental, including the team building that will perform the risk assessment. It is recommended that this team be formed of a reduced number of people, and these people should have technical domain and experience in the process. Besides, planning also includes the description of goals, governance strategy and definition of documentation required [18].

FMEA uses a form that includes the whole risk assessment to be done after the planning step. The forms are flexible, giving the possibility of applying it in several sectors, being very adaptable to different realities [2]. The FMEA form includes different elements, for example, the process description, roles and responsibilities, effects and causes of failures, severity grade, probability and detection of failures, and actions that must be implemented to reduce the effects and probability of failures [18]. In Table 1, it is detailed what shall be included in a FMEA form.

Table 1 – Terms and definitions at FMEA

Term	Definition
Document number	Registration code, allowing traceability inside the organization.
Product or process identification	Scope definition for the current FMEA.
Multidisciplinary team	Member's name, role, previous experiences with the product or process.
Process mapping	Building process flow and how the product changes between steps.
Failure mode and effect	Describes how a process or step can fail on achieving needed requirements, and the consequences of a failure when it occurs.
Severity	Impact of failure effects in the process, always focused on customer's perspective.
Cause and occurrence	What brings out a failure mode and how frequent the failure occurs,
Existing controls	Control measurements that are already implemented by the organization.
Detection	How capable the failure is to be identified before the closing of a step.
Risk Priority Number (RPN)	The combination of severity, occurrence and detection. It can be used to prioritize failure modes.

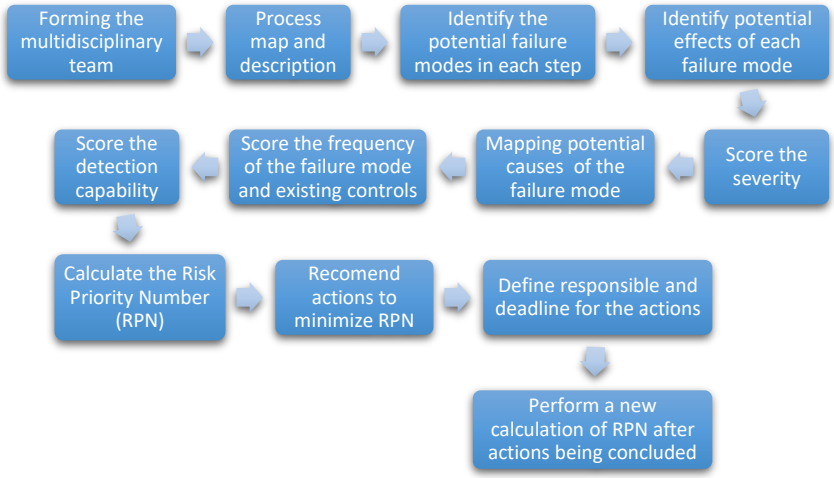
Corrective actions	Actions different from the control measurements already existent.
Updated RPN and evidences	New value for RPN after the implementation of corrective actions and documents, reports and other files that can prove the execution and efficiency of proposed actions

Source: Adapted from Pinho et al. [18].

3 RESEARCH METHOD

The method chosen to conduct this paper was a case study, following a qualitative approach in a canned corn industry. The present case study was carried out in a large food company, focused on corn manufacturing processes to obtain canned corn. The company is in the west-center region of Brazil. The implementation of FMEA and data collection was performed in 2020 from January to June. Some preliminary information was mapped, for example: product description; ingredients; nutritional information; physical-chemical aspects; microbiological standards; package information; label information; codification pattern; and shelf life. The case study was performed following the steps of implementation proposed by Costa et al. [2], following the steps bellow (see figure 1).

Figure 1 – Steps of implementation for FMEA



Fonte: Adapted from Costa et al. [2].

The data collected were obtained from processes specifications, by the technical team formed to build FMEA during normal production. The data collection was independent from shifts or days since the specifications were fixed. This information was available in production sheets, standard operational procedures, equipment manufacturer's manuals, raw materials and package suppliers and

technical lists, including the observation of productive area. As FMEA took in consideration the whole productive chain, it was collected data in each one of the steps including: upper and lower temperature, pressure, flow and hold time limits; specifications for physical and microbiological contaminants detection; minimum and maximum steam pressure and compressed air limits; gross and drained weight for filled products.

The multidisciplinary team analyzed the trends for the processes data listed checking if the specification was being followed. This check was performed using the software PI System (for pressure, temperature, time, flow, steam and compressed air parameters) where it was possible to see the graphs of the data generated during normal production by measuring instruments. In the case of contaminant detection, quality members of the team gathered the historical data of product rejection due to possible contamination, registered in sheets. For the weight parameter, quality members analyzed the reports generated by the precision scales in the line. The team decided to check historical data in an interval of six months before the analysis, for all the parameters, because they considered that this interval was representative, and it was usual for the business to use this range to perform other kinds of analysis.

4 RESULTS AND DISCUSSION

4.1 MULTIDISCIPLINARY TEAM

For this case study, it was formed a team with people from the following departments: food safety, quality, maintenance, manufacturing, engineering and supply planning. For food safety department, it was represented by a microbiologist, food safety coordinator and thermal processes analyst. For quality department, it was represented by the quality coordinator and packaging supervisor. For maintenance and engineering, the coordinators of the areas, and for supply planning, the scheduling analyst. The team members were graduated on Chemical Engineering, Food Engineering, Mechanical Engineering and Biology. The whole team had previous experiences on food industry.

The implementation of FMEA shall be articulated by people with minimum acknowledge of the process, operationally and technically. A significant number of

meetings must be performed with this team, in this context, the people involved on performing FMEA must put a lot of effort in this initiative. This might be seen as a cost for the business. Although this fact, when the FMEA is being performed, the organization can face this cost as an investment [5, 19]. It was observed during this study that the schedule of the human resources involved was a challenge, due to the conflict with other demands on site. In this context, the leadership support was crucial for engaging the team in delivering the risk analysis.

4.2 PROCESS MAP AND DESCRIPTION

Based on the observation of the process, it was built a process flow, including the steps, equipment, inputs and outputs of ingredients, packages, water, steam, and compressed air. After the visual flow, the process was fully described by the specialists.

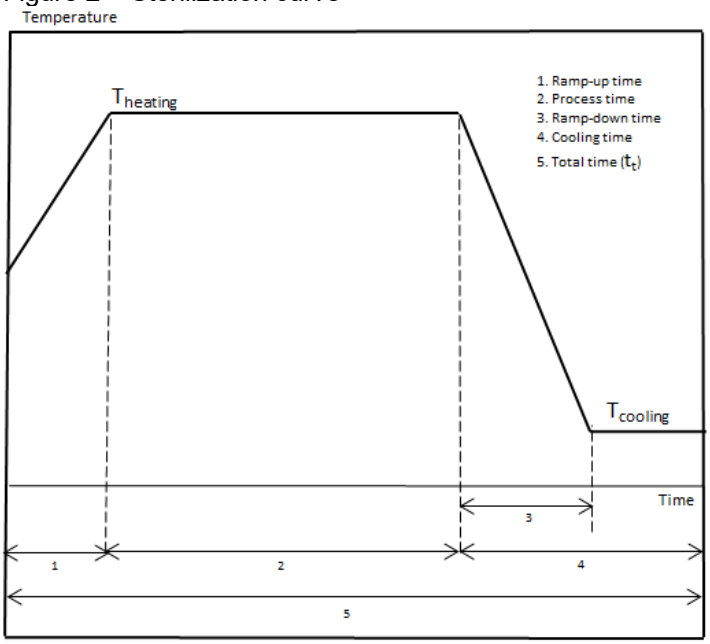
The “in nature” corn arrives at the productive area in bucked trucks. It is performed a previous verification in the material and the weighing. Thus, the truck goes to a classification zone, where is performed a sampling, and these samples are sent to the laboratory. In this step, some analyses are performed, like humidity, color and defects.

The truck goes to the corn processing, being pre-washed with water. After this step, the corn husks are removed and the corns without husks go to a manual selection mat, and to equipment that segregates the corn grains from the cob. The grains follow to the next process by water, to be selected. In this step the grains pass for strainers. After the selection, the grains are directed to a bleaching process, which is a previous cooking. The bleached grains are forwarded to the filling lines, which can be filled in metallic cans. The grains receive a salty solution at 80 °C. The grains already closed into a package go to the sterilization process.

This step is critical for the process because it is directly related to the lethality of Clostridium botulinum. The heat penetration in the products depends on the size of the package, initial temperature of the product and headspace [20]. The sterilization is a thermal process applied to preserve this kind of food and contributes positively to maintain nutritional properties of the canned vegetables [21]. The thermal process is performed inside huge horizontal autoclaves, with a specific rate of temperature and pressure. Inside the autoclave, the grains go through a heating step, until achieve the

sterilization temperature. After achieving this value, the product must be kept in this temperature for a certain time. Finished this time, the product is cooled. The figure 1 represents the sterilization curve. After the sterilization, the finished products are removed from the autoclave and forwarded to the palletizing sector, being able to be sent to the customers.

Figure 2 – Sterilization curve



Source: Adapted from Fravet [21].

4.3 EXECUTION OF FMEA

The assessment was performed based on the process steps mapped on the process flow. Every failure mode was pointed by the multidisciplinary team during brainstorming discussions. The brainstorming is a very usual tool in FMEA, it is known as a tool that gathers information from the whole team, being very effective during the evaluation [22]. The FMEA layout used was suggested for the corporative level of the organization. At the figure 2 it is described a part of the form, where the assessment is performed considering the “as is” process.

Figure 3 – First part of FMEA form

Step of the process	Function of the step	Potential failure mode	Potential effects of the failure	Sev.	Potential Causes	Ocurrence	Existing controls	Detection	Tools to control risk	RPN

Source: Elaborated by the authors.

The rates of severity, occurrence and detection must be given in ascending order, according to the negative impact at the process. For example, higher is the severity number, higher is the impact for the customer; higher is the detection value, harder is to identify the deviation; higher the occurrence, higher is the frequency of failure. The multiplication of these three rates indicates the Risk Priority Number, or RPN. This value will head the team during the prioritization step [1]. For this case study, it was defined by the multidisciplinary team that RPN higher than 100 should be prioritized. To define the scores of severities, occurrence and detection of effects, it was used a risk matrix with some questions to head the team to decide the score, as showed by tables 2, 3 and 4.

Table 2 – Severity criteria

Score	Classification	Description	Additional comment
10	Dangerous without warning	It puts in risk the health of a person. It does not attend regulatory requirements.	Surely it will result in a disease or a serious injure due to the presence of a pathogen or a physical contaminant. It is harmful even when the person is exposed to a low level of contamination.
9	Dangerous with warning		
8	Very high	High rupture at the market. A disease or injure would be likely. The waste generated in the process and the whole batch would be discharged.	
7	High	Low rupture at the market. It would create losses and the product should be replaced or discharged. The customer would experience delays to receive products without defects. It would be expected a lot of complaints and returns of important customers.	It will be harmful only if the person is exposed to a high level of contamination. It will result in a disease in case of continuous exposure.
6	Moderate	Low rupture at the market. It would create losses and the product must be replaced or discharged. The customer would experience delays to receive products without defects.	
5	Low	Low rupture at the market. It would create losses and the product must be replaced or discharged. The customer would not suffer to receive products without defects.	The effect on health is not completely established, but it can result in a disease or injure. A physical hazard which the damage depends on the size of the contaminant.
4	Very low	It is expected a minimum waste. A medium amount of customer complaints would be expected.	
3	Minimum	A defect would be observed by an average of customers. It is expected a few of customer complaints.	
2	Almost no impact	The defect would be observed by a few customers. Complaints are unlikely.	

Source: Elaborated by the authors.

Table 3 – Occurrence criteria

Score	Classification	Description
10	It happens many times by shift (eight hours)	The failure is almost unavoidable.
9	It happens at least once a shift (eight hours)	
8	It happens at least once each 24 hours	The process is not under statistical control. Similar processes face the same problems.
7	It happens at least once a week	
6	It happens once a month, approximately	The process is under statistical control and may experience punctual failures. Previous processes suffer occasional failures or conditions out of control.
5	It does not happen more than once a quarter	
4	It happens once each six months	
3	It happens less than once a year	The process is under statistical control.
2	It happened once in the last 2-5 years	Only punctual failures associated to processes that are almost similar.
1	It happened once in the last five years or more	The failure is unlikely, and failures associated to similar processes are unknown.

Source: elaborated by the authors.

Table 4 – Detection criteria

Score	Classification	Description	Additional Comment
10	Almost impossible	No detection control determined	Defect detected randomly.
9	Very remote	The control probably will not detect	Occasional unities are verified by a visual inspection.
8	Remote	The control has remote chance of detection	The unities are sampled and inspected.
7	Very low	The control has low chance of detection	100% of the unities are inspected manually.
6	Low	Controls can detect	Inspection and re-inspection of 100% of the unities
5	Moderated	Controls can detect, but manual actions are necessary.	The process is monitored by Statistical Process Control and inspected manually;
4	Moderated high	Controls have a good chance of detection	Statistical Process Control is used to enable an immediate action for conditions out of control
3	High detection	Controls have a good chance of detection	100% of the unities are inspected automatically and an alarm notifies the defect, but it is necessary a manual action to remove the defect.
2	Very high	Controls certainly detect	The defect is very clear during the manual inspection.100% of the unities are automatically inspected and the defects are automatically rejected.
1	Extremely high	Controls certainly detect and reject	Defects are prevented due to physical design and restrictions.

Source: elaborated by the authors.

4.4 POTENTIAL CAUSES OF FAILURE, EXISTING CONTROLS, RECOMMENDED ACTIONS AND PRIORITIZATION OF RPN

Control actions have the goal of mitigating or removing any abnormality found at the process. These actions can be implemented together with corrective actions [23]. The recommended actions during the execution of FMEA must guarantee the elimination of root causes. For this step, the Ishikawa Diagram can be applied, being a very simple and effective tool used to suggest what causes affects the process [24].

As examples of correction and corrective actions adopted in this case study it can be mentioned: interrupt the startup of the production; communicate the immediate leader of the area; calibrate measuring instruments, etc. As examples of corrective actions, it can be mentioned: review of sampling plans and creation of programing logics to block critical parameters.

With this study, it was possible to see that the level of details is crucial for directing the team to define the correct actions to mitigate risk, in a way that prevents a failure to occur. If an action is defined in an inconsistent way, it could be a loss of money, time, and other resources. For this reason, the good prioritization depends on the quality of the actions proposed.

As defined by the multidisciplinary team, every step with a RPN higher than 100 should be prioritized. Some examples of these steps were: selection, flotation, filling, addition of salty solution and hermetical closing. For these steps, control actions were proposed to reduce the RPN. Some actions required investments or programmed stops. For this reason, the execution has not been completed and the new RPN after the implementation of control actions was not recalculated.

5 FINAL CONSIDERATIONS

Based on the case study, the FMEA implementation was successfully applied, showing huge benefits, like the reduction of failures in the process. The most sensible steps were related to physical contamination prevention, regulatory and microbiological controls. The limitation of this paper consists in the application of the tool in a single process of the factory. It is relevant to complement that the corn harvest,

transportation and storage can be decisive for the whole chain, although this effort was not focused on these parts of the chain.

Some challenges were observed, when it comes about the availability of human resources for the execution of the FMEA, the flow of execution of actions to mitigate risk, due to other priorities of the business. Another important consideration is about the need of financial resources to implement some control actions. It can be considered as a barrier for the full application of FMEA, and it must be constantly reviewed after new actions being concluded.

Finally one can conclude that FMEA tool can be effective and simple for the food industry context, once it brings relevant data and actions to prevent failures, that in some cases, could be drastic for the organization. For further studies, this risk analysis could be implemented at the production of another kind of canned vegetables, for example, pea, beans, carrot, and potatoes. Also, it can be proposed the recalculation of RPN after the actions be completed. It could be a future work to study the risks involving the supply chain, applying the FMEA focusing on the previous steps outside the manufacturing context.

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