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IMPLEMENTATION OF THE FMEA METHOD AS A SUPPORT FOR THE HACCP SYSTEM IN THE POLISH FOOD INDUSTRY

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Abstract:
The main objective of the work was to assess the possibility of using and implementing the FMEA method as an effective support for the HACCP system in a selected food industry enterprise. The research entity was a food enterprise located in central Poland and the subject of the research was canned meat with gravy in glass jars and their production line. In the study, programs such as draw.io, Excel, and Statistica were used. The study was conducted based on interviews with company employees, value stream analysis and nonconformance reports. During the site visit, an assessment of the company's infrastructure was also carried out to evaluate the possibility of implementing the FMEA method. Data analysis showed that in the examined company there are non-compliances with varying degrees of impact on the final quality of the product or on the production process of this product. The analysis of the company's infrastructure, in turn, confirms that it is possible to integrate the HACCP system with the FMEA method. The results indicate that the synergy of HACCP and FMEA will bring benefits to the company in the form of improved risk management, quality control and safety in food production. The results of this study suggest that implementing such a connection may bring many, various benefits to food companies not only in Poland but also in another countries.

Key words: *FMEA, food industry, food safety, HACCP, Poland*

INTRODUCTION

Food safety is an extremely important issue, especially considering the aspect of globalization. From research conducted on over 700 recorded food incidents in the world in the years 1828-2015, it can be concluded that over half of them (approximately 65%) occurred in the 21st century (2001-2015). The modern consumer is increasingly interested and aware of the importance of food safety, and at the same time more and more concerned about it. According to data published by The European Food Safety Authority (EFSA), a significant part (as many as 44% of respondents) of consumers living in the European Union (EU) would like to be informed about a potential risk immediately after its identification, even in the absence of scientific evidence of its impact on health. The most common concerns of EU consumers regarding the food they consume are chemicals used during its production, the presence of bacteria and viruses and food fraud [1, 2, 3, 4, 5, 6, 7]. Consumer concerns are not unfounded, as unsafe/unfit food is responsible for over 200 diseases, which are usually toxic or infectious. Foodborne illnesses, in addition to causing typical digestive symptoms (food poisoning), can lead to long-term disability and even death. The World Health Organization (WHO) reports that 420,000 people die each year as a result of eating contaminated food, including a significant number of children under 5 years of age (125,000 people). Moreover, according to the WHO, 600 million people are likely to become ill each year as a result of eating them, making unsafe foods a serious threat to public health [2, 8]. Unfortunately, incidents involving food that endangers or misleads consumers still occur. For example, in the years 2018-2022, the percentage of food samples that did not meet the applicable health quality requirements in Poland was: 3.03, 2.55, 3.09, 2.13, 2.29%. During this time period, the most common hazard in reported products was the presence of Salmonella in food/feed. In 2022 alone, as many as 6,546 cases of Salmonella were confirmed [9, 10, 11, 12, 13].

In order to ensure safe and high-quality products worldwide and to protect the health and interests of consumers, a wide range of legal regulations have been created that food producers must comply with in order to be able to guarantee such food. These regulations encompass provisions regarding, among others hygiene requirements or the manner of food labeling. In addition, there are also so-called food safety management systems, which play an important role as tools supporting enterprises in achieving the above-mentioned goals [5, 14, 15]. EU law makes some food safety management systems mandatory, but there are also optional systems. Mandatory systems include: Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP) and Hazard Analysis Critical Control Point (HACCP). In Europe, the obligation to implement HACCP in the food industry was imposed in 1993 by Council Directive 93/43/EEC. The document currently in force in the EU imposing the obligation to implement the HACCP system on entities related to the food market is Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [15, 16, 17, 18, 19]. Unfortunately, despite the legally imposed obligation to use mandatory food quality management systems, many enterprises do not undertake to implement them in Poland. However, a slow increase in the number of lending enterprises implementing these systems can be observed since Poland's accession to the EU. After a year of integration (2005), the GMP system was used by 45%, GHP – 50%, and HACCP only 21% of food industry enterprises. In 2015, GHP and GMP systems were introduced in all plants processing products of animal origin, while in the case of products of non-animal origin, the average level of their implementation was only 86%. The main problems (55.7%) during audits in food enterprises in 2005-2013 concerned the implementation of GMP and GHP systems. In 2015, the HACCP system was used by only 83% of enterprises processing products of plant origin and 66% of enterprises processing products of animal origin. The highest percentage of the HACCP system implemented in 2015 (data from December 31) was recorded in the sugar industry (100%), while the lowest percentage was in the other products industry (53%) and the meat industry (55%) [20, 21, 22]. In 2022, GHP/GMP principles were implemented in 464,956 plants, while HACCP only in 264,818 (supervised) [13]. Non-mandatory systems (e.g. International Food Standard (IFS) or British Retail Consortium (BRC)), the use of which is voluntary and not required by law, are chosen by a small percentage (< 5% – in 2012) of enterprises, most often leaders in particular sectors of the food industry [23].

In order to guarantee high-quality, safe food, it is advisable to implement mandatory food health safety systems in enterprises. It is also worth considering the implementation of non-obligatory systems that can additionally improve quality standards (including safety). In addition to, of course, taking care of the broadly understood consumer good, the systems increase the competitiveness of the companies implementing them, contributing to greater financial benefits [21]. Equally important in terms of the quality and safety of products intended for consumption is also the development of existing structures (i.e. systems), the synergy of existing methods to increase efficiency and food safety, or the creation of completely new ideas that can improve and create effective management.

LITERATURE REVIEW

Generally, achieving a high-quality end product relies on three key steps. The first (1) is programming guaranteed good quality products by eliminating the risk of imperfections, the second (2) is quality control during product creation, and the third (3) is quality control of the finished product. Final product quality control used to be the most popular and widely used method of food quality control, but it is now losing its importance. Nowadays, the most important emphasis is placed on methods to prevent the production of low-quality products in all processes occurring in the food chain [15]. The flagship system of this type, aimed at ensuring food safety, is the HACCP system, based on risk assessment, identification and elimination of hazards during the production of products, and not only after its completion, in the final product [24, 25].

Methods based on control and actions aimed at preventing the production of low-quality products at every stage of the food chain are gaining particular importance in the era of advancing globalization, which, among others lengthens supply chains, simultaneously creating potential risks to consumer health [1]. However, due to the intensification of globalization processes, increasing consumer demands regarding food and desire to improve or strengthen the market position of enterprises, the implementation of the HACCP system alone may not be sufficient [1, 26, 27, 28]. Modern society requires modern solutions that will be able to increase food safety even more than before, which is why companies are increasingly deciding to combine several methods that will be able to guarantee this.

The FMEA (Failure Mode and Effects Analysis) method is a systematic and structured approach to identifying potential failures in systems, processes, products, or services, and assessing their consequences and causes. The primary goal of FMEA is to proactively manage risk by detecting possible issues early and eliminating or minimizing their impact on system performance [29, 30, 31]. FMEA analysis is based on identifying failure modes, which are the ways in which individual components can fail, and assessing the effects of these failures on the overall system's operation. This process involves interdisciplinary teams of experts who utilize their knowledge and experience to identify potential problems at various stages of the product or process lifecycle [32, 33, 34]. FMEA supports the approach of continuous improvement, aligning with quality philosophies such as Kaizen or Lean Manufacturing.

Through systematic risk analysis and preventive measures, organizations can improve the reliability of their products and processes, leading to increased customer satisfaction and reduced costs associated with failures and downtime [35, 36, 37].

The synergy of the HACCP system and the FMEA method (Failure modes and effects analysis) is a relatively new approach in the aspect of food quality management, which is gaining popularity among various types of food producing enterprises. FMEA is a preventive method whose priority is to predict, identify and minimize/eliminate the risk of problems at the design stage. It is based on the claim that most errors (3/4 of all errors/inconsistencies) have their source already at this stage. Numerous benefits (e.g. cost reduction, shortening the time to market, improving safety) resulting from the implementation of this method mean that companies that decide on it are often powerful competitors on the market [38, 39, 40, 41].

The implementation of the combined FMEA method with the HACCP system has already been undertaken by various types of the food industry, and case studies cover both typical and more unique productions. The first group includes examples of industries such as vegetable or plastry processing, , as well as companies producing food from other product categories, e.g. potato chips or chocolate manufacturing [42, 43, 44, 45]. In turn, the second group includes, for example, the production of raw unclean edible birds nests in a plant located in Malaysia, during which the integration of the FMEA method was used in the verification phase of the implemented HACCP system [46]. This technique, i.e. the use of FMEA when implementing HACCP as an auxiliary tool in food industry plants, is the most popular. However, the spectrum of application of FMEA with the HACCP system is much wider. For example, such synergy can be used to interpret audit results for the purpose of verifying the effectiveness of the HACCP system. An example of such a study is the study by Trafialek and Kolanowski from 2014, which was conducted in Poland in two bakeries [47]. The synergy of these two methods is also used to analyze the assessment of risk levels that may arise during various stages of production of a given food product. This practice has been successfully implemented, for example, in the case of common octopus processing [48]. Moreover, such a combination is also promising in terms of information for preventive purposes already at the early stages of the chain – on the farm. This practice may be used, for example, to reduce salmonellosis in pork production [49].

The main objective of this work was to assess the possibility of using and implementing the FMEA method as an effective+ support for the HACCP system in a selected Polish food industry enterprise. The general assumption of the work was that the integration of the FMEA method with the HACCP system will contribute to improving the overall effectiveness of risk management in the food industry, which will result in increased safety.

METHODOLOGY OF RESEARCH

The research object of this work was a company located in in the Republic of Poland, operating in the meat and vegetable processing industry. The company has been operating on the market for many years and specializes in the production of, among others: soups, canned goods, pâtés. Products manufactured by the company are sold both through large retail chains and traditional channels (wholesaler). The object of interest in this work was a jar made of glass filled with meat, which should be eaten cold (without heat treatment). According to the division included in the Table 1, it is sterilized, canned meat (or edible offal) with gravy. According to the manufacturer's recommendations, it should be stored in a dry place at room temperature, and after opening it should be kept in the refrigerator and consumed within 48 hours.

Table 1

Division of meat preserves/canned goods

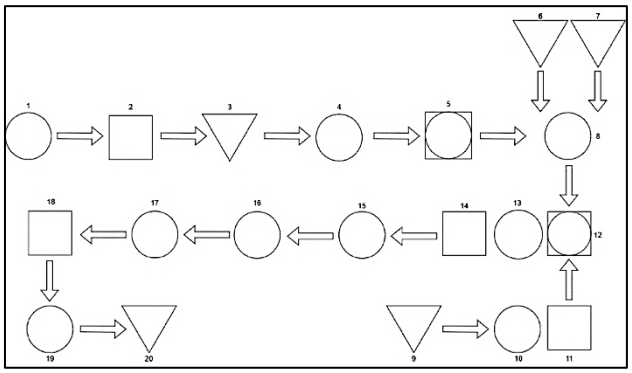
Category	Subcategories
Composition of raw material, form of binding, type of input	• Canned meat • Canned variety meats • Canned formed meat • Canned animal fat • Canned pate • Canned meat or edible offals with gravy
Heat treatment method and microbiological stability	• Pasteurized canned food • Sterilized canned goods • Canned food that is stable at ambient temperature
Type of unit packaging	• Canned food in metal cans • Canned goods in metal cans with plastic lids • Canned food in multi-layer foil • Canned food in glass jars

Source: [50].

Based on an interview with quality department employees, quantitative and qualitative analysis of value streams, non-compliance reports and an assessment of the infrastructure of the examined food enterprise, the possibility of using the FMEA method in the most critical area of production was assessed and a reference model was proposed. Microsoft Excel Spreadsheets and the statistical program Statistica 13.3 StatSoft Polska were used for data analysis. Based on the collected data, a Pareto-Lorenz diagram was developed and risk priorities were assigned for individual data based on the formula: $RPN = S \times O \times D$ (FMEA). In this article, diagrams.net (draw.io) was also used to present, among others, the production cycle diagram (Figure 1).

The production cycle of a selected food product begins with the delivery of raw material, i.e. meat, by suppliers to the production plant. Each delivery is checked in terms of the condition of the raw material (e.g. freshness, presence of foreign bodies), the condition of the packaging (e.g.

tightness) and transport conditions (e.g. temperature). At this stage, documentation is also checked, including, for example, ante-mortem inspections.



Explanation:
1 – product receipt, 2 – control of delivered products, 3 – raw material storage, 4 – meat injection, 5 – meat massaging and control, 6 – spice storage, 7 – fat storage, 8 – grinding with added fat and spices, 9 – packaging warehouse, 10 – washing jars, 11 – packaging inspection, 12 – portioning, packing into jars and batch control, 13 – closing the packaging, 14 – closing control, 15 – washing, 16 – autoclave, 17 – cooling, 18 – detector control, 19 – labeling, 20 – finished products warehouse
Fig. 1 Diagram of the production cycle of the selected product

If the product meets certain requirements, it is accepted by employees and transported to a cold warehouse, where it is kept. In the process of storing raw material in a refrigerated warehouse, appropriate temperature conditions are maintained (which are monitored few times a day), ensuring the freshness and quality of the raw material. In the warehouse, the raw material is divided into individual batches and marked with labels that allow, among others, to verify the maximum time of keeping meat in cold storage. In the next stage of the production cycle, the meat is transported to a room called the curing room, where injectors and tumblers are located. First, a special curing brine is introduced into the meat through a specialized set of needles located in the injector. Then the injected meat is transported to the tumbler, where the massaging process, also called plasticization or plasticizing, is carried out. This operation involves intensive mixing and simultaneous kneading of pieces of meat in a rotating drum or stationary tank using a mixer. Fat and spices are also added to the mixer, where they blend with the meat. During these treatments, employees focus on, among others: on temperature control and control of uniformity of mixing. Such a mixture is ready for portioning and packing into previously prepared packaging (glass jars and lids are washed, dried and inspected outside the production hall). The range of meat mass to be placed in the jar is regulated using a portioning and dosing machine. At this stage of production, the weight of the packaging and its contents is checked. The jars are closed with a sealer, their tightness and integrity are checked, then they are washed and sterilized in autoclaves. After the sterilization process, the canned food is cooled in cold water and chilled in a cooling chamber. Each jar is then passed through a detector to detect any contaminants or foreign objects. The penultimate stage of this production cycle is labeling, during which the jars are equipped with an appropriate label using a special, automatic, linear machine (labeling machine). The finished, labeled preserves are transported to the finished goods warehouse, where they await external transport/distribution.

The surveyed company implemented systems such as GMP, GHP, HACCP and BRC to ensure high food quality and high food safety standards. The company's HACCP system is characterized by the following control points:

1. Input inspection (inspection covering raw materials before the processing process that arrives at the plant, e.g. meat, vegetables);
2. Packaging inspection (inspection of packaging closure before the sterilization process);
3. Autoclave;
4. Detection.

RESULTS OF RESEARCH

Product nonconformity structure and identification of critical points

In order to increase the quality and safety of manufactured products, it was proposed to supplement the existing HACCP system with identified new monitoring points for which risks were determined and CCP was designated for this production cycle (Table 2).

Based on the non-compliance records of the production line of a given product, a total of 43 cases of non-compliance in various categories were recorded in a given research period (confidential data). The following categories of non-compliance were identified:

a) Product contamination with glass (presence of glass in products);
b) Unsealing the packaging (packaging integrity issues);
c) Presence of metal in detection rejects (metal detection);
d) Inconsistent physicochemical results (differences between declared and actual product parameters);
e) Incorrect labeling (errors in product labeling);
f) Underestimated Fo value in the sterilization process (insufficient sterilization);
g) Packaging damage (mechanical damage to the packaging);
h) Contamination of products with another material (cross-contamination);
i) Equipment/Hardware Failure (e.g. damaged autoclave DO probe);
j) Improper storage of materials (incorrect storage conditions of raw materials).

All the above identified and described categories of nonconformities affect production processes and product quality. Most of these categories of errors pose a threat to the health and life of consumers (e.g. consumption of the glass contained in the product).

Table 2
Identification of CPPs of the HACCP system in analyzed enterprise

Process stage	Type and source of the hazard	Control	CCP
Raw material reception	Infected (e.g. bacteria) raw materials	Approvals, visual assessment, system procedure	CCP 1
	Incorrect composition of raw materials (e.g. too much fat)		
	Foreign bodies in raw materials (e.g. fragments of metal)		
Raw material storage	Lack of compliance with hygiene rules by employees	GHP Code	CCP 2
	Development/growth of microorganisms caused by for e.g. inappropriate storage conditions (temperature, humidity)	Approvals, system procedure	CCP 3
	Pests and their droppings	Approvals, system procedure	CCP 4
Spending raw materials	Lack of compliance with hygiene rules by employees	GHP Code	CCP 2
	Undefined hazard	-	-
Meat injection and massaging	Incorrect concentration of brines/marinades	Approvals, system procedure	CCP 5
	Improper/uneven distribution of brine in the meat	Approvals, system procedure	CCP 6
	Development of microorganisms due to inadequate hygiene of equipment (e.g. imprecise cleaning of needles)	Approvals, system procedure	CCP 7
	Improper adjustment of parameters (e.g. temperature, speed)	System procedure	CCP 8
Grinding with addings	Lack of compliance with hygiene rules by employees	GHP Code	CPP 2
Packaging storage	Mechanical damage to the jar	Approvals, visual assessment, system procedure	CCP 9
Packaging washing	Inappropriate methods for cleaning and sterilizing jars	Approvals, visual assessment, system procedure	CCP 10
	Remains of cleaning agents	Visual assessment	
	Mechanical damage to the jar	Approvals, visual assessment	
Portioning	Lack of compliance with hygiene rules by employees	GHP Code	CPP 2
	Improper hygiene of equipment	GMP Code, approvals, visual assessment	CPP 11
	Incorrect amount/weight of filled jars	Approvals, weighing instructions	CCP 12
	Mechanical damage to the jar	Visual assessment	-
Closing and washing of packagings	Incomplete sealing of packaging	Visual assessment	-
	Lid damage or mechanical damage to the jar	Visual assessment	-
	Remains of cleaning agents	Visual assessment	CPP 13
Cooling of packagings	Mechanical damage to the jar	-	-
	Corrosion of caps	-	-
	Water condensation on the outer surface of the packaging	-	-
	Cross-infection (due to contact with: contaminated surfaces, equipment or personnel)	GHP Code	-
Labeling	Improper hygiene of labellers	-	-
	Incorrect equipment parameters in relation to the type of packaging (e.g. too fast speed of belt conveyors)	-	-
	Incorrect information on the label	-	-
Storage of final products	Development/ growth of microorganisms caused by for e.g. inappropriate storage conditions (temperature, humidity)	System procedure	CPP 16
	Pests and their droppings	System procedure	CCP 17
	Exceeding the shipping deadline for the product	Approvals	CCP 18

The variety of types of nonconformities highlights the need for a comprehensive approach to product quality and safety management. By analyzing the potential causes of the occurrence of individual groups of non-compliances, it is possible to indicate specific areas that require attention in order to eliminate them:

a) Product contamination with glass:
   - Damage to glass packaging during production, transportation or storage.
   - Improper procedures for removing cullet on the production line.
   - Lack of appropriate protection of machines and devices that may generate glass breakage.
b) Unsealing the packaging:
   - Defective packaging materials that are not resistant to the conditions of the sterilization or storage process.
   - Incorrect configuration of packaging machines, leading to mechanical damage to packaging.
   - Errors in the packaging closing process, e.g. incorrect welding parameters.
c) Presence of metal in detection rejects:
   - Contamination of raw materials with metal elements during production or processing.
   - Damage to parts of production machinery that may enter the product.
   - Improper elimination of metal contaminants at the quality control stage.
d) Inconsistent physicochemical results:
   - Errors in the product formulation process, e.g. incorrect dosing of ingredients.
   - Changes in the properties of raw materials not included in the product specification.
   - Incorrect testing procedures or calibration of laboratory equipment.
e) Incorrect labeling:
   - Human errors in the printing and application of labels.
   - Insufficient visual inspection of labels before application to the product.
   - Outdated product data in IT systems.
f) Underestimated Fo value in the sterilization process:
   - Incorrect settings of sterilization process parameters.
   - Failure or improper functioning of autoclaves.
   - Improper calibration of devices monitoring the sterilization process.
g) Packaging damage:
   - Mechanical damage on the production line or during transport.
   - Improper storage conditions leading to degradation of the packaging material.
   - Use of packaging of insufficient strength.
h) Contamination of products with other materials:
   - Errors in the segregation of raw materials at the production preparation stage.
   - Cross-contamination on the production line.
   - Improper storage of raw materials in the warehouse.
i) Equipment/Hardware Failure:
   - Lack of regular maintenance and technical inspections of production machines.
   - Outdated machinery exposed to frequent breakdowns.
   - Improper use of devices by personnel.
j) Improper storage of materials:
   - Inappropriate temperature, humidity or light conditions in warehouses.
   - Lack of systematic inventory rotation, leading to storage of raw materials beyond the deadline.
   - Insufficient protection of raw materials against contamination or pests.

Based on the register, a Pareto-Lorenz analysis was performed, the results of which are presented in Table 3 and Figure 2.

Table 3
Summary of results for Pareto-Lorenz analysis

No	Incompability	Quantity	Percentage of total number [%]	Cumulative percentage [%]
1	Incorrect labeling	10	23.26	23.26
2	Unsealing of packaging	7	16.28	39.53
3	Damage to packaging	6	13.95	53.49
4	Glass contamination	5	11.63	65.12
5	Presence of metal	4	9.30	74.42
6	Discordant physicochemical results	3	6.98	81.40
7	Contamination with another material	3	6.98	88.37
8	Underestimated Fo value	2	4.65	93.02
9	Improper storage of materials	2	4.65	97.67
10	Equipment/Hardware failure	1	2.33	100.00

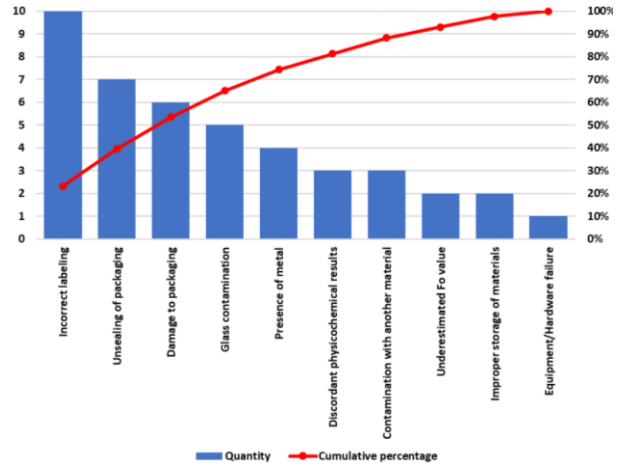


Fig. 2 Pareto-Lorenz analysis for identification incompatibilities

Incorrect labeling (N1) dominates as the single leading cause of non-compliance, accounting for over 23% (10 cases) of all cases. This indicates a problem with product labeling processes, which may lead to inaccurate information for consumers and problems with product identification. Moreover, incorrectly labeled products mislead the consumer. Packaging leaks and damage to packaging also contribute significantly to the total number of nonconformities. These three categories account for more than half of all identified nonconformities (53.49%) and they are indicate the need for closer supervision of labeling processes, introduction of additional quality controls to ensure compliance of information on labels with actual product parameters, better management of packaging processes and investment in more durable packaging materials or more advanced packaging technologies. Although focusing on the most common nonconformities can bring quick and significant results, it is also important to have a comprehensive approach to quality management that covers all potential sources of nonconformities, including those less frequent but posing a significantly greater risk to the consumer's health and life due to direct threat to life (glass contamination/metal).

Proposal for preventive actions

Preventive actions are aimed primarily at minimizing the risk of non-compliance and improving the overall quality (including safety) of products. There are many benefits from introducing preventive actions, such as increasing the company's competitiveness on the domestic/international market, reducing costs by reducing losses (due to, among others, loss of raw materials, complaints and returns), or increasing the level of employee awareness.

It is proposed to implement the following preventive actions for the identified types of non-compliance in the examined enterprise:

1. Incorrect labeling (N1):
   a) Implementation of automatic label verification systems in real time:
      – The use of advanced Optical Character Recognition (OCR) technologies to recognize text on labels and verify compliance with the database.
      – Integration of vision systems with production lines that can automatically detect and reject products with incorrectly applied or incomplete labels.
   b) Creating operational instructions and quality control procedures for labeling:
      – Develop detailed operational instructions for labeling processes that are easily accessible to employees.
      – Implementation of quality control procedures at every stage of the labeling process, from label design to its application on the product.
   c) The use of redundancy in label control systems:
      – Implementation of dual label verification systems to increase the reliability of error detection and reduce the risk of missing errors.
   d) Training for employees on current labeling standards:
      – Introduction of training programs on the importance of labeling for consumer safety and product quality.
      – Organization of cyclical workshops on changes in regulations and labeling standards, taking into account the specificity of the industry and legal requirements.
   e) Regular audits of labeling processes:
      – Conducting internal and external audits of labeling processes to identify potential areas of risk and non-compliance.
      – Establishing a procedure for quick response to detected non-compliances, including mechanisms for correcting them.
   f) Improving communication and cooperation with label suppliers:
      – Implementing procedures for assessing and selecting label suppliers based on their ability to meet required quality standards and on-time delivery.
      – Maintain constant communication with label suppliers to ensure label materials meet the highest quality standards.
2. Unsealing the packaging (N2):
   a) Leak tests at various stages of the packaging process:
      – Implementation of packaging tightness testing procedures at various stages of the production line.
      – Use of modern leak testing equipment that can quickly detect and eliminate defective packaging.
   b) Implementation of packaging quality control before use:
      – Introduction of detailed procedures for assessing the quality of packaging materials when they are accepted into the warehouse.
   c) Analysis of the causes of leaks and implementation of corrective actions:

- Systematic analysis of packaging leakage cases to identify common causes and sources of the problem.
- Implementing corrective actions in response to identified problems, e.g. changing the supplier of packaging materials, modifying the packaging structure.

d) The use of advanced packaging technologies:
- Investments in modern packaging technologies that offer better process control and increase the chance of obtaining tight packaging.
- Exploring the possibilities of using vacuum or modified atmosphere packaging for products requiring particularly tight packaging.

e) Review and optimization of packaging machine parameters:
- Regular technical inspections of packaging machines to ensure their proper functioning.
- Optimization of machine operating parameters, such as sealing pressure and temperature, to adapt them to the specificity of the products being packed and the packaging materials used.

f) Strengthening cooperation with suppliers of packaging materials:
- Building close relationships with suppliers to ensure high quality of delivered packaging materials.
- Regular audits of suppliers to verify their production processes and quality control systems.

g) Staff training:
- Organizing regular training for warehouse employees on identifying defects in packaging materials.
- Organizing regular training for packaging line employees in the proper operation of machines and packaging materials.
- Developing staff awareness of the impact that unsealing packaging has on product quality and safety.

3. Damage to packaging (N3):

a) Analysis of the causes of damage and adjustment of packaging methods:
- Conduct detailed case studies of packaging damage to identify common factors contributing to the problem.
- Implementation of changes in packaging methods (e.g. changing the arrangement of products in the packaging, using additional separators or shock-absorbing fillers).

b) Improving packaging protection during internal and external transport:
- The use of special pallets and transport containers designed to protect delicate products.
- Development and implementation of detailed loading and unloading procedures to minimize the risk of mechanical damage.

c) Introduction of more durable packaging materials:
- Research and testing of new packaging materials with better strength and resistance to damage.
- Cooperation with packaging suppliers to develop non-standard packaging solutions tailored to the specificity of the products.

d) Monitor and track packaging throughout the supply chain:
- Implementation of packaging tracking systems that enable identification of the stages of the supply chain where damage most often occurs.
- Using data from tracking systems to optimize logistics and warehouse processes.

e) Staff training in proper packaging and manipulation of packaging:
- Organizing regular training for employees responsible for packaging, storage and transport, focusing on techniques to minimize the risk of damage.
- Using data from tracking systems to optimize logistics and warehouse processes.

f) Regular audits and risk assessments in the packaging and transport process:
- Checking the technical condition of packaging and warehouse control (packaging storage conditions).
- Periodic inspection of suppliers, monitoring of loading and unloading techniques.

4. Glass contamination (N4):

a) Strengthening procedures for controlling and removing glass cullet in production areas:
- Development and implementation of detailed procedures for dealing with glass cullet, including the designation of safe methods of its removal, staff training and selection of appropriate personal protective equipment for employees.

b) Monitoring and analysis of glass contamination trends:
- Introducing a system to monitor and record glass-related incidents to analyze trends and identify areas requiring particular attention.
- Regularly reviews data and adapts preventive strategies based on analysis results.

c) Installation of additional glass detectors at key stages of production:
- Implementation of modern glass detection systems that can detect its presence in both raw materials and finished products.
- Ensuring glass detectors are regularly maintained and calibrated to maintain their high detection efficiency.

d) Increasing staff awareness of the risk of glass contamination:
- Regular training of employees on the risk of glass contamination, methods of preventing it and procedures for safe handling of glass and what to do in the event of glass damage.

- introduction of a system of rewards and distinctions for employees for actively engaging in activities aimed at eliminating the risk of glass contamination.

e) Optimization of packaging design to minimize the risk of damage:
- Cooperation with packaging productents/suppliers to optimize the design of glass packaging to make it more resistant to damage and, as a result, less susceptible to breakage.
- Considering the use of double packaging or additional protection for products that are particularly vulnerable to damage.

f) Use of alternative materials where possible:
- Review of product and packaging mix to identify opportunities to replace glass with materials with a lower risk of contamination (such as high-quality plastics, metal or other innovative materials).
- Testing and validating alternative materials for their impact on overall product (in terms of e.g. safety of use and consumer acceptance).

5. Metal presence (N5):

a) Optimization of production processes and product design:
- Analysis of production processes to identify potential sources of metal contamination and their elimination through process optimization.
- Designing products and production processes in a way that minimizes the risk of contact with metals that may become a source of contamination.

b) Implementation of a change management system for new machines and processes:
- Implementation of change management procedures for the introduction of new machines, devices and modifications of production processes in order to assess potential risks related to metal contamination.
- Conducting rigorous testing and risk assessments before approving changes to manufacturing processes.

c) Regular inspection and maintenance of production equipment:
- Introducing a plan for regular inspections and maintenance of production machinery and equipment to prevent breakdowns that could lead to metal contamination.
- Documentation of all inspections and maintenance activities as part of the quality management system.

d) Implementation of procedures for checking raw materials for the presence of metal:
- Carrying out detailed inspections of raw materials before they enter the production process to eliminate the risk of introducing metal contaminants.
- Collaborating with suppliers to ensure that delivered materials meet high quality standards (e.g. metal-free).

e) Installing or improving metal detection systems:
- Implementation of advanced metal detection systems at key stages of the production process (including the entry of raw materials and the final stages of product packaging).
- Regular testing and calibration of metal detectors to ensure maximum detection efficiency.

f) Employee training on the dangers of metal contamination of food:
- Organization of periodic training for technical employees on the proper operation, maintenance and cleaning of machines to avoid/minimize the risk of introducing metal contaminants into products.
- Introduction of emergency procedures for employees, explaining what to do if metal contamination is detected.

6. Discordant physicochemical results (N6):

a) Introduction of more stringent quality control procedures at the stage of receiving raw materials:
- Development of detailed specifications for each type of raw material, containing clear quality requirements (e.g. physicochemical parameters).

b) Regular calibrations of measuring devices:
- Establish a regular calibration schedule for all measurement and analytical equipment to ensure accuracy and reliability of results;
- Implementation of procedures for verifying the correct operation of devices before analyzing critical quality parameters.

c) Analysis of the causes of non-compliance and implementation of corrective actions:
- Conducting a detailed causal analysis to identify the source of the problem resulting from the situation of incompatibility of physicochemical parameters;
- Development and implementation of corrective and preventive actions to eliminate identified problems.

d) Strengthening cooperation with suppliers to ensure consistency of raw material specifications:
- Development of strategic partnerships with key suppliers to ensure stability and high quality of supplies;
- Introduction of a system of regular meetings and exchange of information with suppliers on changes in raw material specifications, innovations and potential quality challenges.

e) Training for employees in the field of food quality control (including safety):
- Organization of regular training for laboratory employees, quality control department and other people involved in production processes, focusing on the importance and methods of

ensuring product compliance with quality requirements.

f) Implementation of a quality management system based on continuous improvement:
   - Implementation or improvement of quality management systems (e.g. FMEA or KAIZEN).

7. Contamination with another material (N7):
   a) Implementation of strict procedures for segregating raw materials:
      - Develop clear guidelines for storing raw materials to prevent accidental mixing.
      - The use of color coding and physical barriers in raw material storage to clearly separate different types of materials.
   b) Monitoring and control of production processes:
      - Implementation of real-time monitoring systems for key production stages that may be at risk of cross-contamination.
      - Regular audits of production processes to identify potential weaknesses and implement corrective actions.
   c) Implementation of cleaning and disinfection procedures:
      - Developing and enforcing strict procedures for cleaning and disinfecting equipment and work surfaces (taking into account especially raw materials that may cause allergies).
   d) Employee training in hygiene and cross-contamination control:
      - Organizing regular training for employees (at all levels), focusing on the importance of hygiene and preventing cross-contamination.
      - Introducing a certification program for employees to demonstrate their understanding and ability to apply hygiene and anti-contamination practices.
   e) Introduction of a food quality (including safety) management system:
      - Implementation of quality standards, e.g. ISO 9001, ISO 22000, FSSC 22000, IFS Food, which are specially designed to identify, assess and control food safety hazards.
   f) The use of advanced technologies to identify raw materials:
      - The use of technologies such as barcode scanners or RFID (Radio-Frequency Identification) systems to track and verify raw materials at every stage of the production process.
   g) Optimization of the spatial layout of the production plant:
      - Redesigning the layout of the production plant to minimize the flow of raw materials and products between areas where there is a risk of cross-contamination.
8. Underestimated Fo value (N8):
   a) Improvement of risk analysis and critical points in the sterilization process (HACCP):
      - Conducting a detailed risk analysis of the sterilization process, identifying potential critical points (CCPs) and implementing control measures to prevent underestimation of Fo.
      - Regular reviews and updates of the HACCP plan based on new data and experience.
   b) Optimization of sterilization process parameters:
      - Conducting detailed analyzes of sterilization processes to identify optimal time, temperature and pressure conditions for various types of products.
      - Implementation of adaptive sterilization process control algorithms that can dynamically adjust parameters depending on observed process conditions.
   c) Regular validations and inspections of autoclaves:
      - Establish a schedule for regular validation of autoclaves, including steam penetration and temperature distribution tests, to ensure they meet the required sterilization standards (also taking into account the specifications required by the country).
      - Implement preventive maintenance programs for autoclaves, focusing on regular inspections and replacement of parts that may affect sterilization efficiency.
   d) Implementation of real-time monitoring systems:
      - The use of advanced systems for monitoring and recording data from the sterilization process, enabling ongoing tracking and analysis of critical parameters.
      - Using monitoring data to continuously improve the sterilization process and quickly respond to possible irregularities.
   e) Development of emergency procedures and corrective action plans:
      - Development of clear procedures in the event of detection of irregularities in the sterilization process (including corrective and preventive action plans).
   f) Training in monitoring sterilization processes:
      - Organization of specialized training for technical staff and autoclave operators, aimed at deepening knowledge about the principles and techniques of effective sterilization.
      - Introduction of training modules on interpreting data from the sterilization process and taking corrective actions in the event of deviations from standards.
      - Training staff in emergency procedures and methods for quickly resolving sterilization problems.
9. Improper storage of materials (N9):
   a) Implementation of clearly defined storage guidelines for each type of raw material, available to employees:
      - Development and distribution of comprehensive/well-established and detailed storage instructions that take into account specific requirements regarding temperature, humidity,

light and other factors affecting the quality of raw materials.
- Defining rules for segregating raw materials in the warehouse to prevent contamination (cross-contamination) and maintain their properties.

b) Monitoring storage conditions, including temperature and humidity:
- Installation of advanced monitoring systems that constantly record conditions in warehouses and automatically alert in the event of deviations from established standards.
- Conducting regular audits of storage conditions (including checking the tightness of packaging and expiration dates of raw materials).

c) Regular training of warehouse staff:
- Organization of periodic training in the field of best warehousing practices, including proper handling of raw materials, maintaining cleanliness and order in the warehouse.
- Introduction of a certification program for warehouse employees, confirming their competences in raw materials management.

d) Regular reviews and updates of storage procedures:
- Introduction of a procedure for regular reviews of storage procedures and their updating based on the latest technical knowledge and changing legal requirements and quality standards.
- Collaborate with external experts and suppliers to obtain recommendations on best practices for storing specific raw materials.

e) Introduction of inventory management systems:
- Implementation of IT systems for inventory management that enable tracking of batches of raw materials, their expiration dates and ensure order automation.
- Analyzing inventory turnover and optimizing inventory levels to minimize the risk of keeping raw materials beyond their optimal storage period.

f) Optimization of warehouse layout:
- Redesigning the warehouse layout to ensure optimal flow of raw materials, easy access to them and effective use of available space.
- Introduction of designated storage zones for raw materials requiring special conditions, e.g. cold stores for perishable products.

10. Equipment/Hardware failure (N10):

a) Introduction of a planned maintenance and technical inspection schedule:
- Regular technical inspections and diagnostics of devices to early detect signs of wear or potential failures.
- Development and enforcement of a detailed preventive maintenance plan for each type of machine and device, taking into account manufacturers' recommendations and operational experience.

b) Implementation of a quick response system to failures and ensuring the availability of spare parts:
- Creation of rapid failure response teams, ready to intervene 24/7, with clearly defined procedures for dealing with various types of failures.
- Maintaining a strategic inventory of critical spare parts and consumables to minimize downtime in the event of a breakdown.

c) The use of predictive technology to monitor the condition of machines:
- Implementation of advanced condition monitoring systems (e.g. vibration, temperature) that allow failure prediction and planning of corrective actions in advance.
- Analysis of historical and current data to optimize maintenance and inspection schedules.

d) Technical training for personnel responsible for operating machines:
- Organization of regular technical training and workshops for machine operators and maintenance staff to increase their competence in operation, diagnostics and basic repairs.
- Introduction of a technical skills certification program, improving employee qualifications and ensuring a high level of technical knowledge in the plant.

e) Developing change management procedures for new or modified equipment:
- Introducing standard change management procedures that ensure that any changes to equipment/processes/software are carefully assessed for their impact on safety and operational efficiency.

f) Strengthening cooperation with equipment suppliers and external services:
- Building long-term relationships with suppliers and external services to ensure quick response and technical support in the event of failure and access to specialized technical knowledge.

Application of the FMEA Method

Existing systems in the examined enterprise (e.g. HACCP) can be effectively supported by the FMEA method by limiting the occurrence of the discussed non-compliances, reducing the degree of their risk/danger or increasing their detection.

Table 4 presents the FMEA analysis for the analyzed company and Figure 3 shows the results before and after its potential implementation (simulation results). The data shows significant risk reductions in virtually every type of non-compliance after implementing corrective actions (decrease in RPN), highlighting the effectiveness of the intervention. The only exception where the RPN value has not changed after introducing corrective actions is non-compliance no. 10 – equipment/hardware failure. The lack of change in the RPN value is not due to the lack of improvement as a result of intervention activities, but due to the very high significance of the error in this area. The

occurrence of any equipment/hardware error results in the suspension of production and financial losses.

Table 4
FMEA analysis

No.	Non-Conformity	Part of the chain (responsibility)	Severity (S)	Occurrence (O)	Detection (D)	Initial RPN	Corrective Actions	Post-Action Severity (S)	Post-Action Occurrence (O)	Post-Action Detection (D)	Post-Action RPN
1	Incorrect labeling	Suppliers, labeling	8	6	4	192	Automated labeling system; staff training	8	3	2	48
2	Unsealing of packaging	Suppliers, packing, warehouse	9	5	3	135	Quality control; upgrade packaging materials	9	2	2	36
3	Damage to packaging	Suppliers, warehouse, washing, autoclaves, packing	7	5	4	140	Equipment checks; handling training	7	3	3	63
4	Contamination with glass	Suppliers, production, autoclaves, labeling	10	4	2	80	Raw material inspection; supplier standards	10	2	1	20
5	Presence of metal	Suppliers, production, autoclaves, labeling	9	3	3	81	Metal detectors; maintenance	9	1	1	9
6	Discordant physicochemical results	Food technology department, production	8	3	5	120	Production process optimization	8	2	4	64
7	Contamination with another material	Warehouse, production, transport	7	3	4	84	Raw material verification process	7	2	3	42
8	Underestimated Fo value	Autoclaves, food technology department	9	2	5	90	Processing parameters adjustment; monitoring	9	1	4	36
9	Improper storage of materials	Warehouse	7	2	3	42	Storage conditions improvement; audits	7	1	2	14
10	Equipment/hardware failure	Production, suppliers	9	1	1	9	Preventive maintenance; training	9	1	1	9

Explanation: For S, O indicator number 1 – very low/improbable risk; For indicator D – number 1 – very high risk

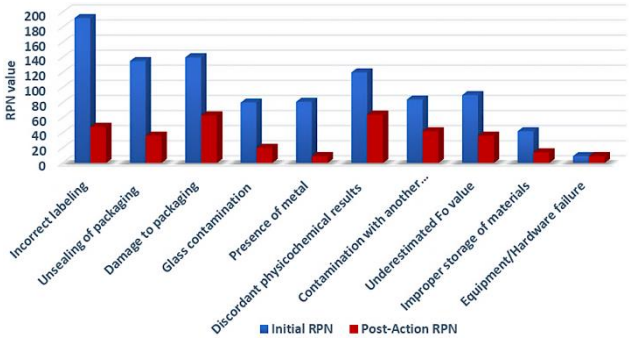


Fig. 3 Values are calculated by RPN before and after corrective actions – FMEA method

In the analysis, the main focus was on reducing incidence (O) and improving detection (D), which are more controllable factors in the short term. The results of analysis O and D show significant improvement, confirming the effectiveness of preventive measures and improved detection techniques/methods, thus confirming their importance. The approach of prioritizing high-risk areas for immediate corrective action has proven effective in managing and reducing risk in the production process. Continuous improvement and adaptation of new technologies or methodologies can further reduce the level of risk.

Proposal for a model of integrating HACCP and FMEA

The following model combining FMEA and HACCP was proposed (Figure 4) in order to increase the efficiency of this production cycle of the examined company. This model combines proactive identification of potential non-compliance and failure points (FMEA) with a systematic approach to their control and elimination (HACCP), enabling a holistic approach to food safety management in the examined company. The synergy effect is a higher level of safety of food products in the company.

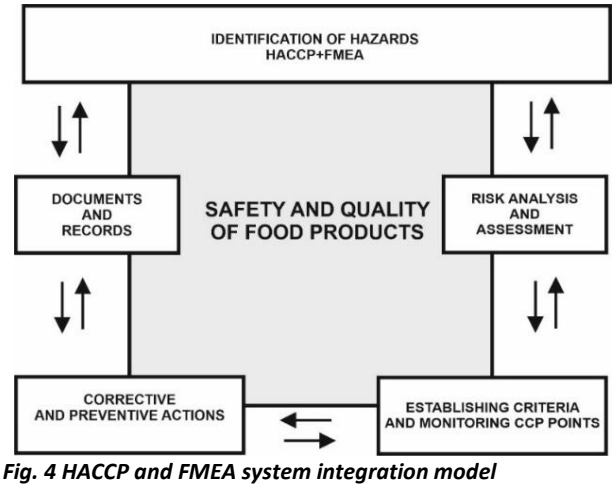


Fig. 4 HACCP and FMEA system integration model

This model was developed based on the following implementation steps (Figure 5):

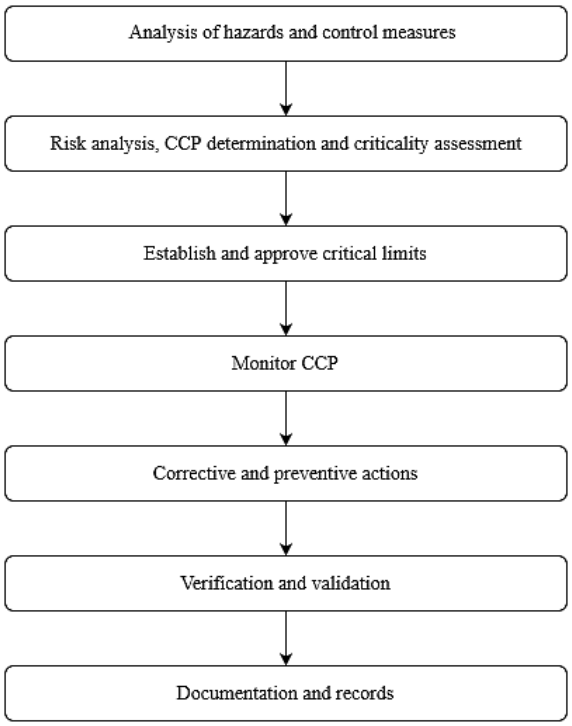


Fig. 5 Steps of an integrated HACCP + FMEA system

Step 1: Analysis of hazards and control measures (HACCP principle 1/step 6 + FMEA)
- Identify all potential threats that may occur at every stage of the food chain (from raw material receipt to the final product).
- Identify all possible ways in which machines, processes or raw materials could fail (mode failure).
- Assess the significance of the hazards, their likelihood of occurrence and suggested control measures.

Step 2: Risk analysis, CCP determination and criticality assessment (HACCP principle 2/step 7 + FMEA)
- Perform a risk analysis for each identified hazard, assessing the probability of occurrence and potential impacts (different scenarios) on food safety using the FMEA methodology.
- Within HACCP, identify critical control points (CCPs) where risks can be effectively controlled or eliminated. NOTE – take into account that several control points can be designated for one hazard.
- Use FMEA to more precisely determine the criticality of each potential failure mode.

Step 3: Establish and approve critical limits (HACCP principle 3/step 8 + FMEA)
- Establish clearly defined, transparent and detailed critical criteria for each CCP (NOTE - one CCP may cover several limits).
- Consider the data generated by the FMEA analysis, including maximum acceptable risk levels.

Step 4: Monitor CCP (HACCP principle 4/step 9 + FMEA)
- Develop and implement a CCP monitoring plan that includes regular, continuous measurement and observation of sensitive points to ensure the process remains under control.

Step 5: Corrective and preventive actions (HACCP principle 5/step 10 + FMEA)
- Develop corrective action procedures for each CCP when a deviation from established critical criteria occurs/is noted.
- Use FMEA to identify and implement preventive actions to eliminate or reduce the risk of failures that may lead to food safety hazards.
- Record all corrective actions taken and related information when a deviation occurs.

Step 6: Verification and validation (HACCP principle 6/step 11 + FMEA)
- Before implementing the HACCP system in combination with the FMEA method, verify and validate it to ensure that all activities within it are able to operate effectively, efficiently and are able to ensure the safety of the final product.
- Regularly verify and validate the effectiveness of the HACCP system and the effectiveness of implemented FMEA preventive actions to ensure that the system is up to date and responsive to any changes in production processes.

Step 7: Documentation and records (HACCP principle 7/step 12)
- Maintain accurate, detailed and clear records and documentation of HACCP and FMEA risk analysis, monitoring, corrective actions and verification processes.
- Archive data in manual and computerized form, for a period extending beyond the shelf life of the analyzed products and for an internally determined period after changing procedures or replacing machines (or improving them).

DISCUSSION

The FMEA method, through a thorough analysis of the probability of possible failures (non-compliance) and the assessment of their effects, helps to identify and implement more targeted preventive actions, which in turn increases the effectiveness and precision of identification and control of CCPs in the HACCP system and the effectiveness of preventive actions. The integration of the HACCP and FMEA system allows for better risk assessment at each stage of production, and also enables better resource allocation, focusing attention and resources on the most critical aspects of production processes. This allows you to optimize operating costs while minimizing the risk of hazards, while increasing product safety. Thanks to the integration of FMEA and HACCP, risk management is more focused and effective. Moreover, FMEA supports the philosophy of continuous improvement, which is the basis of the HACCP system, which contributes to raising food quality standards (including, above all, safety).

CONCLUSIONS

The examined company was analyzed for any non-compliances on the production line of canned meat in glass jars in the selected period (confidential data). Based on the

analysis of the results, it was determined that there were non-conformities in the company that had a greater or lesser impact on the quality of the final product or production process. It was found that it is possible to improve the existing technical and organizational infrastructure in the enterprise in terms of the possibility of implementing a system based on the synergy of the HACCP system and the FMEA method. The obtained simulation results indicate that a quality system combining HACCP and FMEA offers a more comprehensive approach to risk management, better than using HACCP alone. It has been shown that the synergy of HACCP and FMEA increases the efficiency and effectiveness of identifying, controlling and eliminating critical hazards, confirming the positive impact of FMEA implementation on the functionality of the HACCP system and hazard management in the food production process. It was also concluded that the actions taken were worth recommending due to future benefits. Additionally, it was also proposed to expand the currently operating HACCP system. The extension and improvement of the HACCP system in the aspect of the production cycle of sterilized meat products in jars (meat in jars) allows us to focus on its key elements that may affect food safety, which emphasizes the need to monitor and control critical control points (CCP) to ensure high quality products. In conclusion, the integration of the FMEA method with the HACCP system is most beneficial and advisable to improve risk management, quality control and safety in food production.

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